VELTEK ASSOCIATES, INC.

Innovators for Contamination Control

STERILE.COM

2022 DEC CATALOG

Veltek Associates, Inc.

Read more about Veltek Associates on pages 2-9

Founded: 1981
Headquarters: Malvern, Pennsylvania USA (Suburban Philadelphia)
Customers: More than 500 companies worldwide
Employees: 200

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Listening Solicits Innovation

For more than 40 years, Veltek Associates, Inc. (VAI®), headquartered in Malvern, PA, has pioneered the design and manufacture of hundreds of cleanroom solutions that surround contamination control. These innovations, many of them landmarks in the industry's history, allow our customers to overcome challenges and reach their business goals. Plus, VAI clients have more than a solutions provider, they have a partner and trusted advisor. With today's complex research challenges, new competition, and increasing government regulations, a true partnership is more important than ever.

For us, it's simple. Innovation is about listening to industry challenges directly from our customers and not stopping until we find the answer. Together with our clients, we have been developing new solutions for the cleanroom industry for more than 40 years attaining over 150 worldwide patents. Our innovations have allowed our clients to do remarkable things—from biotechnology breakthroughs to pharmaceutical discoveries—that help millions of people every day. From our early days of developing the first sterile garments to our latest innovations, VAI develops products that revolutionize and simplify aseptic manufacturing.

Our innovations have allowed our clients to do remarkable things—from biotechnology breakthroughs to pharmaceutical discoveries—that help millions of people every day.

Our goal is to provide complete, full circle contamination control products, service, testing and training. Unmatched in the industry, VAI combines multiple disciplines and related products and services that all combine together to provide a full circle contamination control partner and resource for GMP, Healthcare, Lab Animal Semiconductor and Electronics requirements.

However, it is not enough to just listen. VAI's corporate directive is to assure that we use and QC the finest raw ingredients/components, manufacture the highest quality product, test the product to the highest standards, stay on the cutting edge of innovation and technology, assure timely delivery and have unmatched client relationships and customer service.

Combining experience, innovation, performance, GMP manufacturing, GLP Testing Services, and unrelenting service has propelled VAI as the ultimate innovative leader in the market.

The History of Veltek Associates, Inc.

VAI® was founded in 1981 by Arthur L. Vellutato, Sr. as a direct result of his answers to the challenges the industry faced. Our main goal, therefore, became developing simple and concise solutions to the common problems experienced within cleanroom operations.

Applying his more than 30 years of experience in finding alternative methods for established industry practices in the pharmaceutical industry, his leadership of VAI resulted in a continuous stream of successful products that is still carried on today. If one word was synonymous with VAI it would be innovation. Since its founding, VAI has followed two corporate principles—listen and innovate. Together with our customers, we have designed and manufactured countless products and services that are designed to meet current industry needs, as well as serving the industry for years to come.

After Arthur L. Vellutato, Sr.'s passing in 2009, his son, Arthur L. Vellutato, Jr., took over as President and CEO of VAI after over 20 years serving as the Director of Sales, Marketing, and Technical Operations. Arthur L. Vellutato, Jr. brought his love of VAI and constant attention to customer satisfaction to his new role as leader and driving force of VAI's continued success.

With its continued strong growth, VAI is poised to create innovative products and services to further simplify and advance the pharmaceutical, biotechnology, and research and development industries.

With its continued strong growth, VAI is poised to create innovative products and services to further simplify and advance the pharmaceutical, biotechnology, and research and development industries. Our inspiration is to use the knowledge we have acquired along with the assistance of our customers to continue developing alternative methods to aid and simplify established industry practices, as well as create new and innovative processes. Our promising future will be built upon our past successes and driven by our unwavering commitment to our customers and innovation.

More than 500 pharmaceutical, biotechnology, and healthcare clients around the world turn to VAI® because we understand the challenges they face. Our experience and unsurpassed technical expertise means "real-world" solutions from customers who have worked in the industry. Due to extensive product lines, a relationship with VAI means a cost-effective way to buy cleanroom products.

At VAI, we develop our products in an environment that mimics your environment, providing a seamless development process that ensures accuracy and precision.

When you work with us, you get recommendations from technical experts who have extensive industry experience, not just sales people. This means you get exactly what you need, and nothing you don't.

1981

We produced the first disposable garments manufactured, from start to finish, in a cleanroom environment. From that point on, manufacturers were assured the cleanliness of the final product.

1985

Four years later, we designed the SMA®, the first microbial air sampler that could be completely sterilized.

SMA®

1993

VAI scientists developed the first 0.2 micron filtered alcohol that was irradiated sterile in a non-aspirating aerosol spray container and in bulk containers.

That same year, we developed the first sterilized disinfectants and sporicides that were filtered at 0.2 microns and packaged in unit dose and bulk containers.

1996

We introduced the first 0.2 micron filtered and sterilized cleanroom lubricants, bringing a new level of flexibility and security to cleanroom environments.

SMA®

1997

We designed and manufactured the first sterile chemicals for use in parenteral manufacturing and introduced the first computerized microbial air sampling system.

2000

VAI developed the Core2Clean Plus® Spray/Mop/Fog System that modernized the way cleaning and disinfection was accomplished in the industry by providing an all-in-one, versatile unit to replace conventional cleaning equipment.

CORE2CLEAN

2003

VAI developed the SimpleMix® System, the first sealed, multi-chamber container that houses both VAI® WFI Quality Water and the correct use dilution sporicide or disinfectant.

2008

VAI® took garments to a new level with the Easy2Gown System®. Our patented fold provides technicians with fewer garment manipulations. This results in reduced training time, reduced down time, reduced contamination risk, and increased manufacturing time.

2006

The complete line of Process2Clean products are released. Designed specifically for critical clean-in-place applications, these products are VAI's most effective solution for preventing and removing product residues and help assure contamination control.

PROCESS2CLEAN
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

A Timeline of our Historical Firsts

2011

First EPA registered 70% Isopropyl alcohol and Water for Injection.

SMA OneTouch ICS

2013

SMA® takes viable monitoring to a new level with the SMA OneTouch® ICS, a computerized, automated viable air monitoring system.

2016

VAI revolutionizes the previously arduous task of cleanroom cart transferring and makes it simple, with Cart2Core®, by allowing the cart top to be detached from its base, therefore leaving the contamination behind.

SMA MicroParticle ICS®
Non-Viable Particle Counters

2018

VAI introduces a new line of particle counters. The SMA MicroParticle ICS® units utilize the latest innovations in particle counting technology and integrate several features not found in other Particle Counters.

2009

VAI has answered the needs of the pharmaceutical industry by developing the first sterile sodium hypochlorite (HYPO-CHLOR®) and hydrogen peroxide (STERI-PEROX®) wipes for use in cleanroom environments.

2012

Patented and marketed the first viable facility microbial monitoring system that incorporates plate bar code reading and data exchange to LIMS and other software systems.

2014-2015

CleanPrint 10® synthetic writing substrate is used for our Core2Write® products, a line of pre-printed logbooks, ID tags, and labels customized for the users' needs.

VAI makes printing in a controlled area possible with the Core2Print® cleanroom printing system that uses CleanPrint 10 non-shedding paper.

CleanPrint 10®
Core2Print®
Core2Write®

2017

Clean and sterile end-to-end cleanroom and controlled environment tracking with RFID, QR, and Barcode technology becomes feasible with VAI's Core2Scan System. Entire operations can be tracked automatically without exacerbating contamination.

Core2Scan®

2019

VAI develops HYPO-CHLOR® Neutral, an enhanced sodium hypochlorite solution with a neutral pH, available in our SimpleMix configuration. By lowering the pH of sodium hypochlorite, the biocidal activity increases and corrosivity decreases.

Corporate GMP Overview and Facilities

Serving GMP Pharmaceutical and Biotechnology, Medical Device, Healthcare, Lab Animal, Semi-conductor and Electronics organizations worldwide is complimented by VAI's internal directive that all products and lab services be manufactured and tested in accordance with GMP requirements. To start, VAI is an FDA and EPA registered facility and encompasses registrations worldwide with agencies such as the European Commission (ECHA), TGA, and Health Canada. But that is just the beginning of the story. While VAI manufactures over 1,900 products and incorporates Labs services that serve the worldwide marketplace, all of our products and services, whether they require registration or not are all made in accordance with GMP. This unique combination has propelled VAI as the leader in contamination control products and services.

All manufacturing, testing and storage sites follow this creed and VAI's multi-location manufacturing, storage and testing operations assures redundancy so our clients can rest assure, VAI will manufacture, test and deliver a quality product each and every time, on time. And there will be no quality issues!

Registrations: FDA, EPA, Health Canada (NNHPD), COFEPRIS (Mexico), North America (NAFTA/USMCA), TGA (Australia), European Commission/ECHA (Europe), HSE (United Kingdom), Regional Authority (China), Ministry of Health (Panama).

Manufacturing/Testing Facilities:

Malvern, PA: 50,000 sq ft GMP Manufacturing and Testing Facility

Exton, PA: 70,000 sq ft GMP Manufacturing and Testing Facility

Warehouse Operations:

Exton, PA: 150,000 sq. ft. GMP Warehousing Operation/Label Bureau

Hamburg, Germany: GMP Warehousing Operation

CREAMERY WAY

LEE BOULEVARD

TABAS LANE

The Divisions of Veltek Associates, Inc.

Sterile Chemical Manufacturing Division (SCMD):

The division manufactures a complete line of sanitizers, disinfectants, sporicides, CIP/COP Cleaners, residue removers, lubricants and cleaning devices that possess a multitude of patents products and.

VAI Laboratories/CORE Laboratories:

The division operates as a contract laboratory that conducts Antimicrobial Effectiveness Testing (disinfectant efficacy) studies for disinfectant validations. The division utilizes user isolates, ATCC cultures, user facility surfaces, multiple contact times, and provides GLP reporting to meet worldwide guidelines and regulations. The division also provide pre-validation testing of clean-in-place (CIP) cleaning agents by testing them against facility product residues on end user surfaces.

Disposable Products Manufacturing Division (DPMD):

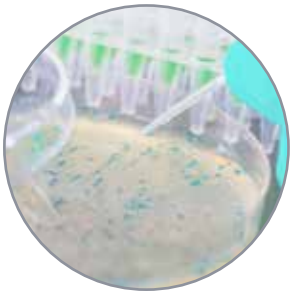
The division manufactures a complete line of patented disposable garments, patented garment systems, and clean dry and saturated wipers.

Environmental Control Monitoring Division (ECMD):

The division manufactures a complete line of patented environmental monitoring equipment designed to test airborne particulates and microbials, relative humidity, temperature, pressure and particulate/shedding features cleanroom components.

Cart Documentation Tracking Division (CDTD):

The division provides patented cart transfer equipment, customized cleanroom documentation including logbooks, labels, paper, forms, notebooks, and tags, a patented cleanroom printing systems, and patented chemical resistant RFID tags, readers, and software.



Aseptic Processing, Inc. (API):

API is the consulting and training division of VAI. The key focus of this division is to lead the industry in specific contamination control and environmental monitoring systems. Uniquely, the division works to combine all contamination control aspects within a customer's organization into one system that is complaint, effective, and assures repeatable success. API has assisted a multitude of pharmaceutical, biotechnology, and medical device organizations worldwide.

USP <797> COMPLIANCE

Healthcare Division:

The division serves the Healthcare market focusing on compounding sterile preparations and USP <797> and <800> compliance. Our unique products are derived from the multitude of VAI divisions while also customizing specific products and services to meet the necessary regulatory requirements.

What is True Contamination Control?

Complete Contamination Control begins with the understanding that it is not our lack of efficacious solutions applied to surfaces or our lack of cleaning techniques. True contamination control starts with understanding the meaning of "War at the Door™." This phrase symbolizes our critical need for the control of contamination from the exterior environment (outside world and our unclassified areas) to our classified areas. This requires a firm to control contamination from the exterior and uncontrolled areas by means of strategic packaging (like the ABCD Cleanroom Introduction System® by VAI, and/or cleaning/disinfecting of items entering prior to the Controlled Not Classified areas). This system continues in each classification from the next level of Grade D (ISO 8) to Grade C (ISO 7) and finally to Grade A/B (ISO 5).

Once a firm places controls for the introduction of contamination in place, particulate and bioburden levels will naturally be reduced. But it won't be perfect. So through one's environmental monitoring program, one can develop a listing of routine isolates that are seen in the environment. In short, things the control system missed. Such contamination, may it be particulate or more notably in GMP operations, bioburden, should then be identified to a genus and subsequent species level.

Now that the routinely seen isolates have been identified, a GMP firm, in search of regulatory compliance, should conduct Antimicrobial Effectiveness Testing to assure the appropriate validated demise of the bioburden from the agents we have chosen. This should be done on varying facility surfaces where we would expect the organism to reside and incorporate a multitude of contact (dry) times to accommodate varying application scenarios.

This AET Validation information will provide the framework to choose sanitizers, disinfectants, sporicides, cleaners, cleaning tools, sponges, mops, wipers, gowning and enable us to write SOP's and train personnel.

At this juncture personnel gowning in all classifications needs to be evaluated, SOP's written, personnel trained and qualified. Personnel may be one of the main sources of contamination, however, a company with a continued personnel gowning contamination problem is a company that is in drastic need of reevaluation of practices. Gowning products and systems in present day with appropriate training and routine qualifications should be capable of removing this contamination source from the scope of concern.

Once a firm accomplishes the above, one can compliantly conduct "In-Situ" field studies whereby a dirtied room is monitored (environmental monitoring done at a higher than normal level), and cleaned with the appropriate validated agent using approved SOP's and trained personnel. And then subsequently monitored again. This validation exercise is noted in regulatory guidelines (ex. 2004 FDA Aseptic Processing Guide) and tells a GMP firm whether what they have validated in really working and/or where problematic situation could and may arise.

True contamination control starts with understanding the meaning of "War at the Door™."

Simultaneously, Clean-in-Place (CIP), Clean Out of Place (COP) systems also need to be validated, followed by validation of Steam-in Place (SIP) systems. This assures that product contact surfaces have been appropriately cleaned and validated as sterile.

Once a firm accomplished the above, many firms need to understand that they have potentially looked at their internal operations, systems and validation for so long that the words, systems, and practices may all be blurred. In short, we need another outside set of eyes. And at this juncture, it is prudent to utilize an outside consultant to evaluate and recommend how the system may be improved.

VAI has developed not only products but also services that can assist in all phases of the above process. We have developed over many years a complete contamination control system, that incorporates ex-industry personnel and ex-regulatory personnel. We've lived, every day for 40 years, the subject of contamination control and how it is best done. And as a multitude of firms worldwide have experienced, having VAI as part of the team is an invaluable experience.

VAI®'s Full Circle Approach


SCMD

200L
sterile
aseptic
cleaners
sanitizers
sporicides
bag in bottle
gamma radiation

Sanitizers, Disinfectants, Sporicides, Cleaners, and Lubricants

quadruple bagged
0.2 µm filtered
disinfectants
SimpleMix
lubricants
patented
aerosol
GMP

Welcome to SCMD

Sterile Chemical Manufacturing Division

VAI®'s SCMD manufacturing operations mirror current GMP's and enforce the adherence to USP specifications for testing of all manufactured products, where applicable. VAI is an EPA and FDA registered facility and possesses worldwide registrations. SCMD has designed and produced a complete range of sterile and non-sterile sanitizers, disinfectants, sporicides, lubricants, waters, and cleaners for controlled manufacturing areas and classified operations.

SCMD represents a majority of the square footage of the Malvern, PA and Exton, PA facilities. All VAI manufacturing operations are completely validated and assure that critical validation parameters are within tolerance to assure product integrity. VAI capabilities for manufacturing products include the ability to fill aerosol, bulk, and unit dose packages in ISO 5 (Grade A/B, former Class 100). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Absolute assurances are taken in every aspect of SCMD concerning sterility and particulate removal.

SCMD has taken an additional advancing step in product quality assurances by incorporating USP Water for Injection (WFI) into a majority of our products. The validated WFI systems in our chemical manufacturing facility offer an advantage to the use of our products. The mission of VAI's SCMD is to manufacture top-of-the-line quality products that address any regulatory requirements demanded.

SCMD has the manufacturing capability to produce both VAI products and contract custom manufacturing designs. VAI's SCMD uncompromising cGMP manufacturing style and our complete adherence to USP specifications has assured outside organizations that their products will not only be produced and tested as sterile, but moreover, their product will be completely documented, traceable, and validated. VAI's SCMD is proud of our history and track record.

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43 VAI® PRODUCT LABEL COLORS
30 VAI® WFI QUALITY WATER

DEC-ASSURE

Biodecontamination Program

The DEC-ASSURE Biodecontamination® Program has been developed to assist you in maintaining acceptable environmental conditions while addressing the requirements of regulatory agencies. “Testing and Addressing” contamination in a documented system is the goal of the DEC-ASSURE Biodecontamination Program. The following is a brief summary.

Criteria # 1: Controlling Incoming Contamination

The control for contamination from the exterior environment to the interior is the most critical function a firm can implement. Even the most thought out cleaning and disinfection program will fail if the source of contamination is reduced or eliminated. This requires a firm to assess incoming components, supplies, personnel, carts, tanks, equipment and all other items that are routed from the exterior environment or less classified areas to the critical environment. In many cases this would be the Grade A/B area but some processes utilize Grade C or D areas. Whatever classification is deemed the most critical, potential particulate and microbial contamination should all be addressed and validated mechanisms should be in place to reduce the influx to the controlled environments.

Criteria # 2: Test And Address Contamination

Through your environmental monitoring program, you can develop a list of environmental isolates that have been noticed in your operations. Once developed, the key is to successfully integrate and document a plan for assuring the demise of these organisms.

Criteria # 3: Antimicrobial Effectiveness Studies

Determining what chemical agents will destroy a known level of your environmental isolates is the next step. Prior to conducting either a Time Contact Kill Study (Tube Dilution), a Time Contact Kill Study (On User Surfaces), or an AOAC Protocol Study, you will need to review the available disinfecting agents and determine which is initially appropriate for your operation. Upon choosing 1 or 2 disinfecting agents and a sporicide, you can continue with our antimicrobial effectiveness studies. Antimicrobial effectiveness studies must be based on realistic bioburdens that may be observed in your controlled areas. It is normal to test an enumeration greater than or equal to 1.0 x 104 cfu’s. This testing will provide the justification for using our chemical agents.

Criteria # 4: Choosing A Disinfection System

Varying applications require various solutions to be in place. VAI® has established three systems that will net success. The choice to use a

Double Bagged STER-AHOL® Product

ABCD Cleanroom Introduction System® Cleanroom Packaging System Available for Numerous VAI® Products

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed, individual containers are each additionally contained in two easy tear bags.

Sterile VAI Products available in our ABCD Cleanroom Introduction System are denoted as such in the Features and Benefits section of each product page.

phenolic, quaternary ammonium, or hydrogen peroxide delineates the rotation parameters. The choice of one disinfectant and a sporicide is completely appropriate, however, some may decide to rotate similar disinfectants while also utilizing a sporicide.

Rotation systems are designed to address known or possibly existent contamination with proven efficacious disinfectants. The basis for the rotation of disinfecting or sporicidal agents is to address an organism that may not be destroyed by a particular disinfectant with another that has proven efficacy performance against the organism.

For example, a phenol, while being effective against other contamination, may not kill a B. subtilis in a 5-10 minute contact time. Therefore, the rotation to a more efficacious product, such as a sporicide, may be warranted to destroy this organism. Even though organisms do not develop an immunity or resistance to a chemical agent over time, scientific evidence of such occurrences have never been documented as factual in the cleanroom. Thus, the basis for rotation is to address the organism that is not destroyed by, nor ever was destroyed by one chemical agent, with another that has proven efficacy and performance against such organism.

Destroying contamination in a cleanroom operation requires addressing the known vegetative cells and the spores. In the present design of a rotation system, there are two types: 1) A single disinfectant rotated with a sporicide, and 2) A two disinfectant system (rotated monthly) plus a sporicide. Either system requires, at minimum, a monthly sporicidal application. This frequency may be increased or decreased and is determined by the environmental conditions.

The use of DEC-Clean® is considered an optional step in controlling existent residues and should be done at least once a quarter (suggested monthly). Furthermore, to assure that all cleaning is effective, DEC-AHOL WFI® or STER-AHOL® WFI should be used on process equipment as a final wipe down.

Criteria # 5: Conducting An “In-Situation” Field Study

Once a disinfection system has been chosen and antimicrobial effectiveness testing has been completed, conducting an “in situation” field study is important to prove the effectiveness of the combination of our cleaning Standard Operating Procedures (SOP’s) and our antimicrobial effectiveness testing. Simply, environmental monitoring (both air and surface) is conducted in a dirtied room. Upon completion of the monitoring, the room is cleaned and disinfected per the current SOP’s. Upon completion and drying of all

surfaces, the room is monitored again. Satisfactory results need to be obtained in 3 different and separate in-situation field studies prior to acceptance of the disinfection system.

Criteria # 6: Updating Your Profile

As time progresses, it is possible that organisms not previously tested may be noticed in operations. Antimicrobial effectiveness testing should be performed on these contaminants to continue to prove and document the disinfection system as validated to current operations. Changes over time may also occur in production scenarios, processes, and personnel. Reviewing SOP's for cleaning and disinfection should be done routinely to address current situations.

DEC-ASSURE ROTATION SYSTEMS:

Month 1: Rotating One Disinfectant and a Sporicide

Day(s)	Phenolic	Quaternary Ammonium	Hydrogen Peroxide
Day 1-13	DEC-CYCLE®II	DEC-QUAT® 100 or 200C	STERI-PEROX 6%
Day 14 (if warranted EM Data)	DEC-CLEAN® followed by HYPO-CHLOR® 0.52%, STERI-PEROX® 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus®.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.
Day 15-29	DEC-CYCLE II	DEC-QUAT 100 or 200C	STERI-PEROX 6%
Day 30	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.

Month 2: Rotating Two Disinfectants and a Sporicide

Day(s)	Phenolic	Quaternary Ammonium	Hydrogen Peroxide
Day 1-13	DEC-CYCLE II	DEC-QUAT 100 or 200C	STERI-PEROX 6%
Day 14 (if warranted EM Data)	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.
Day 15-29	DEC-SPORE® 200 Plus Disinfectant	STERI-PEROX 6%	DEC-QUAT 100 or 200C
Day 30	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.	DEC-CLEAN followed by HYPO-CHLOR 0.52%, STERI-PEROX 6%, HYPO-CHLOR Neutral 0.25% or 0.52%, or DEC-SPORE 200 Plus.

After disinfection all critical surfaces should be rinsed with hot WFI or an IPA wipe down should be performed.

DEC-AHOL® WFI Formula

70% USP Isopropyl Alcohol and 30% USP Water for Injection

DECWFI-SP-70-E

DECWFI-TR-04-E

DECWFI-SQ-16Z-E

DECWFI-B-70-E

VAI®'s EPA registered DEC-AHOL WFI Formula is formulated with 70% USP Isopropyl Alcohol (IPA) and 30% USP Water for Injection (WFI). DEC-AHOL WFI® Formula 70% is an EPA registered hard surface disinfectant and sanitizer when used as directed.

DEC-AHOL WFI Formula Products have been designed specifically for pharmaceutical, biotechnology, healthcare, and medical device cleaning rotations for use in both aseptic and non-aseptic environments.

Quality and Manufacturing*

- Components are air washed with 0.2 micron filtered air before assembly
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely lot traceable from start to finish
- Completely validated for sterility and shelf life
- Formulated with USP Water for Injection (0.25 EU/mL)
- Assayed according to current USP Compendium
- Manufactured within a closed system where endotoxin levels are controlled

Features and Benefits*

- Each sterile container is double bagged
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report tested to current USP compendium
- Individually labeled with lot number and expiration
- Low remaining residue
- Low in endotoxin levels
- For use on a multitude of surfaces
- Ready-to-use

Product Uses*

- Where a sterile alcohol solution that is formulated with USP Water for Injection is required
- In spray and wipe downs on hard, non-porous, inanimate surfaces
- Aseptic filling, gowning rooms, general manufacturing areas, process lines
- Machinery, tools, tables, counters, laminar flow benches, carts, shelves
- Exterior packaging, accessories
- Glass, plastic, vinyl, stainless steel
- Gloves

Order Number	*Description*	*Qty/Cs*
DECWFI-SP-70-E	DEC-AHOL Aerosol WFI Formula, 325 mL Aerosol Spray/Mist, Sterile	24
DECWFI-ST-70-E	DEC-AHOL Aerosol WFI Formula, 325 mL Aerosol Stream, Sterile	24
DECWFI-SP-70-B-E	DEC-AHOL Aerosol WFI Formula, 325 mL Aerosol "Inverta" Spray/Mist, Sterile	24
DECWFI-TR-04-E	DEC-AHOL WFI Formula, 473 mL Attached Trigger, Sterile	12
DECTR-08-E	DEC-AHOL WFI Formula, 473 mL Attached Trigger, Sterile, Parametric	12
DECWFI-TR-05-E	DEC-AHOL WFI Formula, 946 mL Attached Trigger, Sterile	12
DECTR-07-E	DEC-AHOL WFI Formula, 946 mL Attached Trigger, Non-Sterile	12
DECWFI-SQ-16Z-E	DEC-AHOL WFI Formula, 473 mL Squeeze, Sterile	12
DECWFI-B-70-E	DEC-AHOL WFI Formula, 3.79 Liter, Sterile	4
DECWFI-B-70-NS-E	DEC-AHOL WFI Formula, 3.79 Liter, Non-Sterile	4
DECWFI-B-5G-70-E	DEC-AHOL WFI Formula, 18.9 Liter, Sterile	1
DECWFI-BOT-01-E	DEC-AHOL WFI Formula, 946 mL Bottle for ASEPTI-CLEANSE®, Non-Sterile	12
DECWFI-BOT-02-E	DEC-AHOL WFI Formula, 946 mL Bottle for ASEPTI-CLEANSE, Sterile	12

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-AHOL® WFI Formula Bag in Bottle

70% USP Isopropyl Alcohol and 30% USP Water for Injection

DECWFI-TR-04-BB-E

DECWFI-TR-05-BB-E

VAI®'s EPA registered DEC-AHOL WFI Formula is formulated with 70% USP Isopropyl Alcohol (IPA) and 30% USP Water for Injection (WFI). DEC-AHOL WFI Formula 70% is an EPA registered hard surface disinfectant and sanitizer when used as directed.

DEC-AHOL WFI Formula Products have been designed specifically for pharmaceutical, biotechnology, healthcare, and medical device cleaning rotations for ruse in both aseptic and non-aseptic environments.

VAI's DEC-AHOL WFI Formula is available in "bag in bottle" technology. Much like aerosol containers of DEC-AHOL WFI Formula, bag in bottle technology containers do not allow for aspiration of the room's air to the master reservoir, therefore assuring sterility from the first drop down to the last drop. Furthermore, wasting IPA is minimized as this technology allows for every last drop in the container to be used. VAI's DEC-AHOL WFI Formula Bag in Bottle containers are available in 16 oz and 32 oz sizes.

Quality and Manufacturing*

- Components are air washed with 0.2 micron filtered air before assembly
- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely lot traceable from start to finish
- Completely validated for sterility and shelf life
- Formulated with USP Water for Injection (0.25 EU/mL)
- Assayed according to current USP compendium
- Manufactured within a closed system where endotoxin levels are controlled

Features and Benefits*

- Each sterile container is double bagged
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report tested to current USP compendium
- Individually labeled with lot number and expiration
- Bag in bottle technology does not aspirate the rooms air
- Minimize waste by being able to use every last drop of IPA in the container
- Low remaining residue
- Low in endotoxin levels
- For use on a multitude of surfaces
- Ready-to-use

Product Uses*

- Where a sterile alcohol solution that is formulated with USP Water for Injection is required
- In spray and wipe downs on hard, non-porous, inanimate surfaces
- Aseptic filling, gowning rooms, general manufacturing areas, process lines
- Machinery, tools, tables, counters, laminar flow benches, carts, shelves
- Exterior packaging, accessories
- Glass, plastic, vinyl, stainless steel
- Gloves

Order Number	*Description*	*Qty/Cs*
DECWFI-TR-04-BB-E	DEC-AHOL WFI Formula, 473 mL Bag in Bottle, Attached Trigger, Sterile	12
DECWFI-TR-05-BB-E	DEC-AHOL WFI Formula, 946 mL Bag in Bottle, Attached Trigger, Sterile	12

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STER-AHOL® WFI Formula

70% Denatured Ethanol and 30% USP Water for Injection

DSTER-WFI-TR-04

DSTER-WFI-SP-70

DSTER-WFI-B-70

DSTER-WFI-70-5G

VAI® manufactures an EPA registered denatured ethanol formulated to 70% with a small percentage of methyl alcohol and 30% USP Water for Injection for use as a sanitizer and disinfectant in classified manufacturing and testing environments.

STER-AHOL WFI Formula can be used for the disinfection and decontamination of cleanrooms, controlled areas, hard non-porous environmental surfaces, and many other applications that require the use of a sterile alcohol solution. STER-AHOL WFI Formula has been designed for use in the pharmaceutical, biotechnology, medical device, healthcare, and diagnostic manufacturing facilities.

Quality and Manufacturing

- Filled in ISO 5 (Grade A/B, Former Class 100)
- Formulated with USP Water for Injection (0.25 EU/mL)
- Components are air washed with 0.2 micron filtered air before assembly
- Filtered at 0.2 microns
- Gamma irradiated to a sterility assurance level of 10^{-6}
- Sterility tested according to Current USP Compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, Certificate of Sterility, and LAL Test Report tested to current USP compendium
- For use on a multitude of surfaces
- Ready-to-use

Product Uses

- On non-food contact, hard non-porous, inanimate surfaces
- Aseptic filling and gowning rooms
- Manufacturing areas and laboratories
- Machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves
- Glass, plastic, vinyl, chrome, stainless steel

Order Number	*Description*	*Qty/Cs*
DSTER-WFI-SP-70	STER-AHOL WFI Formula, 325 mL Aerosol Spray/Mist, Sterile	24
DSTER-WFI-SP-70-B	STER-AHOL WFI Formula, 325 mL Aerosol “Inverta” Spray/Mist, Sterile	24
DSTER-WFI-TR-04	STER-AHOL WFI Formula, 473 mL Attached Trigger, Sterile	12
DSTER-WFI-B-70	STER-AHOL WFI Formula, 3.79 Liter, Sterile	4
DSTER-WFI-70-5G	STER-AHOL WFI Formula, 18.9 Liter, Sterile	1

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STER-AHOL® WFI Formula Bag in Bottle

70% Denatured Ethanol and 30% USP Water for Injection

DSTER-WFI-TR-04-BB

DSTER-WFI-TR-05-BB

VAI® manufactures an EPA registered denatured ethanol formulated to 70% with a small percentage of methyl alcohol and 30% USP Water for Injection for use as a sanitizer and disinfectant in classified manufacturing and testing environments.

STER-AHOL WFI Formula can be used for the disinfection and decontamination of cleanrooms, controlled areas, hard non-porous environmental surfaces, and many other applications that require the use of a sterile alcohol solution. STER-AHOL WFI Formula has been designed for use in the pharmaceutical, biotechnology, medical device, healthcare, and diagnostic manufacturing facilities.

VAI's STER-AHOL WFI Formula is available in "bag in bottle" technology. Much like aerosol containers of STER-AHOL WFI Formula, bag in bottle technology containers do not allow for aspiration of the room's air to the master reservoir, therefore assuring sterility from the first drop down to the last drop. Furthermore, wasting IPA is minimized as this technology allows for every last drop in the container to be used. VAI's STER-AHOL WFI Formula Bag in Bottle containers are available in 16 oz and 32 oz sizes.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Formulated with USP Water for Injection (0.25 EU/mL)
- Components are air washed with 0.2 micron filtered air before assembly
- Filtered at 0.2 microns
- Gamma irradiated at a sterility assurance level of 10^{-6}
- Sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and LAL Test Report tested to current USP compendium
- Individually labeled with lot number and expiration
- Bag in bottle technology does not aspirate the rooms air
- Minimize waste by being able to use every last drop of IPA in the container
- For use on a multitude of surfaces
- Ready-to-use

Product Uses

- On non-food contact, hard non-porous, inanimate surfaces
- Aseptic filling and gowning rooms
- Manufacturing areas and laboratories
- Machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves
- Glass, plastic, vinyl, chrome, stainless steel

Order Number	*Description*	*Qty/Cs*
DSTER-WFI-TR-04-BB	STER-AHOL WFI Formula, 473 mL Bag in Bottle, Attached Trigger, Sterile	12
DSTER-WFI-TR-05-BB	STER-AHOL WFI Formula, 946 mL Bag in Bottle, Attached Trigger, Sterile	12

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-HAND®

FDA Registered Ethanol Based Hand Sanitizer

DH-06-E

DH-10-E

DH-100

VAI® manufactures an ethanol based, gelled, instant hand sanitizer, DEC-HAND. DEC-HAND complies with the requirement for transport into classified areas within the cleanroom operation, therefore, making it an ideal product for hand sanitizing before glove donning in gowning rooms. DEC-HAND is an FDA registered product.

DEC-HAND is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. DEC-HAND is available in two sizes, including a 32 oz bottle for the ASEPTI-CLEANSE®, a hands free dispensing system.

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Manufactured in accordance with 21 CFR Part 211 Good Manufacturing Practices for Drugs

Features and Benefits*

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- FDA Registered
- 946 mL container size compatible with our hands free dispensing system, ASEPTI-CLEANSE
- 473 mL bottles delivered with an optional attachable pump
- 473 mL can be mounted directly to the wall using the DH-100
- Ready-to-use

Product Uses

- As an instant hand sanitizer
- Throughout the entire facility
- Hand sanitizing before glove donning

Order Number	*Description*	*Qty/Cs*
DH-04-E	DEC-HAND, 473 mL, Attachable Pump, Non-Sterile	12
DH-06-E	DEC-HAND, 473 mL, Attachable Pump, Sterile	12
DH-09-E	DEC-HAND, 946 mL, Bottle for ASEPTI-CLEANSE, Non-Sterile	12
DH-10-E	DEC-HAND, 946 mL, Bottle for ASEPTI-CLEANSE, Sterile	12
DH-100	DEC-HAND, Wall Dispenser, For 473 mL Bottles, 316 L Stainless Steel	1

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

ASEPTI-CLEANSE®

Hands-Free Dispensing System for DEC-AHOL® WFI FORMULA and DEC-HAND®

DEC-301

DEC-301TRAY

DEC-301STANDSS

VAI® developed the ASEPTI-CLEANSE to meet the requirements of cGMP cleanroom operations. The dispensing system is the most advanced infrared sensor dispensing system available in the pharmaceutical and biotechnology industries. It can be set to dispense approximately 1, 2, or 3 mL of solution. It dispenses a pre-measured dose to the hand without user contact.

The ASEPTI-CLEANSE can be mounted directly to glass or walls which makes it an excellent choice for gowning rooms and aseptic manufacturing areas.

Simply place your hand underneath the ASEPTI-CLEANSE to deliver a pre-measured dose to the hand with no contact between the user and the ASEPTI-CLEANSE.

Features and Benefits

- Compatible with 32 oz bottles of DEC-AHOL WFI Formula or DEC-HAND
- Photo-eye operated
- Equipped with dual power supply – 4 D Cell batteries (can last over 1 year) and connector for DC power cord
- Mountable directly on glass or walls
- Water resistant
- Americans with Disabilities Act (ADA) compliant
- UL Medical Device listed
- Able to be maintained without tools
- Compactly sized 6.75 × 4 × 11 in (L × W × H)

Order Number	*Description*	*Qty/Cs*
DEC-301	ASEPTI-CLEANSE Dispenser, for 946 mL Bottles	1
DECWFI-BOT-01-E	DEC-AHOL WFI Formula, 946 mL Bottle for ASEPTI-CLEANSE, Non-Sterile	12
DECWFI-BOT-02-E	DEC-AHOL WFI Formula, 946 mL Bottle for ASEPTI-CLEANSE, Sterile	12
DH-09-E	DEC-HAND, 946 mL Bottle for ASEPTI-CLEANSE, Non-Sterile	12
DH-10-E	DEC-HAND, 946 mL Bottle for ASEPTI-CLEANSE, Sterile	12
DEC-301TRAY	ASEPTI-CLEANSE Plastic Drip Tray, Additional	1
DEC-301STANDSS	ASEPTI-CLEANSE Stainless Steel Stand	1

INSERTING THE DEC-AHOL WFI BOTTLE

DEC-50 Dispenser

Aerosol Dispenser for Use with DEC-AHOL® Aerosol and STER-AHOL® Aerosol

DEC-50

DEC-50-FR

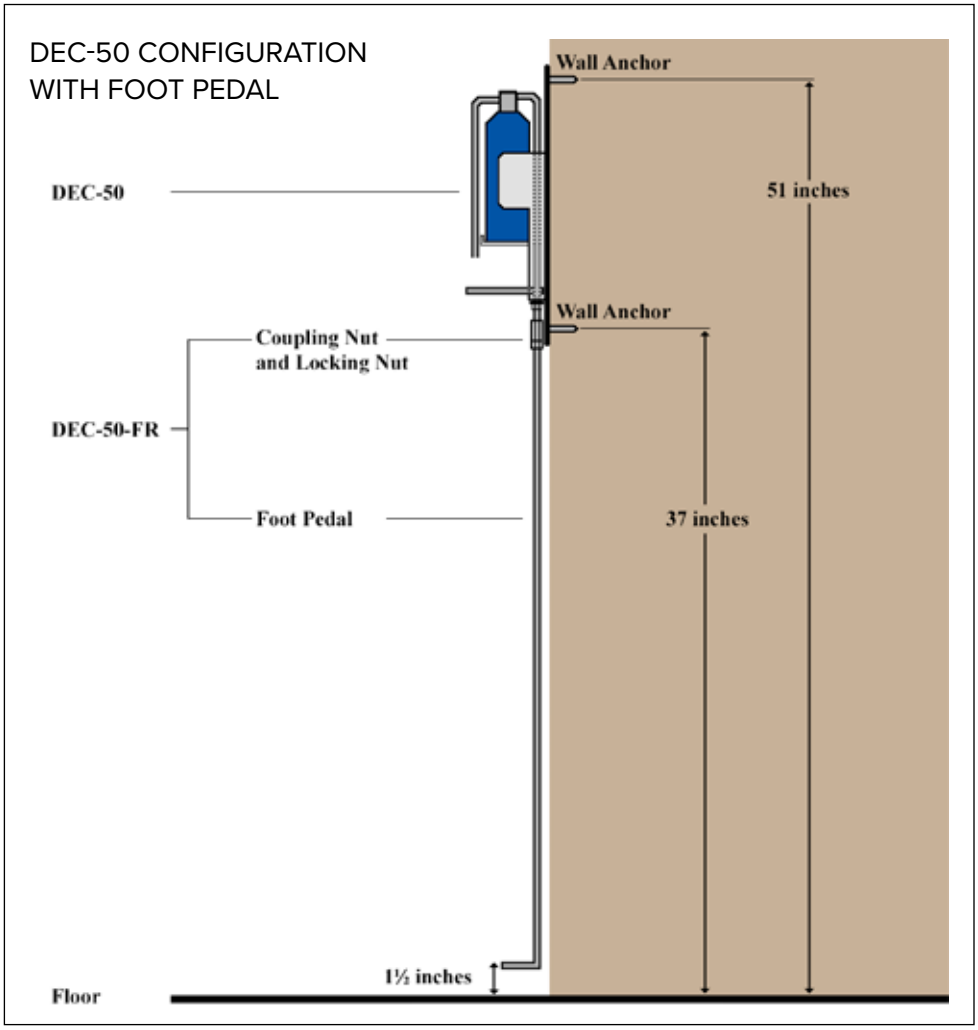
The DEC-50 is a dispensing system for VAI DEC-AHOL Aerosol WFI Formula and STER-AHOL Aerosol WFI Formula. It minimizes cross-contamination from user to user during handling of the alcohol container. The user simply places the back of their hand on the DEC-50 Actuation Arm to dispense solution rather than handling the aerosol container itself.

The DEC-50-FR Foot Pedal is an optional accessory that attaches to the DEC-50 and allows the user to press a Foot Pedal to dispense solution.

Features and Benefits

- Designed to minimize cross-contamination in cleanroom operations
- Constructed of 316L stainless steel
- Wall mountable
- Water resistant
- Compactly sized 7 × 6 × 15 in (L × W × H)
- Autoclavable – Easily slide the base and dispenser mechanism from the permanently installed wall plate
- Compatible with 11 oz DEC-AHOL and STER-AHOL spray/mist aerosol cans

Order Number	*Description*	*Qty/Cs*
DEC-50	Back-of-Hand-Activated Dispenser, For Aerosol Cans, 316L Stainless Steel	1
DEC-50-FR	DEC-50 Foot Pedal Accessory	1
DECWFI-SP-70-E	DEC-AHOL Aerosol WFI Formula, 325 mL Aerosol Spray/Mist, for DEC-50, Sterile	24
DSTER-WFI-SP-70	STER-AHOL WFI Formula, 325 mL Aerosol Spray/Mist, for DEC-50, Sterile	24



DEC-CYCLE® II

Low pH Phenolic

DCY2-02-E

DCY2-03-1Z-E

DCY2-04-1Z-E

DCY2-06-16Z-02-E

VAI manufactures a low pH phenolic that is effective as hard non-porous surface disinfectant/ detergent formulated for effective aseptic and controlled environment sanitation. DEC-CYCLE II's sterile pharmaceutical clean room formula is for broad spectrum disinfection use, as demonstrated by US EPA A.O.A.C efficacy testing against gram negative Pseudomonas aeruginosa and gram positive Staphylococcus aureus bacteria.

DEC-CYCLE II is acceptable for use by pharmaceutical and biotechnology industries, medical device manufacturers, hospitals, and any healthcare institutions that are dedicated to controlling the hazards of cross contamination. DEC-CYCLE II can be used on surfaces in aseptic filling and gowning rooms, in general manufacturing areas, or on numerous other surfaces that require cleaning.

Disinfectant – Detergent – Deodorizer

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- Each sterile container is double bagged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System made with USP Water for Injection (0.25 EU/mL)
- Sterile pharmaceutical cleanroom formula
- Multiple convenient container sizes – Unit Dose, 473 mL, 3.79 Liter, and 200L
- Broad spectrum efficacy confirmed by using A.O.A.C protocol testing at a use dilution of 1:256

Product Uses*

- Hard, inanimate surfaces in filling and gowning rooms
- General manufacturing areas
- Machinery, tables, counters, laminar flow benches, floors, and walls
- Stainless steel, glazed porcelain, glass, and chrome

Order Number	*Description*	*Qty/cs*
DCY2-01-E	DEC-CYCLE II, 3.79 Liter Concentrate, Non-Sterile	4
DCY2-02-E	DEC-CYCLE II, 3.79 Liter Concentrate, Sterile	4
DCY2-03-1Z-E	DEC-CYCLE II, 30 mL Concentrate, Unit Dose, Sterile	24
DCY2-03-2Z-E	DEC-CYCLE II, 59 mL Concentrate, Unit Dose, Sterile	24
DCY2-04-1/2Z-E	DEC-CYCLE II, 3.79 Liter SimpleMix, Use Dilution 1:256, Sterile	4
DCY2-04-1Z-E	DEC-CYCLE II, 3.79 Liter SimpleMix, Use Dilution 1:128, Sterile	4
DCY2-05-1/2Z-E	DEC-CYCLE II, 3.79 Liter SimpleMix, Use Dilution 1:256, Non-Sterile	4
DCY2-06-16Z-01-E	DEC-CYCLE II, 473 mL SimpleMix, Attached Trigger, Use Dilution 1:256, Sterile	12
DCY2-06-16Z-02-E	DEC-CYCLE II, 473 mL SimpleMix, Attached Trigger, Use Dilution 1:128, Sterile	12
DCY2-07-16Z-01-E	DEC-CYCLE II, 473 mL SimpleMix, Attached Trigger, Use Dilution 1:256, Non-Sterile	12
DCY2-07-16Z-02-E	DEC-CYCLE II, 473 mL SimpleMix, Attached Trigger, Use Dilution 1:128, Non-Sterile	12
DCY2-10-200L-CI-E	DEC-CYCLE II, 200L, SimpleMix Drum, Use Dilution 1:128 Sterile	1

* All points do not apply to Non-Sterile products

DEC-QUAT® 100

Phosphate-Free Quaternary Ammonium Solution

DQ100-03-8Z-E

DQ100-02-E

DQ100-04-2Z-E

DQ100-06-16Z-01-E

VAI® manufactures an EPA registered one-step, phosphate-free, quaternary ammonium solution that is a proven cleaner, sanitizer, mildewstat and virucide. DEC-QUAT 100 is a broad-spectrum hard surface disinfectant in presence of organic soil (5% blood serum) when used as directed.

DEC-QUAT 100 is recommended for the use in the pharmaceutical, lab animal, biotechnology, medical device, and healthcare industries. DEC-QUAT 100 has been designed to provide effective cleaning, deodorizing, and disinfection in areas where housekeeping and controlling the hazards of cross-contamination in treated surfaces is of prime importance.

Cleaner – Disinfectant – Sanitizer – Deodorizer – Fungicide – Mildewstat – Virucide*

*when used as directed

Quality and Manufacturing**

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits**

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System made with USP Water for Injection (0.25 EU/mL)
- One-step disinfectant that is effective against a broad spectrum of bacteria, is virucidal*, and inhibits the growth of mold and mildew and their odors when used as directed
- Meets OSHA Bloodborne Pathogen Standard for HIV, HBV, and HCV
- Effective non-food contact sanitizer in the presence of 5% serum contamination on hard, non-porous, non-food contact surfaces at 200 ppm active
- Non-abrasive formula will not harm or scratch surfaces, is non-staining, and non-dulling
- Contains no fragrances or phosphates and will not leave grit or soap scum

Product Uses**

- General hard, non-porous surfaces
- Floors, finished floors, walls, ceilings
- Glass, aluminum, brass, copper, laminated surfaces, metal, plated steel, stainless steel, plastic (such as polycarbonate, polyvinylchloride, polystyrene or polypropylene), chrome, plexiglass, enameled surfaces, formica, and vinyl

Order Number	Description	Qty/Cs
DQ100-01-E	DEC-QUAT 100, 3.79 Liter Concentrate, Non-Sterile	4
DQ100-02-E	DEC-QUAT 100, 3.79 Liter Concentrate, Sterile	4
DQ100-03-2Z-E	DEC-QUAT 100, 59 mL Concentrate, Unit Dose, Sterile	24
DQ100-03-8Z-E	DEC-QUAT 100, 237 mL Concentrate, Unit Dose, Sterile	24
DQ100-04-2Z-E	DEC-QUAT 100, 3.79 Liter SimpleMix, Sterile	4
DQ100-05-2Z-E	DEC-QUAT 100, 3.79 Liter SimpleMix, Non-Sterile	4
DQ100-06-16Z-01-E	DEC-QUAT 100, 473 mL SimpleMix, Attached Trigger, Sterile	12
DQ100-07-16Z-01-E	DEC-QUAT 100, 473 mL SimpleMix, Attached Trigger, Non-Sterile	12
DQ100-10-200L-2XI-E	DEC-QUAT 100, 200 L SimpleMix Drum, Sterile	11

** All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-QUAT® 200C

5th Generation Quaternary Ammonium Solution

DQ200C-03-8Z-E

DQ200C-02-E

DQ200C-05-2Z-E

DQ200C-06-16Z-01-E

VAI® manufactures an EPA registered, one-step, fifth generation quaternary ammonium solution. When used as directed, DEC-QUAT 200C is highly effective against a broad spectrum of pathogenic microorganisms including bacteria, anti-biotic resistant bacteria, viruses*, fungi, mold, and mildew. DEC-QUAT 200C is effective in hard water up to 400 ppm hardness (Calculated as CaCO3) in the presence of 5% serum contamination.

DEC-QUAT 200C is recommended for use in pharmaceutical, biotechnology, and medical device manufacturing facilities, in healthcare facilities, and hospitals. DEC-QUAT 200C is a neutral pH and phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection in areas where housekeeping is of prime importance in controlling the hazard of cross-contamination on treated surfaces.

Cleaner – Disinfectant – Non-Food Contact Sanitizer – Deodorizer – Fungicide – Mildewstat – Virucide*

*when used a directed

Quality and Manufacturing**

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits**

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System made with USP Water for Injection (0.25 EU/mL)
- Proven one-step disinfectant, cleaner, sanitizer, fungicide, mildewstat, and virucide when used as directed
- Meets OSHA Bloodborne Pathogen Standard for HIV, HBV, and HCV
- One-step hospital-use germicidal disinfectant
- No-rinse disinfectant cleaner that disinfects, cleans, and deodorizes in one labor-saving step
- Neutral pH, chemically balanced, contains no fragrances, and contains no phosphorous
- Will not harm most surfaces and will not leave grit or soap scum

Product Uses**

- Hard, inanimate surfaces in filling and gowning rooms
- General manufacturing areas
- Machinery tables, counter tops, laminar flow benches, floors, and walls
- Stainless steel, porcelain, glass, and chrome

Order Number	*Description*	*Qty/Cs*
DQ200C-01-E	DEC-QUAT 200C, 3.79 Liter Concentrate, Non-Sterile	4
DQ200C-02-E	DEC-QUAT 200C, 3.79 Liter Concentrate, Sterile	4
DQ200C-03-2Z-E	DEC-QUAT 200C, 59 mL Concentrate, Unit Dose, Sterile	24
DQ200C-03-8Z-E	DEC-QUAT 200C, 237 mL Concentrate, Unit Dose, Sterile	24
DQ200C-04-2Z-E	DEC-QUAT 200C, 3.79 Liter SimpleMix, Sterile	4
DQ200C-05-2Z-E	DEC-QUAT 200C, 3.79 Liter SimpleMix, Non-Sterile	4
DQ200C-06-16Z-01-E	DEC-QUAT 200C, 473 mL SimpleMix, Attached Trigger, Sterile	12
DQ200C-07-16Z-01-E	DEC-QUAT 200C, 473 mL SimpleMix, Attached Trigger, Non-Sterile	12

** All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

HYPO-CHLOR®

Sodium Hypochlorite Solution

SHC-16Z-0.25-E

SHC-16Z-0.52-E

SHC-02-5.25-E

SHC-13Z-5.25-E

VAI® manufactures three EPA registered sodium hypochlorite solutions, formulated with USP Water for Injection and concentrated at 0.25%, 0.52%, or 5.25%, that are used to disinfect and sanitize cleanrooms and controlled areas. HYPO-CHLOR products are effective, one-step, ready-to-use, sanitizers, disinfectant, and fungicides.

HYPO-CHLOR Products are recommended for use in healthcare institutions, biopharmaceutical, medical device, and diagnostic manufacturing facilities. HYPO-CHLOR Products have been developed for use in cleaning rotation cycles on most washable, non-porous, hard, inanimate environmental surfaces for maintaining a clean environment.

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Formulated with USP Water for Injection (0.25 EU/mL)
- 5.25% assayed to current USP compendium

Features and Benefits*

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility tested to current USP compendium
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Available in three ready-to-use solutions: 0.25%, 0.52%, and 5.25%
- Designed for all washable environmental surfaces
- 16 oz containers come with sterile spray attachment

Product Uses*

- Cleanroom and controlled areas
- Aseptic filling and gowning rooms, general manufacturing areas, laboratories
- Machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves
- Plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, stainless steel

Order Number	*Description*	*Qty/Cs*
SHC-01-5.25-E	HYPO-CHLOR 5.25%, 3.79 Liter, Non-Sterile	4
SHC-01-0.52-E	HYPO-CHLOR 0.52%, 3.79 Liter, Non-Sterile	4
SHC-01-0.25-E	HYPO-CHLOR 0.25%, 3.79 Liter, Non-Sterile	4
SHC-02-5.25-E	HYPO-CHLOR 5.25%, 3.79 Liter, Sterile	4
SHC-02-0.52-E	HYPO-CHLOR 0.52%, 3.79 Liter, Sterile	4
SHC-02-0.25-E	HYPO-CHLOR 0.25%, 3.79 Liter, Sterile	4
SHC-13Z-5.25-E	HYPO-CHLOR 5.25%, 384 mL, Unit Dose, Sterile	12
SHC-16Z-5.25-E	HYPO-CHLOR 5.25%, 473 mL, Unattached Trigger, Sterile	12
SHC-16Z-0.52-E	HYPO-CHLOR 0.52%, 473 mL, Unattached Trigger, Sterile	12
SHC-16Z-0.25-E	HYPO-CHLOR 0.25%, 473 mL, Unattached Trigger, Sterile	12
SHC-10-200L-0.25-E	HYPO-CHLOR 0.25%, 200L Drum, Sterile	1

*All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

HYPO-CHLOR® Neutral

Neutralized Sodium Hypochlorite

SHC-NPH-0.25-16Z

SHC-NPH-0.25-02

SHC-NPH-0.52-16Z

SHC-NPH-0.52-02

VAI® manufactures two effective, neutralized sodium hypochlorite solutions formulated with USP Water for Injection at 0.25% or 0.52% concentrations. This neutralized solution can be used as an improved and enhanced sodium hypochlorite cleaner on numerous cleanroom surfaces with reduced consequences of corrosion, pitting, and rusting.

HYPO-CHLOR Neutral Products have been designed for all pharmaceutical, biopharmaceutical, biotechnology, healthcare, medical device, and diagnostic manufacturing cleaning rotations that demand a neutral pH sodium hypochlorite solution adequate for maintaining a clean and critical environment.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Formulated with USP Water for Injection (0.25 EU/mL)

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System
- Available in two concentrations: 0.25% and 0.52%
- Effective for up to 24 hours post activation
- Enhanced cleaning applications over a standard sodium hypochlorite solution
- Increased cleaning surface compatibility
- Neutralized sodium hypochlorite will significantly reduce corroding, rusting, and pitting of cleanroom surfaces
- Designed for all washable non-porous environmental surfaces

Product Uses

- Cleanroom and controlled areas
- Non-porous, inanimate surfaces
- Aseptic filling and gowning rooms, general manufacturing areas, laboratories
- Machinery, tools, tables, counters, laminar flow benches, floors, walls, carts, shelves
- Plastic, glass, vinyl, glazed porcelain, laminates, glazes tiles, stainless steel

Order Number	*Description*	*Qty/Cs*
SHC-NPH-0.25-16Z	HYPO-CHLOR Neutral 0.25%, 473 mL SimpleMix, Attached Activator, Attached Trigger, Sterile	12
SHC-NPH-0.25-02	HYPO-CHLOR Neutral 0.25%, 3.79 Liter SimpleMix, Attached Activator, Sterile	4
SHC-NPH-0.25-200L	HYPO-CHLOR Neutral 0.25%, 200 L SimpleMix Drum, Attached Activator, Sterile	1
SHC-NPH-0.52-16Z	HYPO-CHLOR Neutral 0.52%, 473 mL SimpleMix, Attached Activator, Attached Trigger, Sterile	12
SHC-NPH-0.52-02	HYPO-CHLOR Neutral 0.52%, 3.79 Liter SimpleMix, Attached Activator, Sterile	4
SHC-NPH-0.52-200L	HYPO-CHLOR Neutral 0.52%, 200 L SimpleMix Drum, Attached Activator, Sterile	1

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-PEROX®

Hydrogen Peroxide Solution

SPER-16Z-6%

SPER-01-6%

SPER-32Z-3%

SPER-02-3%

VAI® manufactures two hydrogen peroxide solutions formulated with USP Water for Injection, STERI-PEROX® 3% and 6%. As an effective one-step, ready-to-use, oxidizing cleaner, STERI-PEROX, penetrates to the surface and is tough on a variety of soils. STERI-PEROX reduces exposure concerns for VOC's in cleanroom operations, leaves a low remaining residue, and is designed for most washable, non-porous, hard, inanimate environmental surfaces.

STERI-PEROX Products are processed to comply with the standards required by the pharmaceutical, biotechnology, healthcare, and medical device industries. STERI-PEROX is recommended for use in cleanroom cleaning rotations that demand the use of a sterile hydrogen peroxide solution adequate for maintaining a clean and critical environment.

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Formulated with USP Water for Injection (0.25 EU/mL)

Features and Benefits*

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility tested to current USP compendium
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Compatible with most surfaces
- Available in two ready-to-use solutions: 3% and 6% concentrations
- 16 oz and 32 oz containers come with sterile spray attachments
- Low remaining residue

Product Uses*

- Most environmental, hard, non-porous surfaces
- Manufacturing equipment, packaging equipment, filling equipment
- Glass, plexiglass, stainless steel
- Walls, ceilings
- Compatible with many types of glove materials

Order Number	*Description*	*Qty/Cs*
SPER-01-3%	STERI-PEROX 3%, 3.79 Liter, Non-Sterile	4
SPER-01-6%	STERI-PEROX 6%, 3.79 Liter, Non-Sterile	4
SPER-02-3%	STERI-PEROX 3%, 3.79 Liter, Sterile	4
SPER-02-6%	STERI-PEROX 6%, 3.79 Liter, Sterile	4
SPER-16Z-3%	STERI-PEROX 3%, 473 mL, Unattached Trigger, Sterile	12
SPER-16Z-6%	STERI-PEROX 6%, 473 mL, Unattached Trigger, Sterile	12
SPER-32Z-3%	STERI-PEROX 3%, 946 mL, Unattached Trigger, Sterile	12
SPER-10-200L-3%	STERI-PEROX 3%, 200L Drum, Sterile	1
SPER-10-200L-6%	STERI-PEROX 6%, 200L Drum, Sterile	1

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-SPORE 200 Plus®

Peracetic Acid and Hydrogen Peroxide Solution

DS200-03-13ZA-E

DS200-02A-E

DS200-04-1/2ZA-E

DS200-06-16Z-01-E

VAI® manufactures an EPA Registered Peracetic Acid and Hydrogen Peroxide solution that is for use as a broad spectrum sanitizer, disinfectant, virucide, sporicide, sterilant, fungicide, cleaner and deodorizer. DEC-SPORE 200 Plus is a proven "one-step" disinfectant - virucide that cleans as it disinfects in one operation and has been shown to be effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

DEC-SPORE 200 Plus is recommended for use in the pharmaceutical, biotechnology, medical device, hospital, healthcare, and lab animal research industries. DEC-SPORE 200 Plus has been developed for use in cleaning rotation cycles where hard surface disinfectants are essential to maintaining a clean environment.

Sanitizer – Disinfectant – Virucide* – Fungicide – Sporicide – Sterilant – Deodorizer – Cleaner

* When used as directed

Quality and Manufacturing**

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Aseptically filled into sterile components via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits**

- Each sterile container is individually bagged in easy tear packaging
- Each sterile container of SimpleMix is individually double bagged in easy tear packaging
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis and Certificate of Sterility tested to current USP compendium
- Available in three configurations: concentrate, disinfectant use dilution, and sporicidal use dilution
- Available in the convenient, one-step, ready-to-use, SimpleMix® System made with USP Water for Injection (0.25 EU/mL)
- Concentrated broad-spectrum disinfectant-virucide
- Disinfects as it at cleans in one operation
- Designed for the sterilization of manufacturing, filling, and packaging equipment in aseptic processes
- Proven one-step disinfectant-cleaner for use in healthcare settings and quickly removes dirt, grime, blood, and other organic matter commonly found in healthcare facilities
- Effective disinfectant in water up to 500ppm hardness in the presence of 5% serum contamination and dried soap film residue

Product Uses**

- Floors, walls, tables, chairs, counter tops, sinks, shelves, racks, carts
- Filling equipment, packaging equipment
- Tiles, linoleum, vinyl, glazes porcelain, plastic, stainless steel, glass

Order Number	*Description*	*Qty/Cs*
DS200-01A-E	DEC-SPORE 200 Plus, 3.79 Liter Concentrate, Non-Sterile	4
DS200-02A-E	DEC-SPORE 200 Plus, 3.79 Liter Concentrate, Sterile	4
DS200-03-2ZA-E	DEC-SPORE 200 Plus, 59 mL Concentrate, Unit Dose, Sterile (disinfectant w/15.14 Liter of water)	24
DS200-03-13ZA-E	DEC-SPORE 200 Plus, 384 mL Concentrate, Unit Dose, Sterile (sporicidal w/7.6 Liter of water)	12
DS200-04-1/2ZA-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Disinfectant Dose, Sterile	4
DS200-04A-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Sporicidal Dose, Sterile	4
DS200-05-1/2ZA-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Disinfectant Dose, Non-Sterile	4
DS200-05A-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Sporicidal Dose, Non-Sterile	4
DS200-06-16Z-01-E	DEC-SPORE 200 Plus, 473 mL SimpleMix, Sporicidal Dose, Attached Trigger, Sterile	12
DS200-06-16Z-02-E	DEC-SPORE 200 Plus, 473 mL SimpleMix, Disinfectant Dose, Attached Trigger, Sterile	12
DS200-07-16Z-01-E	DEC-SPORE 200 Plus, 473 mL SimpleMix, Sporicidal Dose, Attached Trigger, Non-Sterile	12
DS200-07-16Z-02-E	DEC-SPORE 200 Plus, 473 mL SimpleMix, Disinfectant Dose, Attached Trigger, Non-Sterile	12
DS200-10-200L-SD-CIE	DEC-SPORE 200 Plus, 200 L SimpleMix Drum, Sporicidal Dose, Sterile	1
DS200-11-200L-SD-CIE	DEC-SPORE 200 Plus, 200 L SimpleMix Drum, Disinfectant Dose, Sterile	1

** All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

VAI® WFI Quality Water

USP Grade Bulk Water for Injection

VAI-WFI-16Z

VAI-WFI-1G

VAI-WFI-SP-11Z

VAI-WFI-2G

VAI® manufactures a USP grade bulk Water for Injection (WFI), VAI WFI Quality Water, that is ready-to-use and can be used throughout any facility for chemical formulation, disinfectant dilution, cleaning, rinsing, and lubrication. VAI's WFI Quality Water is produced from a 6 effect distilled water system that is validated, routinely monitored, and passes all USP monograph requirements for "Water for Injection".

VAI WFI Quality Water is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. VAI WFI Quality Water is an innovative solution for GMP facilities that demand the use of a sterile WFI quality water in their daily operations but do not have it readily available on site.

VAI WFI QUALITY WATER IS NOT FOR HUMAN OR ANIMAL INJECTION, DIAGNOSTIC, OR THERAPEUTIC USE.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Lot tested for endotoxins
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Produced from a validated 6 effect distilled water system
- Passes all USP monograph requirements for "Water for Injection"

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- For use on a multitude of surfaces
- Lubricates for continuous and effortless manufacturing
- Meets the needs for USP grade WFI when required in cleanroom operations
- Ideal for operations that do not have USP grade WFI readily available

Product Uses

- Chemical formulation, disinfectant dilution
- Lubricating
- Rinsing, cleaning

Order Number	*Description*	*Qty/Cs*
VAI-WFI-16Z	VAI WFI Quality Water, 473 mL, Attached Trigger, Sterile	12
VAI-WFI-SP-11Z	VAI WFI Quality Water, 325 mL, Aerosol Spray/Mist, Unattached Nozzle Extension, Sterile	24
VAI-WFI-1G	VAI WFI Quality Water, 3.79 Liter, Sterile	4
VAI-WFI-2G	VAI WFI Quality Water, 7.6 Liter, Sterile	2
VAI-WFI-200L	VAI WFI Quality Water, 200 L Drum, Single Bagged, Sterile	1
VAI-WFI-200L-2B	VAI WFI Quality Water, 200 L Drum, Double Bagged, Sterile	1

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-WATER®

USP Purified Water

STWA-16Z

STWA-02

STWA-2G

STWA-8L

VAI® manufactures a USP grade purified water, STERI-WATER that is an excellent choice for chemical formulation, disinfectant dilution, cleaning, lubricating, rinsing, and many other applications within a cleanroom.

STERI-WATER is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. STERI-WATER is ready-to-use and is ideal for operations that do not have USP grade purified water readily available on site when it is required for operational procedures.

STERI-WATER IS NOT FOR HUMAN OR ANIMAL INJECTION, DIAGNOSTIC, OR THERAPEUTIC USE.

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Specifically formulated as a sterile pharmaceutical cleanroom formula
- Lubricates for continuous and effortless manufacturing
- Designed for all washable environmental surfaces
- Meets the needs for USP purified water required in cleanroom operations
- Ideal for operations that do not have USP purified water readily available

Product Uses*

- Chemical formulation, disinfectant dilution
- Lubricating
- Rinsing, cleaning

Order Number	*Description*	*Qty/Cs*
STWA-01	STERI-WATER, 3.79 Liter, Non-Sterile	4
STWA-02	STERI-WATER, 3.79 Liter, Sterile	4
STWA-16Z	STERI-WATER, 473 mL, Attached Trigger, Sterile	12
STWA-2G	STERI-WATER, 7.6 Liter, Sterile	2
STWA-8L	STERI-WATER, 8 Liter Pail, Sterile	2
STWA-5G	STERI-WATER, 18.9 Liter, Sterile	1

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

SIMPLEMIX® Systems

For The Exact Formulation Of Disinfectants and Sporicides*

- The patented system eliminates concerns by regulatory agencies for proper mixing and sterility of the solution
- No filtering solutions to aseptic manufacturing areas
- No need to assure sterile USP Water for Injection is present in the aseptic area
- No concern for mixing and handling concentrate phenolics, quaternary ammonium, peracetic acid and H202, or cleaners with sterile water in aseptic manufacturing operations
- The system assures the appropriate dilution is made each time in a closed sterile system
- Dilutions are made safely as concentrates are never handled
- Chemical agents and the USP Water for Injection (0.25 EU/mL) are filtered at 0.2 microns and manufactured in ISO 5 (Grade A/B, former Class 100)
- The contents of the double bagged packages are sterilized through a validated gamma irradiation cycle that assure a 10^{-6} Sterility Assurance Level or via aseptic fill
- All product lots are sterility tested per current USP compendium
- Available in 3 sizes: 473 mL trigger sprayer, 3.79 Liter, and 200 Liter
- Easy to use, just push the plunger completely down, swirl to allow the concentrate to mix with the water, and the solution is then ready to use (473 mL and 3.79 L sizes only)
- Available in sterile and non-sterile versions of the following VAI products: DEC-CLEAN®, DEC-CYCLE® II, DEC-QUAT® 100, DEC-QUAT® 200C, DEC-SPORE 200® Plus, and HYPO-CHLOR® Neutral

* All points do not apply to Non-Sterile products

SIMPLEMIX® 1 Gallon/3.79 L Aseptic Mixing System

For the Exact Formulation of 1 Gallon/3.79 L Size Disinfectants and Sporicides

Ready-to-Use Mixing Instructions

1) To prepare use solution, open cap.

2) Peel off inner seal by grasping tab at far edge and pulling off.

3) Firmly push small, inner container all the way down.

4) Replace cap and tighten.

5) Slowly swirl for 15 seconds.

6) Open small side spout and peel off inner seal, as above.

7) Pour solution from small side spout onto surfaces to be treated or alternate containers.

8) Follow directions for use on label.

3.79 Liter STERILE

Order Number	*Description*	*Qty/Cs*
DCY2-04-1/2Z-E	DEC-CYCLE® II, 3.79 Liter SimpleMix, Use Dilution 1:256	4
DCY2-04-1Z-E	DEC-CYCLE II, 3.79 Liter SimpleMix, Use Dilution 1:128	4
DQ100-04-2Z-E	DEC-QUAT® 100, 3.79 Liter SimpleMix	4
DQ200C-04-2Z-E	DEC-QUAT® 200C, 3.79 Liter Simple Mix	4
DS200-04-1/2ZA-E	DEC-SPORE 200 Plus®, 3.79 Liter SimpleMix, Disinfectant Dose	4
DS200-04A-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Sporicidal Dose	4
DC-04-1Z-E	DEC-CLEAN®, 3.79 Liter SimpleMix	4
SHC-NPH-0.25-02	HYPO-CHLOR® Neutral 0.25%, 3.79 Liter SimpleMix	4
SHC-NPH-0.52-02	HYPO-CHLOR Neutral 0.52%, 3.79 Liter SimpleMix	4

3.79 Liter NON-STERILE*

DCY2-05-1/2Z-E	DEC-CYCLE II, 3.79 Liter SimpleMix, Use Dilution 1:256	4
DQ100-05-2Z-E	DEC-QUAT 100, 3.79 Liter SimpleMix	4
DQ200C-05-2Z-E	DEC-QUAT 200C, 3.79 Liter Simple Mix	4
DS200-05-1/2ZA-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Disinfectant Dose	4
DS200-05A-E	DEC-SPORE 200 Plus, 3.79 Liter SimpleMix, Sporicidal Dose	4
DC-05-1Z-E	DEC-CLEAN , 3.79 Liter SimpleMix	4

SIMPLEMIX® 16 oz/473 mL Aseptic Mixing System

For the Exact Formulation of 16 oz/473 mL Disinfectants and Sporicides

Ready-to-Use Mixing Instructions

1) To prepare use solution, open cap.

2) Peel off inner seal by grasping tab at far edge and pulling off.

3) Firmly push small, inner container all the way down.

4) Replace cap and tighten.

5) Slowly swirl for 15 seconds.

6) Move spray nozzle to open position.

7) Follow directions for use on label.

473 mL STERILE		
DCY2-06-16Z-01-E	DEC-CYCLE® II, 473 mL SimpleMix, Use Dilution 1:256	12
DCY2-06-16Z-02-E	DEC-CYCLE II, 473 mL SimpleMix, Use Dilution 1:128	12
DQ100-06-16Z-01-E	DEC-QUAT® 100, 473 mL SimpleMix	12
DQ200C-06-16Z-01-E	DEC-QUAT® 200C, 473 mL SimpleMix	12
DS200-06-16Z-01-E	DEC-SPORE 200 Plus®,473 mL SimpleMix, Sporicidal Dose	12
DS200-06-16Z-02-E	DEC-SPORE 200 Plus,473 mL SimpleMix, Disinfectant Dose	12
DC-06-16Z-01-E	DEC-CLEAN®, 473 mL SimpleMix	12
SHC-NPH-0.25-16Z	HYPO-CHLOR® Neutral 0.25%, 473 mL SimpleMix	12
SHC-NPH-0.52-16Z	HYPO-CHLOR Neutral 0.52%, 473 mL SimpleMix	12

473 mL NON-STERILE*		
DCY2-07-16Z-01-E	DEC-CYCLE II, 473 mL SimpleMix, Use Dilution 1:256	12
DCY2-07-16Z-02-E	DEC-CYCLE II, 473 mL SimpleMix, Use Dilution 1:128	12
DQ100-07-16Z-01-E	DEC-QUAT 100, 473 mL SimpleMix	12
DQ200C-07-16Z-01-E	DEC-QUAT 200C, 473 mL SimpleMix	12
DS200-07-16Z-01-E	DEC-SPORE 200 Plus,473 mL SimpleMix, Sporicidal Dose	12
DS200-07-16Z-02-E	DEC-SPORE 200 Plus,473 mL SimpleMix, Disinfectant Dose	12
DC-07-16Z-01-E	DEC-CLEAN, 473 mL SimpleMix	12

SIMPLEMIX® 200 L Aseptic Mixing System

For Large Scale Aseptic Manufacturing Environments

DCY2-10-200L-CI-E

The SimpleMix 200 L Aseptic Mixing System provides the ability to mix 200 Liters of disinfectants and sporicides in a closed system for users whom require larger volumes of cleaning agents in their operations. The closed mixing system incorporates three integral parts: a 200 L container of 0.2 micron filtered sterile USP WFI Quality Water (bottom container), a cubicontainer of 0.2 micron filtered sterile concentrate disinfectant, sporicide or cleaner (top container), and a hose and valve system. The 200 L container and the cubicontainer are connected via the sterile hosing and valve system awaiting activation by the end user. The entire 200 L system container, cubicontainer, and hoses are double bag packaged and shipped to the end user.

The method of attaining a sterile product by Veltek Associates, Inc. is dependent upon the concentrate disinfectant/sporicide's stability in varying sterilization methodologies. Two methodologies are employed. Products are either aseptically filled in a ISO 5 (Grade A, former Class 100) area utilizing pre-sterilized components (containers, hoses, and bags) or packaged in a ISO 5 (Grade A, former Class 100) area and subsequently terminally sterilized through a validated 10^{-6} SAL gamma radiation cycle. The SimpleMix 200 L Aseptic Mixing System (WFI water and disinfectant/sporicide) are subsequently tested per lot for sterility via current USP protocol in either manufacturing methodology.

As received by the end user, the entire 200 L container is double bag packed and skidded. The end user can transfer the container via dolly, manual, or automated lifting/transporting device to the ISO 8 (Grade D, former Class 10,000) area where one outer bag is removed. The 200 L container is then transferred to the ISO 7 (Grade C, former Class 10,000) area where the second outer bag is removed prior to entry to the ISO 5 (Grade A, former Class 100). At this point, one hose is inserted into the peristaltic pump. The pump can technically be located in any grade as the SimpleMix 200 L is a closed system of mixing. The container can be mixed in lower classifications and pumped to the desired end use point or mixed within the higher classification areas as all inside the double bag has been rendered sterile. The peristaltic pump mixes the cubicontainer containing the concentrate with the WFI Quality Water for approximately 15 minutes. The solution is contained in a closed sterile disposable system. By opening of the dispense valve the sterile solution can be distributed through the sterile closed system to point of use. Once the end valve is closed, the system ensures its sterile integrity for the next use.

The SimpleMix 200 L Aseptic Mixing System is another innovative solution from Veltek Associates, Inc. to assist large scale manufacturing operations with the difficult task of getting sterile disinfectants and sporicides to the aseptic area.

Order Number	*Description*	*Qty/Cs*
DC-10-200L-CI-E	DEC-CLEAN®, 200 L SimpleMix Drum, Sterile	1
DCY2-10-200L-CI-E	DEC-CYCLE® II, 200 L SimpleMix Drum, Sterile	1
DQ100-10-200L-2XI-E	DEC-QUAT® 100, 200 L SimpleMix Drum, Sterile	1
DS200-10-200L-SD-CI-E	DEC-SPORE 200 Plus®, 200 L SimpleMix Drum, Sporicidal Dose, Sterile	1
DS200-11-200L-SD-CI-E	DEC-SPORE 200 Plus, 200 L SimpleMix Drum, Disinfectant Dose, Sterile	1
SHC-NPH-0.25-200L	HYPO-CHLOR® Neutral 0.25%, 200 L SimpleMix Drum, Attached Activator, Sterile	1
SHC-NPH-0.52-200L	HYPO-CHLOR Neutral 0.52%, 200 L SimpleMix Drum, Attached Activator, Sterile	1

SIMPLEMIX® 200 L Aseptic Mixing System

For Large Scale Aseptic Manufacturing Environments

Ready-to-Use Mixing Instructions

Remove drum from double-bag packaging.

Remove cubic container from top of drum.
1) Close all valves. 2) Uncoil hoses.

3) Connect center hose to pump between X and Y.

4) Open valve 1, then valve 2, then valve 4.

5) START pump to empty cubic container.
6) When cubic container is empty, turn pump OFF.

7) Close valve 1 and valve 2.

8) Open valve 6 and valve 5.

9) Re-start pump and mix 15 minutes.
10) Stop pump.

11) Close valve 4.
12) To dispense: Open valves 3 and 7. Run pump only when dispensing.
13) Follow directions for use on label.

DEC-CLEAN®

Residue Remover and Cleaner

DC-03-4Z-E

DC-02-E

DC-04-1Z-E

DC-06-16Z-01-E

VAI® manufactures an effective one-step residue remover and cleaner, DEC-CLEAN. Using DEC-CLEAN, one can assure that noticeable and unnoticeable residues are removed, thus returning the surface to its original form. Residues left behind from disinfectants, sanitizers, and sporicidies, including sodium hypochlorite can be easily removed using DEC-CLEAN. Returning the surface to its original form assures that future decontamination will be able to penetrate to the surface.

DEC-CLEAN is designed for and processed to meet the standards required by pharmaceutical, biotechnology, healthcare, and lab animal research operations that demand a cleaning agent to remove residues left behind from disinfecting agents. Due to DEC-CLEAN's formulation it is an excellent cleaner designed for all washable, non-porous environmental surfaces.

Quality and Manufacturing*

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in our convenient, one-step, ready-to-use, SimpleMix System made with USP Water for Injection (0.25 EU/mL)
- Removes residues from sanitizers, disinfectants, and sporicides
- Excellent cleaning characteristics

Product Uses*

- All washable, non-porous, environmental surfaces
- Aseptic filling suites, controlled corridors
- Aseptic connections, process lines
- Walls, floors, ceilings, counter tops
- Stainless steel

Order Number	*Description*	*Qty/Cs*
DC-01-E	DEC-CLEAN, 3.79 Liter Concentrate, Non-Sterile	4
DC-02-E	DEC-CLEAN, 3.79 Liter Concentrate, Sterile	4
DC-03-4Z-E	DEC-CLEAN, 118 mL Concentrate, Unit Dose, Sterile	24
DCWFI-SP-11Z-E	DEC-CLEAN, 325 mL Aerosol Spray/Mist, Sterile	24
DC-04-1Z-E	DEC-CLEAN, 3.79 Liter SimpleMix, Sterile	4
DC-05-1Z-E	DEC-CLEAN, 3.79 Liter SimpleMix, Non-Sterile	4
DC-06-16Z-01-E	DEC-CLEAN, 473 mL Simple Mix, Attached Trigger, Sterile	12
DC-07-16Z-01-E	DEC-CLEAN, 473 mL Simple Mix, Attached Trigger, Non- Sterile	12
DC-10-200L-CI-E	DEC-CLEAN, 200 L Simple Mix Drum, Sterile	1

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STEEL-BRIGHT®

Stainless Steel Polish and Cleaner

SB-02

VAI® manufactures a sterile stainless steel polish and cleaner to remove residues, spots, and stains. STEEL-BRIGHT has been developed for use in cleaning rotation cycles that demand a sterile stainless steel polish and cleaner for use in aseptic manufacturing areas and cleanroom operations.

STEEL-BRIGHT is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, lab animal, and healthcare industries. With sterile STEEL-BRIGHT, stainless steel can be restored to a residue free finish that will not rainbow or accumulate to a heavy build up. Surfaces will remain cleaner longer because there is no residue film to attract the soil. The gloss of the stainless steel is renewed and retained with wiping and buffing with no lasting powdery residue

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Conformance, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in an 8 oz aerosol that will not aspirate the room's air
- Specifically formulated as a sterile cleanroom formula
- Professional strength stainless steel cleaner
- Brightens and polishes without leaving a powdery residue
- Pleasantly lemon scented
- Contains no acids or abrasives

Product Uses

- Remove chemical residues and spotting and staining caused by water and oils on stainless steel
- Brighten and polish stainless steel
- Can also be used on chrome, brass, aluminum, and copper
- Using STEEL-BRIGHT, spray surface with STEEL-BRIGHT or wipe on with STEEL-BRIGHT Wipe then wipe with a dry wipe after drying, and a dry wipe again

Order Number	*Description*	*Qty/Cs*
SB-02	STEEL-BRIGHT, 8 oz Aerosol Spray/Mist, Sterile	24

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-GLASS®

Glass And Plexiglass Residue Remover and Cleaner

DG-03-16Z-E

VAI® manufactures an effective, one-step, ready-to-use, residue remover, and glass and plexiglass cleaner that is formulated with USP Water for Injection. DEC-GLASS removes noticeable and unnoticeable residues, smudges, oils, and dirt build up, thus returning the surface to its original form. Return of the surface to the original form assures that future decontamination operations will address surfaces and not the existing residues.

DEC-GLASS is designed for pharmaceutical and biotechnology cleaning cycles that demand a sterile glass and plexiglass cleaner capable of removing residues from disinfecting agents. DEC-GLASS is an excellent cleaner designed for all washable, non-porous environmental surfaces.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Formulated with USP Water for Injection (0.25 EU/mL)
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Specifically formulated as a glass cleaner and degreaser
- Designed for all washable environmental surfaces
- Streak free and incorporates detergency characteristics
- Low remaining residue

Product Uses

- Environmental, hard, non-porous surfaces
- Glass, plexiglass
- Applications that require the use of a streak free sterile glass cleaner
- Use where there is a build-up of previous disinfectants, oil, or residue as a residue remover

Order Number	*Description*	*Qty/Cs*
DG-03-16-E	DEC-GLASS, 473 mL, Attached Trigger, Sterile	12

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-BUFFER® 90 & 99

Sterile Phosphate Buffer pH 7.2 ± 0.2

SB100-99

SB100-90

VAI® manufactures two sterile, disposable, sodium phosphate buffer solutions, STERI-BUFFER 90 & 99, that are assayed to current USP Standards (Bufferfield's Buffer) and buffered to a pH of 7.2 ± 0.2. STERI-BUFFER Products are available in either a 90 mL or 99 mL fill level.

STERI-BUFFER Products are processed to comply with the standards required by pharmaceutical, biotechnology, and medical device industries. STERI-BUFFER Products have been developed for use as a buffer solution and diluent in lab testing such a bioburden testing, pharmaceutical microbial limits testing, and AET testing and as a rinsing agent.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Formulated with USP Water for Injection (0.25 EU/mL)
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is bagged two per bag in easy tear bags and packaged in two case liners for easy transport to the core
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation tested to current USP compendium
- Available in two fill levels, 90 mL or 99 mL to fit your operation's needs
- Assayed to current USP Standards (Butterfield's Buffer)
- Buffered to a pH of 7.2 ± 0.2
- Each bottle has a "no tamper strip" that breaks once the bottle has been opened
- Disposable
- Odorless

Product Uses

- Rinsing agent
- Buffer solution in laboratory testing including bioburden testing, pharmaceutical microbial limits testing, and AET testing

Order Number	*Description*	*Qty/Cs*
SB100-90	STERI-BUFFER, Phosphate Buffer Solution, 90 mL, Sterile	72
SB100-99	STERI-BUFFER, Phosphate Buffer Solution, 99 mL, Sterile	72

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-SILICON®

Silicone Lubricant And Releasing Spray

SSIL-02

VAI® manufactures a sterile silicon lubricant and releasing spray, STERI-SILICON. STERI-SILICON has been developed for use as a sterile silicon lubricant in aseptic manufacturing areas and cleanrooms to speed up operations in heat sealing, packaging, and general processing.

STERI-SILICON is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, and healthcare industries. STERI-SILICON is an excellent choice for machinery lubrication which is essential for trouble free equipment operations during manufacturing of products, for stopping squeaks, to release sticking objects, and for protecting and prolonging machinery life.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Conformance, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Available in an 8 oz aerosol that will not aspirate the room's air
- Delivered with one unattached nozzle extension per bottle for use in hard to reach areas or when lubricating intricate machinery and equipment parts
- Specifically formulated as a sterile cleanroom formula
- Allows for trouble free processing during manufacturing
- Colorless, has excellent thermal stability, and is inert

Product Uses

- Spray on parts to stop squeaks
- Lubricate moving parts, machinery, and equipment for trouble free operations
- Speed up heat sealing, packaging, and processing
- Release sticking objects
- Use on chains, rollers, delivery chutes, hinges, latches, belts, rubber moldings, and drawers

Order Number	*Description*	*Qty/Cs*
SSIL-02	STERI-SILICON, 237 mL Aerosol Spray/Mist, Sterile	24

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-OIL® 200

Sterile Mineral Oil Lubricant

SO200-A1Z

Dropper

VAI® manufactures a sterile, USP grade, penetrating mineral oil lubricant, STERI-OIL. STERI-OIL 200 has been developed for use as a sterile lubricant in aseptic manufacturing areas and cleanrooms to reduce items from sticking, penetrate and lubricate mechanisms, and for moisture displacement.

STERI-OIL 200 is processed to comply with the standards required by pharmaceutical, biotechnology, medical device, and healthcare industries. STERI-OIL 200's heavy consistency provides lubrication, prevents metal-to-metal contact, can withstand high friction without displacement, and reduces metal fatigue. STERI-OIL 200 is ideal for machinery lubrication, which is an essential step for trouble free equipment operation during manufacturing.

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at a 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Each sterile container is double bagged in easy tear packaging
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium
- Specifically formulated as a sterile cleanroom formula
- Available in an 1 oz bottle with a dropper tip for precise application
- Bottle design prevents over use and over application
- Heavy consistency ensures excellent lubrication and penetration
- Allows for trouble free processing during manufacturing
- 100% mineral oil

Product Uses

- Lubricate moving parts, machinery, and equipment for trouble free operations
- Penetrate mechanisms
- Prevent metal-to-metal contact and reduce metal fatigue
- Moisture displacement
- Reduce items from sticking
- On intricate machinery parts or where precise lubrication application is required

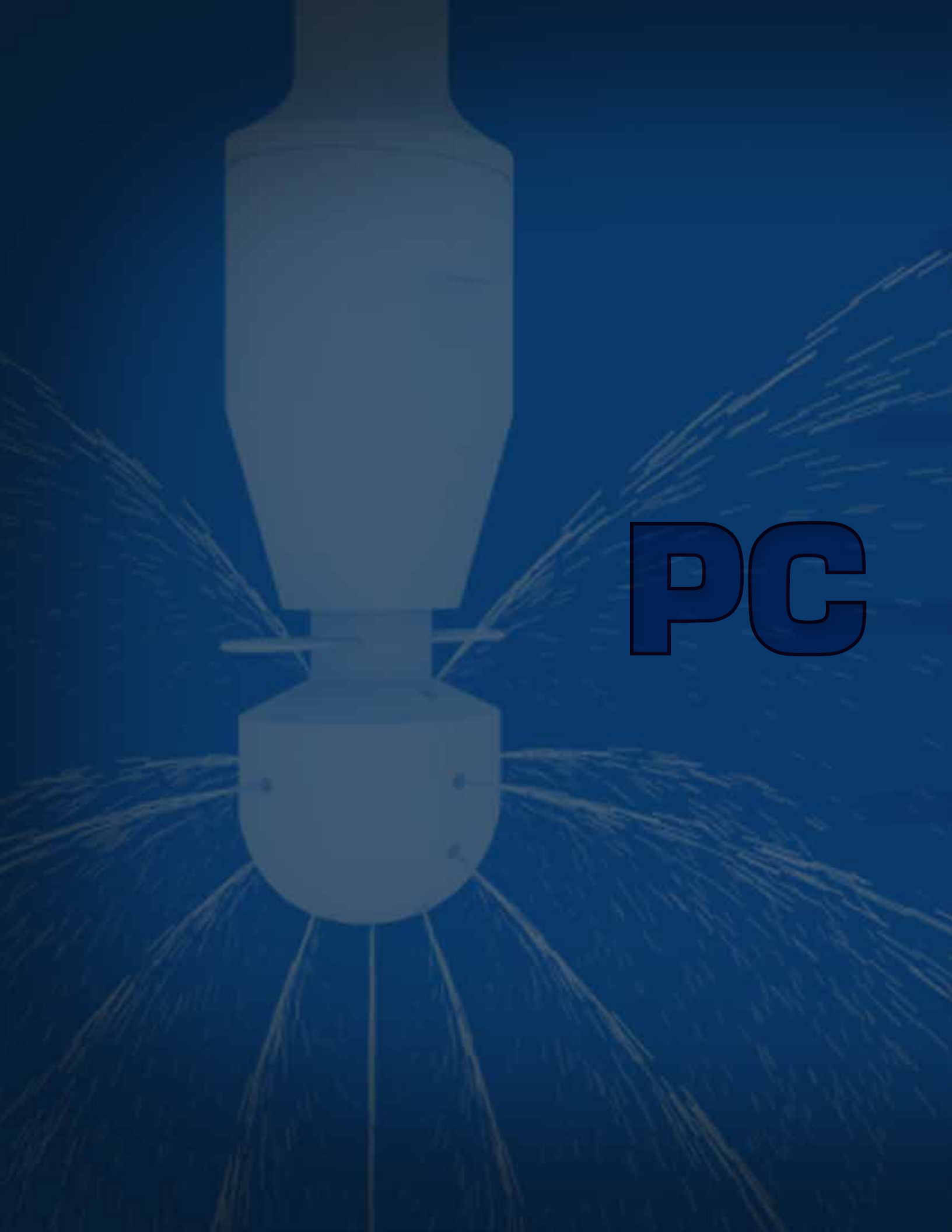
Order Number	*Description*	*Qty/Cs*
SO200-A1Z	STERI-OIL 200, 30 mL Dropper, Sterile	250

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

VAI® Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DEC-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-AHOL WFI FORMULA 60%	WHITE	LIGHT BLUE		
DEC-AHOL WFI FORMULA 91%	WHITE	LIGHT BLUE		
DEC-AHOL FORMULA 99%	WHITE	LIGHT BLUE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DEC-HAND STERILE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-HAND NON-STERILE	CLEAR	LIGHT BLUE		
DEC-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STERI-OIL 200	WHITE	WHITE		
STERI-BUFFER 90 & 99	CLEAR	WHITE		
DEC-CYCLE II	WHITE	LIGHT BLUE		
DEC-CLEAN	WHITE	LIGHT BLUE		
DEC-QUAT 100	WHITE	LIGHT BLUE		
DEC-QUAT 200C	WHITE	LIGHT BLUE		
DEC-QUAT 200V	WHITE	LIGHT BLUE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DEC-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
DEC-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	LIGHT BLUE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DEC-GLASS	WHITE	LIGHT BLUE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		


PC

GMP
275 gallon
Concentrated
Clean-in-place
Acid detergent
Process cleaning
Clean-out-of-place
Neutral pH detergent

Process Cleaners

Automation cleaning
Alkaline detergent
Chelating agents
Remove soils
Surfactants
Rinse free
55 gallon
WFI

Welcome to Process2Clean

Process Cleaning Detergents

Process2Clean cleaning products have been specifically formulated for critical process cleaning applications. In this venue, the appropriate use of process cleaning detergents warrants two concerns. The first concern relates to the ability of the chosen detergent to remove existent product residues that may exist in either open or closed process manufacturing equipment, vessels, or line circuits. The second concern is the ability to rinse free the process soil and detergent down to acceptable trace residual limits. This process assures that all product contact surfaces are clean prior to the formulation of subsequent product lots and eliminates the possibility of product contamination or product adulteration.

Process2Clean cleaning products have been engineered to effectively remove a multitude of pharmaceutical, biotechnology, cosmetic, medical device, food & beverage, and research & development manufacturing residues. All products are formulated with Water For Injection (WFI) and follow the highest quality manufacturing standards in VAI®'s GMP manufacturing facility. All VAI Process2Clean detergents are available in both sterile and non-sterile versions. The sterile version is ultra clean and assures that less contamination is introduced to the system.

A complete lot documentation package is provided with each product shipped. Also a comprehensive support package specific to each individual, VAI, detergent product is available to assist you with your cleaning validation plans.

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53 PROCESS2CLEAN 3 HYDROXYACETIC ACID CLEANER
54 PROCESS2CLEAN 4 GENERAL PURPOSE CLEANING DETERGENT
55 PROCESS2CLEAN 5 NEUTRAL PH CLEANER AND/OR ADDITIVE
56 PROCESS2CLEAN 6 CHLORINATED ALKALINE CLEANING DETERGENT

Lot Specific Documentation Package

Every Process2Clean product is shipped with a complete lot certification and documentation package to ensure product consistency, integrity, and traceability. All lots are traced through the master batch records.

Features

- Designed for the pharmaceutical, biotechnology, cosmetic, medical device, animal research, and food and beverage industries
- Enhanced cleaning properties with very free rinsing capabilities
- Highly concentrated formulas provides low cost per use
- Use dilutions range from .5% to 5% dependent upon the soil load and application
- Most product sizes are available in sterile or non-sterile formulas
- Available in 3.79, 18.9, 113.6, 208, and 1041 Liter containers
- Recycling options offered for 113.6, 208, and 1041 Liter containers
- Contains chelating agents for hard water tolerance
- Contains premium surfactants for great wetting ability and optimal penetration
- Optimal formulation eliminates the need for hazardous organic solvents
- Phosphate free formulas are ecologically safe
- Low and non-foaming formulas are ideal for optimal automated cleaning
- Excellent detergency
- Complete solubility
- Biodegradable

Testing and Validation

Customize an optimal cleaning program to meet your specific process needs with VAI's comprehensive validation support packages and customized testing program. Validation support

Critical Ongoing Residue Evaluation®

Routine cleaning evaluations against your process soils is essential to achieve or maintain overall operation optimization. VAI's CORE Lab program is offered to assist our customers in performing these essential on-going cleaning evaluations. CORE provides scientific data to determine the level of cleaning achieved by our Process2Clean detergents. In addition, CORE can perform side-by-side studies with your existing detergent to ascertain cleaning equivalence. Our comprehensive Process2Clean & CORE program includes but is not limited to the following support documentation specific to our products: substrate compatibility studies, conductivity and TOC curves, toxicological reports including ADE's, specific and non-specific analytical methods for residue detection, and product validation reports. See page 172 for more information regarding VAI's CORE Lab program.

packages include last-to-rinse studies and specific and non-specific analytical product residue detection methods. VAI®'s CORE® (Critical Ongoing Residue Evaluation) Laboratory program will assist with customized soil testing to meet your specific needs. Contact your VAI sales representative for more information.

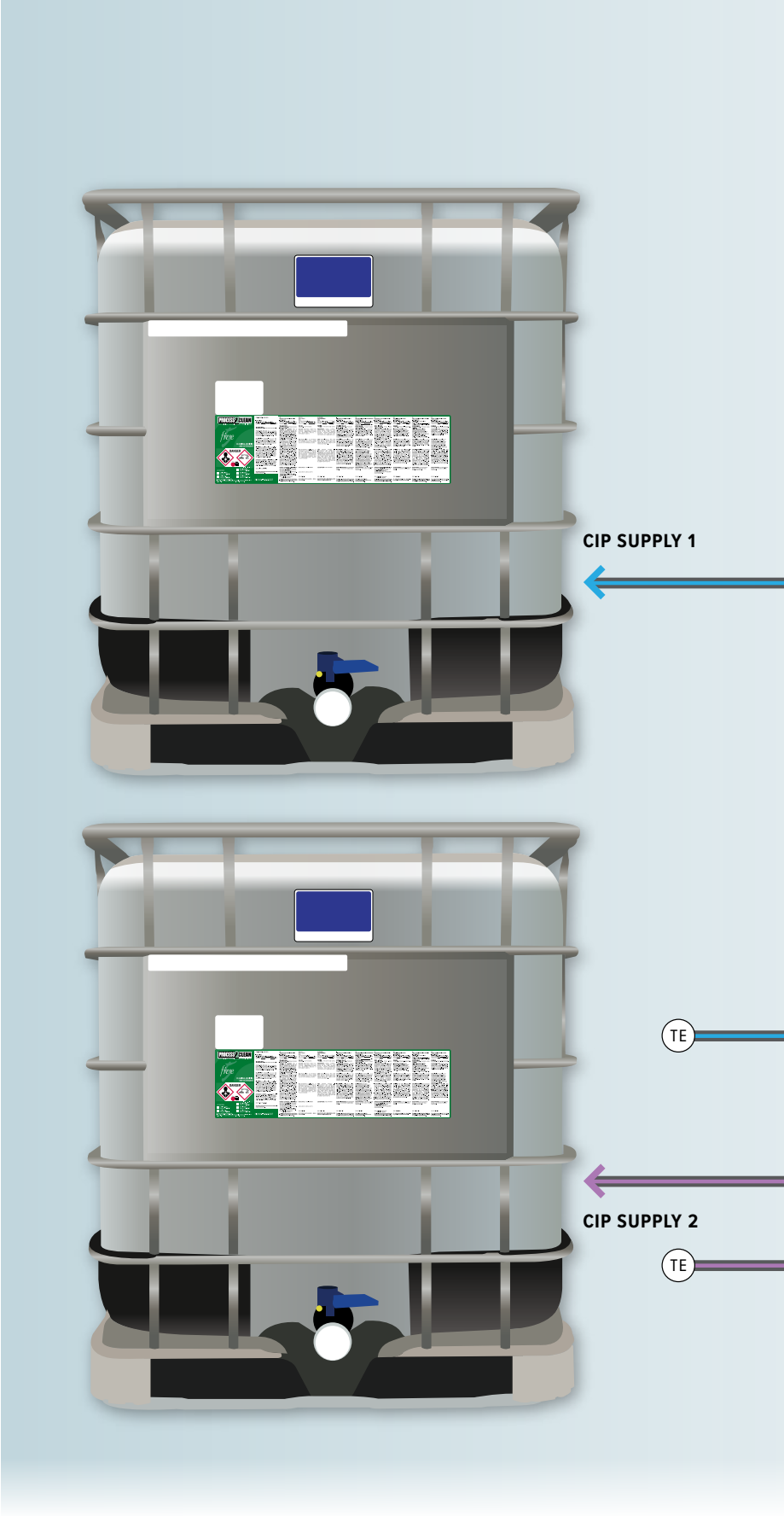
Safety

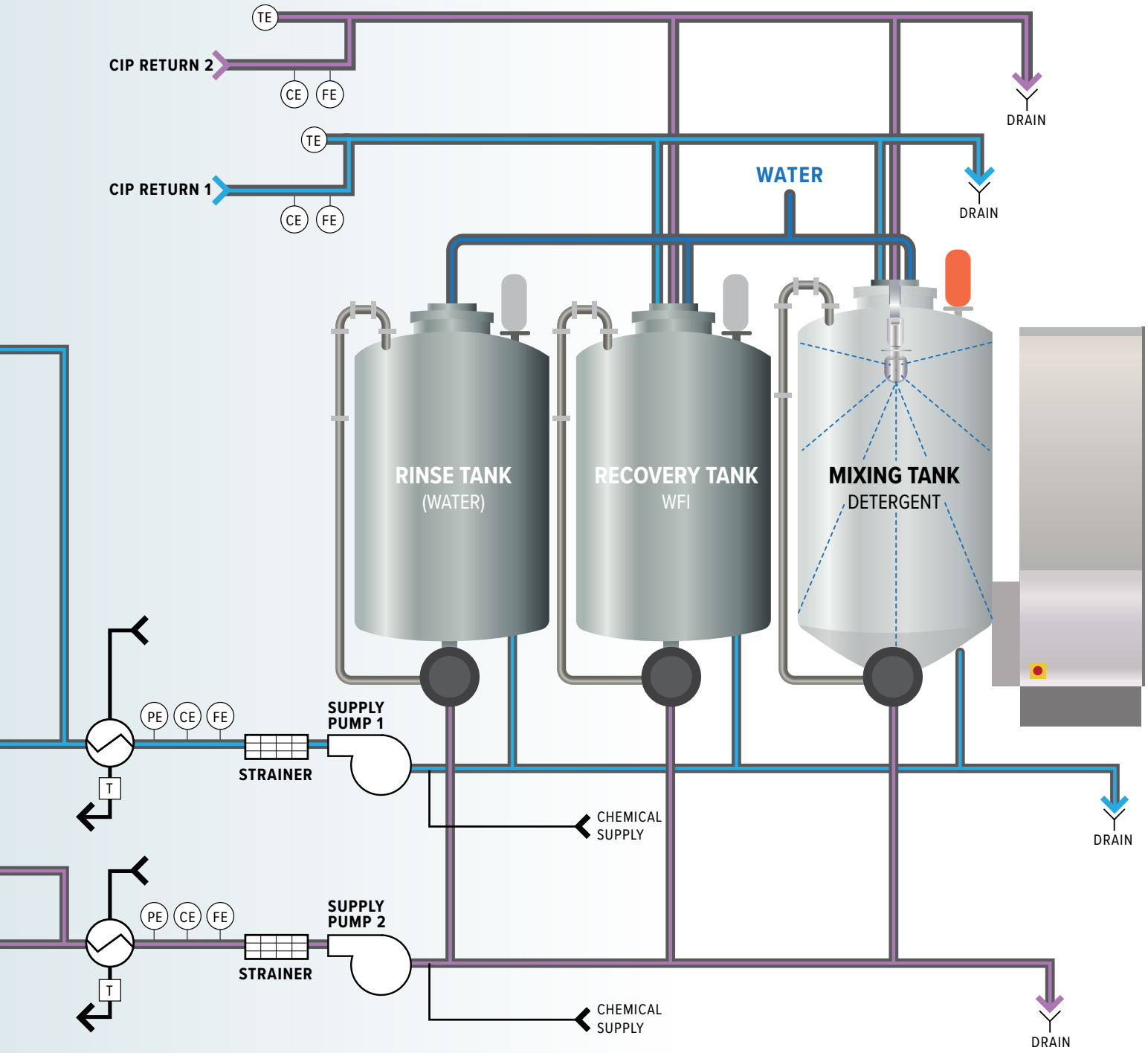
For cautionary and first aid information, consult the material safety data sheet or product label. Please contact your VAI sales representative for further safety and or use recommendations.

Other Technical Data Available Upon Request

A comprehensive support package specific to each individual product is available to assist with your cleaning validation plans. Documents include but are not limited to:

- Product Validation Report
- Product Sterility Validation Report
- Technical Product PDF File
- Safety Data Sheet
- Last-to-Rinse reports
- Specific and Non-Specific Analytical Test Methods for Residue Detection
- Toxicological studies
- Product compatibility studies
- Product formulation disclosure
- On-site technical assistance

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DRAIN

Rinse Your Process Clean

- **Superior cleaning performance against most all tenacious inorganic process soils**
- **Shortens the cleaning program and gets you back manufacturing quickly**
- **Neutral pH cleaning solution**
- **Avoids costly effluent downstream treatment expenses**
- **GRAS ingredients in formulation**
- **Single highly built aqueous detergent**
- **Eliminates the need for both high alkaline and high acidic products for use**
- **Process2Clean 5 is the ideal choice for both manual and automation type cleaning applications**

Learn more: sterile.com/P2C5

PROCESS 2 CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

one

PC-1-1G-01

PC-1-5G-01

PC-1-30G-01

PC-1-275G-01

Process2Clean 1 Alkaline Detergent is a high performance and concentrated detergent that is one of VAI®'s most effective broad spectrum cleaning agent for removing a wide array of residues. This potassium hydroxide detergent formulated with surfactants and chelating agents, has been specifically designed for automation cleaning (CIP) requirements as well as manual applications, and is capable of removing most all organic soil loads. Process2Clean 1 is phosphate free, has minimal to no foaming, and has excellent detergency and rising capabilities.

Process2Clean 1 Alkaline Detergent Specifications*	
Characteristic	Alkaline
Color	Colorless
Appearance	Clear
Odor	Slight odor
Specific Gravity	1.20 - 1.40
pH (1% solution)	11.8 - 13.8
Conductivity (1% solution)	10.0 - 15.0 mS
P Content	0.00%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Minimal to none
Storage Recommendation	Ambient
Process2Clean 1 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass, enamel, plastics, and most elastomers	
Process2Clean 1 Cleaning Residue Specialties	
Proteins, excipients, fine chemicals, silicones, oils, petrolatum, polymers, waxes, fats, and most all types of organics	
Process2Clean 1 Applications	
Automated washers, spray systems, soak, or manual washing	

Order Number	*Description*	*Qty/Cs*
PC-1-1G-01	Process2Clean 1, 3.79 Liter, Non-Sterile	4
PC-1-1G-02	Process2Clean 1, 3.79 Liter, Sterile	4
PC-1-5G-01	Process2Clean 1, 18.9 Liter Drum, Non-Sterile	1
PC-1-5G-02	Process2Clean 1, 18.9 Liter Drum, Sterile	1
PC-1-30G-01	Process2Clean 1, 113.6 Liter Drum, Non-Sterile	1
PC-1-30G-02	Process2Clean 1, 113.6 Liter Drum, Sterile	1
PC-1-55G-01	Process2Clean 1, 208 Liter Drum, Non-Sterile	1
PC-1-55G-02	Process2Clean 1, 208 Liter Drum, Sterile	1
PC-1-275G-01	Process2Clean 1, 1041 Liter Drum, Non-Sterile	1

* All points do not apply to Non-Sterile products

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.

PROCESS 2 CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

two

PC-2-1G-01

PC-2-5G-01

PC-2-30G-01

PC-2-275G-01

Process2Clean 2 Acid Based Detergent is a high performance and concentrated detergent that is one of VAI®'s most effective acid cleaning agents for removing a wide array of residues. This phosphoric acid detergent formulated with surfactants and chelating agents, helps to reduce corrosion, pitting, and rusting and is capable of removing most all inorganic soil loads. Process2Clean 2 is low foaming, has excellent detergency characteristics, and is very free rinsing.

Process2Clean 2 Acid Based Detergent Specifications*	
Characteristic	Acidic
Color	Clear - pale yellow
Appearance	Clear
Odor	Slight odor
Specific Gravity	1.170 - 1.370
pH (1% solution)	0.86 - 2.86
Conductivity (1% solution)	5.1 - 9.1 mS
P Content	29.70%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Low
Storage Recommendation	Ambient
Process2Clean 2 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass, and a variety of plastics	
Process2Clean 2 Cleaning Residue Specialties	
Inorganic soils including scale deposits, fine chemicals, polymers, particulate carbons, and coatings	
Process2Clean 2 Applications	
Automated wash equipment, spray systems, soak, and manual cleaning	

Order Number	*Description*	*Qty/Cs*
PC-2-1G-01	Process2Clean 2, 3.79 Liter, Non-Sterile	4
PC-2-1G-02	Process2Clean 2, 3.79 Liter, Sterile	4
PC-2-5G-01	Process2Clean 2, 18.9 Liter Drum, Non-Sterile	1
PC-2-5G-02	Process2Clean 2, 18.9 Liter Drum, Sterile	1
PC-2-30G-01	Process2Clean 2, 113.6 Liter Drum, Non-Sterile	1
PC-2-30G-02	Process2Clean 2, 113.6 Liter Drum, Sterile	1
PC-2-55G-01	Process2Clean 2, 208 Liter Drum, Non-Sterile	1
PC-2-55G-02	Process2Clean 2, 208 Liter Drum, Sterile	1
PC-2-275G-01	Process2Clean 2, 1041 Liter Drum, Non-Sterile	1

* All points do not apply to Non-Sterile products

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.

PROCESS 2 CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

three

PC-3-1G-01

PC-3-5G-01

PC-3-30G-01

PC-3-275G-01

Process2Clean 3 Hydroxyacetic Acid Cleaner is a high performance and concentrated environmentally friendly detergent that is extremely effective and capable of removing a wide array of inorganic soils and residues. This hydroxyacetic acid (glycolic acid) detergent formulated with surfactants and chelating agents, is helpful in the removal of free metals with routine use reducing corrosion, pitting, and rusting. Process2Clean 3 is phosphate free, is minimal to non-foaming at all temperatures, has excellent detergency, and is very free rinsing.

Process2Clean 3 Hydroxyacetic Acid Cleaner Specifications*	
Characteristic	Acidic
Clarity	Clear
Appearance	Clear - pale yellow
Odor	Slight odor
Specific Gravity	1.020 - 1.220
pH (1% solution)	1.67 - 3.67
Acidity	17.0 - 27.0%
P Content	0.00%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Minimal to none
Storage Recommendation	Ambient
Process2Clean 3 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass, and a variety of plastics	
Process2Clean 3 Cleaning Residue Specialties	
Inorganic soils including scale deposits, fine chemicals, polymers, particulate carbons, coatings, and is especially effective on antacid formulations	
Process2Clean 3 Applications	
Automated wash equipment, spray systems, soak, and manual cleaning	

Order Number	*Description*	*Qty/Cs*
PC-3-1G-01	Process2Clean 3, 3.79 Liter, Non-Sterile	4
PC-3-1G-02	Process2Clean 3, 3.79 Liter, Sterile	4
PC-3-5G-01	Process2Clean 3, 18.9 Liter Drum, Non-Sterile	1
PC-3-5G-02	Process2Clean 3, 18.9 Liter Drum, Sterile	1
PC-3-30G-01	Process2Clean 3, 113.6 Liter Drum, Non-Sterile	1
PC-3-30G-02	Process2Clean 3, 113.6 Liter Drum, Sterile	1
PC-3-55G-01	Process2Clean 3, 208 Liter Drum, Non-Sterile	1
PC-3-55G-02	Process2Clean 3, 208 Liter Drum, Sterile	1
PC-3-275G-01	Process2Clean 3, 1041 Liter Drum, Non-Sterile	1

* All points do not apply to Non-Sterile products

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

PROCESS 2 CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

four

PC-4-1G-01

PC-4-5G-01

PC-4-30G-01

PC-4-275G-01

Process2Clean 4 General Purpose Cleaning Detergent is a high performance and concentrated mild detergent with elevated foam characteristics that is extremely effective in removal of a wide array of residues. This glycolic acid detergent formulated with surfactants and chelating agents, can be used as a stand-alone cleaner or as an additive to alkaline cleaners to enhance their cleaning capabilities. Process2Clean 4 is phosphate free and has excellent detergency with the ability to rinse free from systems.

Process2Clean 4 General Purpose Cleaning Detergent Specifications*	
Characteristic	Mild detergent
Clarity	Clear
Appearance	Yellow
Odor	Slight odor
Specific Gravity	1.000 - 1.200
pH (1% solution)	8.0 - 10.0
Conductivity (1% solution)	0.8 - 2.1 mS
P Content	0.00%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Moderate to high
Storage Recommendation	Ambient
Process2Clean 4 Material Compatibility At Recommended Use Dilutions	
Most all process and environmental substrates and can be used as a cleaner for use on equipment exteriors, walls, floors, and ceilings	
Process2Clean 4 Cleaning Residue Specialties	
Ointments, creams, oils, waxes, polymers, and petrolatum based products	
Process2Clean 4 Applications	
All low agitation applications, spray systems, soak systems, or manual applications, not suitable for automated recirculation cleaning applications	

Order Number	*Description*	*Qty/Cs*
PC-4-1G-01	Process2Clean 4, 3.79 Liter, Non-Sterile	4
PC-4-1G-02	Process2Clean 4, 3.79 Liter, Sterile	4
PC-4-5G-01	Process2Clean 4, 18.9 Liter Drum, Non-Sterile	1
PC-4-5G-02	Process2Clean 4, 18.9 Liter Drum, Sterile	1
PC-4-30G-01	Process2Clean 4, 113.6 Liter Drum, Non-Sterile	1
PC-4-30G-02	Process2Clean 4, 113.6 Liter Drum, Sterile	1
PC-4-55G-01	Process2Clean 4, 208 Liter Drum, Non-Sterile	1
PC-4-55G-02	Process2Clean 4, 208 Liter Drum, Sterile	1
PC-4-275G-01	Process2Clean 4 , 1041 Liter Drum, Non-Sterile	1

*All points do not apply to Non-Sterile products

Lot Specific Documentation Package

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All lots are traced through the master batch records.

PROCESS2CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

five

PC-5-1G-01

PC-5-5G-01

PC-5-30G-01

PC-5-275G-01

Process2Clean 5 Neutral pH Cleaner and/or Additive is a high performance and concentrated neutral pH additive detergent that is capable of removing of a wide array of residues. This detergent's stabilized formula with surfactants and chelating agents is a uniquely blended high performance and concentrated neutral pH additive/detergent that is capable of removing a wide array of the most tenacious and insoluble residues, and can be used as a stand-alone cleaner or as an additive to improve the cleaning performance of all VAI® cleaners. Process2Clean 5 is phosphate free, is low foaming at elevated temperatures, has excellent wetting ability, and is free rinsing.

Process2Clean 5 Neutral pH Cleaning Additive Specifications*	
Characteristic	Neutral pH
Clarity	Clear
Appearance	Yellow
Odor	Slight chemical characteristics
Specific Gravity	0.990 - 1.100
pH (1% solution)	7.5 - 9.0
Conductivity (1% solution)	0.05 - 0.20 mS
P Content	0.00%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Minimal to none - 120°F Cloud Point - Offers foam below that set point and no foam realized above that set point for automated cleaning applications
Storage Recommendation	Ambient
Process2Clean 5 Material Compatibility At Recommended Use Dilutions	
Most all substrate material	
Process2Clean 5 Cleaning Residue Specialties	
Oils, waxes, greases, petrolatum-based products, coatings, emulsions, and most all other types of inorganic materials	
Process2Clean 5 Applications	
Recirculated systems, soak tanks, and spray or manual cleaning	

Order Number	*Description*	*Qty/Cs*
PC-5-1G-01	Process2Clean 5, 3.79 Liter, 5 Non-Sterile	4
PC-5-1G-02	Process2Clean 5, 3.79 Liter, 5 Sterile	4
PC-5-5G-01	Process2Clean 5, 18.9 Liter Drum, Non-Sterile	1
PC-5-5G-02	Process2Clean 5, 18.9 Liter Drum, Sterile	1
PC-5-30G-01	Process2Clean 5, 113.6 Liter Drum, Non-Sterile	1
PC-5-30G-02	Process2Clean 5, 113.6 Liter Drum, Sterile	1
PC-5-55G-01	Process2Clean 5, 208 Liter Drum, Non-Sterile	1
PC-5-55G-02	Process2Clean 5, 208 Liter Drum, Sterile	1
PC-5-275G-01	Process2Clean 5, 1041 Liter Drum, Non-Sterile	1

*All points do not apply to Non-Sterile products

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
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PROCESS 2 CLEAN®
FOR CRITICAL CLEAN IN PLACE APPLICATIONS

six

PC-6-1G-01

PC-6-5G-01

PC-6-30G-01

PC-6-275G-01

Process2Clean 6 Chlorinated Alkaline Cleaning Detergent is a high performance and concentrated detergent that is capable of removing of a wide array of residues. This detergent's potassium hydroxide and sodium hypochlorite formula with surfactants and chelating agents, has been designed specifically for the removal of proteinaceous soils in manual and automation cleaning applications. Process2Clean 6 has excellent rinsing capabilities, has minimal to no foaming, contains buffering agents, and contains no phosphates.

Process2Clean 6 Chlorinated Alkaline Cleaning Detergent Specifications*	
Characteristic	Alkaline
Clarity	Clear
Appearance	Yellow
Odor	Chlorine - like
Specific Gravity	1.100 - 1.300
pH (1% solution)	11.0 - 13.0
Conductivity (1% solution)	6.50 - 8.50 mS
P Content	0.00%
Detergency	Excellent
Solubility	Miscible with water
Foaming	Minimal to none
Storage Recommendation	Ambient
Process2Clean 6 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass, most elastomers, and contains a buffering agent that promotes optimal substrate integrity	
Process2Clean 6 Cleaning Residue Specialties	
Proteins, excipients, silicones, ointments, creams, oils, waxes, animal fats, greases, petrolatum-based products, and most all organic material	
Process2Clean 6 Applications	
Mechanical systems, automated wash, spray, soak, pressure spray, or manual washing	

Order Number	*Description*	*Qty/Cs*
PC-6-1G-01	Process2Clean 6, 3.79 Liter, Non-Sterile	4
PC-6-1G-02	Process2Clean 6, 3.79 Liter, Sterile	4
PC-6-5G-01	Process2Clean 6, 18.9 Liter Drum, Non-Sterile	1
PC-6-5G-02	Process2Clean 6, 18.9 Liter Drum, Sterile	1
PC-6-30G-01	Process2Clean 6, 113.6 Liter Drum, Non-Sterile	1
PC-6-30G-02	Process2Clean 6, 113.6 Liter Drum, Sterile	1
PC-6-55G-01	Process2Clean 6, 208 Liter Drum, Non-Sterile	1
PC-6-55G-02	Process2Clean 6, 208 Liter Drum, Sterile	1
PC-6-275G-01	Process2Clean 6, 1041 Liter Drum, Non-Sterile	1

* All points do not apply to Non-Sterile products

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

CAGE2WASH®

Welcome to Cage2Wash

VAI® offers a very comprehensive cleaning and decontamination program specific to the Biomedical Research field. VAI's line of Cage2Wash cleaning products have been specifically formulated for lab animal cage washing, ancillary component cleaning, and environmental decontamination applications. The proper selection and use of the appropriate cleaning and decontamination agents to remove animal waste and control environmental contamination is critical to any research program.

VAI's highly built GMP detergents are exceptionally effective in cleaning a wide variety of residues including, but not limited to; uric scale, water scale, animal fats, oils, organics, other related animal byproducts, and bioburden residues. VAI also has a line of enzymatic detergents ideal for surgical instrument cleaning and scale removal.

VAI's LAR program also includes a wide line of veterinary disinfectants, sporicidal agents, disposable garments, shoe covers, bouffant hats, chemical application equipment, and more. All of these products work together to control contamination and build a comprehensive LAR program solution for your operation. We also help you spec out and optimize your operations by offering a full line of equipment including, foam units, sprayers, proportioners, and chemical delivery pumps where applicable.

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59 CAGE2WASH 1 ALKALINE DETERGENT

60 CAGE2WASH 2 ENHANCED ALKALINE DETERGENT

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63 CAGE2WASH 5 CITRIC ACID CLEANER DETERGENT/DE-SCALER

64 CAGE2WASH N ALKALINE BASED NEUTRALIZER

58 CRITICAL ONGOING RESIDUE EVALUATION (CORE)

65 DEC-QUAT 200V

Lot Specific Documentation Package

Every Cage2Wash product is shipped with a complete lot certification and documentation package to ensure product consistency, integrity, and traceability. All lots are traced through the master batch records.

Features

- Enhanced cleaning properties with free rinsing capabilities
- Highly concentrated formula provides low cost per use
- Contains chelating agents for hard water tolerance
- Contains premium surfactants for excellent wetting ability and optimal penetration
- Optimal formulation eliminates the need for hazardous organic solvents
- Phosphate free formulas are ecologically safe
- Low and non-foaming formulas are ideal for optimal automated cleaning
- Complete solubility
- Biodegradable
- Available in 3.79, 18.9, 113.6, 208, and 1041 Liter containers
- Recycling options offered for 113.6, 208, and 1041 Liter containers

Other Technical Data Available Upon Request

- Sample Lot Specific Certification
- Technical Product PDF File
- Safety Data Sheet
- Compatibility Reports

Critical Ongoing Residue Evaluation®

Routine cleaning evaluations against your process soils is essential to achieve or maintain overall operation optimization. VAI's CORE Lab program is offered to assist our customers in performing these essential on-going cleaning evaluations. CORE provides scientific data to determine the level of cleaning achieved by our Cage2Wash detergents. In addition, CORE can perform side-by-side studies with your existing detergent to ascertain cleaning equivalence. Our comprehensive Cage2Wash & CORE program includes but is not limited to the following support documentation specific to our products: substrate compatibility studies, conductivity and TOC curves, toxicological reports including ADE's, specific and non-specific analytical methods for residue detection, and product validation reports. See page 172 for more information regarding VAI's CORE Lab program.

C-1-1G-01

C-1-5G-01

C-1-30G-01

C-1-275G-01

Cage2Wash 1 Alkaline Detergent is a high performance concentrated liquid alkaline cleaning agent designed specifically for automation cleaning in the lab animal research field. Cage2Wash 1 is formulated with potassium hydroxide, surfactants and other critically essential cleaning ingredients. This product is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems.

Cage2Wash 1 Alkaline Detergent Specifications	
Characteristic	Alkaline
Detergency	Excellent
Color	Colorless
Clarity	Turbid
Odor	Slight odor
Specific Gravity	1.240 - 1.440 mS
pH (1% solution)	11.8 - 13.8
Foaming	Low foaming
Storage Recommendation	Ambient
Phosphate Free	Yes
P Content	0.00%
N Content	0.00%
Cage2Wash 1 Material Compatibility At Recommended Use Dilutions	
Stainless steel, aluminum, copper, galvanized steel, soft metals, glass, polypropylene, polycarbonates, polysulfone, polyetherimide, and a wide variety of plastics	
Cage2Wash 1 Cleaning Residue Specialties	
Proteins, oils, serums, animal fats, and most types of organics	
Cage2Wash 1 Application Guide	
Automated wash, spray, soak, and manual applications	
Cage2Wash 1 Industry Uses	
All types of animal housing and accessories and all process and laboratory equipment. Designed specifically for lab animal research facilities and for removal of moderate to heavy soil build-up.	

Order Number	*Description*	*Qty/Cs*
C-1-1G-01	Cage2Wash 1, 3.79 Liter, Non-Sterile	4
C-1-5G-01	Cage2Wash 1, 18.9 Liter Drum, Non-Sterile	1
C-1-30G-01	Cage2Wash 1, 113.6 Liter Drum, Non-Sterile	1
C-1-55G-01	Cage2Wash 1, 208 Liter Drum, Non-Sterile	1
C-1-275G-01	Cage2Wash 1, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

CAGE2WASH® two

C-2-1G-01

C-2-5G-01

C-2-55G-01

C-2-275G-01

Cage2Wash 2 Enhanced Alkaline Detergent is a concentrated, high performance alkaline cleaning agent designed for both mechanical and manual cleaning applications. Cage2Wash 2 is formulated with a dual surfactant system and other critically essential cleaning ingredients including high levels of chelating agents that make this product an ideal detergent in all water conditions. This product is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems.

Cage2Wash 2 Enhanced Alkaline Detergent Specifications	
Characteristic	Mild alkaline
Detergency	Excellent
Appearance	Colorless
Clarity	Clear
Odor	Slight
Specific Gravity	1.000 - 1.200
pH (1% solution)	10.2 - 12.2
Foaming	Low foaming
Storage Recommendation	Ambient
Conductivity (1% @ 21°C)	0.05 - 2.00 mS
Phosphate Free	Yes
P Content	0.00%
N Content	0.00%
Cage2Wash 2 Material Compatibility At Recommended Use Dilutions	
Stainless steel, aluminum, copper, galvanized steel, soft metals, glass, polypropylene, polycarbonates, polysulfone, polyetherimide, plexiglass, and a wide variety of plastics	
Cage2Wash 2 Cleaning Residue Specialties	
Proteins, silicones, oils, petrolatum, polymers, serums, urine scales, animal fats, and most all types of organics	
Cage2Wash 2 Application Guide	
Mechanical, soak, and manual applications	
Cage2Wash 2 Industry Uses	
All hard water conditions, all animal housing, and all accessories. Ideal for rodent cage cleaning, environmental cleaning, and lab glassware cleaning applications.	

Order Number	*Description*	*Qty/Cs*
C-2-1G-01	Cage2Wash 2, 3.79 Liter, Non-Sterile	4
C-2-5G-01	Cage2Wash 2, 18.9 Liter Drum, Non-Sterile	1
C-2-30G-01	Cage2Wash 2, 113.6 Liter Drum, Non-Sterile	1
C-2-55G-01	Cage2Wash 2, 208 Liter Drum, Non-Sterile	1
C-2-275G-01	Cage2Wash 2, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

C-3-1G-01

C-3-5G-01

C-3-30G-01

C-3-275G-01

Cage2Wash 3 Acid Based Detergent is a high performance concentrated phosphoric acid liquid cleaning agent designed specifically for automation equipment cleaning requirements. Cage2Wash 3 is formulated with phosphoric acid, surfactants and other critically essential cleaning ingredients. This product is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. Routine use of this product reduces corrosion, pitting, and rusting.

Cage2Wash 3 Acid Based Detergent Specifications	
Characteristic	Acidic
Detergency	Excellent
Color	Colorless
Clarity	Clear
Odor	Slight odor
Specific Gravity	1.170 - 1.370
pH (1% solution)	0.86 - 2.86
Foaming	Low foaming
Storage Recommendation	Ambient
Conductivity (1% @ 21°C)	5.1-9.1 mS
Phosphate Free	No
P Content	29.7%
N Content	0.00%
Cage2Wash 3 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass-enamel, glass, polycarbonate, polysulfone, polyetherimide, plexiglass, aluminum, plastics, and most elastomers	
Cage2Wash 3 Cleaning Residue Specialties	
Inorganic salts, water scales, particulate carbon, urine scales, silicones, oils, petrolatum, polymers, and most all types of inorganics	
Cage2Wash 3 Application Guide	
Mechanical, soak, automated washes, spray systems	
Cage2Wash 3 Industry Uses	
For removal of moderate to heavy buildup of inorganic soils, animal buildup, and water scale buildup. Reduces corrosion, pitting, and rusting on all animal housing and accessories.	

Order Number	*Description*	*Qty/Cs*
C-3-1G-01	Cage2Wash 3, 3.79 Liter, Non-Sterile	4
C-3-5G-01	Cage2Wash 3, 18.9 Liter Drum, Non-Sterile	1
C-3-30G-01	Cage2Wash 3, 113.6 Liter Drum, Non-Sterile	1
C-3-55G-01	Cage2Wash 3, 208 Liter Drum, Non-Sterile	1
C-3-275G-01	Cage2Wash 3, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

CAGE2WASH® four

C-4-1G-01

C-4-5G-01

C-4-30G-01

C-4-275G-01

Cage2Wash 4 Hydroxyacetic Acid Detergent is a high performance concentrated hydroxyacetic acid cleaner/descaler liquid cleaning agent designed specifically for automation cleaning requirements. Cage2Wash 4 is formulated with glycolic acid, surfactants and other critically essential cleaning ingredients. This product is a non-foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from systems. Routine use of this product is helpful in the removal of free metals and reduces corrosion, putting, and rusting.

Cage2Wash 4 Hydroxyacetic Acid Cleaner Specifications	
Characteristic	Acidic
Detergency	Excellent
Color	Clear - pale yellow
Clarity	Clear
Odor	Slight odor
Specific Gravity	1.020 - 1.220
pH (1% solution)	1.67- 3.67
Foaming	Minimal to none
Storage Recommendation	Ambient
Phosphate Free	Yes
P Content	0.00%
N Content	0.00%
Cage2Wash 4 Material Compatibility At Recommended Use Dilutions	
Stainless steel, glass, polycarbonate, polysulfone, polyetherimide, plexiglass, aluminum, and most elastomers	
Cage2Wash 4 Cleaning Residue Specialties	
Inorganic salts, scales, particulate carbon, proteins, urine scale (on polycarbonate, stainless, and other caging materials), water scales, free metals, excipients, fine chemicals, silicones, oils, petrolatum, and most types of inorganics	
Cage2Wash 4 Application Guide	
Soak, manual, automated washers, spray systems, and both CIP and COP applications	
Cage2Wash 4 Industry Use	
Phosphate free removal of inorganic compounds found in animal research facilities, and on all types of animal housing and accessories. Reduces corrosion, pitting, and rusting and helps maintain equipment integrity.	

Order Number	*Description*	*Qty/Cs*
C-4-1G-01	Cage2Wash 4, 3.79 Liter, Non-Sterile	4
C-4-5G-01	Cage2Wash 4, 18.9 Liter Drum, Non-Sterile	1
C-4-30G-01	Cage2Wash 4, 113.6 Liter Drum, Non-Sterile	1
C-4-55G-01	Cage2Wash 4, 208 Liter Drum, Non-Sterile	1
C-4-275G-01	Cage2Wash 4, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification. All lots are traced through the master batch records.

C-5-1G-01

C-5-5G-01

C-5-30G-01

C-5-275G-01

Cage2Wash 5 Citric Acid Cleaner Detergent/De-Scaler is a high performance concentrated liquid citric acid cleaner/descaler cleaning agent designed specifically for automation, soak, and prep cleaning requirements. Cage2Wash 5 is formulated with citric acid and a unique dual surfactant system with other critically essential cleaning ingredients for the easy removal of tough uric scale build-up. This product is a low foaming cleaning agent (at all temperatures) and has enhanced cleaning ability to rinse free from all systems. This stand alone cleaner can be used in all water conditions.

Cage2Wash 5 Citric Acid Cleaner and De-Scaler Detergent Specifications	
Characteristic	Acidic
Detergency	Excellent
Color	Colorless to light straw
Clarity	Clear
Odor	Acidic
Specific Gravity	1.040 - 1.240
pH (1% solution)	1.93 - 3.93
Foaming	Low foaming
Storage Recommendation	Ambient
Phosphate Free	Yes
P Content	0.00%
N Content	0.00%
Cage2Wash 5 Material Compatibility At Recommended Use Dilutions	
Stainless steel, soft metals, assorted polymers (caging materials), galvanized steel, aluminum, polypropylene, polycarbonate, polysulfone, polyetherimide, plexiglass, glass, and a wide variety of plastics	
Cage2Wash 5 Cleaning Residue Specialties	
Inorganic salts, water scales, proteins, particulate carbon, uric scales, animal fats, oils, and most all types of inorganics	
Cage2Wash 5 Application Guide	
Recirculation, automation, soak, spray, manual, mechanical	
Cage2Wash 5 Industry Use	
For fast removal of tough uric stone build-up for effective pre-cleaning of animal cages. Greatly minimizes cleaning prep time. Ideal stand alone cleaner for most all tunnel wash applications. Excellent choice for cage and rack washer equipment. For use in all water conditions. Routine use reduces corrosion, putting, and rusting.	

Order Number	*Description*	*Qty/Cs*
C-5-1G-01	Cage2Wash 5, 3.79 Liter, Non-Sterile	4
C-5-5G-01	Cage2Wash 5, 18.9 Liter Drum, Non-Sterile	1
C-5-30G-01	Cage2Wash 5, 113.6 Liter Drum, Non-Sterile	1
C-5-55G-01	Cage2Wash 5, 208 Liter Drum, Non-Sterile	1
C-5-275G-01	Cage2Wash 5, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

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CAGE2WASH®

C-N-1G-01

C-N-5G-01

C-N-30G-01

C-N-275G-01

Cage2Wash N Alkaline Based Neutralizer is a highly concentrated liquid alkaline based neutralizing agent used to raise solution pH, and is specifically designed for all types of effluent treatment. It is used to neutralize acidic solutions and allow for permissible effluent compliance where pH ranges are established. Cage2Wash N is phosphate free and non-foaming. The concentrated formula minimizes the actual use dilution for low cost per use.

Cage2Wash N Alkaline Based Neutralizer Specifications	
Characteristic	Alkaline
Detergency	Low-moderate
Appearance	Clear to opaque
Odor	Odorless
pH (1% solution)	13.5-14.1
Foaming	Non-foaming
Storage Recommendation	Ambient
Phosphate Free	Yes
P Content	0.00%
N Content	0.00%
Cage2Wash N Application Guide	
Effluent pH balancing and automatic cleaning. Safe for use on all stainless steel surfaces.	
Cage2Wash N Industry Use	
Used wherever pH adjustment is needed; raises solution pH to neutralize acidic solutions for permissible effluent compliance. Concentrate use dilution will be condition on the pH desired and the solution “soil” to be adjusted. This product, at appropriate use dilution will adequately address prions. It also cleans and decontaminates process filtration systems at effective concentrations.	

Order Number	*Description*	*Qty/Cs*
C-N-1G-01	Cage2Wash N, 3.79 Liter, Non-Sterile	4
C-N-5G-01	Cage2Wash N, 18.9 Liter Drum, Non-Sterile	1
C-N-30G-01	Cage2Wash N, 113.6 Liter Drum, Non-Sterile	1
C-N-55G-01	Cage2Wash N, 208 Liter Drum, Non-Sterile	1
C-N-275G-01	Cage2Wash N, 1041 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.

DEC-QUAT® 200V

Veterinary Quaternary Ammonium Disinfectant

DQ200V-1G-01-E

DEC-QUAT 200V is an EPA registered veterinary disinfectant, virucide, and fungicide that is proven to be effective against a wide array of organisms when used as directed. The verified results provide an added level of quality assurance to your overall cleaning and disinfection program. DEC-QUAT 200V is manufactured and tested from beginning to end in an EPA registered manufacturing facility, and meets the highest standards in manufacturing and processing. This assures the highest level of quality and integrity of the final product. Lot specific analysis is available and the product is fully traceable.

Disinfectant - Virucide* - Sanitizer - Germicidal Detergent - Deodorant - Fungicide - Cleaner - Mildewstat.
* When used as directed.

DEC-QUAT 200V is a neutral 5th generation pH quaternary ammonium solution. It is non-corrosive to most all substrates at recommended use dilution. Pitting and corrosion is often the result of other aggressive decontamination agents. That corrosion may lead to harborage of organisms that may adversely affect your overall cleaning program.

The highly concentrated formula has a very low cost per use. Actual use dilution is dependent upon the decontamination requirements of the specific organisms present. For example, efficacy can be achieved as low as 660 ppm active or 1/2 ounce per gallon of water for most broad spectrum claims, animal virucidal claims, and fungicidal claims. For Canine Parvovirus and Rabies claims, 2.25 ounces of DEC-QUAT 200V per gallon of water with a 10 minute contact time is required.

DEC-QUAT 200V can be used in the life science and research and development industries as well as the following applications: veterinary, dairy, equine, poultry plants, poultry/turkey farms, institutional, and industrial use.

DEC-QUAT 200V Neutral pH Quaternary Ammonium Disinfectant/Cleaner	
Liquid Appearance	Clear, colorless to straw liquid
Specific Gravity	0.95-1.10
pH @ 1% Solution (normal)	6.00-10.50
Foaming	Moderate
Rinsing	Excellent
Viscosity @ 22°C, 71.6°F	13.6 mm^2/s

Order Number	*Description*	*Qty/Cs*
DQ200V-1G-01-E	DEC-QUAT 200V, 3.79 Liter, Non-Sterile	4
DQ200V-5G-01-E	DEC-QUAT 200V, 18.9 Liter Drum, Non-Sterile	1
DQ200V-30G-01-E	DEC-QUAT 200V, 113.6 Liter Drum, Non-Sterile	1

Lot Specific Documentation Package

All product is lot traceable and delivered each time with the lot specific certification.
All lots are traced through the master batch records.


DPMD

GMP
sterile
wipers
aseptic
patented
saturated
disinfecting
0.2 µm filtered

Garments and Wipers

quadruple bagged
gamma irradiation
Low Particulate
Easy2Gown
garments
sorbant
clean
mops

Welcome to VAI® Wipers

Dry and Saturated Wipers

VAI offers a complete line of wipers, using various clean substrates and packaging to meet the needs of our diverse types of customers. VAI provides wipers in multiple chemical saturations, sizes, sorbency, and materials.

VAI wipers are available sterile or non-sterile and either saturated or dry. For sterile products, wipers are manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100) or filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently terminally sterilized to 10^{-6} sterility assurance level. All materials are quality assurance tested and released to specifications defined by IEST and ASTM test methods. Individual lots are sterility tested according to the USP compendium with lot specific documentation available upon delivery.

Our wipers can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel, lexan, polycarbonate, glass, and any critical surface that requires cleaning. Our wipers are available in HYPO-CHLOR® Sodium Hypochlorite with Water For Injection in 0.25%, 0.52%, or 5.25% solutions, STERI-PEROX® Hydrogen Peroxide with Water For Injection in either 3% or 6% solutions, DEC-CLEAN® residue remover and cleaner, THIO-WIPE® 2% sodium thiosulfate with surfactant, individual ALCOH-GLOVE® and ALCOH-WIPE® USP Isopropyl Alcohol with Water For Injection formulated at 70%, STER-AHOL® Denatured Ethanol with Water For Injection at 70%, bulk packaged Process2Wipe® USP Isopropyl Alcohol with Water For Injection at 70%, STEEL-BRIGHT® stainless steel cleaner, DAS-WIPE 100™ Sterile lubricant and stainless steel cleaner, WipeDown 1-2-3 USP <800> wipe kit, and finally our two dry wipers, WipeDown® and WipeDown® HC.

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WipeDown®

Laundered Polyester Dry Wipe

VEL8-12X12-S-3002

WipeDown Material

VAI®'s WipeDown Dry Wipes are an ultra-clean, superior, laundered dry wipe suitable for use in a cleanroom environment. WipeDown Dry Wipes are ideal for use in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, lexan, polycarbonate, glass, and any critical surface that requires cleaning. WipeDown Dry Wipes are available sterile in a standard 12"x12" size.

The material used in our WipeDown Dry Wipes is a 100% continuous knit polyester filament that has been specifically designed to be exceptionally clean and absorbent. Particulates, residues, and foreign matter is effectively entrapped in the webbing of the material. The knit construction and pattern has been developed to ensure the greatest product integrity and cleaning performance while offering high resistance to abrasion and picking. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. These wipes are packaged 20 wipers per bag in an opaque, easy-tear style bag.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Packaged in ISO 5 (Grade A/B, Former Class 100)
- Gamma irradiated to 10^{-6} SAL
- Cut using FocusEdge cutting technology
- Lot sterility tested according to current USP Compendium
- Completely lot traceable
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is bulk packaged in an additional single outer bag pack
- Packaged in an opaque, easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- For use on a multitude of surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ideal for disinfectant application in cleanroom environments
- Delivered with lot specific Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- Disinfectant application

Order Number	*Description*	*Qty/Cs*
VEL8-12X12-S-3002	WipeDown Dry Wipe, 20 wipes/bag, 5 bags/pack, 6 packs/case, Sterile	600

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI)

WipeDown® HC

Polyester and Cellulose Dry Wipe

VEL13-9X9-S-3013

VEL13-9X9-NS-HC-3024

VAI®'s WipeDown HC Dry Wipes are high performance dry cleaning wipes that have been specifically designed for pharmaceutical, biotechnology, medical device, healthcare, pharmacy, compounding pharmacy, and hospital uses. These wipes can be used in clean environments on any critical surface that requires cleaning. WipeDown HC are the superior methodology for per-forming USP <797> compliant wipe downs. WipeDown HC Dry Wipes are available sterile or non-sterile in a 9"x9" size.

The material used in our WipeDown HC is a strong blend of polyester and cellulose that is low in particles, is low in lint, has non-shedding features, and has excellent sorbancy. VAI's sterile WipeDown HC Dry Wipes are packaged folded 20 wipers per bag with an additional single over bag. The non-sterile WipeDown HC Dry Wipes are packaged flat with 300 wipers per bag.

Quality and Manufacturing*

- Packaged in ISO 5 (Grade A/B, Formed Class 100)
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- Packaged in an opaque, easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- For use on multiple surfaces
- Ideal for use in clean environments
- Superior methodology for performing USP <797> compliant wipe downs
- A polyester and cellulose blend wiper material that is designed to be clean and absorbent
- Material is low in particulates and has excellent non-shedding features
- Delivered with lot specific Certificate of Sterility and Certificate of Irradiation tested to current USP compendium

Product Uses*

- In clean environments
- For surface clean ups, IPA wipe downs, and cleaning and decontamination
- General wiping and contamination control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- Performing USP <797> compliant wipe downs

Order Number	*Description*	*Qty/cs*
VEL13-9X9-S-3013	WipeDown HC Dry Wipe, Packaged Folded, 20 wipes/bag, 20 bags/case, Sterile	400
VEL13-9X9-NS-HC-3024	WipeDown HC Dry Wipe, Packaged Flat, 300 wipes/bag, 5 bags/case, Non-Sterile	1500

* All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI)

WipeDown® High Sorb Dry Wipes

Laundered Polyester Dry Wipe

VEL8-12X12-S-3031

VAI®'s WipeDown High Sorb Dry Wipes are an ultra-clean, superior, laundered dry wipe suitable for use in a cleanroom environment. WipeDown High Sorb Dry Wipes are ideal for use in both aseptic and non-aseptic areas to keep the surface dry, residue free, and streak free after chemical application. WipeDown High Sorb Dry Wipes are available sterile and non-sterile in a standard 12"x12" size.

The material used in our WipeDown High Sorb Dry Wipes is a 100% continuous knit polyester filament that has been specifically designed to be exceptionally clean and absorbent. Particulates, residues, and foreign matter is effectively entrapped in the webbing of the material. The knit construction and pattern has been developed to ensure the greatest product integrity and cleaning performance while offering high resistance to abrasion and picking. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. These wipes are packaged 20 wipers per bag in an opaque, easy-tear style bag.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Packaged in ISO 5 (Grade A/B, Former Class 100)
- Gamma irradiated to 10^{-6} SAL
- Cut using FocusEdge cutting technology
- Lot sterility tested according to current USP Compendium
- Completely lot traceable
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is bulk packaged in an additional single outer bag pack
- Packaged in an opaque, easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- For use on a multitude of surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Designed to keep the surface dry, residue free, and streak free
- Has the sorbancy of a two ply wipe in a single wipe; designed to be very absorbent
- Delivered with lot specific Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Post chemical application clean-up to wipe the surface dry and keep streak free
- To remove excess liquid and residue from the surface; spill control/product spills
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning.

Order Number	*Description*	*Qty/Cs*
VEL8-12X12-S-3031	WipeDown High Sorb Dry Wipe, 20 wipes/bag, 5 bags/pack, 6 packs/case, Sterile	600

Process2Wipe®

70% USP Isopropyl Alcohol And 30% USP Water For Injection

VEL12-12X12-S-3023

VEL12-12X12-S-3023

VEL12-12X12-S-3030

Process2Wipe IPA70 wipes are ready-to-use and saturated with VAI®'s 70% USP Isopropyl Alcohol formulated with 30% USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs on any critical surface that requires cleaning. Process2Wipe is available sterile in standard 9"x9" and 12"x12" sizes.

VAI's Process2Wipe wipers are available in two packaging options: 20 wipers per pack or 30 wipers per pack. The 20 wipers per pack option is packaged in an opaque, ported, peel and reseal style bag. The 30 wipers per pack is packaged in an opaque, zip-lock style, ported bag. Each packaging option allows for continued use after opening via either a peel and reseal label or zip closure.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- 70% USP IPA formulated with 30% USP Water for Injection (0.25 EU/mL) is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque bag
- 20 pack has peel and reseal label and 30 pack is packaged in a zip-lock style bag for continued use after opening
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- Low endotoxins
- Reduced VOC's
- For use on a multitude of surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Delivered with lot specific Certificate of Irradiation, Certificate of Sterility, Certificate of Analysis, Certificate of Conformance, and LAL Test Report tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To prevent overuse of Isopropyl Alcohol when compared to using trigger sprayers or gallon pour
- General wiping and contamination control

Order Number	*Description*	*Qty/Cs*
VEL12-12X12-S-3023	Process2Wipe IPA70, 12"x12", Peel and Reseal Packaging, 20 wipes/bag, 10 bags/case, Sterile	200
VEL12-12X12-S-3030	Process2Wipe IPA70, 12"x12", Zip-Lock Style Packaging, 30 wipes/bag, 10 bags/case, Sterile	300
VEL12-9X9-S-3036	Process2Wipe IPA70, 9"x9", Peel and Reseal Packaging, 20 wipes/bag, 10 bags/case, Sterile	200

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

Process2Wipe® Non-Woven

70% USP Isopropyl Alcohol and 30% USP Water for Injection

VEL12-9X9-S-3032

Process2Wipe Non-Woven IPA70 wipes are ready-to-use and saturated with VAI®'s 70% USP Isopropyl Alcohol formulated with 30% USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, lexan, polycarbonate, glass, and any critical surface that requires cleaning. Process2Wipe Non-Woven wipers are available sterile in a standard 9"x9" size.

The material used in our Process2Wipe Non-Woven wipers is a white, non-woven 100% polyester material that has low shedding characteristics and is manufactured to be clean and absorbent by minimizing fiber and particulate release. VAI's Process2Wipe Non-Woven wipers are packaged in an opaque, ported, peel and reseal style bag with 50 wipers per bag. The peel and reseal style bag allows for continued use after opening.

Quality and Manufacturing

- Filled in ISO 5 (Grade A/B, Former Class 100)
- 70% USP IPA formulated with 30% USP Water for Injection (0.25 EU/mL) is filtered at 0.2 microns
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP Compendium
- Completely lot traceable

Features and Benefits

- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Individually labeled with lot number and expiration
- Reduced VOC's
- Low endotoxins
- For use on multiple surfaces
- Wipes folded for easy removal
- 100% polyester non-woven material designed to be clean and absorbent
- Material has low shedding characteristics
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis, LAL Test Report, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packaging machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To prevent overuse of Isopropyl Alcohol when compared to using trigger sprayers or gallon pour
- General wiping and contamination control

Order Number	*Description*	*Qty/Cs*
VEL12-9X9-S-3032	Process2Wipe Non-Woven IPA70, 50 Wipes/Bag, Sterile	1000

ALCOH-WIPE®

Individually Packaged 70% USP Isopropyl Alcohol and 30% USP Water for Injection

VEL6-12X12-S-2302

The ALCOH-WIPE is ready-to-use, individually packaged, and saturated with VAI®'s 70% USP Isopropyl Alcohol and 30% USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs on any critical surface that requires cleaning. The ALCOH-WIPE has been specifically designed for operations that require the use of an individually packaged and sterile IPA wipe. The ALCOH-WIPE is available sterile in a 6"x6", 12"x12", and 18"x18" sizes.

The material used in our ALCOH-WIPE is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI's ALCOH-WIPE is packaged in an opaque, ported, and easy-tear style bag.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- 70% USP IPA and 30% USP Water for Injection (0.25 EU/mL) solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Individually bagged with two liner bags
- Packaged in an opaque easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- For use on multiple surfaces
- Low endotoxins
- Reduced VOC's
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Available in three sizes
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- In operations that require an individually bagged IPA wiper
- To prevent overuse of IPA when compared to using trigger sprayers or gallon pour

Order Number	*Description*	*Qty/Cs*
VEL6-6X6-S-2307	ALCOH-WIPE, 6"x6", Individually Bagged, Sterile	100
VEL6-12X12-S-2302	ALCOH-WIPE, 12"x12", Individually Bagged, Sterile	100
VEL6-18X18-S-2304	ALCOH-WIPE, 18"x18", Individually Bagged, Sterile	100

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

ALCOH-GLOVE®

Individually Packaged 70% USP Isopropyl Alcohol and USP 30% Water for Injection

AG-04-70%-9053

The ALCOH-GLOVE is a ready-to-use and individually packaged glove style wiper that is saturated with VAI®'s 70% USP Isopropyl Alcohol and 30% USP Water for Injection. The ALCOH-GLOVE is a remarkable innovation that resembles the shape of a dust mitten. This contoured product provides 100% coverage of the hand. With the ability to assure pinpoint cleaning, the ALCOH-GLOVE places an additional assurance level to cleaning operations. The ALCOH-GLOVE is available in an 8"x 4" glove size and sterile.

The material used in our ALCOH-GLOVE is a white, clean, and absorbent 100% tubular knit polymer that is sewn at one end and then turned inside out. VAI's ALCOH-GLOVE is packaged in a clear and easy-tear style bag.

Quality and Manufacturing

- 70% USP IPA and 30% USP Water for Injection (0.25 EU/mL) solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- Individually bagged with two liner bags
- Packaged in a clear easy-tear style bag
- Glove folded for easy removal
- Individually labeled with lot number and expiration
- For use on multiple surfaces
- Ready-to-use
- 100% tubular knit polymer that is manufactured to be clean and absorbent
- 8"x4" size – resembles the shape of a dust mitten for full coverage
- Assures pinpoint cleaning in critical environments
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, and Certificate of Analysis tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- In operations that require an individually bagged IPA wiper that provides full coverage of the hands
- For pinpoint cleaning in critical environments
- To prevent overuse of IPA when compared to using trigger sprayers or gallon pour

Order Number	*Description*	*Qty/Cs*
AG-04-70%-9053	ALCOH-GLOVE, Individually Bagged, Sterile	100

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STER-AHOL® Wipe

70% Denatured Ethanol and 30% USP Water for Injection

VEL6-12X12-S-2320

The STER-AHOL Wipe is ready-to-use, individually packaged, and saturated with VAI®'s 70% Denatured Ethanol and 30% USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs on any critical surface that requires cleaning. The STER-AHOL Wipe has been specifically designed for operations that require the use of an individually packaged and sterile EtOH wipe. The STER-AHOL Wipe is available sterile in a standard 12"x12" size.

The material used in our STER-AHOL Wipe is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI's STER-AHOL Wipe is packaged in an opaque, ported, and easy-tear style bag.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- 70% Denatured Ethanol and 30% USP Water for Injection (0.25 EU/mL) solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Individually bagged with two liner bags
- Packaged in an opaque easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- For use on multiple surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- In operations that require an individually bagged denatured ethanol wiper
- To prevent overuse of EtOH when compared to using trigger sprayers or gallon pour

Order Number	*Description*	*Qty/Cs*
VEL6-12X12-S-2320	STER-AHOL Wipe, Individually Bagged, Sterile	100

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STERI-PEROX® Wipe

Hydrogen Peroxide And Water For Injection

VEL10-12X12-S-3014

VEL10-12X12-S-3014

VEL10-12X12-3016

VEL10-12X12-3017

STERI-PEROX Wipes are saturated with a ready-to-use 3% or 6% concentration of hydrogen peroxide solution formulated with USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs on any critical surface that requires cleaning. Ideal use is in broad or intricate locations where the need to reduce possible VOC's is required. STERI-PEROX Wipes are available sterile or non-sterile in standard 9"x9" and 12"x12" sizes.

The material used in our STERI-PEROX Wipes is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI® uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI's STERI-PEROX Wipes are packaged in an opaque, ported, peel and reseal style bag that allows for continued use after opening.

Quality and Manufacturing*

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Hydrogen peroxide solution is filtered at 0.2 microns
- Formulated with USP Water for Injection (0.25 EU/mL)
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Aseptically filled into sterile components via gamma irradiation at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- Two concentrations: 3% or 6% to fit your needs
- Reduced VOC's
- For use on multiple surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses*

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To reduce VOC's
- To prevent overuse of hydrogen peroxide when compared to using trigger sprayers or gallon pour

Order Number	*Description*	*Qty/Cs*
VEL10-12X12-S-3014	STERI-PEROX 3% Wipe, 12"x12", 20 wipes/bag, 10 bags/case, Sterile	200
VEL10-12X12-3015	STERI-PEROX 3% Wipe, 12"x12", 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL10-9X9-S-3035	STERI-PEROX 3% Wipe, 9"x9", 20 wipes/bag, 10 bags/case, Sterile	200
VEL10-12X12-S-3016	STERI-PEROX 6% Wipe, 12"x12", 20 wipes/bag, 10 bags/case, Sterile	200
VEL10-12X12-3017	STERI-PEROX 6% Wipe, 12"x12", 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL10-9X9-S-3034	STERI-PEROX 6% Wipe, 9"x9", 20 wipes/bag, 10 bags/case, Sterile	200

*All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

HYPO-CHLOR® Wipe

Sodium Hypochlorite And Water For Injection

VEL9-12X12-S-3020

VEL9-12X12-S-3018

VEL9-12X12-S-3025

VEL9-12X12-S-3026

HYPO-CHLOR Wipes are saturated with a ready-to-use 0.25%, 0.52%, or 5.25% concentration of sodium hypochlorite formulated with USP Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs on any critical surface that requires cleaning. Ideal use is in broad or intricate locations where a sodium hypochlorite spray could create an excess of residue. HYPO-CHLOR Wipes are available sterile or non-sterile in a standard 12”x12” size.

The material used in our HYPO-CHLOR Wipes is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI®’s HYPO-CHLOR Wipes are packaged in an opaque, ported, zip lock style bag that allows for continued use after opening.

Quality and Manufacturing*

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Sodium hypochlorite solution is filtered at 0.2 microns
- Formulated with USP Water for Injection (0.25 EU/mL)
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Aseptically filled into sterile components via gamma irradiation at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits*

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque, zip-lock style, easy tear bag
- Resealable for continued use after opening
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- Three concentrations: 0.25%, 0.52%, 5.25%
- For use on multiple surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses*

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- Where a sodium hypochlorite spray would create excess residue
- To prevent overuse of sodium hypochlorite when compared to using trigger sprayers or gallon pour

Order Number	*Description*	*Qty/Cs*
VEL9-12X12-3021	HYPO-CHLOR 0.25% Wipe, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL9-12X12-S-3020	HYPO-CHLOR 0.25% Wipe, 20 wipes/bag, 10 bags/case, Sterile	200
VEL9-12X12-3019	HYPO-CHLOR 0.52% Wipe, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL9-12X12-S-3018	HYPO-CHLOR 0.52% Wipe, 20 wipes/bag, 10 bags/case, Sterile	200
VEL9-12X12-S-3025	HYPO-CHLOR 5.25% Wipe, 20 wipes/bag, 5 bags/case, Sterile	100
VEL9-12X12-S-3026	HYPO-CHLOR 0.52% Wipe, Individually Bagged, Sterile	100

*All points do not apply to Non-Sterile products

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DEC-CLEAN® Wipe

Residue Remover and Cleaner

VEL14-12X12-S-4002-E

VEL14-12X12-S-4002-E

DEC-CLEAN Wipes are ready-to-use and saturated with VAI®'s DEC-CLEAN residue remover and cleaner solution. DEC-CLEAN Wipes are designed to remove residue from disinfecting agents left behind on any critical surface that requires cleaning. DEC-CLEAN Wipes are available sterile in a standard 12"x12" size.

The material used in our DEC-CLEAN Wipes is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI's DEC-CLEAN Wipes are packaged in an opaque, ported, peel and reseal style bag that allows for continued use after opening.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Filtered at 0.2 microns
- DEC-CLEAN Wipe residue remover and cleaner solution is filtered at 0.2 microns and formulated with USP Water for Injection (0.25 EU/mL)
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- Removes residues left behind from disinfecting agents that build up on surfaces overtime
- For use on multiple surfaces
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Delivered with lot specific Certificate of Irradiation, Certificate of Sterility, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses

- Removes residues left behind from disinfecting agents
- Returns the surface to its original form for future disinfection
- General wiping in aseptic or non-aseptic environments
- Wipe downs on filling and packaging machinery
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To prevent overuse of chemicals when compared to using trigger sprayers or gallon pours

Order Number	*Description*	*Qty/Cs*
VEL14-12X12-S-4002-E	DEC-CLEAN Wipe, 20 wipes/bag, 10 bags/case, Sterile	200

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

DAS-WIPE 100 Sterile

Stainless Steel Cleaner and Lubricant

DW100-12X12-S-2319

The DAS-WIPE 100™ Sterile is a ready-to-use, individually packaged, and saturated wipe with VAI®'s DAS stainless steel cleaner and lubricant solution. The DAS-WIPE 100 Sterile has been specifically designed to replace silicon in aseptic manufacturing areas. These wipes are also an excellent choice for cleaning metals, including stainless steel, in cleanroom operations due to its excellent cleaning capabilities and low remaining residue. The DAS-WIPE 100 Sterile is available sterile in a standard 12"x12" size.

The material used in our DAS-WIPE 100 Sterile is a 100% continuous knit polyester filament that has been specifically designed to be clean and absorbent. VAI uses FocusEdge cutting technology to cut their wipes that seals the edges and reduces shedding to a minimum during wipe downs or general use. VAI®'s DAS-WIPE 100 Sterile is packaged in a clear and easy-tear style bag.

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- DAS-WIPE 100 Sterile solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Individually bagged with two liner bags
- Packaged in a clear easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Ready-to-use
- Excellent for cleaning metals including stainless steel and as a general lubricant
- Replaces silicon in critical aseptic manufacturing areas and ensure bottles do not stick as they approach the critical fill site
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis, and Certificate of Conformance tested to current USP compendium

Product Uses

- Aseptic or non-aseptic environments
- To replace silicon in aseptic manufacturing areas
- Ideal on turntables and process lines to assure bottles do not stick during movement to critical fill site
- As a general lubricant
- Polish stainless steel and other materials
- In operations that require an individually bagged and sterile lubricating wipe

Order Number	*Description*	*Qty/Cs*
DW100-12X12-S-2319	DAS-WIPE 100 Sterile, Individually Bagged, Sterile	100

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

STEEL-BRIGHT® Wipe

Stainless Steel Polish and Cleaner

SBW-12X12-S-2315

The STEEL-BRIGHT Wipe is ready-to-use, individually packaged, and saturated with VAI®'s STEEL-BRIGHT stainless steel polish and cleaner solution. The STEEL-BRIGHT Wipe is an excellent choice for cleaning, removing spots and stains, and polishing metal and equipment in cleanroom operations due to its excellent cleaning capabilities and low remaining residue. These wipes can be used on stainless steel, chrome, brass, aluminum, and copper. The STEEL-BRIGHT Wipe is available sterile in a standard 12"x12" size.

The material used in our STEEL-BRIGHT Wipe is a white 100% polyester material that is manufactured to be clean and absorbent by minimizing fiber and particulate release. VAI's STEEL-BRIGHT Wipe is packaged in an opaque and easy-tear style bag.

Quality and Manufacturing

- STEEL-BRIGHT solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Individually bagged with two liner bags
- Packaged in a opaque easy-tear style bag
- Wipes folded for easy removal
- Individually labeled with lot number and expiration
- 100% polyester wipe material designed to be clean and absorbent
- Professional strength cleaner that brightens and polishes without leaving a powdery residue
- Has excellent cleaning capabilities
- Emulsion based cleaner that will not rainbow or accumulate to a heavy build up
- Surfaces will remain cleaner longer because there is no residue film to attract soil
- Ready-to-use
- Pleasantly lemon scented and contains no acids or abrasives
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, and Certificate of Conformance tested to current USP compendium

Product Uses

- Stainless steel, chrome, brass, aluminum and copper
- Aseptic or non-aseptic environments on metals and equipment
- To clean, brighten, polish, remove spots and stains, and remove chemical residues
- In operations that require an individually bagged stainless steel cleaner and polish

Order Number	*Description*	*Qty/Cs*
SBW-12X12-S-2315	STEEL-BRIGHT Wipe, Individually Bagged, Sterile	100

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

WipeDown® 1-2-3

Deactivates, Decontaminates, and Cleans Most Hazardous Drug Surfaces For USP <800> Compliance in a Simple, Sterile, 3 Step Applicator Kit

VEL13-9X12-S-3123

Individual
WipeDown 1-2-3 Kit

WipeDown 1-2-3
Packaging

VAI®'s WipeDown 1-2-3 has been designed to address the risk of occupational exposure to most hazardous drugs during compounding sterile preparations, and administering, as outlined in USP <800>. WipeDown 1-2-3 is a sterile 3 step application wipe kit, that when used in sequence, provides deactivation, decontamination, and cleaning of sterile compounding surfaces from most hazardous drugs. WipeDown 1-2-3 satisfies both USP <797> compounding sterile preparations and USP <800> hazardous drugs – handling in healthcare settings.

Each Sterile WipeDown 1-2-3 kit includes:

- Packet #1 – HYPO-CHLOR®, USP 5.25% sodium hypochlorite for deactivation
- Packet #2 – THIO-WIPE®, 2% USP sodium thiosulfate for decontamination
- Packet #3 – ALCOH-WIPE®, 70% USP Isopropyl Alcohol for cleaning

All three packets consist of non-woven, non-shedding, 12"x12" premium 100% polyester wiper materials that are designed to be exceptionally clean, to have excellent absorption capabilities, and to provide a substantial 9 square foot surface coverage. Each chemical component is formulated with Water for Injection and filtered at 0.2 microns with sterility assurance via aseptic filtration into sterile components or through gamma irradiation. Individual kits, containing all three packets, are individually bagged and packaged into a liner bag for easy transport into sterile areas. Each kit is individually labeled with lot number and expiration and each shipment of WipeDown 1-2-3 is supported by lot specific documentation.

Quality and Manufacturing*

- Lot sterility tested according to current USP compendium
- Formulated with USP Water for Injection (0.25 EU/mL)
- Filtered at 0.2 microns
- Completely lot traceable
- All three chemicals are assayed according to current USP compendium
- Gamma irradiated or aseptically filled into sterile components

Features and Benefits*

- Wipes are individually packaged
- Wipes folded for easy removal
- Packaged in an opaque, easy-tear style bag
- Kit is single bagged sterile with one box liner bag
- Designed to comply with USP <797>
- Ready-to-use
- 12"x12" size
- Wiper material is low in particulate shedding and soluble extracts
- Deactivates most hazardous drugs present on compounding surface
- Delivered with lot specific documentation
- Each kit is individually labeled with lot number and expiration date

Order Number	*Description*	*Qty/Cs*
VEL13-12X12-S-123	WipeDown 1-2-3, 3 Step Applicator Kit, 3 wipes/kit, 10 kits/box, 12 boxes/case, Sterile	120 kits

*All points do not apply to each product

Other Technical Data Available Upon Request

Product Technical Data Report • MSDS/SDS

THIO-WIPE® 2%

Sodium Thiosulfate and Water for Injection

VEL13-12X12-S-3033

VAI®'s THIO-WIPE 2% is a 12"x12" saturated USP 2% Sodium Thiosulfate and USP Water for Injection wipe that has been formulated with surfactants critical for optimal surface penetration and cleaning. THIO-WIPE 2% can be used in sequence with VAI's HYPO-CHLOR® 5.25% and Process2Wipe® IPA 70 wipes, as step #2 for addressing USP <800> Hazardous Drugs – Handling in Healthcare Settings. Furthermore, THIO-WIPE 2% is sterile, therefore, ideally suited for introduction into the ISO 5 areas and for USP <797> compliance.

This Sodium Thiosulfate wipe addresses the sterile pharmacy compounding department's needs by neutralizing the Sodium Hypochlorite solution and cleaning and decontaminating surface of previously deactivated hazardous drugs. Via neutralization of harsh sodium hypochlorite, sodium thiosulfate helps protect stainless steel compounding surface from corrosion and pitting. Cleaning the surface of these residues improves the overall longevity of the sterile compounding equipment while staying USP <797> and USP <800> compliant.

Quality and Manufacturing

- Formulated with USP Water for Injection (0.25 EU/mL)
- Assayed according to USP compendium
- Filtered at 0.2 microns
- Filled in ISO 7 (Former Class 10,000), filtered at 0.2 microns
- Gamma irradiated sterile
- Individual lots are sterility tested to current USP compendium
- Completely lot traceable

Features and Benefits

- Standard 12"x12"
- Wiper material is 100% continuous polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Material is resistant to abrasion and picking
- Quadruple bagged via the ABCD Cleanroom Introduction System®
- Each sterile bag is double bagged in easy tear bags
- Individually labeled with lot number and expiration
- Packaged in a peel and reseal style bag that allows for continued use after opening
- Packaged in an opaque bag
- Wipes folded for easy removal
- Ready-to-use
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, and Certificate of Conformance tested to current USP compendium

Product Uses

- For use on multiple surfaces
- To neutralize Sodium Hypochlorite solution
- Help protect stainless steel compounding surfaces from corrosion and pitting

Order Number	*Description*	*Qty/Cs*
VEL13-12X12-S-3033	THIO-WIPE 2% Wipe, 20 wipes/bag, 10 bags/case, Sterile	200

Other Technical Data Available Upon Request

Product Technical Data Report • Validation Report • Specific Test Reports (Consult VAI) • MSDS/SDS

Welcome to Garments

VAI®'s Disposable Products Manufacturing Division (DMPD) has addressed the needs of the pharmaceutical, biotechnology, semi-conductor, medical device, electronics, and healthcare industries by designing a complete range of sterile and non-sterile disposable garments. Product lines include: sterile and non-sterile disposable garments, sterile and non-sterile face masks, and non-sterile cleanroom apparel.

The disposable garment product lines have been designed specifically for the needs of an aseptic cleanroom operation. VAI's sterile disposable garments consist of two fabric types that are constructed identically but cited for two different uses. The 1800 SMS Mitcool garment line is built with a high quality spunbond-meltblown-spunbond (SMS) non-woven polypropylene fabric that provides excellent breathability while maintaining protection. Our 1700 MP Mitcool line is built using a non-woven, microporous, coated material that provides even greater personal protection in the cleanroom. VAI's disposable garments provide 100% garment sterility assurance and a significantly reduced chance of gowning contamination, while keeping the comfort and breathability when compared to traditional, reusable garments.

VAI's sterile and non-sterile face masks are soft and comfortable while offering protection and filtration efficiency. VAI's face masks are offered in three varieties, the PF-2 mask, the PF-4 mask, and the FaceVector mask, all cited for specific industries and uses.

Additionally, VAI offers a variety of additional cleanroom apparel including bouffant hats, sweat-less headbands, and shoe and boot covers.

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EASY2GOWN® SYSTEM

An innovative, easy system developed to reduce user contamination during the critical process of aseptic gowning

Disposable garments are packaged in VAI's, patented, Easy2Gown System®. The Easy2Gown System is a fold that makes a proper aseptic gowning procedure an easy process rather than a routine challenge. The Easy2Gown design allows operators to have fewer manipulations while donning, therefore, reducing cross contamination.

This patented fold has been designed to minimize contact between the operator and the outside of the gown. By presenting the interior of the gown upon opening the package, the sterile exterior is protected from the transfer of contamination during the gowning process. Trained personnel able to gown without contact to the sterile, exterior, portion of the gown. The easily distinguished surface creates signification reduction in operator prep time while reducing manipulation of the garment itself.

Easy2Gown System Benefits

- Reduced training time and gowning time because the coverall is pre-folded to be donned properly
- Better efficiency and performance in gowning qualifications
- Risk of operator contamination is greatly reduced during gowning process
- On-site training available upon request

EASY2GOWN® SYSTEM 1800 SMS Mitcool Garments

Sterile Disposable Coveralls, Frocks, and Hoods

SMS Easy2Gown Coverall with Attached Boots and SMS Hood with Integrated Face Mask

SMS Easy2Gown Classic Coverall with SMS Open Face Hood

SMS Easy2Gown Coverall with Attached Hood and Boots

VAI®'s disposable garment product line has been redeveloped and newly designed specifically for the needs of an aseptic cleanroom operation. The disposable garments have been refined to include more flexibility while maintaining a tailored design that works for all body types. VAI's disposable garments provide 100% garment sterility assurance and a significantly reduced chance of gowning contamination, while keeping the comfort and breathability when compared to traditional, reusable garments.

VAI's 1800 SMS Mitcool garments are built using high quality spunbond-meltblown-spunbond (SMS) nonwoven polypropylene fabric @ 60g/m2 basis weight. This fabric type has high strength and outstanding moisture vapor transmission, which translates to overall increased operator comfort. Select the SMS garment line when comfort and breathability is the highest priority and minimal to moderate splash protection is required. The SMS garment material has excellent bacterial filtration efficiency.

Quality and Manufacturing

- Raw materials are quality assurance tested and lot controlled
- Fully assembled in a controlled environment
- Sewing area employs CAD assisted cutting and seaming equipment, therefore, reducing manual manipulation of the garment
- Individually packaged and labeled with the lot number and expiration date
- Packaged in easy tear bags with two liner bags per case
- Completely lot traceable
- Validated sterile with a 5 year closed bag expiration
- Lot sterility tested according to current USP compendium
- All garments are delivered with lot specific documentation packages including Certificates of Irradiation and Certificates of Sterility
- Garments are sized to ANSI standards for disposable coveralls

Features and Benefits

- High quality spunbond-meltblown-spunbond (SMS) nonwoven PP Fabric
- Ideal for minimal to moderate splash protection
- Suited for use where comfort and breathability is a priority
- Fabric construction provides increased operator comfort
- Highly breathable fabric that releases heat while maintaining protection
- Fabric has outstanding moisture vapor transmission
- Excellent bacterial filtration efficiency
- A 100% bound seam construction for increased durability and reduced particle permeability
- Double layer front flaps for increased protection from contamination
- Elastic thumb loops and tunnelized elastic wrists and ankles
- Elastic in high movement areas for ease of movement and to ensure appropriate garment fit
- Active athletic styling with a tailored design for flexibility and to fit all body types
- Easy2Gown folded to reduce operator contamination and reduce gowning time
- CE marked as category 1 PPE

SMS Fabric Configurations Available

- Classic coveralls
- Coveralls with attached boots
- Coveralls with attached hood and boots
- Open face hoods
- Hoods with integrated face mask
- Frocks

SMS Easy2Gown Classic Coverall with SMS Open Face Hood

SMS Easy2Gown Coverall with Attached Boots

SMS Easy2Gown Coverall with Attached Hood and Boots

SMS Garments - Coveralls

Order Number	*Description*	*Qty/Cs*
1800P-E-S-1800	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1800P-E-S-1801	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1800P-E-S-1802	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1800P-E-S-1803	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1800P-E-S-1804	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1800P-E-S-1805	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1800P-E-S-1806	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25
1800P-E-S-1807	SMS Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 6XL, Sterile	25

SMS Garments - Coveralls with Attached Boots

Order Number	*Description*	*Qty/Cs*
1800P-EB-S-1815	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1800P-EB-S-1816	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1800P-EB-S-1817	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1800P-EB-S-1818	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1800P-EB-S-1819	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1800P-EB-S-1820	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1800P-EB-S-1821	SMS Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25

SMS Garments - Coveralls with Attached Hood & Boots

Order Number	*Description*	*Qty/Cs*
1800P-EHB-S-1808	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1800P-EHB-S-1809	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1800P-EHB-S-1810	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1800P-EHB-S-1811	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1800P-EHB-S-1812	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1800P-EHB-S-1813	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1800P-EHB-S-1814	SMS Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25

SMS Open Face Hood

SMS Hood with Integrated Face Mask

SMS Frock

SMS Garments - Open Face Hoods

Order Number	*Description*	*Qty/Cs*
1800P-H-UC-S-1822	SMS Hood, Open Face, Easy2Gown, Individually Packaged, White, Small/Medium, Sterile	100
1800P-H-UC-S-1823	SMS Hood, Open Face, Easy2Gown, Individually Packaged, White, Large/XL, Sterile	100

SMS Garments - Hood with Integrated Face Mask

Order Number	*Description*	*Qty/Cs*
1800P-HM-S-1824	SMS Hood, Integrated Face Mask, Easy2Gown, Individually Packaged, White, Small/Medium, Sterile	100
1800P-HM-S-1825	SMS Hood, Integrated Face Mask, Easy2Gown, Individually Packaged, White, Large/XL, Sterile	100

SMS Garments - Frocks

Order Number	*Description*	*Qty/Cs*
1800-LC-S-1826	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Small, Sterile	30
1800-LC-S-1827	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Medium, Sterile	30
1800-LC-S-1828	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Large, Sterile	30
1800-LC-S-1829	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, XL, Sterile	30
1800-LC-S-1830	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, 2XL, Sterile	30
1800-LC-S-1831	SMS Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, 3XL, Sterile	30

EASY2GOWN® SYSTEM 1700 MP Mitcool Garments

Sterile & Non-Sterile Disposable Coveralls, Frocks, Boots, Hoods, and Sleeves

MP Knee-High Boot

Opening MP Easy2Gown Classic Coverall

VAI®'s disposable garment product line has been redeveloped and newly designed specifically for the needs of an aseptic cleanroom operation. The disposable garments have been refined to include more flexibility while maintaining a tailored design that works for all body types. VAI's disposable garments provide 100% garment sterility assurance and a significantly reduced chance of gowning contamination, while keeping the comfort and breathability when compared to traditional, reusable garments.

VAI's 1700 MP Mitcool garments are built using a heavy weight, non-woven, high quality microporous coated material. The MP disposable garments are extremely tough and fluid resistant and have superior barrier performance. This MP fabric has the best particulate performance in its segment. MP fabric is suited for use where maximum protection to product or wearer is required. The MP material has excellent water and liquid repellence to low level splashes and sprays and is resistant to chemicals. MP garments create an impervious barrier that prevents passage of bacteria and non-viable particulates through the garment material.

Quality and Manufacturing*

- Raw materials are quality assurance tested and lot controlled
- Fully assembled in a controlled environment
- Sewing area employs CAD assisted cutting and seaming equipment, therefore, reducing manual manipulation of the garment
- Individually packaged and labeled with the lot number and expiration date
- Packaged in easy tear bags with two liner bags per case
- Completely lot traceable
- Validated sterile with a 5 year closed bag expiration
- Lot sterility tested according to current USP compendium
- All garments are delivered with lot specific documentation packages including Certificates of Irradiation and Certificates of Sterility
- Garments are sized to ANSI standards for disposable coveralls

Features and Benefits*

- Heavy weight, non-woven and high quality microporous (MP) coated material
- Suited for use where maximum protection to product or wearer is required
- Fabric is heavy weight and extremely tough
- Excellent liquid resistance, especially to chemicals
- Provides protection to low level splashes and sprays
- Has a leading bacterial and particle filtration efficiency creating an impervious barrier
- A 100% bound seam construction for increased durability and reduced particle permeability
- Double layer front flaps for increased protection from contamination
- Elastic thumb loops and tunnelized elastic wrists and ankles
- Elastic in high movement areas for ease of movement and to ensure appropriate garment fit
- Active athletic styling with a tailored design for flexibility and to fit all body types
- Easy2Gown folded to reduce operator contamination and reduce gowning time
- CE marked as category 1 PPE

MP Fabric Configurations Available

- Classic coveralls
- Coveralls with attached boots
- Coveralls with attached hood
- Coveralls with attached hood and boots
- Open face hoods
- Hoods with integrated face mask
- Knee-high boots
- Protective sleeves
- Frocks

*not all points apply to non-sterile product

MP Easy2Gown Classic Coverall with MP Open Face Hood

MP Easy2Gown Coverall with Attached Boots

MP Garments - Coveralls

Order Number	*Description*	*Qty/Cs*
1700P-E-S-17000	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1700P-E-S-17001	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1700P-E-S-17002	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1700P-E-S-17003	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1700P-E-S-17004	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1700P-E-S-17005	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1700P-E-S-17006	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25
1700P-E-S-17007	MP Coverall, Classic, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 6XL, Sterile	25

MP Garments – Coveralls with Attached Boots

Order Number	*Description*	*Qty/Cs*
1700P-EB-S-17042	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1700P-EB-S-17043	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1700P-EB-S-17044	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1700P-EB-S-17045	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1700P-EB-S-17046	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1700P-EB-S-17047	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1700P-EB-S-17048	MP Coverall, Attached Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25

MP Garments - Coveralls with Attached Hood and Boots

Order Number	*Description*	*Qty/Cs*
1700-EHB-S-17008	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Sterile	25
1700-EHB-S-17009	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Sterile	25
1700-EHB-S-17010	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Sterile	25
1700-EHB-S-17011	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Sterile	25
1700-EHB-S-17012	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Sterile	25
1700-EHB-S-17013	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Sterile	25
1700-EHB-S-17014	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 4XL, Sterile	25
1700-EHB-S-17015	MP Coverall, Attached Open Face Hood and Boots, Easy2Gown, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 5XL, Sterile	25

MP Open Face Hood

MP Hood with Integrated Face Mask

MP Protective Sleeve

MP Frock

MP Garments - Open Face Hoods

Order Number	*Description*	*Qty/Cs*
1700P-H-UC-S-17017	MP Hood, Open Face, Easy2Gown, Individually Packaged, White, Small/Medium, Sterile	100
1700P-H-UC-S-17035	MP Hood, Open Face, Easy2Gown, Individually Packaged, White, Large/XL, Sterile	100

MP Garments - Hood with Integrated Face Mask

Order Number	*Description*	*Qty/Cs*
1700P-HM-S-17037	MP Hood, Integrated Face Mask, Easy2Gown, Individually Packaged, White, Small/Medium, Sterile	100
1700P-HM-S-17038	MP Hood, Integrated Face Mask, Easy2Gown, Individually Packaged, White, Large/XL, Sterile	100

MP Garments - Protective Sleeves

Order Number	*Description*	*Qty/Cs*
1700-PS-S-1792	MP Protective Sleeve, Pair of Two, One Size, Sterile	100

MP Garments - Frocks

Order Number	*Description*	*Qty/Cs*
1700-LC-S-1720	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Small, Sterile	30
1700-LC-S-1721	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Medium, Sterile	30
1700-LC-S-1722	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, Large, Sterile	30
1700-LC-S-1723	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, XL, Sterile	30
1700-LC-S-1724	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, 2XL, Sterile	30
1700-LC-S-1725	MP Frock, Elastic Wrists, Zipper Closure, Individually Packaged, White, 3XL, Sterile	30

MP Garments - Sterile Knee-High Boots

Order Number	*Description*	*Qty/Cs*
1700P-MC-NS-S-17039	MP Knee-High Boot, Pair of Two, 18” Tall, 10” Opening Size, Small/Medium, Sterile	100
1700P-MC-NS-S-17040	MP Knee-High Boot, Pair of Two, 18” Tall, 12” Opening Size, Large/XL, Sterile	100
1700P-MC-NS-S-17041	MP Knee-High Boot, Pair of Two, 18” Tall, 14” Opening Size, 2XL/3XL, Sterile	100

Non-Sterile

MP Easy2Gown Classic Coverall with MP Open Face Hood

MP Easy2Gown Coverall with Attached Hood and Boots

MP Open Face Hood

MP Garments - Coveralls

Order Number	*Description*	*Qty/Cs*
1700-E-17042	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Non-Sterile	25
1700-E-17043	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Non-Sterile	25
1700-E-17044	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Non-Sterile	25
1700-E-17045	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Non-Sterile	25
1700-E-17046	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Non-Sterile	25
1700-E-17047	MP Coverall, Classic, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Non-Sterile	25

MP Garments - Coveralls with Attached Hood

Order Number	*Description*	*Qty/Cs*
1700-EH-17048	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Non-Sterile	25
1700-EH-17049	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Non-Sterile	25
1700-EH-17050	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Non-Sterile	25
1700-EH-17051	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Non-Sterile	25
1700-EH-17052	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Non-Sterile	25
1700-EH-17053	MP Coverall, Attached Open Face Hood, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Non-Sterile	25

MP Garments - Coveralls with Attached Hood and Boots

Order Number	*Description*	*Qty/Cs*
1700-EHB-17054	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Small, Non-Sterile	25
1700-EHB-17055	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Medium, Non-Sterile	25
1700-EHB-17056	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, Large, Non-Sterile	25
1700-EHB-17057	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, XL, Non-Sterile	25
1700-EHB-17058	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 2XL, Non-Sterile	25
1700-EHB-17059	MP Coverall, Attached Open Face Hood and Boots, Elastic Wrists and Ankles, Zipper Closure, Individually Packaged, White, 3XL, Non-Sterile	25

MP Garments - Open Face Hoods

Order Number	*Description*	*Qty/Cs*
1700-HO-17060	MP Hood, Open Face with Elastic, Easy2Gown, Individually Packaged, White, One Size, Non-Sterile	100

USP <800> Gowns

Barrier Gown for USP <800> Uses

1900-F-1904

VAI® offers sterile barrier gowns for use where handling hazardous drugs or chemicals*, where exposure to bloodborne pathogens, or where liquid splashes are a concern. USP <800> Gowns have been designed and tested specifically for compliance with the USP <800> recommended guidance for handling of hazardous drugs. USP <800> recommends the use of a gown during hazardous compounding that has been shown to resist hazardous drugs. These gowns are constructed of a multi-layer blend of polyethylene and propylene that has been tested and shown as resistant to hazardous drugs and chemicals per a modified test for gowns ASTM 6978 Chemotherapy Drug Permeation Testing. In addition, these gowns have low particulate shedding characteristics, therefore, are USP <797> compliant for critical environments and cleanrooms.

USP <800> Gowns come standard with liquid proof taped seams, tunnelized elastic wrists, elastic thumb loops, a Velcro neck loop closure, and extra-long coated waist ties for easy front or rear closure. All gowns have serged seams that are sealed with a proprietary co-polymer tape. This makes both the gown's fabric and seams tested and verified hazardous drug barriers. USP <800> Gowns are blue with blue taped seams and available in two sizes: small/medium and large/XL. Each gown is individually inspected for sizing, stitching, and workmanship. USP <800> Gowns are designed to be disposable and are not reusable after initial use.

Quality and Manufacturing

- Fully assembled in a controlled environment
- Individually inspected for sizing, stitching, and workmanship
- Individually packaged and labeled with lot number and expiration date
- Completely lot traceable
- 10 year closed bag expiration

Features and Benefits

- Designed and tested gown for compliance with USP <800> recommended procedure for the handling of hazardous drugs*
- Gown tested per modified ASTM D6978 Chemotherapy Drug Permeation Testing to demonstrate resistance to hazardous drugs as per USP <800> guidance recommendation
- Suitable for use where liquid splash is a concern and resistant to many hazardous liquids
- Resistant against bloodborne pathogens per ASTM F1671 Testing
- Suitable for critical and cleanroom environments; low particulates
- ISO Cleanroom Class 6 per Helmke Drum Testing
- Liquid proof seams
- Class 1 Flammability per CPSC 1610 Testing
- Tunnelized elastic wrists and elastic thumb loops
- Velcro neck loop closure and extra long coated waist ties for easy front or rear closure
- Constructed of a blend of polyethylene and polypropylene fabrics
- Neatly folded and packaged
- Packaged in easy tear vacuum sealed bags.
  10 individual bags per sealed inner polybag, 3 inner polybags per sealed master

Order Number	*Description*	*Qty/cs*
1900-F-1904	USP <800> Gown, Elastic Wrists and Thumbloops, Tie Closure, Individually Packaged, Blue, Size S/M, Non-Sterile	30
1900-F-1905	USP <800> Gown, Elastic Wrists and Thumbloops, Tie Closure, Individually Packaged, Blue, Size L/XL, Non-Sterile	30

* Tested against Carmustine with a breakthrough time of 27.6 minutes and Thiotepa with a breakthrough time of greater than 240 minutes.

PF-2 Face Masks

Elastic and Four Tie Masks

PF-2SM-T-4-S-2021

PF-2SM-2-S-2026

The PF-2 face masks have been innovatively designed for use in the pharmaceutical, biotechnology, and medical device industries or in any cleanroom operation. VAI®'s PF-2 face masks are made of 100% rayon. The PF-2 face masks allows for excellent breathability, comfort, and protection, while maintaining filtration efficiency. The mask is designed to absorb moisture, therefore, it continually improves its own filtration efficiency. VAI's face masks are low in particulate and shedding characteristics and offer a barrier between the environment and the user.

PF-2 face masks come standard with a comfort fit nose piece that, along with the face mask's absorption efficiency, virtually eliminates fogging of one's own goggles. The comfort fit nose piece also protects the wearer from the lower edge of the goggle. This feature makes it unnecessary to continually adjust the goggles.

For pharma/biotech/compounding pharmacies only.

Features and Benefits

- Sterile masks are available individually packaged with bulk non-sterile packaging available
- Available in two different styles: either two elastic straps or 4 ties
- Sterile face masks are process in an ISO 5/6 (former Class 100/1000, Grade A/B) manufacturing area
- Five year validated closed packaged expiration date with sterility assured via gamma irradiation
- Lot sterility tested according to current USP compendium
- Delivered each time with lot specific Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance tested according to current USP compendium
- Completely lot traceable
- Soft, comfortable, and breathable
- Low particulate and shedding characteristics
- Mask continually improves its own filtration efficiency
- Goggle fogging is virtually eliminated due to absorption efficiency
- CE marked as category 1 PPE

Order Number	*Description*	*Qty/Cs*
PF-2SM-T-4-S-2021	PF-2 Face Mask, 4 Ties, Individually Packaged, One Size, Sterile	500
PF-2SM-2-2027	PF-2 Face Mask, 2 Elastic Straps, One Size, Non-Sterile	500
PF-2SM-2-S-2026	PF-2 Face Mask, 2 Elastic Straps, Individually Packaged, Inner Bags of 50, One Size, Sterile	500

PF-4 Face Mask

Non-Woven Mask

PF-4SM-2-S-2029

The PF-4 face mask is made up of 3 layers of non-woven material. This material has a soft layer which helps prevent skin irritation or allergy problems. A coated metal strip acts as a nose piece to keep the mask secure when worn. This mask is electro-mechanically sealed, completely machine made in a clean environment.

All sterile masks are delivered with a Certificate of Irradiation, Certificate of Sterility, Certificate of Conformance, and are completely lot traceable. Sterility is assured through gamma irradiation at 10.0-20.0 kGy and all sterile masks carry a five-year closed package expiration date through high quality packaging for air tight seals.

For pharma/biotech/compounding pharmacies only.

Features and Benefits

- Sterile face masks are available individually packaged
- Sterile masks are gamma irradiated at 10.0 – 20.0 kGy
- Five-year closed bag expiration date
- High quality packaging with air tight seals
- Delivered with lot specific Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance tested according to current USP compendium
- Completely machine made in a clean environment
- Hypoallergenic-soft surface layers that prevents skin irritation and allergy problems
- Silicon free headloop OP bands
- Loop bands are ultrasonic bonded ensuring a cleaner mask by reducing contamination and outgassing
- Coated metal piece keeps the mask secure when worn
- CE marked as category 1 PPE

Order Number	*Description*	*Qty/Cs*
PF-4SM-2-S-2029	PF-4 Face Mask, Elastic Straps, Individually Packaged, One Size, Sterile	500
PF-4SM-T-4-S-2032	PF-4 Face Mask, 4 Ties, Individually Packaged, One Size, Sterile	500

FaceVector

Earloop 3-Ply Mask

PF-6-SM-2031

FaceVector™ masks are made up of 3 layers of Spunbound Polypropylene (SBPP) material which has soft layers that help prevent skin irritation or allergy problems. A coated metal strip acts as a nose piece to keep the mask secure when worn. FaceVector masks comply with ASTM F2100-19 Level 1 and EN 14683 Type 1 parameters for barrier testing, physical testing, and safety testing. Intended use is in the pharmaceutical, biotechnology, compounding, lab animal, healthcare, and hospital industries.

Features and Benefits

- Loop bands are ultrasonic bonded ensuring a cleaner mask by reducing contamination and outgassing
- Manufactured and packed in cleanroom environment
- Machine made, ultrasonic welded
- Mask's material is made of Spunbound Polypropylene (SBPP)
- Silicon-free and lint-free Opelon and Polyurethane bands
- Mask provides 99.84% BFE at 3.0 micron size and 99.61% PFE at 0.1 micron size
- Complies with ASTM F2100-19 Level 1 and EN 14683 Type 1 parameters
- Size: 17.5 cm x 9.5 cm (+/- 0.5 cm)
- CE marked as category 1 PPE

Donning Procedure

1. Place mask over nose and mouth
2. Pull bottom of mask under chin
3. Mold nose piece around the nose

Order Number	*Description*	*Qty/Cs*
PF-6-SM-2031	FaceVector, 3-Ply Mask, Earloop, Blue, Size: 17.5cm x 9.5cm (+/- 0.5cm), Non-Sterile	50 Masks per Box, 60 Boxes per Case, 3,000 Masks Total

Boot Covers and Shoe Covers

Boot Covers

Shoe Covers

Cleanroom Boot Covers are latex and lint free, with a seamless bottom, suitable for use in a clean environment. The boot covers are manufactured from a blend of polyolefin coated polypropylene then uniquely constructed to create an impervious sole and side with an elastic ankle. This combination offers extraordinary traction and skid resistance. Furthermore, the covers are extremely durable, and resistant to liquids. Overall, this is the toughest, most durable and impervious boot cover currently on the market. The boot covers are ideal for wash down uses, cleanroom uses, and are built specifically for use in low traction areas.

VAI®'s Shoe Covers are latex and lint free, with a surged bottom seam that is made to be suitable for the use in clean environments. These shoe covers are a special polyolefin blend laminated to a polypropylene substrate. Due to this special blend, these shoe covers offer the best traction properties and skid resistance currently available in any shoe cover. These shoe covers are built specifically for use in low traction areas. Furthermore, the covers are extremely durable, resistant to liquids, and have an elasticized top opening.

Features and Benefits

- Individually inspected for size, stitching, and workmanship
- Neatly stacked and cleanroom packaged
- Extremely durable and resistant to liquids
- Latex & lint free
- Built for low traction areas
- Resistant against blood borne pathogens
- 100 pieces per inner polybag, 2 polybags per sealed bag

Order Number	*Description - Non-Sterile*	*Qty/Cs*
150-SC-NS-1520	Boot Covers, Gray, Non-Skid, 7.75" Tall, Large, Non-Sterile	100 pairs
150-SC-NS-1521	Boot Covers, Gray, Non-Skid, 7.75" Tall, XL, Non-Sterile	100 pairs
150-SC-NS-1522	Shoe Covers, Blue, Non-Skid, 16" Long, Large, Non-Sterile	100 pairs
150-SC-NS-1523	Shoe Covers, Blue, Non-Skid, 18" Long, XL, Non-Sterile	100 pairs

Bouffant Hats

Bouffant Hat

Bouffant Hat Folded

VAI®'s bouffant head covers are designed and manufactured in a pleated design that is low in lint and full coverage, for use in a cleanroom setting. They are made from 100% virgin polypropylene. While a standard bouffant is hand sewn, our pleated design is made by fully automated equipment, therefore, lowering possible contamination and bio-burden. They are lightweight, cool, breathable and latex free for added comfort. Having a pleated design allows for greater storage capacity in the gowning room and ease of handling and filling. Less waste is experienced because it is easier for the operator to just take one.

Features and Benefits

- Individually inspected for size, stitching, and workmanship
- Neatly stacked and clean room packaged
- Low linting fabric
- Compact design
- 100 pieces per inner polybag, 10 polybags per sealed master bag

Order Number	*Description*	*Qty/Cs*
150-BF-NS-1530	Bouffant Hat, Blue, 21" in Diameter, Non-Sterile	1000
150-BF-NS-1531	Bouffant Hat, Blue, 24" in Diameter, Non-Sterile	1000

Sweat-less Headbands

Sweat-Less Headband

VAI® offers a protective and comfortable sweat-less headband for use under a bouffant hat in a clean environment. The headbands were designed specifically for the comfort of the end user. Made of a laundered nylon, the sweat-less headbands are soft, comfortable, and absorbent. The intended function is to provide a mechanism to absorb perspiration in an easy to use, disposable, and clean product. Overall, this product will reduce a potential contamination risk and the need for an employee to use products from outside the operation.

Features and Benefits

- Put on before the bouffant hat for added protection
- Available in multiple sizes
- Fabric is 100% nylon for user comfort and perspiration absorption
- Soft, cool and comfortable
- Fabric is stretchable but coils to a secure fit
- Bagged and boxed in 200 per case
- All headbands are white in color

Order Number	*Description*	*Qty/Cs*
SL-01-S	Sweat-less Headband, White, Small, Non-Sterile	200
SL-01-M	Sweat-less Headband, White, Medium, Non-Sterile	200
SL-01-L	Sweat-less Headband, White, Large, Non-Sterile	200

H-Y Tumble Drum®

HYEDR-100

HYE-101

VAI®'s Environmental Control Monitoring Division (ECMD) has addressed the needs of cleanroom laundries, and the pharmaceutical, biotechnology, semiconductor, and electronics industries with the Helmke-Yeich (H-Y) Tumble Drum.

The purpose of the H-Y Tumble Drum is to test garments, wipers, gloves, and other cleanroom ready products to determine the amount of particulates and shedding. The H-Y Tumble Drum provides effective measurement of quality levels to ensure facilities are meeting the required standards.

In the Institute of Environmental Sciences and Technology document, "Garment System Considerations for Cleanrooms and Other Controlled Environments IEST-RP-CC003.2" the H-Y Tumble Drum is recommended for testing garments, wipers, gloves, and other cleanroom ready products.

The H-Y Tumble Drum tumbles items in a rotating drum to release particles from the surface of the item. It is designed to be connected to an automatic particle counter in order to sample the air within the drum to determine the average particle concentration of the air. Results depict the level of contamination the product will emit to the cleanroom environment per minute.

Features and Benefits

- Easily connected to a particle counter
- Designed to be used in a clean controlled area, i.e. laminar flow hood or contained area under HEPA filters
- Compact enough to fit under a laminar flow hood
- Durable and requires little maintenance
- Constructed of mirror finished Stainless Steel
- Removable baffles for easy cleaning
- Sealed direct drive motor assembly assures no particulates are generated from the motor or assembly that may affect testing
- Variable speed control and digital readout
- Entire platform can be rotated 90 degrees
- Mobile stand is counter weighted for stabilization
- IEC IP65 rated for front panel wash down
- Meets North American (ETL) safety standards

Order Number	*Description*
HYEDR-100	H-Y Tumble Drum With Dial Control, Variable Speed
HYE-101	H-Y Drum Only

Other Technical Data Available Upon Request

H-Y Tumble Drum Operator's Manual • Technical Data File

ECMD

RFID
viable
alarms
Delta V
software
211 Part 11
fixed systems
Stainless Steel
Environmental Monitoring
capture efficiency
calibrated airflow
3 hour sampling
compressed air
sterilizable
nonviable
portable
reliable
rapid
ISO

Welcome to SMA®
Microbial Air Sampling Systems

VAI®'s Environmental Control Monitoring Division (ECMD) addresses the needs of the pharmaceutical, biotechnology, semiconductor, and electronics industries with a complete range of facility wide viable environmental monitoring equipment.

VAI's viable air monitoring equipment is designed to sample a quantifiable amount of air for viable contamination using our patented Sterilizable Microbial Atrium (SMA®) and a standard media plate. A SMA Atrium® is a 316L Stainless Steel capture device that is connected to a controlled vacuum source, such as the SMA OneTouch® ICS. Air is directed from the environment to impact onto a media plate contained inside of the Atrium. The media plate is then incubated and tested to determine the number of viable organisms per cubic foot or liter of air.

SMA OneTouch ICS© and SMA OneTouch© Command Systems are used to control calibrated and timed vacuum sequences to connected SMA Atriums. The SMA OneTouch ICS features computerized air monitoring and a touchscreen interface. SMA OneTouch Command Systems are made up of SMA©Digital Display Control Centers (DDC) and SMA OneTouch ICS Control Panels. Both systems allow you to start, stop, and monitor the sample cycle from within a controlled environment while locating the flow center and vacuum pump in a non-controlled environment.

The SMA OneTouch ICS and SMA OneTouch Command Systems are both available in Isolator configurations which provide non-aspiration of possible contaminates from the exterior to the Isolator.

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116 SMA® DDC SCHEMATIC

114 SMA DIGITAL DISPLAY CONTROL CENTERS (DDC)

115 SMA DIGITAL DISPLAY CONTROL CENTERS (DDC) FOR ISOLATORS

118 SMA ONETOUCH ® COMMAND SYSTEM

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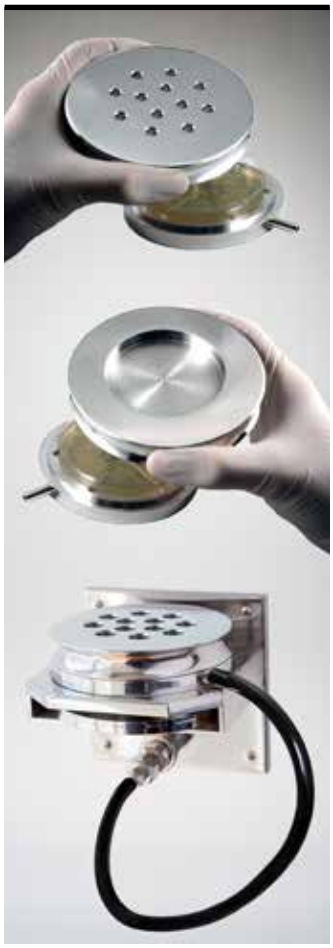
SMA Atrium®



SMA Atriums are Stainless Steel collection devices that connect to the SMA OneTouch® Integrated Control System (ICS), SMA® Digital Display Control Center (DDC), or SMA MicroPortable® Air Sampler. When partnered with one of these viable monitoring instruments the SMA Atriums direct air from the environment to impact onto a media plate. The media plate is then evaluated to determine the amount of viable contamination in the environment.

SMA Atriums are the preferred test method of pharmaceutical, biotechnology, semiconductor, and electronics organizations around the world for determining the level of viable contamination in their facilities.

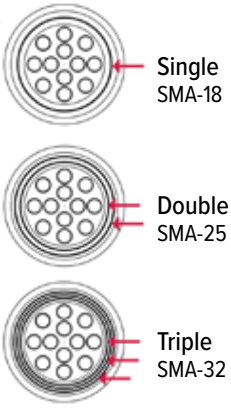
SMA Atriums are available in multiple configurations, including a wall mountable configuration with a specifically designed bracket and Atrium base. The SMA Atrium Easy2Grip™ top has a concave edge designed to make the Atrium easy to handle.

Features and Benefits

- Easily connected to SMA Viable Monitoring Equipment
- Constructed of 316L Stainless Steel
- Completely sterilized by steam, heat, or ethylene oxide (ETO)
- Used with standard media plates (90 or 100 mm) with 18, 25, or 32 mL fill levels
- Available with 1/4 or 1/2 inch sieve diameters
- Requires a vacuum source to operate
- Operate at an air flow of 1 CFM (28.3 LPM)
- Compact size allows the SMA Atriums to be located near critical filling processes where space is limited
- Non-turbulent design causes no disruption in unidirectional air flow, which allows placement in the most critical areas (e.g. RABS)
- Available with a concave, Easy2Grip design

Selecting an SMA Atrium

It is critical to determine the desired sample time and plate exposure period. Extended periods of active sampling can cause desiccation and dehydration of the media plate, resulting in poor or no growth of microorganisms that may have been present in the air sample. The SMA Atrium allows for continuous, active sampling for up to 3 hours (or more), depending on the media plate fill level and selected Atrium top.



Use the following table to determine the correct SMA Atrium for your facility:

Exposure Time*	Plate Fill Level	Sieve Diameter	Air Flow	Assembly**
60 Minutes	18 mL	1/2 inch	1 CFM	SMA-316-18-1/2
90 Minutes	25 mL	1/2 inch	1 CFM	SMA-316-25-1/2
180 Minutes	32 mL	1/2 inch	1 CFM	SMA-316-32-1/2
60 Minutes	18 mL	1/4 inch	1 CFM	SMA-316-18-1/4
90 Minutes	25 mL	1/4 inch	1 CFM	SMA-316-25-1/4
120 Minutes	32 mL	1/4 inch	1 CFM	SMA-316-32-1/4
Sieve diameter is the size of the holes in the top of the Atrium. The sieve diameter affects the velocity of the air flow into the media plate. VAI offers 1/4 and 1/2 inch sieve diameters. The larger, 1/2 inch, sieve diameter allows for a longer sampling period and offers the capacity of implementing a more continuous monitoring effort.				

* Exposure time is based on VAI's internal validation studies (available upon request) as well as customer based validation efforts.

** Also applies to Easy2Grip Atrium Assemblies.

SMA-EG-18-1/4

SMA-EG-18-1/2

SMA-316-T-25-1/2H150

SMA-EG-T-18-1/2

SMA-316-T-18-1/4

Easy2Grip Assemblies • 316L Stainless Steel

Order Number	*Description*
SMA-EG-18-1/2	Easy2Grip, 1/2" diameter sieves, use with 18 mL filled media plates
SMA-EG-25-1/2	Easy2Grip, 1/2" diameter sieves, use with 25 mL filled media plates
SMA-EG-32-1/2	Easy2Grip, 1/2" diameter sieves, use with 32 mL filled media plates
SMA-EG-18-1/4	Easy2Grip, 1/4" diameter sieves, use with 18 mL filled media plates
SMA-EG-25-1/4	Easy2Grip, 1/4" diameter sieves, use with 25 mL filled media plates
SMA-EG-32-1/4	Easy2Grip, 1/4" diameter sieves, use with 32 mL filled media plates
SMA-EG-25-D50	Easy2Grip, 0.4 mm diameter sieves, use with 25 mL filled media plates

All assemblies come with the specified Easy2Grip top, standard base, orifice, and Easy2Grip lid, SMA-316-BOTTOM, SMA-316-ORIFICE-STD, SMA-LID-EG.

SMA Atrium Assemblies • 316L Stainless Steel

Order Number	*Description*
SMA-316-18-1/2	1/2" diameter sieves, use with 18 mL filled media plates
SMA-316-25-1/2	1/2" diameter sieves, use with 25 mL filled media plates
SMA-316-32-1/2	1/2" diameter sieves, use with 32 mL filled media plates
SMA-316-18-1/4	1/4" diameter sieves, use with 18 mL filled media plates
SMA-316-25-1/4	1/4" diameter sieves, use with 25 mL filled media plates
SMA-316-32-1/4	1/4" diameter sieves, use with 32 mL filled media plates
SMA-316-25-D50	0.4 mm diameter sieves, use with 25 mL filled media plates

All assemblies come with the specified top, standard base, orifice, and lid, SMA-316-BOTTOM, SMA-316-ORIFICE-STD, SMA-LID.

Easy2Grip Tops • 316L Stainless Steel

Order Number	*Description*
SMA-EG-T-18-1/2	Easy2Grip, Top Only, 1/2" diameter sieves, use with 18 mL filled media plates
SMA-EG-T-25-1/2	Easy2Grip, Top Only, 1/2" diameter sieves, use with 25 mL filled media plates
SMA-EG-T-32-1/2	Easy2Grip, Top Only, 1/2" diameter sieves, use with 32 mL filled media plates
SMA-EG-T-18-1/4	Easy2Grip, Top Only, 1/4" diameter sieves, use with 18 mL filled media plates
SMA-EG-T-25-1/4	Easy2Grip, Top Only, 1/4" diameter sieves, use with 25 mL filled media plates
SMA-EG-T-32-1/4	Easy2Grip, Top Only, 1/4" diameter sieves, use with 32 mL filled media plates
SMA-EG-T-25-D50	Easy2Grip, Top Only, 0.4 mm diameter sieves, use with 25 mL filled media plates

All Easy2Grip tops come with a lid, SMA-LID-EG.

SMA Atrium Tops • 316L Stainless Steel

Order Number	*Description*
SMA-316-T-18-1/2	Top Only, 1/2" diameter sieves, use with 18 mL filled media plates
SMA-316-T-25-1/2	Top Only, 1/2" diameter sieves, use with 25 mL filled media plates
SMA-316-T-32-1/2	Top Only, 1/2" diameter sieves, use with 32 mL filled media plates
SMA-316-T-18-1/4	Top Only, 1/4" diameter sieves, use with 18 mL filled media plates
SMA-316-T-25-1/4	Top Only, 1/4" diameter sieves, use with 25 mL filled media plates
SMA-316-T-32-1/4	Top Only, 1/4" diameter sieves, use with 32 mL filled media plates
SMA-316-T-25-D50	Top Only, 0.4 mm diameter sieves, use with 25 mL filled media plates
SMA-316-T-25-1/2H150	Top Only, 1/2" diameter sieves, use with 25 mL filled media plates, includes an integrated 1½" handle

All SMA Atrium tops come with a lid, SMA-LID.

SMA-LID-EG

SMA-316-BOTTOM

SMA-316-B-SNTRY75

SMA-EG-25-1/2-WATR and SMA-WALLATR

SMA-WALLATR

Accessories • 316L Stainless Steel

Order Number	*Description*
SMA-316-ORIFICE-STD	Replacement vacuum tubing attachment non-limiting fitting for SMA-316-BOTTOM, SMA-316-BOTTOM-BO, and SMA-316-BOTTOM-WATR. Use with 1/4" ID flexible tubing. 1/pk
SMA-LID-EG	Easy2Grip Aseptic Atrium cover, not compatible with Remote Atriums, 4½" diameter, 1/8" edge.
SMA-LID	SMA Aseptic Atrium cover, not compatible with Remote Atriums or Easy2Grip Atriums, 4½" diameter, 1/4" edge.

Base Only • 316L Stainless Steel

Order Number	*Description*
SMA-316-BOTTOM	Vacuum connection located on the side of the base
SMA-316-BOTTOM-BO	Vacuum connection centrally located on the bottom of the base
SMA-316-B-SNTRY75	Vacuum connection centrally located on the bottom of the base, includes an integrated 3/4" sanitary flange fitting
SMA-316-B-SNTRY150	Vacuum connection centrally located on the bottom of the base, includes an integrated 1½" sanitary flange fitting
SMA-316-B-SNTRY-D15	Vacuum connection centrally located on the bottom of the base, includes an integrated metric (DIN15) sanitary flange fitting.

Eay2Grip Wall Atrium Assemblies • 316L Stainless Steel

Order Number	*Description*
SMA-EG-18-1/2-WATR	1/2" diameter sieves, use with 18 mL filled media plates
SMA-EG-25-1/2-WATR	1/2" diameter sieves, use with 25 mL filled media plates
SMA-EG-32-1/2-WATR	1/2" diameter sieves, use with 32 mL filled media plates

All wall assemblies come with the specified Easy2Grip top, wall base, orifice, and lid, SMA-316-BOTTOM-WATR, SMA-316-ORIFICE-STD, SMA-LID-EG.
The wall bracket is sold separately (SMA-WALLATR).

SMA Wall Atrium Assemblies • 316L Stainless Steel

Order Number	*Description*
SMA-316-18-1/2-WATR	1/2" diameter sieves, use with 18 mL filled media plates
SMA-316-25-1/2-WATR	1/2" diameter sieves, use with 25 mL filled media plates
SMA-316-32-1/2-WATR	1/2" diameter sieves, use with 32 mL filled media plates

All wall assemblies come with the specified top, wall base, orifice, and lid, SMA-316-BOTTOM-WATR, SMA-316-ORIFICE-STD, SMA-LID.
The wall bracket is sold separately (SMA-WALLATR).

Wall Atrium Accessories • 316L Stainless Steel

Order Number	*Description*
SMA-WALLATR	Wall bracket for use with SMA Wall Atriums. Wall mountable, removable, includes quick disconnect fitting and mate which transitions to a 1/4" hose barb, valve seals automatically when disconnected.
SMA-316-BOTTOM-WATR	SMA Atrium base threaded for use with wall mount bracket SMA-WALLATR. Vacuum connection located on the side of the base.

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA® Remote Atrium

Remote Atrium and Isokinetic Probe Connection

SMA-316-RE-25

SMA-ISO-PROBE-1/4

SMA Remote Atriums are designed to sample in places where the use of the standard SMA Atrium® is either impractical due to size and space limitations, or the actual procedure of replacing the media plate would interfere with the manufacturing process. The SMA Remote Atrium extension tube attaches to ¼ inch Hytrel® tubing.

SMA Remote Atriums can be used with VAI's Isokinetic Probe which provides a secure attachment point near the point of sample and improves air flow efficiency. The Isokinetic Probe and tubing can be located near critical filling processes where space is limited.

Features and Benefits

- Easily connected to SMA Viable Monitoring Equipment
- Constructed of 316L Stainless Steel
- Completely sterilized by steam, heat, or ethylene oxide (ETO)
- Used with standard media plates (90 or 100 mm) with 18, 25, or 32 mL fill levels
- Requires a vacuum source to operate
- Operate at an air flow of 1 CFM (28.3 LPM)

Complete Assemblies

Order Number	*Description*
SMA-316-RE-18	SMA Remote Atrium Assembly for use with 18 mL filled media plates, 316L Stainless Steel
SMA-316-RE-25	SMA Remote Atrium Assembly for use with 25 mL filled media plates, 316L Stainless Steel
SMA-316-RE-32	SMA Remote Atrium Assembly for use with 32 mL filled media plates, 316L Stainless Steel

All assemblies come with the specified top, standard base, and orifice, SMA-316-BOTTOM, SMA-316-ORIFICE-STD.

Top Only

Order Number	*Description*
SMA-316-RE-TO-18	SMA Remote Atrium Top for use with 18 mL filled media plates, 316L Stainless Steel
SMA-316-RE-TO-25	SMA Remote Atrium Top for use with 25 mL filled media plates, 316L Stainless Steel
SMA-316-RE-TO-32	SMA Remote Atrium Top for use with 32 mL filled media plates, 316L Stainless Steel

Accessories

Order Number	*Description*
SMA-ISO-PROBE-1/4	Isokinetic Probe with 1/4" Hose Connection, 316L Stainless Steel

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA OneTouch® ICS

The SMA OneTouch® Integrated Control System (ICS) is a computerized, automated viable air monitoring system that controls calibrated, precise air sampling through individual or multiple SMA Atriums®. SMA Atriums are Stainless Steel collection devices that direct air from the environment to impact onto a media plate. The media plate is then evaluated to determine the amount of viable contamination in the air sample.

The SMA OneTouch ICS strictly regulates the air flow rate throughout a sample cycle. The system automatically alarms the operator visually and audibly if the sample becomes compromised or is aborted. In addition, the SMA OneTouch ICS continuously monitors the air flow rate while sampling and will alert the operator if the flow rate deviates from the established 1 Cubic Feet per Minute (CFM) flow rate.

The SMA OneTouch ICS has a touchscreen interface that incorporates facility floor plans and SMA Atrium locations for sample monitoring. User accounts have access levels which limit their access to specific functionality.

VAI also offers the SMA OneTouch ICS for Isolators. This SMA OneTouch ICS configuration includes all the aforementioned benefits, provides secure sampling inside an isolator, and redirects air flow during Vaporized Hydrogen Peroxide (VHP) sterilization.

Product Uses

- Program, start, abort, and monitor all sampling through integrated SMA Atriums
- Monitors all sample parameters (e.g. sample volume, sample duration, and vacuum pump status)
- Provides visual indication of all activity throughout the sampling process
- Immediate audible and visual alarms will sound if the sample is compromised or aborted

Features and Benefits

- Installation requires minimal tubing and wiring which simplifies installation into new and existing facilities
- Integrated with existing facility monitoring and data collection systems using industry standard networking
- Provides system-wide viable monitoring capabilities from a single interface
- Remotely monitored using a variety of handheld, tablet, and computer-based devices

SMA OneTouch ICS Components

The SMA OneTouch ICS comes as a complete assembly that includes: Interface, Flow Center, Controller, and Vacuum components (if ordering SMA OneTouch ICS for isolators, an Isolator Flow Center).

The SMA OneTouch® ICS Interface is a touch screen that is used to monitor and control the SMA OneTouch ICS and all integrated SMA Atriums.

The SMA OneTouch ICS Controller is a computerized system which incorporates a Programmable Logic Controller (PLC) and powers the Interface and Flow Center. It automates all system monitoring, sampling, and alarming functions.

The SMA OneTouch ICS Flow Center contains a series of high accuracy mass-flow controllers (1.0 CFM ± 2%) that automatically regulate the air flow on each sampling line.

VAI® offers on-site calibration and repair services. Please contact us for details.

SMA OneTouch ICS Complete Assemblies

Order Number	*Description*
SMA-ICS-1-A	SMA OneTouch ICS, 1 Sampling Location, 6.5” Interface
SMA-ICS-2-A	SMA OneTouch ICS, 2 Sampling Locations, 6.5” Interface
SMA-ICS-4-A	SMA OneTouch ICS, 4 Sampling Locations, 10” Interface
SMA-ICS-6-A	SMA OneTouch ICS, 6 Sampling Locations, 10” Interface
SMA-ICS-8-A	SMA OneTouch ICS, 8 Sampling Locations, 15” Interface
SMA-ICS-10-A	SMA OneTouch ICS, 10 Sampling Locations, 15” Interface

Available in local voltage requirements.

Isolator Systems Complete Assemblies

Order Number	*Description*
SMA-ICS-1I-A	SMA OneTouch ICS for Isolators, 1 Sampling Location, 6.5” Interface
SMA-ICS-2I-A	SMA OneTouch ICS for Isolators, 2 Sampling Locations, 6.5” Interface
SMA-ICS-4I-A	SMA OneTouch ICS for Isolators, 4 Sampling Locations, 10” Interface
SMA-ICS-6I-A	SMA OneTouch ICS for Isolators, 6 Sampling Locations, 10” Interface
SMA-ICS-8I-A	SMA OneTouch ICS for Isolators, 8 Sampling Locations, 15” Interface
SMA-ICS-10I-A	SMA OneTouch ICS for Isolators, 10 Sampling Locations, 15” Interface

Available in local voltage requirements.

Other Technical Data Available Upon Request

Operator’s Manual • Data Sheet

Three Screen Sizes Available

SMA ONETOUCH® ICS SCHEMATIC

SMA OneTouch® ICS

(1) Cat5 Ethernet Cable

(1) Cat5 Ethernet Cable

(1) Plenum Rated Cable

3/8” Vardex Tubing
for bends (Grey)

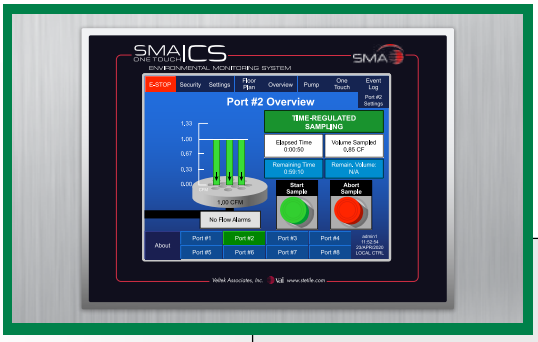
3/8” Hytrel Tubing
for straight runs (Black)

SMA OneTouch ICS
Integrated Controller
& Flow Center

1 1/4” ID Reinforced
Vinyl Tubing

To Dedicated Vaccum Pump or
Central Vacuum System

A SMA OneTouch ICS
Touchscreen Interface



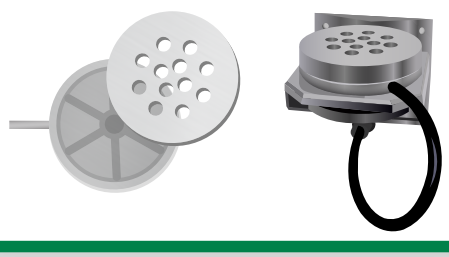
A

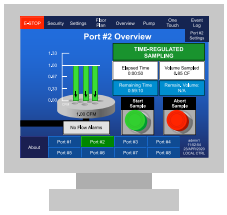
Port 2

B Port 1

1/4” Hytrel Tubing

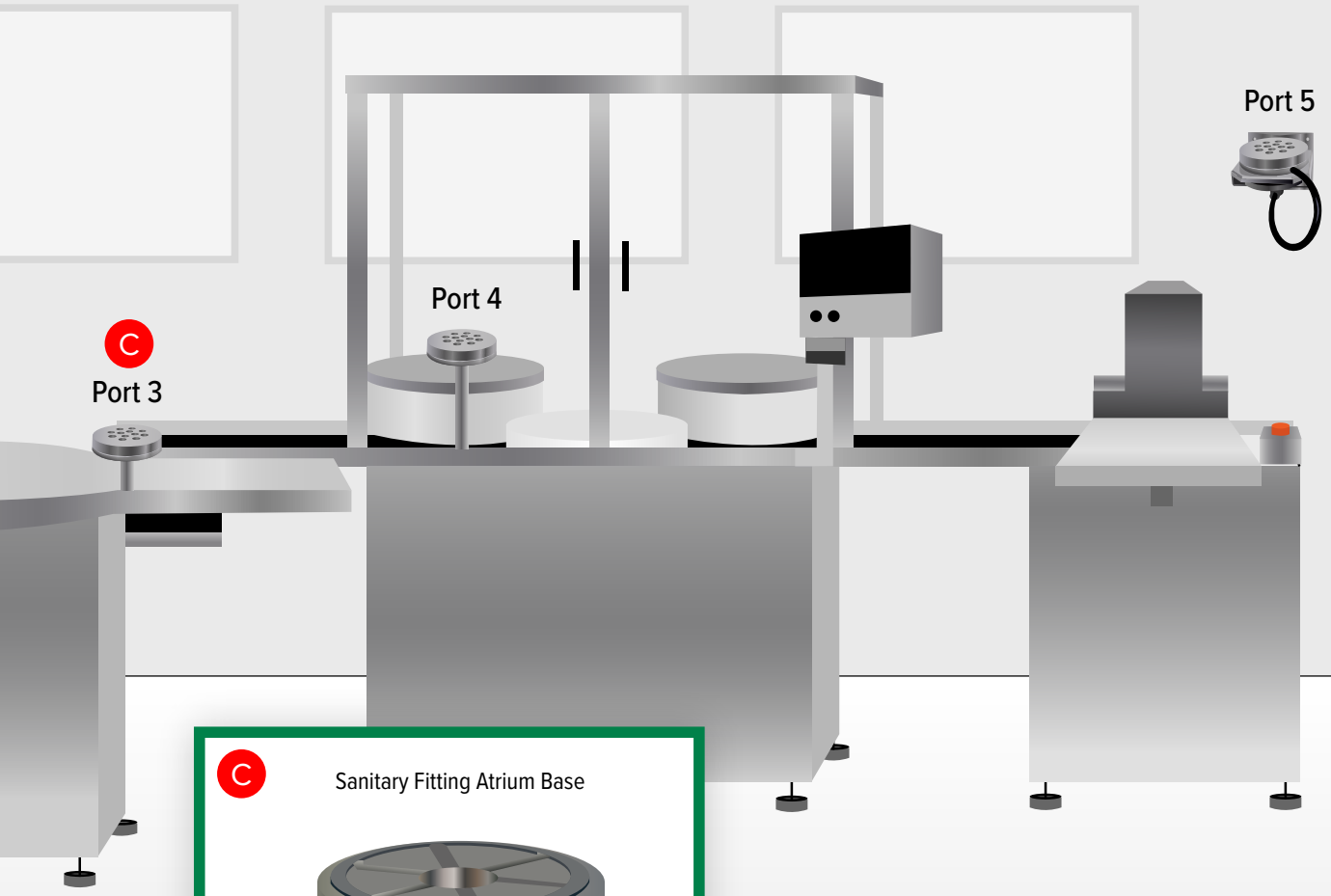
B SMA Atrium® Wall Bracket





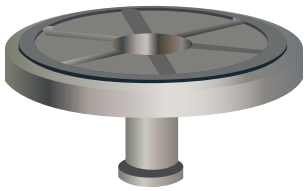
Customer Supplied Computer System VNC/SCADA/PLC/PC

Remotely access and control the interface using a variety of handheld, tablet, and computer based devices. Connect the SMA OneTouch ICS to an existing facility monitoring system.



C

Sanitary Fitting Atrium Base

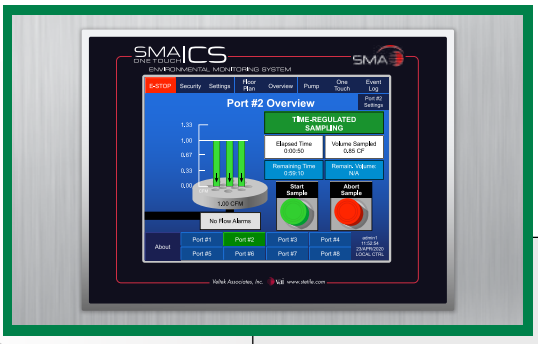


CLEANROOM

SMA OneTouch® ICS for Isolators

(1) Cat5 Ethernet Cable

A SMA OneTouch ICS Touchscreen Interface



Cat5 Ethernet Cable

(1) (1) Plenum Rated Cables

3/8” Vardex Tubing
for bends (Grey)

3/8” Hytrel Tubing
for straight runs (Black)

A

SMA OneTouch ICS Integrated Controller & Flow Center for Isolators

1 1/4” ID Reinforced Vinyl Tubing

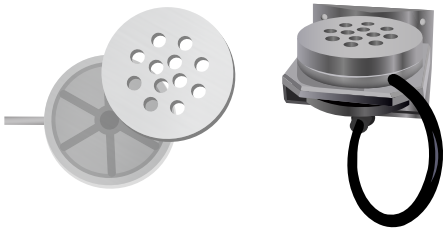
B Port 1

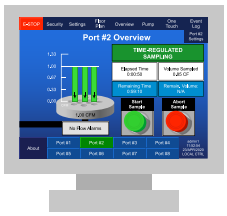
1/4” Hytrel Tubing

To Dedicated Vaccum Pump or Central Vacuum System

Second Vacuum Pump for Isolator Systems only to perform purge

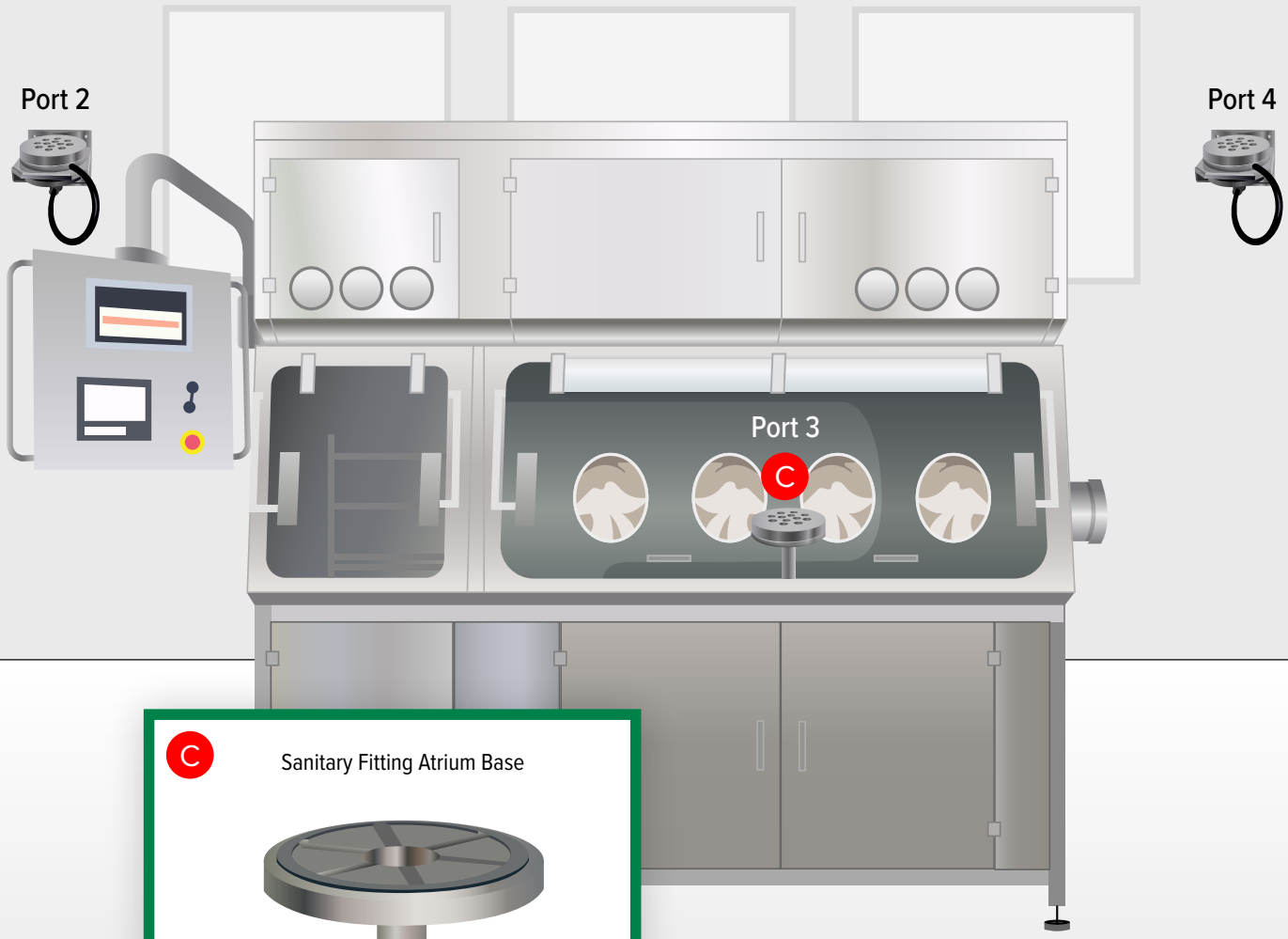
B SMA Atrium® Wall Bracket





Customer Supplied Computer System VNC/SCADA/PLC/PC

Remotely access and control the interface using a variety of handheld, tablet, and computer based devices. Connect the SMA OneTouch ICS to an existing facility monitoring system.



C Sanitary Fitting Atrium Base

CLEANROOM WITH ISOLATOR

SMA® Digital Display Control Centers (DDC)

SMA-DDC-1

SMA-DDC-2

SMA-DDC-3

SMA-DDC-5-5

SMA-DDC-10

SMA Digital Display Control Centers (DDC) are used to control calibrated and timed vacuum sequences to individual or multiple SMA Atriums®. In addition, the DDC provides strict regulation of air flow (1 CFM) and will visually and audibly alarm the operator if the proper air flow is not maintained.

SMA DDCs can be used in conjunction with SMA OneTouch® Control Panels. These devices allow you to manage different aspects of the sample cycle from within a controlled environment while locating the DDC and vacuum pump in a non-controlled environment.

Product Uses

- For Grade A-D rooms
- Program and view a sample time
- Start and cancel a sample cycle
- Monitor and control air flow
- Provide visual notification when the sample cycle is in progress
- Provide audible and visual alarms when
  - The sample cycle is complete
  - There is a 1 CFM error

Features and Benefits

- Easily connected to SMA OneTouch Control Panels and SMA Atriums
- Cabinets are constructed of 304 Stainless Steel
- Disinfect using select VAI® products
- Connect to an external facility control system (e.g. SCADA)
- Meets North American (ETL) and European Community (CE) safety standards
- Available with 1, 2, 3, 5, or 10 sampling locations

VAI offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-DDC-1	SMA Digital Display Control Center, One Location, Includes Pump (Internal)
SMA-DDC-2	SMA Digital Display Control Center, Two Locations, Includes Pump (External)
SMA-DDC-3	SMA Digital Display Control Center, Three Locations, Includes Pump (External)
SMA-DDC-5-5	SMA Digital Display Control Center, Five Locations, Includes Pump (External)
SMA-DDC-10	SMA Digital Display Control Center, Ten Locations, Includes Pump (External)

Available in local voltage requirements.

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA® Digital Display Control Centers (DDC) For Isolators

SMA-DDC-1I

SMA-DDC-2I

SMA-DDC-3I

SMA-DDC-5-5I

SMA-DDC-10I

SMA Digital Display Control Centers (DDC) for Isolators are used to control calibrated and timed vacuum sequences to individual or multiple SMA Atriums® within an isolator system. In addition, the DDCs for Isolators provide strict regulation of airflow (1 Cubic Feet per Meter) and will visually and audibly alarm the operator if the proper air flow is not maintained. DDCs for Isolators assure the non-aspiration or return of possible contaminates from the exterior environment to the isolator system by providing connections for a purge pump.

DDCs for Isolators can be used in conjunction with SMA OneTouch® Control Panels. These devices allow you to manage different aspects of the sample cycle from within a controlled environment while locating the DDC and vacuum pump in a non-controlled environment.

Product Uses

- Program and view a sample time
- Start and cancel a sample cycle
- Monitor and control airflow
- Provide visual notification when the sample cycle is in progress
- Provide audible and visual alarms when
  - The sample cycle is complete
  - There is a 1 CFM error

Features and Benefits

- Easily connected to SMA OneTouch Control Panels and SMA Atriums
- Cabinets are constructed of 304 Stainless Steel
- Disinfect using select VAI® products
- Connect to an external facility control system (e.g. SCADA)
- Meets North American (ETL) and European Community (CE) safety standards
- Available with 1, 2, 3, 5, or 10 sampling locations

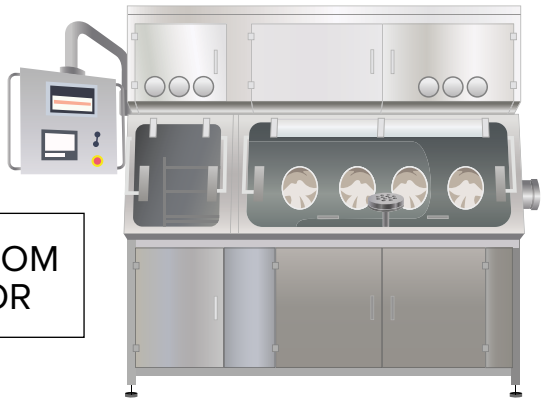
VAI offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-DDC-1I	SMA Digital Display Control Center For Isolators, One Location, Includes Pump (Internal)
SMA-DDC-2I	SMA Digital Display Control Center For Isolators, Two Locations, Includes Pump (External)
SMA-DDC-3I	SMA Digital Display Control Center For Isolators, Three Locations, Includes Pump (External)
SMA-DDC-5-5I	SMA Digital Display Control Center For Isolators, Five Locations, Includes Pump (External)
SMA-DDC-10I	SMA Digital Display Control Center For Isolators, Ten Locations, Includes Pump (External)

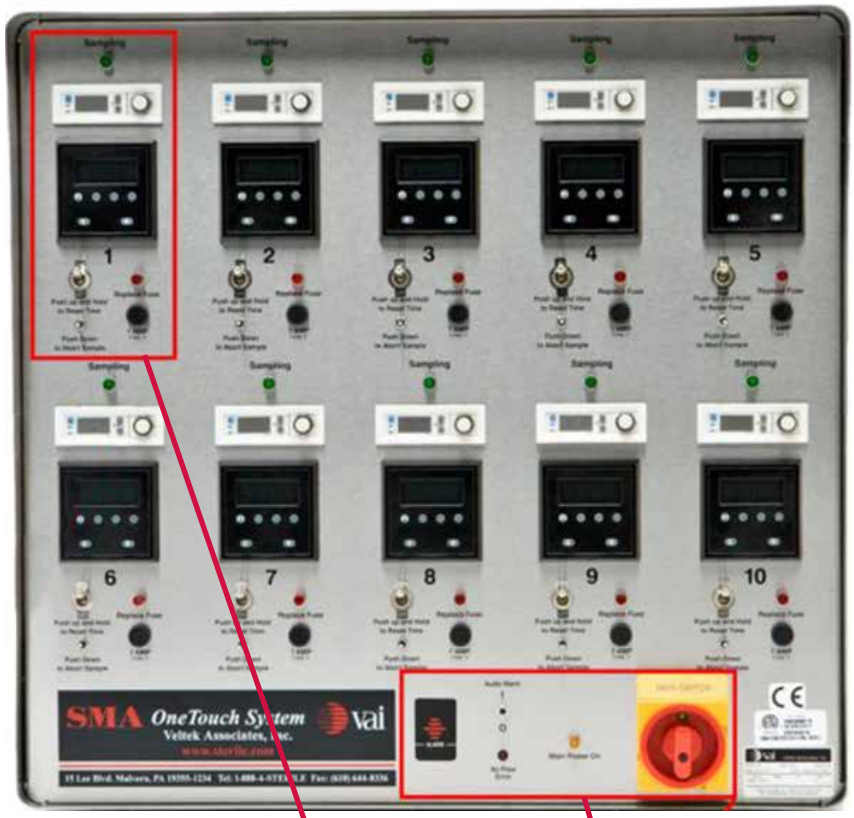
Available in local voltage requirements.

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet



SMA DDC SCHEMATIC



Sampling lights

Air flow switch

Timer

Time display

Programming buttons

Port number

Port power switch

Reset time / Abort sample switch

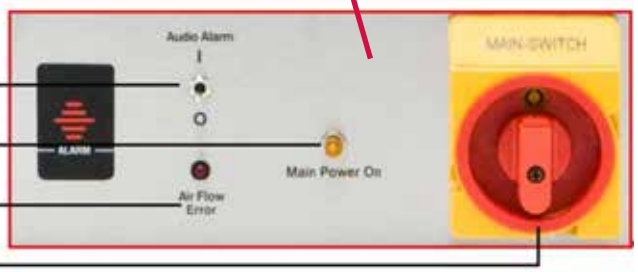
Replace fuse light and Fuse

Audio alarm switch

Main power on light

Air flow error light

Main power switch



SMA OneTouch® Control Panels

SMA-OT-04-101

SMA-OT-04-102

SMA-OT-04-103

SMA-OT-04-105

SMA OneTouch Control Panels are used in conjunction with SMA® Digital Display Control Centers and SMA Atriums®. SMA OneTouch Control Panels allow you to start, stop, and monitor the sample cycle from within a controlled environment while locating the SMA Digital Display Control Center and vacuum pump in a non-controlled environment.

Product Uses

- Program and view a sample time
- Start and cancel a sample cycle
- Provide visual notification when the
  - Sample cycle is in progress
  - Vacuum is present and functioning correctly
  - Sample complete and 1 CFM audible alarms are enabled
- Provide audible and visual alarms when
  - The sample cycle is complete
  - There is no vacuum present
  - There is a 1 CFM error

Features and Benefits

- Easily connected to a SMA Digital Display Control Center
- Constructed with a Stainless Steel bezel and clear PVC laminate face that are completely sealed for disinfection purposes
- Disinfect using select VAI® products
- Allows sampling from multiple Atriums simultaneously or independently
- Meets North American (ETL) and European Community (CE) safety standards
- Available with controls for 1, 2, 3, or 5 Atrium sampling sites

VAI® offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-OT-04-101	SMA OneTouch Control Panel, One Location, Flush Mount
SMA-OT-04-102	SMA OneTouch Control Panel, Two Locations, Flush Mount
SMA-OT-04-103	SMA OneTouch Control Panel, Three Locations, Flush Mount
SMA-OT-04-105	SMA OneTouch Control Panel, Five Locations, Flush Mount

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA® Tubing

VAI® offers Vardex® and Hytrel® tubing and connectors. Hytrel tubing is used for straight runs and Vardex is used for angles. Both are available in 1 foot sections or 100 foot rolls.

Order Number	*Description*
SMA-VH-1/4	Hytrel Tubing, 1/4" ID, 1' Length
SMA-VH-1/4-ROLL	Hytrel Tubing, 1/4" ID, 100' Roll
SMA-VH-3/8	Hytrel Tubing, 3/8" ID, 1' Length
SMA-VH-3/8-ROLL	Hytrel Tubing, 3/8" ID, 100' Roll
SMA-VAR-3/8	Vardex Tubing, 3/8" ID, 1' Length
SMA-VAR-3/8-ROLL	Vardex Tubing, 3/8" ID, 100' Roll
SMA-VARVH	Connector For Hytrel To Vardex Tubing

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA OneTouch® Command System

(11)

Plenum Rated Cables
One for each location and one for Vacuum Sensor

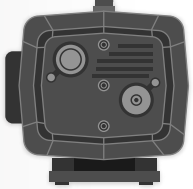
(6)

3/8” Vardex Tubing
for bends (Grey)

3/8” Hytrel Tubing
for straight runs (Black)

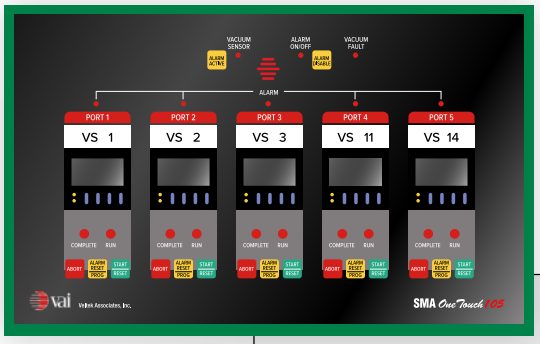
SMA Digital Display Control Center (DDC)

1 1/4” ID Reinforced Vinyl Tubing

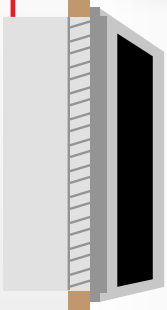


To Dedicated Vaccum Pump or Central Vacuum System

A **SMA OneTouch Control Panel**



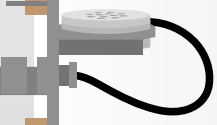
A



Port 2

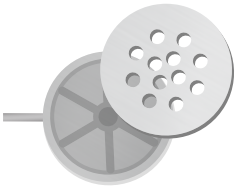
B

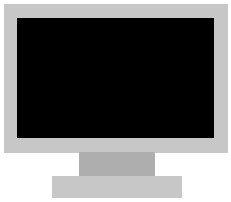
Port 1



1/4” Hytrel Tubing

B **SMA Atrium®** **Wall Bracket**





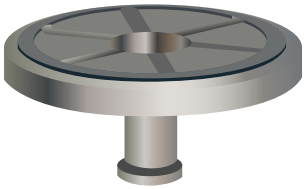
Customer Supplied Computer System
SCADA/PLC/PC
Remotely start or abort sampling and monitor
1 CFM status

Port 5

Port 4

C
Port 3

C
Sanitary Fitting Atrium Base



CLEANROOM

SMA OneTouch® Command System for Isolators

(11)

Plenum Rated Cables
One for each location and one for Vacuum Sensor

(6)

3/8" Vardex Tubing
for bends (Grey)

3/8" Hytrel Tubing
for straight runs (Black)

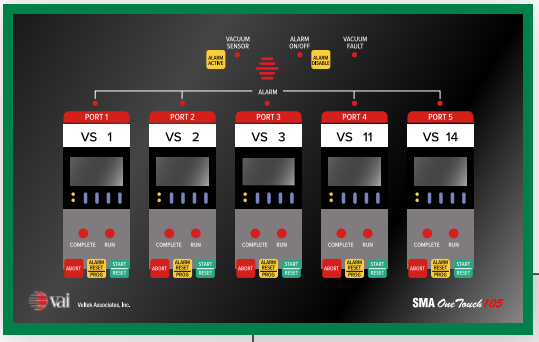
SMA Digital Display Control Center (DDC) for Isolators

1 1/4" ID Reinforced Vinyl Tubing

To Dedicated Vaccum Pump or Central Vacuum System

Second Vacuum Pump for Isolator Systems only to Perform Purge

A **SMA OneTouch Control Panel**

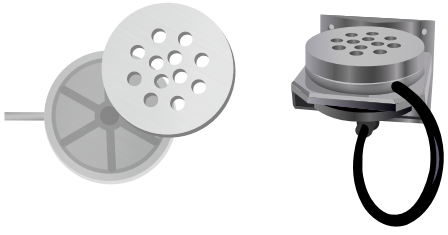


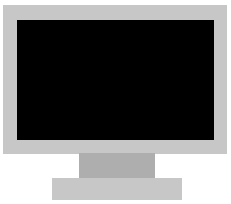
A

B **Port 1**

1/4" Hytrel Tubing

B **SMA Atrium®** **Wall Bracket**





Customer Supplied Computer System
SCADA/PLC/PC
Remotely start or abort sampling and monitor
1 CFM status

C Sanitary Fitting Atrium Base

CLEANROOM WITH ISOLATOR

Welcome to SMA®
MicroPortable Air Sampling Systems

VAI®'s Environmental Control Monitoring Division (ECMD) addresses the needs of the pharmaceutical, biotechnology, semiconductor, and electronics industries with a complete range of portable viable environmental monitoring equipment.

VAI's viable air monitoring equipment is designed to sample a quantifiable amount of air for viable contamination using our patented Sterilizable Microbial Atrium (SMA®) and a standard media plate. A SMA Atrium® is a 316L Stainless Steel capture device that is connected to a controlled vacuum source, such as the SMA MicroPortable ICS® or SMA MicroPortable® Air Sampler. Air is directed from the environment to impact onto a media plate contained inside of the Atrium. The media plate is then incubated and tested to determine the number of viable organisms per cubic foot or liter of air.

In conjunction with an SMA Atrium, SMA MicroPortable® Air Samplers are used for the automated collection of microorganisms in the air. These viable air samplers are battery powered, compact, and lightweight which allows them to be easily moved to desired air sampling points.

Section Contents

125	SMA MICROPORTABLE AIR SAMPLERS
123, 124	SMA MICROPORTABLE ICS
126	SMA MICROPORTABLE MODEL COMPARISONS

SMA MicroPortable ICS®

SMA-P401-03

The SMA MicroPortable® ICS provides continuous air monitoring for viable particles at quality control sample points. The SMA MicroPortable ICS regulates air flow through a SMA Atrium®. A SMA Atrium is a Stainless Steel device that directs air from the environment to impact onto a media plate. The media plate is then tested to determine the amount of viable contamination in the environment.

The SMA MicroPortable ICS is battery powered and compact, which allows it to be easily moved to desired air sampling points. It combines the sampling capability of the SMA Atrium with calibrated air flow and a touchscreen interface.

The SMA MicroPortable ICS provides strict regulation of air flow and will alarm the operator if the air flow deviates beyond the acceptable range. The system also monitors and indicates a variety of operational parameters including the sample's volume and elapsed time.

The SMA MicroPortable ICS is a networked device that may be remotely accessed by operators and administrators. The device can export event history to a removable USB flash drive. Event history includes sampling and calibration events.

Product Uses

- Provides a full-featured solution to control and monitor air sampling in controlled environments
- Regulates air flow for a preset time-duration or until a preset volume has been sampled
- Provides the option to view the interface on a remote desktop using VNC Client
- Initiate, monitor, and abort sampling from the Sample screen
- View and export a log of events from the Event Log screen
- Configure settings such as flow rate, sample mode, alarm audio, units of measure, and labels, etc. from the Settings screen

Features and Benefits

- Touchscreen can be used with gloved hands
- Can be disinfected using select VAI products
- SMA Atrium Top can be completely sterilized by steam, heat, or ethylene oxide (ETO)
- Fully charged battery lasts eight hours

VAI® offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-P401-03	SMA MicroPortable ICS Air Sampler – Stainless Steel Touchscreen Display, 1, 2, and 5 CFM Selectable Flow Rates 316L Stainless Steel Housing *Use with SMA Atrium Tops such as SMA-EG-T-25-1/4 or SMA-316-T-25-1/4.*
SMA-ICSMP-CHGR	Additional Battery Charger for SMA MicroPortable ICS
SMA-ICSMP-BAT	Additional Lithium-Ion Battery for SMA MicroPortable ICS

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA MicroPortable ICS®

SMA-ICSMP-01

The SMA MicroPortable ICS provides continuous air monitoring for viable particles at quality control sample points. The SMA MicroPortable ICS regulates air flow through a SMA Atrium®. A SMA Atrium is a Stainless Steel device that directs air from the environment to impact onto a media plate. The media plate is then tested to determine the amount of viable contamination in the environment.

The SMA MicroPortable ICS is battery powered, compact, and lightweight, which allows it to be easily moved to desired air sampling points. It combines the sampling capability of the SMA Atrium with calibrated air flow and a touchscreen interface.

The SMA MicroPortable ICS provides strict regulation of air flow and will alarm the operator if the air flow deviates beyond the acceptable range. The system also monitors and indicates a variety of operational parameters including the sample's volume and elapsed time.

The SMA MicroPortable ICS is a networked device that may be remotely accessed by operators and administrators. The device can export event history to a removable USB flash drive. Event history includes sampling and calibration events.

Product Uses

- Provides a full-featured solution to control and monitor air sampling in controlled environments
- Regulates air flow for a preset time-duration or until a preset volume has been sampled
- Provides the option to view the interface on a remote desktop using VNC Client
- Initiate, monitor, and abort sampling from the Sample screen
- View and export a log of events from the Event Log screen
- Configure settings such as flow rate, sample mode, alarm audio, units of measure, and labels, etc. from the Settings screen

Features and Benefits

- Touchscreen can be used with gloved hands
- Can be disinfected using select VAI products
- SMA Atrium Top can be completely sterilized by steam, heat, or ethylene oxide (ETO)
- A fully charged battery lasts 8 hours

VAI® offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-ICSMP-01	SMA MicroPortable ICS Air Sampler, Touchscreen Display, 1, 2, and 5 CFM Selectable Flow Rates
SMA-ICSMP-CHGR	Additional Battery Charger for SMA MicroPortable ICS
SMA-ICSMP-BAT	Additional Lithium-Ion Battery for SMA MicroPortable ICS
SMA-ICSMP-CASE	Air Transport Association (ATA) Style Transportation Case for SMA MicroPortable ICS

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA MicroPortable® Air Samplers

SMA-P201-03

SMA-P191-03

SMA-P300-03

SMA MicroPortable Air Samplers are used for the automated collection of microorganisms in the air. These viable air samplers are battery powered, compact, and lightweight which allows them to be easily moved to desired air sampling points. They also make it easy to start and cancel a sample cycle.

SMA MicroPortable Air Samplers incorporate the same multi-orifice sampling methods as the standard SMA Atrium which allows continuous viable air sampling. Furthermore, they allow you to program, save, recall, and view two sample volume amounts and view air flow in Cubic Feet per Minute (CFM) or Liters Per Minute (LPM).

Product Uses

- Program, save, recall, and view two sample volume amounts
- Start and cancel a sample cycle
- Provide visual notification
  - When the sample cycle is in progress
  - Which preset sample volume is selected
  - Which air flow rate is selected, 1 CFM or 5 CFM
  - When the battery requires charging
- Provide audible and visual alarms when the sample cycle is complete

Features and Benefits

- Constructed with 316L Stainless Steel
- Disinfect using select VAI products
- SMA Atriums can be completely sterilized by steam, heat, or ethylene oxide (ETO)
- Battery powered and can operate for 8 hours before requiring a 45 minute recharge
- Meets North American (ETL) and European Community (CE) safety standards
- Includes a battery, battery charger, cover, SMA Atrium top (1/4" 25 mL), and lid

VAI® offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-P201-03	SMA MicroPortable Air Sampler, 316L Stainless Steel Housing, 1 and 5 CFM Selectable Flow Rates
SMA-P191-03	SMA MicroPortable Air Sampler (Lightweight Version), Delrin® Top & Bottom, 1 and 5 CFM Selectable Flow Rates
SMA-P300-03	SMA MicroPortable Air Sampler ("Explosion Proof" Version), 316L Stainless Steel Housing, 1 and 5 CFM Selectable Flow Rates, For Use In Hazardous Environments
SMA-PXXX-BATTERY	Additional NiMH Battery For SMA-P191, SMA-P201, and SMA-P300 SMA MicroPortable Air Samplers
SMA-PXXX-BC-03	Additional Battery Charger for SMA-P191, SMA-P201, and SMA-P300 SMA MicroPortable Air Samplers
SMA-HARDCASE	Air Transport Association (ATA) Style Transportation Case for SMA MicroPortable Air Samplers
SMA-PXXX-CALKIT	Calibration Kit For SMA MicroPortable Air Samplers

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA MICROPORTABLE® MODEL COMPARISONS

SMA-P201-03
316L Stainless Steel

P191 and P300 have additional features.

SMA-P191-03
Lightweight

SMA-P300-03
"Explosion Proof"

SMA-P401-03
316L Stainless Steel

RJ45 and USB Ports (not pictured)

SMA-ICSMP
SMA MicroPortable ICS

Welcome to SMA®

Compressed Air/Gas Sampling Systems

VAI®'s Environmental Control Monitoring Division (ECMD) addresses the needs of the pharmaceutical, biotechnology, semiconductor, and electronics industries with a complete range of compressed air/gas viable environmental monitoring equipment.

VAI offers both the automated SMA® Compressed Air/Gas Sampler, and the manual SMA® Compressed Air/Gas Atrium for the collection of microorganisms in compressed air and gas lines.

The SMA® Compressed Air/Gas Sampler is used for the automated collection of microorganisms in compressed air and gas lines. It monitors and regulates air flow, has a programmable timer, and can sample compressed air/gas lines up to 100 psi at 1 CFM. SMA Compressed Air/Gas Atriums are used for the manual collection of microorganisms in compressed air/gas lines with either a rotameter or a pressure regulator valve.

Section Contents

129 SMA COMPRESSED AIR/GAS ATRIUMS

128 SMA COMPRESSED AIR/GAS SAMPLER

SMA® Compressed Air/Gas Sampler

SMA-CA201

SMA-CA2XX-PHOSE

The SMA Compressed Air/Gas Sampler is used for the automated collection of microorganisms in compressed air and gas lines. It monitors and regulates air flow, has a programmable timer, and can sample compressed air/gas lines up to 100 psi at 1 Cubic Feet per Minute (CFM). The instrument can sample compressed air, nitrogen, carbon dioxide, and argon. Contact VAI before sampling any other gases (e.g. oxygen).

The SMA Compressed Air/Gas Sampler incorporates the same multi-orifice sampling methods as the standard SMA Atrium® that allows continuous monitoring of compressed air/gas lines. The instrument has a safety mechanism that releases pressure when incoming gas pressure exceeds 100 psi. Furthermore, it allows you to view air flow in CFM or Liters Per Minute (LPM).

Product Uses

- Program and view a sample time
- Start and cancel a sample cycle
- Monitor and control air flow
- Release pressure before opening the sampling head
- Provide visual notification when the
  - Sample cycle is in progress
  - Sampling head is under pressure
  - Sample complete audible alarm is enabled
  - Battery requires charging
- Provide audible and visual alarms when
  - The sample cycle is complete
  - There is a 1 CFM error during a sample cycle

Features and Benefits

- Sampling head and hose can be completely sterilized by steam, heat, or ethylene oxide (ETO)
- Disinfect using select VAI® products
- Meets North American (ETL) and European Community (CE) safety standards
- Includes a battery, battery charger, gasket, Stainless Steel pressure hose, and 0.2 micron filter

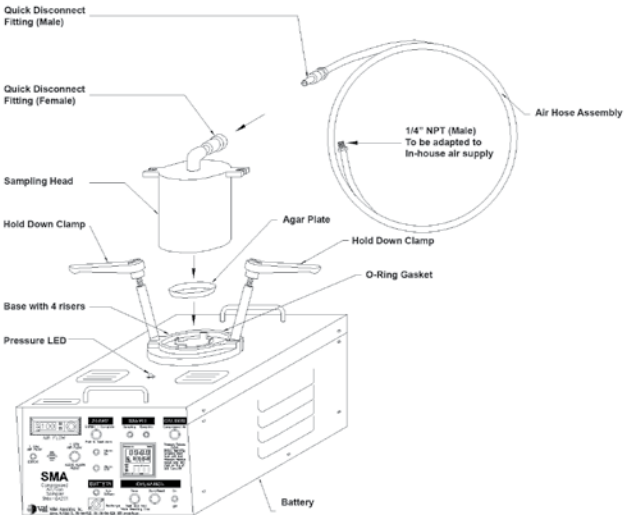
VAI® offers on-site calibration and repair services. Please contact us for details.

Order Number	*Description*
SMA-CA201	SMA Compressed Air/Gas Sampler, Automated, Digital Display
SMA-CA201-BATTERY	Additional Battery, NiMH, 24V, For SMA Compressed Air/Gas Sampler, SMA-CA201
SMA-CA201-BC-03	Additional Battery Charger for SMA Compressed Air/Gas Sampler, SMA-CA201
SMA-CA2XX-PHOSE	Additional Braided Stainless Steel Pressure Hose, For SMA Compressed Air/Gas Samplers, SMA-CA200 and SMA- CA201
SMA-CA2XX-GASKET-B	Replacement Gasket, For SMA Compressed Air/Gas Samplers, SMA-CA200 and SMA-CA201 (Buna-N)
SMA-CA2XX-GASKET-V	Replacement Gasket, For SMA Compressed Air/Gas Samplers, SMA-CA200 and SMA-CA201 (Viton)

Other Technical Data Available Upon Request

Operator's Manual • Data Sheet

SMA COMPRESSED AIR/GAS SAMPLER SCHEMATIC



SMA® Compressed Air/Gas Atriums

SMA-316-CA-18

SMA-ROT-SS-60C
(pictured with optional stand)

SMA Compressed Air/Gas Atriums are used for the manual collection of microorganisms in compressed air/gas lines to determine the level of viable contamination.

A SMA Compressed Air/Gas Atrium is a 316 Stainless Steel capture device that is connected to a compressed air source. It has an extension tube that attaches to ¼ inch Hytrel® tubing. Air is directed from the compressed air source to impact onto a media plate contained inside of the Atrium. The plate is then incubated and tested to determine the level of any present viable contamination.

Air flow calibration and timing must be performed manually using separate instruments. To regulate air flow, install a pressure regulator valve at the point of sample or use our SMA-ROT-SS-60C rotameter.

Features and Benefits

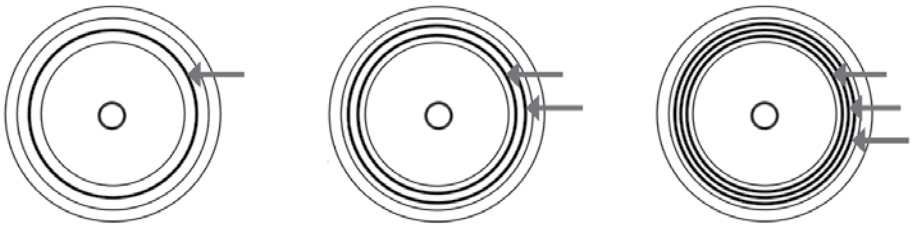
- Easily connected to sample points with sterile 1/4 inch Hytrel® tubing
- Constructed of 316L Stainless Steel
- Completely sterilized by steam, heat, or ethylene oxide (ETO)
- Used with standard media plates (90 or 100 mm) with 18, 25, or 32 mL fill levels, at a flow rate of 1 CFM
- Does not require a vacuum source to operate
- Exhaust air is released from underneath the Atrium without affecting the sample in progress
- Compact size allows them to be located near filling processes where space is limited
- Available as a complete top and bottom assembly
- Vents from the bottom which eliminates the need for additional vacuum connection ports or tubing

Order Number	*Description*
SMA-316-CA-18	SMA Compressed Air/Gas Atrium, 316L Stainless Steel, Use With 18 mL Filled Media Plates (Complete Assembly)
SMA-316-CA-25	SMA Compressed Air/Gas Atrium, 316L Stainless Steel, Use With 25 mL Filled Media Plates (Complete Assembly)
SMA-316-CA-32	SMA Compressed Air/Gas Atrium, 316L Stainless Steel, Use With 32 mL Filled Media Plates (Complete Assembly)
SMA-ROT-SS-60C	Matheson FM-1000 Series Flowmeter (J860), 0-90 SCFH (0 - 1.5 CFM), For Use With Compressed Air/Gas Atriums (SMA-316-CA-XX)

Other Technical Data Available Upon Request

Operator's Manual

SMA COMPRESSED AIR/GAS ATRIUM COMPARISON



Single groove
Use with 18 mL plates
SMA-316-CA-18

Double groove
Use with 25 mL plates
SMA-316-CA-25

Triple groove
Use with 32 mL plates
SMA-316-CA-32

Welcome to SMA®
MicroParticle Air Sampling Systems

VAI®'s Non-Viable Environmental Monitoring systems are used for continuous or intermittent monitoring of particle counts in cleanrooms and critical environments. VAI offers SMA MicroParticle ICS® Particle Counters to meet the needs of the pharmaceutical, biotechnology, semi-conductor, and electronics industries.

SMA MicroParticle ICS® Facility Systems integrate cleanroom ready remote particle counters, specially designed software, vacuum pumps, and control centers into a complete facility particle monitoring system.

SMA Microparticle ICS Facility Systems for Isolators provide secure sampling inside an isolator, and redirect air flow during Vaporized Hydrogen Peroxide (VHP) sterilization.

Section Contents

131 SMA MICROPARTICLE ICS FACILITY SYSTEMS

132 SMA MICROPARTICLE ICS DIAGRAM

134 SMA MICROPARTICLE ICS FOR ISOLATORS DIAGRAM

SMA MicroParticle ICS® Facility Systems

SMA-MP-ENC-F10

SMA-MP-ISOEXT

SMA-MP-BB

SMA MicroParticle ICS Facility Systems feature the installation of Remote Particle Counters to measure particle counts in cleanrooms and controlled environments.

Remote Particle Counters simultaneously measure 2 particle size channels, 0.5 and 5.0 µm, with a flow rate of 1.0 CFM (28.3 LPM). Remote Particle Counters are available in stainless steel surface mount and flush mount enclosures.

Remote Particle Counters are only one piece of the SMA MicroParticle ICS Facility System. Multiple Particle Counters, Vacuum Pumps, and Controllers are combined into one Facility System managed by the SMA MicroParticle ICS Software.

The Remote Particle Counter data is processed by the SMA MicroParticle ICS Software which presents the information in a regulatory compliant, user-friendly interface. The software generates reports, such as: Audit Trail, Status, Measurement Log, Alarm History, Limit Change History, Notes, and Trends. Customer specific reports can also be created to match any further requirements.

SMA Microparticle ICS Facility Systems for Isolators provide secure sampling inside an isolator, and redirect air flow during Vaporized Hydrogen Peroxide (VHP) sterilization. When an operator places the system into Isolator Mode, air (or VHP) is directed to bypass the Control Center. The maintained pressure differential prevents air from the exterior environment from entering the isolator. It also provides a separate path for VHP that is separate from the Control Center..

Product Uses

- Detect and count physical particles
- Monitor air quality

Features and Benefits

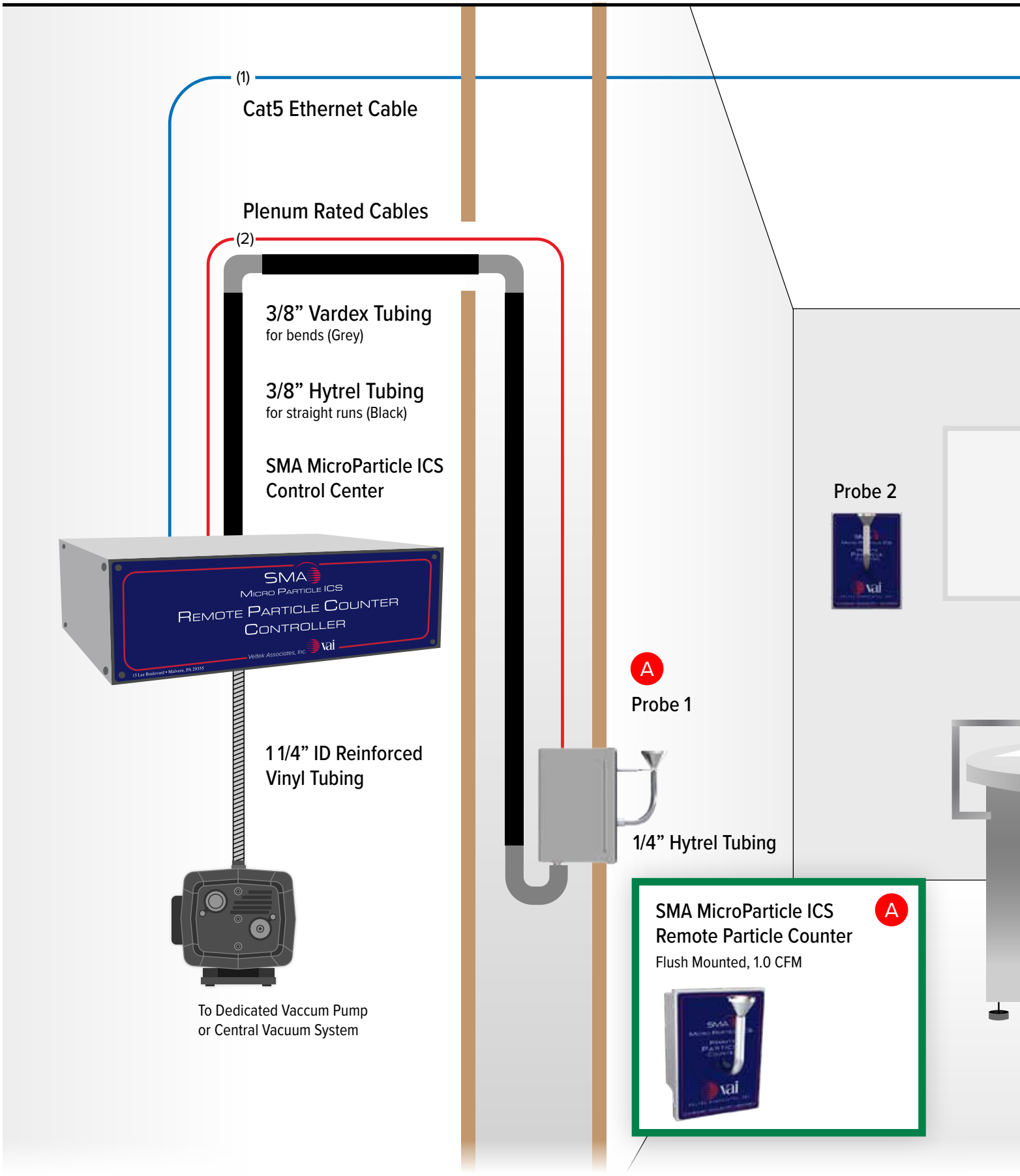
- Flow rate is 1.0 CFM (28.3 LPM)
- Measures 2 channels of simultaneous data, 0.5 to 5.0 µm particles
- MODBUS, TCP/IP, RS485, and RS232 connections
- Concentration limit of 500,000 per ft^3
- Complies with ISO 21501-4 and JIS B9921 standards

Order Number	*Description*
SMA-MP-ENC-F10	Remote Particle Counter, Flush Mt, 1.0 CFM
SMA-MP-ENC-S10	Remote Particle Counter, Surface Mt, 1.0 CFM
SMA-MP-ICS-RC16	Control Center for up to 12 Particle Counters
SMA-MP-CIMSCAN	Software for up to 12 Particle Counters
SMA-MP-CIMSCAN-ATS	Software Required Tech Support, 1 Year
SMA-MP-REM-DP	Differential Pressure/Air Velocity Probe
SMA-MP-REM-RT	Temperature & Humidity Probe
SMA-MP-LSTACK5	Light Stack with Five Lights
SMA-MP-PRB	Purge Filter, 1.0 CFM
SMA-MP-BB	Isoprobe Barbed, 1.0 CFM
SMA-MP-ISOEXT05	Isoprobe, Extension Tube, 3" *
SMA-MP-ISOEXT10	Isoprobe, Extension Tube, 10" *
SMA-MP-ISOEXT15	Isoprobe, Extension Tube, 15" *
SMA-MP-ISOEXT	Isoprobe, Extension Tube, Custom up to 20" *

* All Remote Isoprobes come with probe, lid, washer, and tubing connection.

SMA MicroParticle ICS Facility Systems require system specific vacuum pumps and tubing. Contact your VAI Sales Representative for more information.

SMA MicroParticle ICS®



Customer Supplied Computer System
SMA MicroParticle ICS Software

Probe 5

Probe 4

B

Probe 3

SMA MicroParticle ICS
Remote Particle Counter

Surface Mounted, 1.0 CFM

AND

Isoprobe with 3" Extension

3", 8", 15" and Custom Lengths Available

B

CLEANROOM

SMA MicroParticle ICS® for Isolators

(1)

Cat5 Ethernet Cable

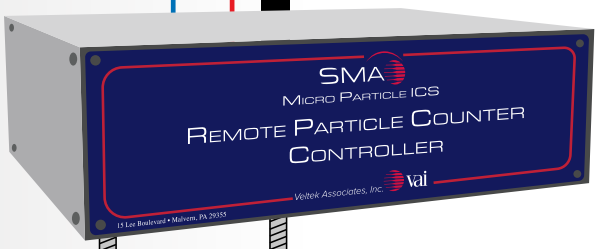
Plenum Rated Cables

(2)

3/8” Vardex Tubing
for bends (Grey)

3/8” Hytrel Tubing
for straight runs (Black)

SMA MicroParticle ICS
Control Center



1 1/4” ID Reinforced
Vinyl Tubing

To Dedicated Vaccum Pump
or Central Vacuum System

Second Vacuum Pump for Isolator
Systems only to perform purge

A

Probe 1

SMA MicroParticle ICS
Remote Particle Counter

A

Flush Mounted, 1.0 CFM

Surface Mounted Enclosure
Also Available

B

SMA MicroParticle ICS
Isoprobe with
3” Extension

3”, 8”, 15”, and Custom
Lengths Available

Customer Supplied Computer System
SMA MicroParticle ICS Software

CLEANROOM WITH ISOLATOR


CS

Fog
Mop
Spray
5 gallon
Core2Clean
Ergonomic cart
Efficient cleaning
Disinfectant application
Cleaning Systems
Controlled environments
Multiple components
Simplify cleaning
Stainless steel
Swivel casters
Autoclavable
2 gallon

Welcome to CORE2CLEAN® PLUS Cleaning Systems

The adequate application of the disinfectant or sporicide to the surface is the final and most important step in assuring the demise of existent viable contaminants in controlled environments. Once we leave the validation study scenario, we are confronted with the complex situation of implementing what we have proven as acceptable into the real-life scope of our operations.

Maintaining a system that is meaningful, manageable, and defendable becomes complex in production areas as we encounter a multitude of variables. The Core2Clean Plus Systems are designed to address the application of cleaning and disinfecting agents to the surface in a meaningful and manageable methodology. Specifically designed for pharmaceutical, biotechnology, and healthcare facilities, the Core2Clean Plus System simplifies application within controlled areas.

The Core2Clean Plus systems were created by Veltek Associates, Inc., to provide specialized cleaning equipment for use in controlled environments. They are specifically designed to:

- Be repeatedly and consistently sterilized
- Use one system to spray, mop, or fog
- Allow operators to maximize disinfectant effectiveness

All the components of the Core2Clean Plus can be autoclaved or connected to a steam source for sterilization. The ability to sterilize the C2C by steam helps to prevent the introduction of viable contamination into the controlled environment.

Core2Clean Plus systems can be configured to operate as three different systems: a sprayer, a wet mop, or a fogger. When configured as a spray or mop system, the operator dispenses disinfectant through a trigger-controlled wand, providing a continuous flow of clean solution through the device and on to the surface. Giving this real-time control to the operator can increase the dwell time and thus, the performance of the disinfectant. When configured as a fogging system, the disinfectant is dispensed through a Stainless Steel fogger that is directly controlled by the Core2Clean Plus unit.

Section Contents

140 CORE2CLEAN PLUS DIAGRAM

142 CORE2CLEAN PLUS CLEANING SYSTEMS PARTS, ACCESSORIES, AND REPLACEMENT PARTS

Core2Clean® Plus

The design of the Core2Clean Plus system allows for repeatability between operators and areas, making it easier for companies to write SOP's for different class areas. To aid in operator instruction, VAI provides an Operator's Manual with instructions for all three system uses, and videos of select processes. The manual is available in hard copy and electronic formats.

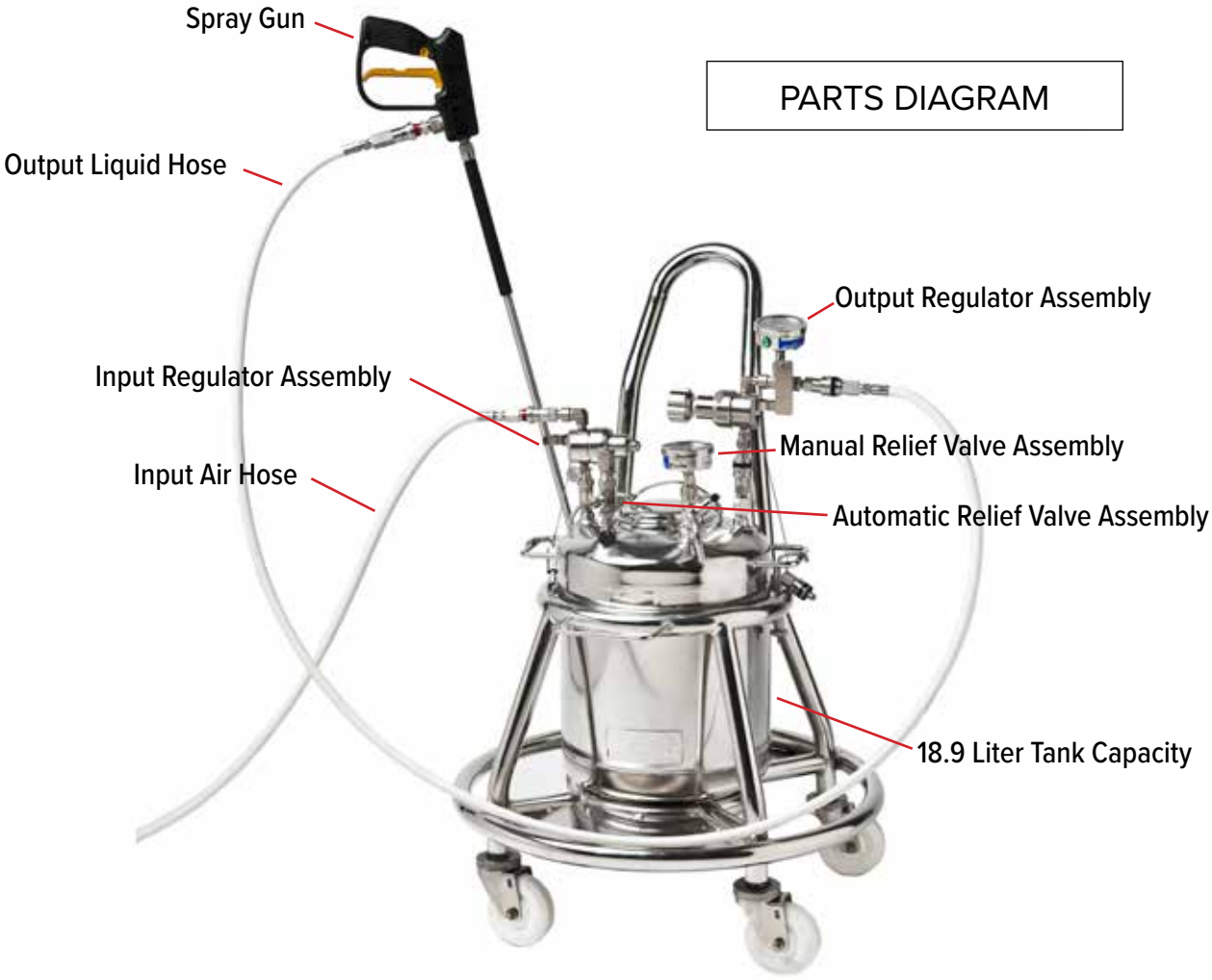
Features And Benefits

- Easily connected to a trigger activated dispensing mop, trigger activated spray nozzle, or fogger
- Constructed of 316L Stainless Steel
- Completely sterilized using an autoclave or steam
- Operate using compressed air, simply charge and go
- Reduce cleaning time and user effort
- Simplify cleaning and disinfecting procedures
- Two and five gallon tank sizes
- Easy to remove tank
- Stainless Steel ergonomic cart with accessory trays and equipment holder
- Four swivel casters provide easy movement throughout the facility
- Allows the operator to control the amount of time the disinfectant spends on the surface which increases the effectiveness of the disinfectant

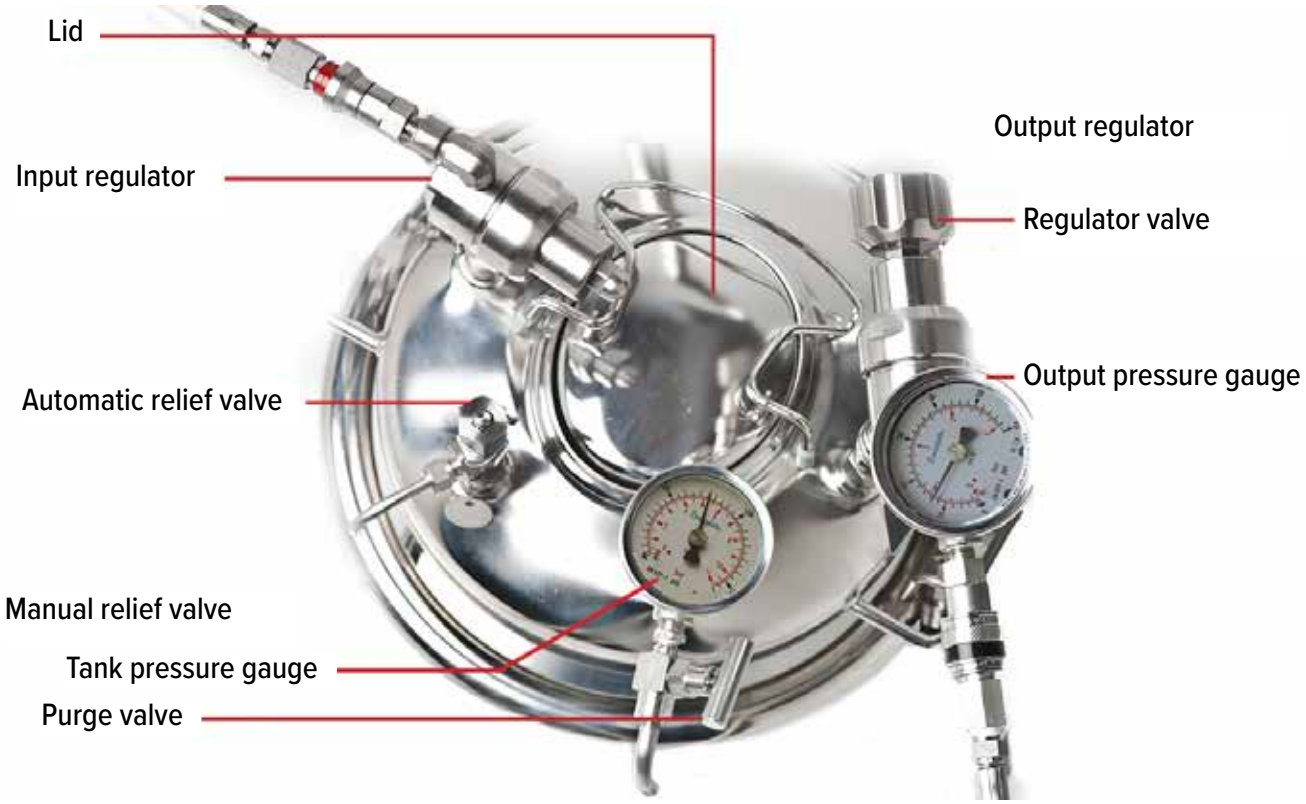
CORE CLEAN® PLUS

AVAILABLE IN
2 GALLON AND
5 GALLON
CONFIGURATIONS

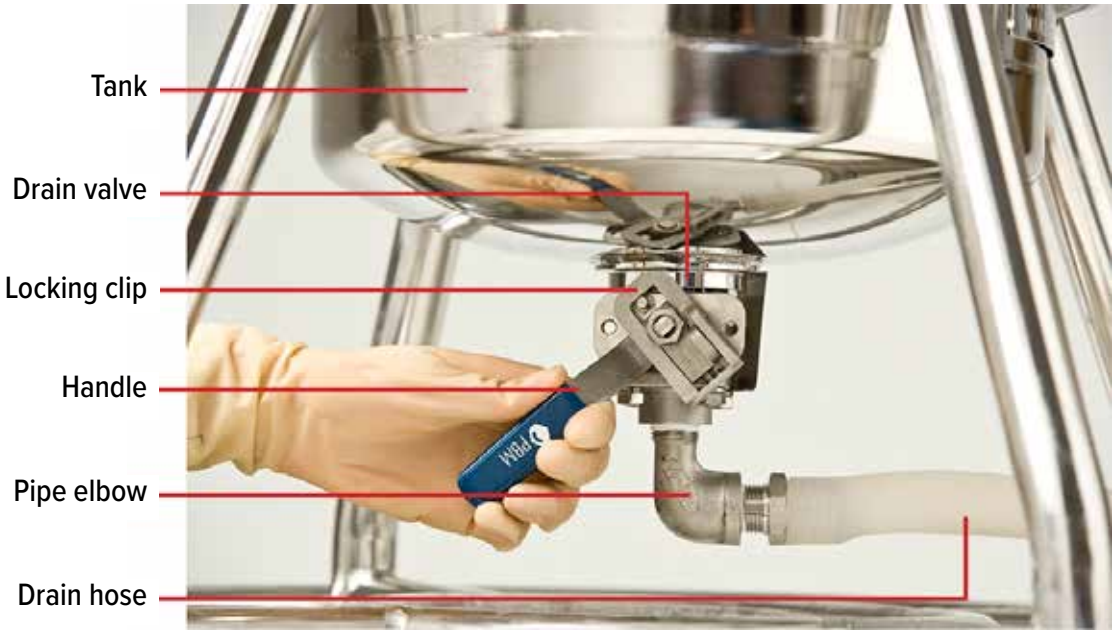
PARTS DIAGRAM



TOP VIEW



BOTTOM VIEW



CORE2CLEAN® PLUS

C2C-102-P

C2C-105-P

Complete Systems

Order Number	*Description*
C2C-102-P	Core2Clean Plus System, 2 Gallon, Stainless Steel Includes a two gallon tank, spray gun with 3 ft wand, spray nozzle, 8 ft output hose, 8 ft input hose, Stainless Steel cart with swivel casters, output regulator with pressure gauge, input regulator, manual relief valve, automatic relief valve, and tank pressure gauge.
C2C-105-P	Core2Clean Plus System, 5 Gallon, Stainless Steel Includes a five gallon tank, spray gun with 3 ft wand, spray nozzle, 8 ft output hose, 8 ft input hose, Stainless Steel cart with swivel casters, output regulator with pressure gauge, input regulator, manual relief valve, automatic relief valve, and tank pressure gauge.

Spray Guns and Accessories

Order Number	*Description*
C2C-100-1	Replacement spray gun with 3 ft wand, spray nozzle, and clamp. Gun has Swagelok fittings and trigger control. Nozzle is 316 Stainless Steel and has a 50° spray pattern of 0.52 GPM at 30 psi.
C2C-100-1-TH	Optional replacement spray wand with 3 ft wand, spray nozzle, and clamp. Gun has Swagelok fittings and thumb-style trigger control. Nozzle is 316 Stainless Steel and has a 50° spray pattern of 0.26 GPM at 30 psi.
C2C-100-22	Spray nozzle, Standard, 0.52 GPM, Stainless Steel
C2C-100-22-03	Spray nozzle, Optional, 0.26 GPM, Stainless Steel
C2C-100-18-36	Extension wand with clamp, bayonet, and Swagelok fittings, 36”
C2C-100-2-CL	Replacement clamp for use with extension wand or mop frame

Note: For original Core2Clean spare parts, please contact VAI® at 1-888-478-3745.
Allow 6-8 weeks for delivery.

Spray gun (C2C-100-1) and Spray Wand (C2C-100-1-TH)

Quick Disconnect Mop

Mophead Sponge

Quick Disconnect Fogger

Quick Disconnect Sprayer

Mop Frames and Mop Heads

Order Number	*Description*	*Qty*
C2C-100-2-7	7” Mop Frame, Stainless Steel	1
C2C-100-2-12	12” Mop Frame, Stainless Steel	1
C2C-100-7	7” Mophead Sponge, Polyester and Foam, Non-Sterile	12
C2C-100-8	7” Mophead Sponge, Polyester and Foam, Sterile	48
C2C-100-9	12” Mophead Sponge, Polyester and Foam, Non-Sterile	32
C2C-100-10	12” Mophead Sponge, Polyester and Foam, Sterile	32
C2C-100-11	7” Mophead Cover, Bouffant Style, Non-Sterile	32
C2C-100-12	7” Mophead Cover, Bouffant Style, Sterile	48
C2C-100-13	12” Mophead Cover, Bouffant Style, Non-Sterile	120
C2C-100-14	12” Mophead Cover, Bouffant Style, Sterile	32

Fogger

Order Number	*Description*
C2C-100-3	Fogger, fogger-tee, and fogger hose
ZC2C-FOGGER-TEE	Fogger-tee only
C2C-100-4C-S	Fogger hose only with Swagelok fittings, 8’

Replacement Parts

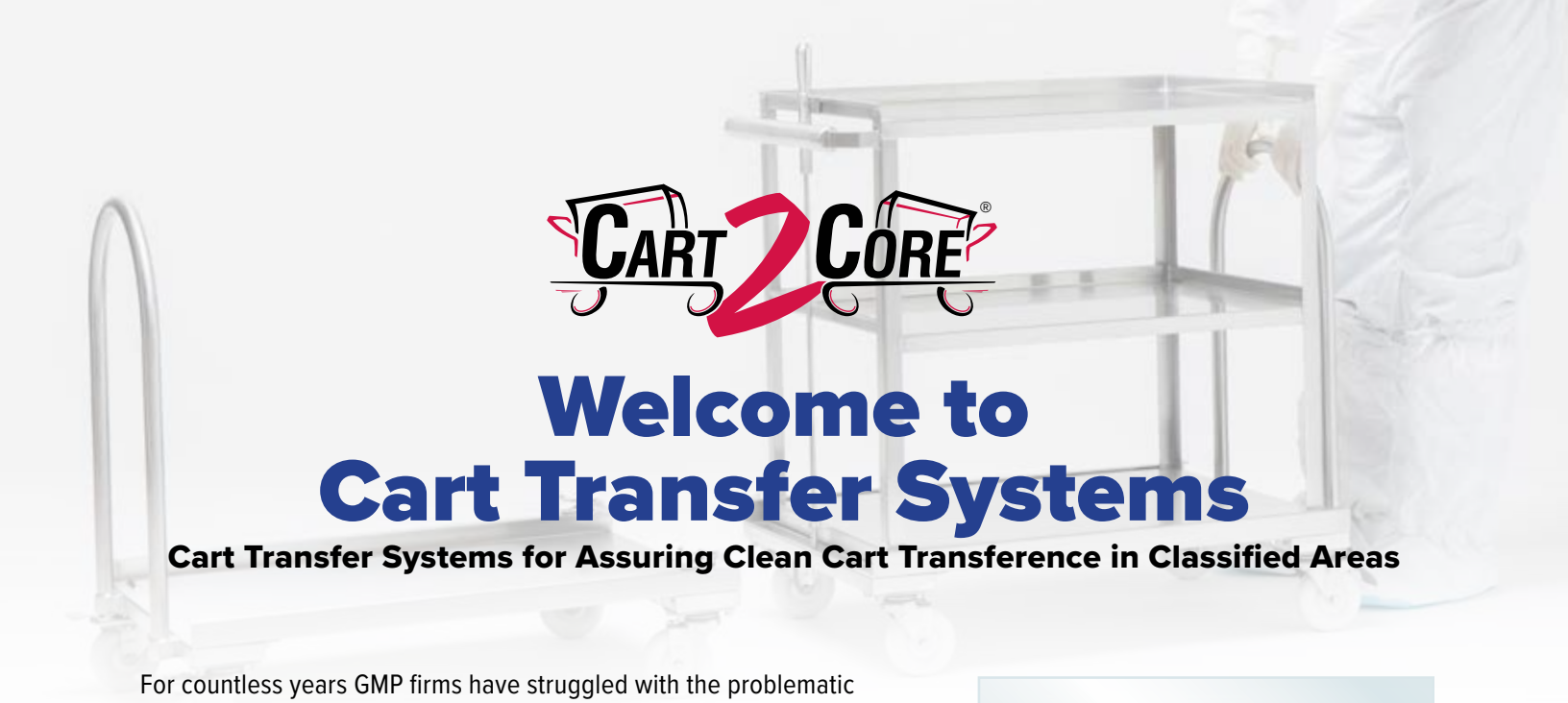
Order Number	*Description*
C2C-100-4A-S	Input hose replacement with Swagelok fittings, 8’
C2C-100-4B-S	Output hose replacement with Swagelok fittings, 8’
C2C-100-4C-S-15	Output hose extension with Swagelok fittings, 15’
C2C-100-25	Replacement swivel caster assembly with standard wheel, white, Stainless Steel frame, stud, axle, and bearings
C2C-100-35	Replacement swivel caster assembly with Heateater wheel, brown, Stainless Steel frame, stud, axle, and bearings
C2C-WHEEL-STD	Replacement standard wheel, white
C2C-WHEEL-NYL	Replacement Heateater wheel, brown
C2C-200-1	Replacement input regulator, Stainless Steel
C2C-200-2	Replacement output regulator, Stainless Steel
C2C-200-3	Manual relief valve, Stainless Steel
C2C-200-4	Automatic relief valve, Stainless Steel
C2C-GAUGE-OUTPUTREG	Output pressure gauge, 0-60 psi scale, 316L Stainless Steel bezel, glass window
C2C-GAUGE-TANK	Tank pressure gauge, 0-160 psi scale, 316L Stainless Steel bezel, glass window
C2C-100-20	Stainless Steel cart

Other Technical Data Available Upon Request

Operator’s Manual • Data Sheet


CDTD

tags
GMP
track
sterile
patented
Depyro
0.2 µm filtered
transfer systems
Cart, RFID, Documentation
quadruple bagged
gamma radiation
low particulate
Stainless Steel
cloud storage
logbooks
labels
carts
RFID



Welcome to Cart Transfer Systems

Cart Transfer Systems for Assuring Clean Cart Transference in Classified Areas

For countless years GMP firms have struggled with the problematic issue of "how do we transfer carts from the exterior unclassified area or the adjacent lesser grade (C/D) classified area to the Grade A/B area?" Cleaning and subsequent disinfection of the upper portions of carts, while labor intense, are manageable. However, the bases and wheels have been one of the most problematic situations in the industry to date.

Cleaning of bases, wheels, casters and underneath the cart are virtually impossible. Any procedure implemented is, on the whole, ineffective in cleaning and disinfecting, a safety issue, and most of the time corrosive to the cart. The inability to easily reach all pertinent surface areas of the base or wheels at the floor level causes problematic situations with assured and effective wiping of these surfaces. Thus, cleaning is compromised.

Subsequent disinfection of the surfaces usually relies on blind spraying which means some areas required to be disinfected are never wetted with the disinfectant. Over spraying of the area becomes a problem and can eventually lead to corrosion and required replacement of parts. Not only do these situations arise, but these "hard to reach locations" can contaminate employees' gloves and gowns, tear gloves, and are a safety hazard as blindly reaching under carts and behind wheels, places employees at risk of injury.

The Cart2Core® System reduces the possibility of particulate and microbial contamination transfer from a lesser classified area to the subsequently cleaner area of the operation. The Cart2Core System allows for transfer of the cart top to another previously cleaned, disinfected, or sterilized cart base located in the next and cleaner classification. Therefore, contamination from lesser classifications coming in contact with the floor or personnel is reduced. With one lift of the handle and a slide, the Cart2Core System transfers any cart top from one cart base to another, leaving the potential contamination behind. The need for ineffective cleaning or disinfection at the floor level is eliminated.

Section Contents

147 CART2CORE FLOW CHART

148 CART2CORE MODELS

149 CART2CORE UTILITY CART DETAILS

How Does Cart2Core® Work?

Ending contamination is as easy as 1 > 2 > 3 >>

STEP 1

The Cart2Core® System cart is pushed to the desired line of demarcation which separates room classifications.

A new, cleaned and disinfected, or potentially sterilized Cart2Core base is located adjacent to the cart with the wheel lock brake engaged.

STEP 2

The Lift-Lock-Transfer handle of the Cart2Core is lifted and the top of the cart slides from one base to another — leaving the contamination from the previous area behind.

STEP 3

The dirtied Cart2Core base is cleaned, disinfected and/or sterilized for the next use within the area. Bases are deemed area-specific.

Cart2Core® Models

Micro Cart, Can/Bottle Cart, Tray Cart, Utility Cart

CC-M-100: Micro Cart

CC-CB-200: Can/Bottle Cart

CC-T-300: Tray Cart

CC-UC-400: Utility Cart

The Cart2Core System has been designed to simplify aseptic cart transferring. This patent pending system provides the ability for cleanroom operations to transfer materials through classified areas while reducing the possibility of particulate and microbial cross-contamination. A previously arduous process has become simple. The cart top is able to be transferred to another previously cleaned, disinfected, or sterilized cart base located in the next classified area. Simply lift the handle and slide the top of the cart onto the next base, leaving the potential contamination behind.

Available cart top configurations include: a Micro Cart for production, micro, and cleaning personnel, a Can/Bottle Cart that is designed to convey large cans and bottles, a Tray Cart for transporting trays of vials, parts, and other needed items, and a Utility Cart for everyday use that is also ideal for pass throughs.

Benefits of the Cart2Core System

- Allows for wheels and bases to be easily and effectively cleaned, disinfected, or sterilized by making the bases and wheels autoclavable
- Reduces safety concerns with cleaning
- Provides the ability to steam sterilize bases and wheels routinely
- Reduces the overuse of disinfectants, therefore, reducing corrosion and pitting
- Reduces garment contamination and glove ripping

Quality, Construction, and Features

- Constructed of a sturdy 316L Stainless Steel for durability and cleanliness
- Fully welded seams that eliminate gaps, unsmooth services, and improves cleaning
- Easy pull handle for cart transfer to another base
- Wheel lock that secures the base during the transfer
- Easy grip push handles
- Are completely autoclavable, sterilizable, and chemical resistant
- Fits in 4ft autoclaves (except CC-CB-200)
- RFID coding optional/available for easy location
- 2,400 pounds weight capacity (caster rating @ 600 psi) / Utility Cart 1,200 pound weight capacity
- 8-point transfer efficiency
- Can/Bottle Cart has removable pipe sides for easy loading and unloading and is able to fit a standard size 208 Liter drum
- Tray Cart has 20 slots for appended trays
- Utility Cart size is comparable to standard Stainless Steel carts
- Custom cart models and sizes available; 304 Stainless Steel available

Order Number	*Description*
CC-M-100	Micro Cart, For production, micro, and cleaning Includes one specified top and two bases, 316L Stainless Steel
CC-M-100-B	Micro Cart Additional Base
CC-CB-200	Can/Bottle Cart, For transportation of 208 Liter drums, large cans, and bottles Includes one specified top and two bases, 316L Stainless Steel
CC-CB-200-B	Can/Bottle Additional Base
CC-T-300	Tray Cart, For transportation of vials, parts, and other items Includes one specified top and two bases, 316L Stainless Steel
CC-T-300-B	Tray Cart Additional Base
CC-UC-400	Utility Cart, For everyday use and pass throughs Includes one specified top and two bases, 316L Stainless Steel
CC-UC-400-B	Utility Cart Additional Base

UTILITY CART DETAILS

VAI®'s Cart2Core® Utility Cart model is a cart that can be used throughout your facility every day, for almost any purpose. The Utility Cart is perfect for getting supplies into your production areas or finished product out the door. This lighter weight model has the maneuverability to be taken anywhere on site. However, because of its base-to-base transfer system, you leave the contamination behind.

1) Permanent handles for moving empty bases

2) A smooth transfer from base-to-base

3) The locking pin is a security feature to help prevent accidents
4) Fully welded seams for easy cleaning
5) Autoclavable wheels and casters
6) Foot brakes keep the units locked in place
7) Latches help align the bases for a seamless transfer
8) Easy to use latches keep the bases together for a one-person transfer
9) Sure grip locking pin handle for ease of use in any condition, even with gloves on

Welcome To Cleanroom Documentation Systems

Synthetic Writing Substrate, Custom Cleanroom Documentation, Cleanroom Printer

GMP firms have a constant struggle with the task of reducing fibers, particulates, and microorganisms within classified areas. A main source of this problem is paper products used to document operations. Characteristically, paper products shed a high level of fibers and particulates. These fibers and particulates can wreak havoc on any aseptic operation by corrupting environmental conditions and final product. In response, VAI has developed an innovative way to address and solve questions surrounding particulate and fiber shedding from cleanroom documentation with our Cleanroom Documentation Systems product lines.

Section Contents

151 CLEANPRINT 10®

153 CORE2PRINT®

152 CORE2WRITE®

CleanPrint 10® is patented synthetic writing substrate that is used as the base for all Core2Write® products and as the printing medium for the Core2Print®. CleanPrint 10 is designed for ultraclean manufacturing environments and is void of any cellulose in its construction. This synthetic substrate is pliable, and is resistant to abrasion, chemicals, and ink smearing. In addition, it is extremely low in particle shedding.

Core2Write is a revolutionary customized documentation system developed specifically for GMP operations. Core2Write offers custom logbooks, notebooks, labels, forms, and tags printed on VAI's CleanPrint 10. All Core2Write products are designed and packaged according to customer specifications and specific documentation requirements. Each product is available in a variety of colors, sizes, thickness, lamination, and configurations, with optional barcoding and RFID incorporation available. In addition to custom documentation, VAI offers attachable RFID facility tags that are compatible with our Core2Scan System.

Core2Print, a patented technology, revolutionizes the method for printing required sterile documentation within aseptic manufacturing environments. The Core2Print is a HEPA filtered cleanroom printer that prints wirelessly into the core from the exterior on VAI's pre-sterilized CleanPrint 10. The Core2Print unit is constructed of 316L Stainless Steel for durability with lexan windows for a clear view of the printer in operation.

CleanPrint 10®

Synthetic Writing Substrate

CLP10-8.5X11-01

CLP10-8.5X11-BLU-01

CLP10-8.5X11-GRE-02

CLP10-8.5X11-YEL-01

CleanPrint 10 is a synthetic writing substrate that has been specifically designed for ultra clean manufacturing environments and is void of any cellulose in its construction. This synthetic substrate is manufactured using patented technologies to assure strength, very low particulate generation, non-shedding characteristics, the inability for ink smearing, chemical resistance, water repellence, sterilization compatibility, and the ability for lamination.

CleanPrint 10 is the substrate used in our Core2Write® products and as the printing medium for our Core2Print®. CleanPrint 10 has been made for use with Core2Print cleanroom printing system to assure the cleanest print and bonding available but can be used with a multitude of other printers. CleanPrint 10 can be used for recording data, note taking in the aseptic core, batch record retention, equipment manuals, work instructions, and procedures.

Features and Benefits

- As much as 10 times stronger than other cleanroom paper; extremely durable
- Chemical and water resistant
- Inks adhere and dry immediately; resistant to ink smearing
- Cellulose and latex free
- Pliable and lightweight even in extreme temperatures, -70°C to 180°C
- Sterilization compatible
- Excellent ability to write
- Low ESD potential for reduced risk of electrostatic damage
- Lamination and finish friendly
- Substrate recycles as a plastic
- Available sterile or non-sterile in standard 8.5”x11” or A4 size, in multiple colors, and pre three hole punched

Quality and Manufacturing

- Assembled in a controlled environment
- Gamma irradiated to 10^{-6} SAL and is completely validated for sterility and shelf life
- Lot sterility tested according to current USP compendium
- Each ream is individually double bagged in easy tear bags and packaged into 2 liner bags using VAI’s ABCD Cleanroom Introduction System®
- Reams are individually labeled with number and expiration
- Completely traceable from start to finish
- Delivered with lot specific Certificate of Conformance, Certificate of Irradiation, and Certificate of Sterility tested to current USP compendium

Order Number	*Description*	*Qty/Cs*
CLP10-8.5X11-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, White, Non-Sterile	500 Sheets
CLP10-8.5X11-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, White, Sterile	500 Sheets
CLP10-A4-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, A4, White, Non-Sterile	500 Sheets
CLP10-A4-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, A4, White, Sterile	500 Sheets
CLP10-8.5X11-3H-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Pre 3 Hole Punched, White, Sterile	500 Sheets
CLP10-8.5X11-BLU-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Blue PMS 290, Non-Sterile	500 Sheets
CLP10-8.5X11-BLU-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Blue PMS 290, Sterile	500 Sheets
CLP10-8.5X11-GRE-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Green PMS 358, Non-Sterile	500 Sheets
CLP10-8.5X11-GRE-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Green PMS 358, Sterile	500 Sheets
CLP10-8.5X11-YEL-01	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Yellow PMS 100, Non-Sterile	500 Sheets
CLP10-8.5X11-YEL-02	CleanPrint 10, 100 Sheets/Ream, 5 Reams/Case, 8.5”x11”, Yellow PMS 100, Sterile	500 Sheets

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI)

Core2Write®

Custom Documentation

Core2Write Logbook

Core2Write Two-Part Tags

Core2Write Labels

VAI-PEN-01

Core2Write is a patented technology that revolutionizes the method of cleanroom documentation by providing custom logbooks, notebooks, one part or two-part identical tear off tags, labels, and forms printed on VAI's cellulose free CleanPrint 10®. The Core2Write product line starts with a custom evaluation of what logbooks, forms, tags or labels are required. Core2Write products are fully customized to the facility's needs. Firms can incorporate their company name, logo, SOP Name & Number and Document Revision Number. Once determined, such documents and artwork are digitally designed into the product required, printed, and RFID, QR, and/or barcoding integrated. In addition, VAI offers standard, blank, labels and notebooks.

Core2Write products, via RFID, QR and barcoding integration, are compatible with our Core2Scan System. These Core2Write products can be used to easily track documentation, assets, and procedures. The Core2Write line also offers gamma irradiated sterile Sharpies® and pens for use alongside documentation materials.

Features and Benefits

- Fully customized to exact customer requirements and facility needs
- Available in thousands of colors
- Logbooks are spiral bound and can incorporate stair side stepping to easily identify a missing page
- Tags have easy tear perforations that will not shed
- Labels have easy peel off non-shedding stick label backs and are available in any size
- RFID key tags are available in Ultra High Frequency RFID
- Packaged to customer requirements
- Constructed of CleanPrint 10 synthetic substrate
- Available gamma irradiated sterile

Quality and Manufacturing

- Assembled in a controlled environment
- Option of double or triple bagging and available in VAI's ABCD Cleanroom Introduction System®
- Gamma irradiated at 10^{-6} SAL
- Completely validated for sterility and shelf life
- Lot sterility tested according to current USP compendium
- Completely lot traceable and delivered with lot specific documentation

Product Uses

- Labeling
- Identify transfer containers
- Transfer cans, tanks, and bottles in Grade A-D environments
- Record cleaning procedures
- Record equipment usage and maintenance
- Document GMP operations
- Tag and track assets and procedures

Order Number	*Description*	*Qty/Cs*
C2WR-4X3-BLK-02	Core2Write Label, Rolls, 4"x3", Blank, 1000 Labels/Roll, 4 Rolls/Case, Sterile	4000
C2WR-4X2-BLK-02	Core2Write Label, Rolls, 4"x2", Blank, 1000 Labels/Roll, 4 Rolls/Case, Sterile	4000
C2WR-3X1.5-BLK-02	Core2Write Label, Rolls, 3"x1.5", Blank, 1000 Labels/Roll, 4 Rolls/Case, Sterile	4000
C2WR-3X1-BLK-02	Core2Write Label, Rolls, 3"x1", Blank, 1000 Labels/Roll, 4 Rolls/Case, Sterile	4000
C2WR-2X1-BLK-02	Core2Write Label, Rolls, 2"x1", Blank, 1000 Labels/Roll, 4 Rolls/Case, Sterile	4000
C2WR-3x1.5-BLK-01	Core2Write Label, Rolls, 3"x1.5", Blank, 1000 Labels/Roll, 4 Rolls/Case, Non-Sterile	4000
C2WR-4x3-BLK-01	Core2Write Label, Rolls, 4"x3", Blank, 1000 Labels/Roll, 4 Rolls/Case, Non-Sterile	4000
C2WR-3x1-BLK-01	Core2Write Label, Rolls, 3"x1", Blank, 1000 Labels/Roll, 4 Rolls/Case, Non-Sterile	4000
C2WR-2x1-BLK-01	Core2Write Label, Rolls, 2"x1", Blank, 1000 Labels/Roll, 4 Rolls/Case, Non-Sterile	4000
C2WR-NB-01	Core2Write Notebook, 5"x7", 25 Pages, Ruled, Top Bound, Non-Sterile	20
C2WR-NB-02	Core2Write Notebook, 5"x7", 25 Pages, Ruled, Top Bound, Sterile	20
C2WR-4X3-SHEET-02	Core2Write Label, 4x3 on 8.5x11 Sheets, 6 Labels/Sheet, 500 Sheets/Case, Sterile	3000
C2WR-4X2-SHEET-02	Core2Write Label, 4x2 on 8.5x11 Sheets, 8 Labels/Sheet, 500 Sheets/Case, Sterile	4000
C2WR-3X1-SHEET-02	Core2Write Label, 3x1 on 8.5x11 Sheets, 24 Labels/Sheet, 500 Sheets/Case, Sterile	12,000
C2WR-2X1-SHEET-02	Core2Write Label, 2x1 on 8.5x11 Sheets, 10 Labels/Sheet, 500 Sheets/Case, Sterile	18,000
VAI-PEN-01	Core2Write, Pen, Blue Ink, 10/bag, 10 bags/case, Sterile	100
VAI-SHA-01	Core2Write, Sharpie Marker, Permanent Black Ink, Fine Tip, Individually Bagged, 1/bag, 5 bags/pack, 20 packs/case, Sterile	100

Core2Write Logbooks, One Part Tags, Two Part Tags, Labels, and Forms are available in custom colors, features, and manufacturing, Sterile or Non-Sterile. *Each Core2Write product is made custom to each customer's specific requirements. Contact your VAI Sales Representative for ordering information.*

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI)

Core2Print®

Cleanroom Printing System

C2P-00: Floor Model

Contains CP10 Printer

C2P-00 Printing on CleanPrint 10

ZCPRT-INK-B

Core2Print, a patented technology, revolutionizes the method for printing required sterile documentation within aseptic manufacturing environments. The Core2Print unit is constructed of 316L Stainless Steel for durability with lexan windows for a clear view of the printer in operation. HEPA filtration in the cabinet is a mandatory feature. Therefore, positive pressure within the cabinet is equally filtered to the controlled environment. The CP10 printer, housed in the cabinet, wirelessly prints onto VAI's pre-sterilized, cellulose free, CleanPrint 10 synthetic writing substrate: the most durable cleanroom "paper" in the industry.

The Core2Print has been designed to provide the capability to print clean, low particulate, and sterile documents within the aseptic manufacturing environment. Due to the many features of the Core2Print unit and the CP10 printer, the cleanroom stays clean throughout documentation efforts. The mandatory HEPA filter continuously prevents contamination from exiting the cabinet.

Features and Benefits

- Chemical resistant and can be completely disinfected
- Wireless capabilities so documentation required in the controlled areas can be signaled to print in the core from the exterior
- Prints on VAI's pre-sterilized CleanPrint 10
- Prints with chemical resistant and permanent ink
- Made for Grades A, B, C, and D
- Delivered as a complete unit
- HEPA filtered
- Replacement ink cartridges available double bagged sterile

Quality and Manufacturing

- Swivel caster wheels for easy transportation and maneuvering (Floor Model Only)
- 316L Stainless Steel
- Lexan windows for a full view of the CP10 Printer
- Standard buttons and lights are programmed into the Core2Print unit to indicate print status and warnings
- Electrical: 110 VAC, 50/60 Hz (220-240 VAC available)

Printer Specifications

- CP10 printer is a sheet fed, high speed, and digital quality printer
- CP10 printer can print up to 12 inches/second, about 60 pages per minute
- High quality resolution: up to 1600x1600 dpi
- Excels at printing readable small fonts and sharp barcodes
- Capable of printing labels
- Ink dry time: 0.19 seconds

Order Number	*Description*	*Qty/Cs*
C2P-00	Core2Print, Cleanroom Printing System, Floor Model, 316L Stainless Steel, Delivered as a Complete Unit	1
C2P-01	Core2Print, Cleanroom Printing System, TableTop Model, 316L Stainless Steel, Delivered as a Complete Unit	1
ZCPRT-INK-B	Core2Print, Replacement Ink Cartridge, Black Ink, 250 mL	1
ZCPRT-INK-C	Core2Print, Replacement Ink Cartridge, Cyan Ink, 250 mL	1
ZCPRT-INK-M	Core2Print, Replacement Ink Cartridge, Magenta Ink, 250 mL	1
ZCPRT-INK-Y	Core2Print, Replacement Ink Cartridge, Yellow Ink, 250 mL	1

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI)

Welcome to Core2Scan

RFID Asset Tracking and Workflow Solution

The Core2Scan Tracking Solution, manages the location, data, and workflows associated with assets in a compliant, accurate manner. Assets may include equipment, products, and even people.

With the Core2Scan Tracking Solution, simply attach a Core2Scan tag to an asset. Then, fixed or mobile readers track its location and send the information to the Core2Scan software. The Core2Scan software manages all of the information related to the asset. This information may include location and documentation, as well as preventative maintenance, calibration, and service workflows.

The Core2Scan Tracking Solution is endlessly customizable to meet the exact needs of your organization. All aspects of Core2Scan, from tag type, to RFID reader type and location, and software configuration, will be selected with care to meet your unique needs.

Core2Scan is compliant with industry regulations and the data contained within the system can be leveraged to support audit, internal review, and data integrity assessments. The Core2Scan software is responsive in design, user-friendly, and most importantly supports 21 CFR and EU Annex 11 compliance.

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166 CORE2SCAN: ASSET TRACKING AND WORKFLOW DIAGRAM

Core2Scan is the Solution to Industry Challenges:

Challenge	✖ Without Core2Scan	✔ With Core2Scan
Asset costs	Asset costs soar when missing items need to be replaced	Core2Scan tracks the location of valuable assets
Time	Time is lost locating assets and records and managing workflows	Core2Scan instantly locates assets, stores records, and manages workflows
Product waste	Product waste is caused by lost batch records or using out of specification equipment	Core2Scan manages records, maintenance, service, and calibration workflows
Compliance	Compliance failures and unfollowed procedures cause major response efforts	Core2Scan is compliant and notifies personnel of upcoming and overdue procedures

RFID Explained

RFID (Radio Frequency Identification) is a valuable business and technology tool that offers strategic advantages for businesses because it tracks assets and inventory in the supply chain more efficiently than existing tracking systems, like barcoding. Providing real-time visibility, RFID automatically captures critical data, thus allowing users to monitor equipment, supplies, and personnel throughout their facilities.

RFID technology is not new; it's a proven technology that has been in use for over twenty years. Used heavily in the retail and warehousing markets, RFID is now being implemented in the pharmaceutical, biotechnology, medical device, and healthcare industries. There are many applications for RFID tracking, and these industries are only beginning to see how far and wide this technology can be used. Asset tracking is only the beginning. From compliance support to process improvement, the data collected from RFID readers can be used to help users gain a better understanding of their workflow and implement changes that can improve processes and save time and money.

How does RFID work?

There are three primary components to any complete RFID tracking solution: hardware, software, and RFID tags. Core2Scan incorporates all these components into one solution. Hardware includes fixed and handheld RFID readers that collect data and send it to VAI's proprietary software. That software organizes the data and displays it in an exceedingly user-friendly platform. The RFID tags contain the data related to each and every asset they are affixed to. Readers "see" an RFID-tagged asset as it passes through its read range. That data is then sent to the software where it can be used in numerous ways. The RFID tags are continually read throughout your facility as they move from one area to another. In doing so, an audit trail is automatically created in the system, which can then be used for documentation purposes.

Core2Scan uses state of the art RFID equipment designed specifically for aseptic manufacturing facilities. VAI's team of experts will work closely with you to determine strategic locations to place fixed RFID readers, both inside and outside of your cleanrooms.

How Can RFID assist in GMP Operations?

Simply, a RFID system allows any authorized user to view where any encoded RFID tag is located within the range of the readers. Such users can be logged in remotely and have the ability to see any tagged asset directly from their computer screen through the Core2Scan software. That means once installed, end users can see not only the tags they affixed, but other RFID tags that the end user may have had suppliers affix.

RFID has been a proven technology for many years among numerous industries worldwide, including GMP/GLP operations. However, its value has just recently been enhanced with the development of the Core2Scan System. While RFID can track an asset, VAI's patented technology has

enhanced the ability of the tracking of multiple assets simultaneously. This allows for not only one asset to be tracked but multiple assets, in conjunction with each other, to be grouped and tracked together. This provides the ability to discern potential process and contamination control investigative scenarios in a more systematic manner. By tracking and reporting the past and present locations of assets, the investigative GMP/GLP professional now has a powerful tool to reduce the scope of investigations to a smaller subset, thus reducing the expensive and time-consuming cost associated with conducting investigations. It can also serve as digital records to compounding operations and confirm appropriate receipt by a patient in personalized medicines.

At the same time, the GMP/GLP professional may also track not only a physical asset's location but also processes, EM sampling, cleaning, incoming components, sterilization, lab functions, incoming materials, receipt of shipments, batch/process records, and a multitude of other invaluable location, time stamp, and process controls. The use of RFID is infinite, and within each organization countless unique and pertinent uses for the technology can easily be ascertained. Assets can be defined as components, fixed equipment, mobile equipment, personnel, records, ingredients/excipients, vials, and potentially final product.

What Disciplines Does RFID Benefit?

Production: Knowledge of the location of equipment, components, supplies, batch records, personnel, product and calibration expiry.

Quality Assurance: Knowledge of the location of EM plates, test instruments, personnel, lab supplies, calibration expiry, reagent expiry and test sample phase.

Quality Control: Knowledge of the location of incoming components and reagents, released/not released status, records, and incoming samples.

Production Supply: Knowledge of the location of all supplies to support product and quality operations.

Warehousing: Knowledge of the location of all warehoused items at multiple locations.

Maintenance: Calibration Expiry, routine maintenance due dates, age of parts, location of spare parts, inventory of supplies.

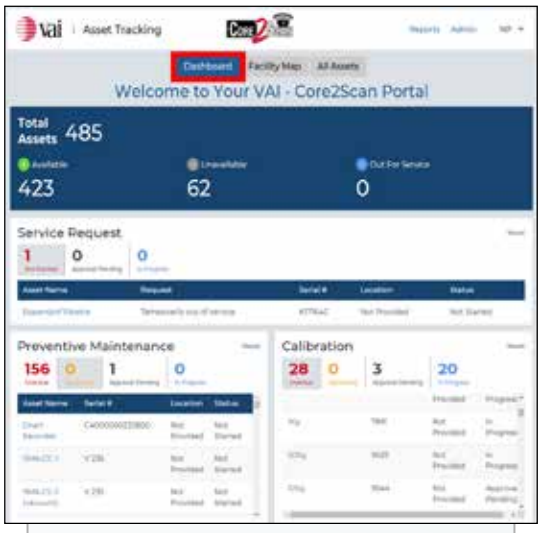
Cleaning/Disinfection Services: Knowledge of the location of cleaning personnel, cleaning agents, time stamp on cleaning times, room release and expiry of agents.

Procurement: Knowledge of the real time location of all items entering multiple plant sites and location of items within a plant site.

Release: Knowledge of the location of sterility samples, batch records, area and location of quarantine, and timeline assessment

Auditing/ Regulatory: Knowledge of the location of all tagged items, equipment, consumables and how each interacted with each other over time.

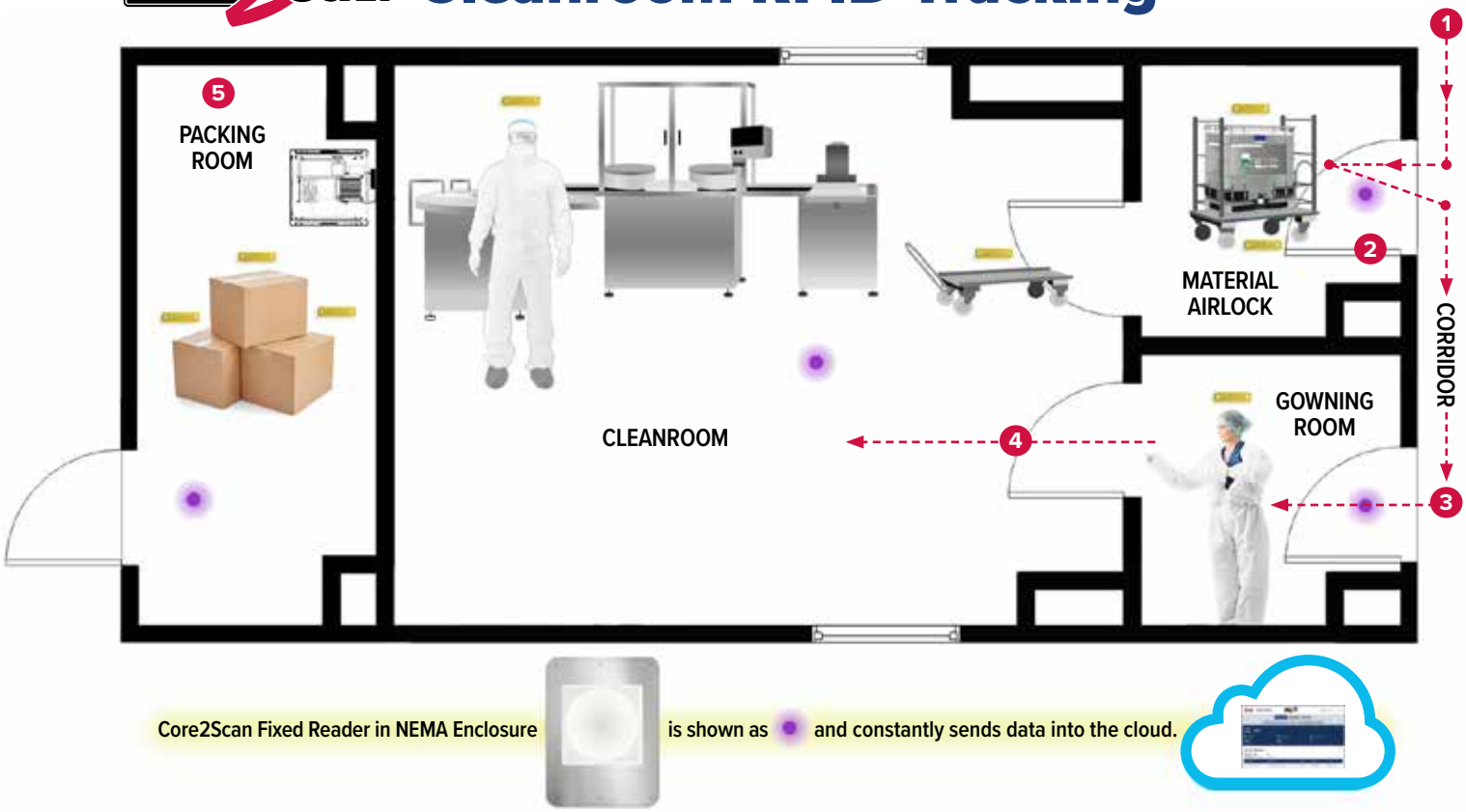
Compounding Pharmacy: Knowledge of the location of the compounding operation and assurance that drug delivery to the patient was done properly.



What does RFID minimally tell GMP/GLP operations from each user screen?

- ✓ Where physical assets are located
- ✓ When incoming shipments arrive and where they are located
- ✓ Where personnel are located
- ✓ When assets (equipment or personnel) enter prohibited areas, with alarms and alerts
- ✓ Location of environmental monitoring plates
- ✓ Location of samples
- ✓ Room cleaning and release/room hold times
- ✓ Location of batches
- ✓ Who and what was used for equipment cleaning
- ✓ Where and when calibrations are required
- ✓ Component inventory
- ✓ Production and lab chemicals and associated expiration dates
- ✓ Cleaning of equipment and incoming items
- ✓ Temperature and Relative Humidity (rH)
- ✓ Stability sample locations
- ✓ Equipment in service location
- ✓ Completion of processes
- ✓ And so much more.....IN SHORT, THIS IS ALL SEEN FROM THE EMPLOYEE'S COMPUTER WITHOUT PERSONAL INTERACTION THAT IS COSTLY

Cleanroom RFID Tracking



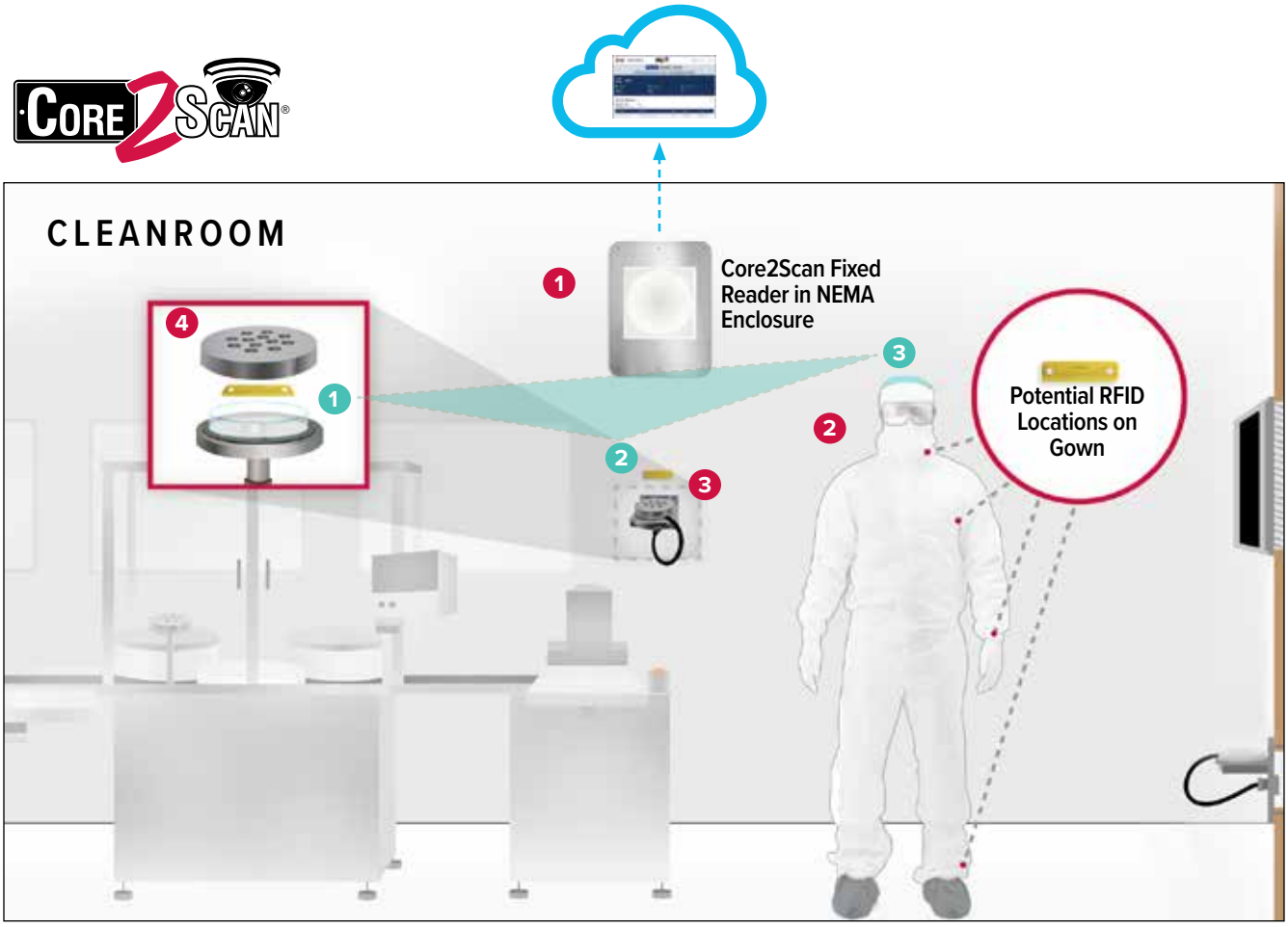
Scenario #1: RFID Tracking

Tracking Assets - In this typical cleanroom scenario:

1. An employee brings a cart loaded with equipment down the corridor, and enters the material airlock, leaving the cart there to be wiped down, and eventually taken into the cleanroom.
2. An RFID reader inside the airlock records this event, with a time and date stamp in Core2Scan software.
3. That employee then enters the gowning area, where another reader records the employee's entry.
4. The employee enters the cleanroom and works throughout their shift with the RFID tagged supplies and equipment that entered the cleanroom.
5. Finished product is then sent into the packing room where cases are RFID tagged for further tracking.

Items to note:

- As depicted in this drawing, all assets can be RFID tagged: carts, equipment, people, raw material, supplies, and finished product.
- Strategically placed RFID readers automatically capture critical data throughout your facility, providing users with complete and actionable information regarding inventory, output, and workflow.
- Core2Scan RFID readers can be mounted on the wall or in the ceiling, in and out of the cleanroom.



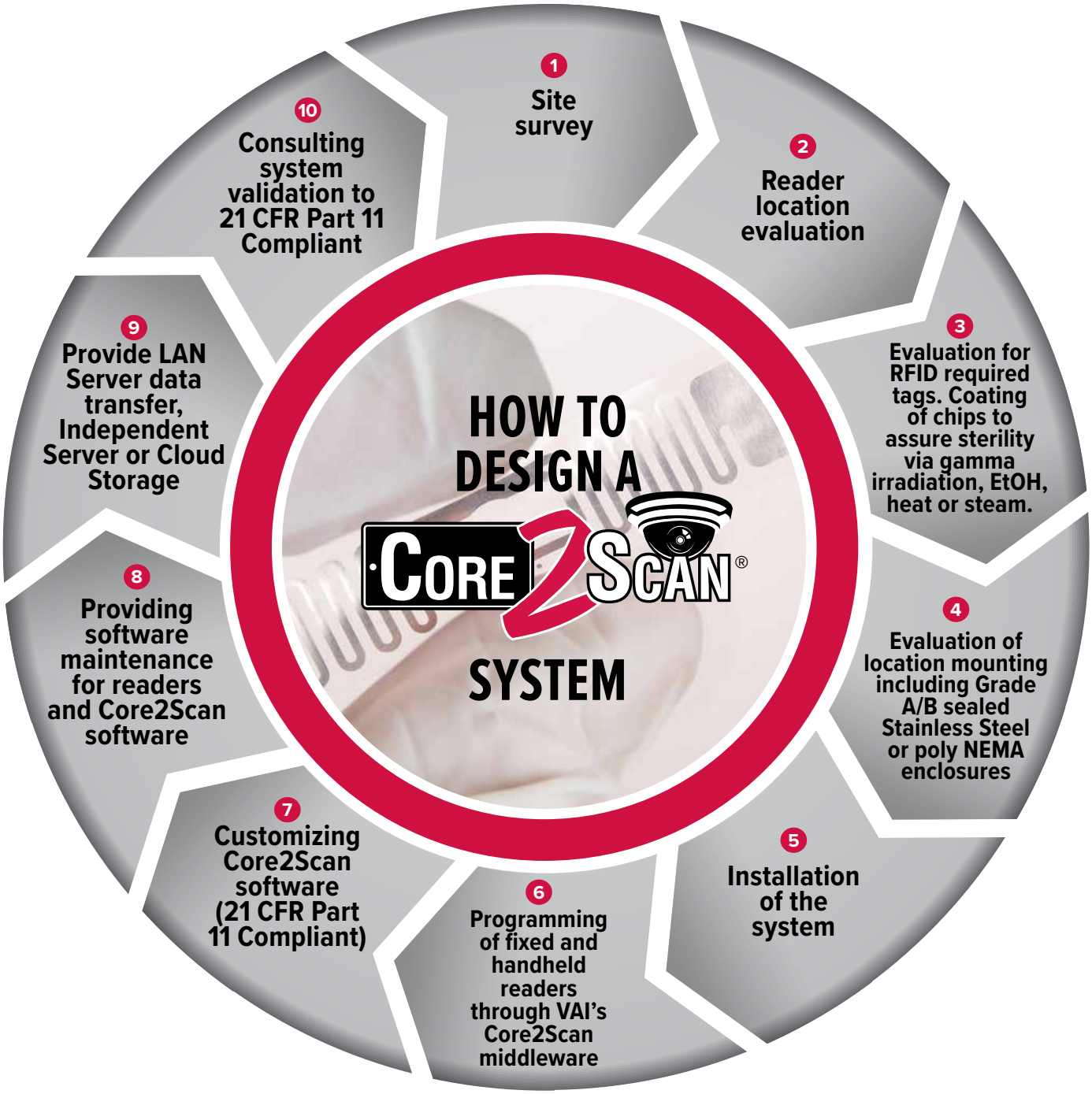
Scenario #2: Cleanroom Tracking

Another practical application for RFID tracking is keeping a documented record of agar plates for environmental monitoring.

1. A cleanroom-ready RFID reader is mounted close to an air sampler so it can read RFID tags that come into range.
2. With RFID tagged plates (1), air samplers (2), and employees (3), the system can track when a plate is placed in a specific sampler and by whom.
3. Tracking can also let the user know when those plates are retrieved.
4. If a plate is accidentally left in an air sampler, users can quickly identify where that missing plate is located.

What is the Core2Scan System?

The Core2Scan System combines all the required components in one package so that GMP/GLP operations do not have to source multiple vendors to accomplish the implementation.



Core2Scan RFID Tags

VAI-TAG-01

VAI-TAG-GAMMA-01

VAI-TAG-FLEX-01

VAI-TAG-SBC-01

Core2Scan tags are the first step in the Core2Scan Solution.

Tags containing Radio Frequency Identification (RFID) inlays are attached directly to an asset. The tags are used to track and store product information such as manufacturer, model number, serial number, lot number, expiration date, sterilization date, configuration data, manufacturing details, maintenance history, and more.

RFID Inlays can be scanned without a direct line of sight or a specific orientation. Information can be added, encrypted, and password protected. RFID Inlays can also store much more information than traditional barcodes.

RFID coded Logbooks, Labels, and Forms are available in custom colors, features, and printing. For more information, see Core2Write on page 158.

Multiple tag options are available to fit specific facility requirements.

Quality and Manufacturing

- **VAI-TAG-01** is manufactured of 2 layers of CleanPrint 10 and laminated for added strength and durability. It does not shed and is chemically resistant to many VAI chemicals.
- **VAI-GAMMA-TAG-01** Has all the qualities of VAI-TAG-01 with the addition of a sterilizable RFID Inlay that has been tested and proven to survive repeated gamma sterilization, X-ray, e-beam, and other types of radiation and sterilization.
- **VAI-TAG-FLEX-01** is manufactured of Thermoplastic Polyurethane Elastomer (TPU). It is extremely flexible and tolerates repeated bending while safeguarding embedded RFID inlays. Attaches firmly to irregular surfaces. It can be autoclaved and sonicated.

Features and Benefits

- Durable for use in long-life industrial applications
- Compatible with RFID readers
- Programmed to hold key information exactly where it is needed
- Equipped to capture large quantities of data accurately and quickly
- Designed for global usage across the entire supply chain
- Economical, can be scanned quickly without the need to unpack boxes

Order Number	*Description*	*Qty/Cs*
VAI-TAG-01	Core2Scan RFID Tag, Laminated CleanPrint 10, White, 2.75x1.375 inch, Non-Sterile	No MOQ*
VAI-GAMMA-TAG-01	Core2Scan RFID Tag, Laminated Clean Print 10, 5x1 inch, Non-Sterile, Can be Gamma Irradiated	No MOQ*
VAI-TAG-FLEX-01	Core2Scan RFID Tag, Flexible Thermoplastic Polyurethane, 3.375x1 inch, Non-Sterile, Can be Autoclaved and Sonicated	No MOQ*
VAI-TAG-SO-01	Core2Scan RFID Tag, Foam back barrier, 2x1 inch, Non-Sterile	No MOQ*
VAI-TAG-RT-01	Core2Scan RFID Tag, Rack Tag, Thin Design, 3x1 inch, Non-Sterile	No MOQ*
VAI-TAG-SS-01	Core2Scan RFID Tag, Stainless Steel, Long Read Range, 2x1x.5 inch, Non-Sterile, Can be Autoclaved	No MOQ*
VAI-TAG-SBC-01	Core2Scan Stainless Steel, Barcode compatible, 2.5x1.5 Inch, Non-Sterile	No MOQ*
VAI-TAG-EB-01	Core2Scan RFID Tag, Laminated CleanPrint 10, 3x2 inch, Non-Sterile, Also available in dual UHF-HF design	No MOQ*

* Minimum Order Quantity (MOQ)

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI)

Core2Scan RFID Readers

C2S-FRP-NEMA-002

C2S-FRP-TM-001

C2S-HH-001

Core2Scan Readers are the second step in the Core2Scan Solution.

VAI offers both Fixed and Handheld Readers that are used to gather information from Core2Scan tags containing an RFID Inlay.

When Core2Scan tags pass through a Fixed Reader's range they are read automatically. Fixed Readers can be placed in any part of a facility and are ideal for tracking the location and movement of large numbers of tagged assets.

Core2Scan Handheld Readers are used to read, write, and locate Core2Scan tags, as well as read 1D and 2D barcodes.

Read - In the Handheld Reader's Inventory mode operators can view the Electronic Product Codes (EPC) of all Inlays within range. Masks can be created to view only the items of interest.

Write - The Tag Access utility can be used to read from and write to specific portions of Inlay memory.

Locate - In Geiger Counter mode users can locate specific Inlays by monitoring the Inlay's signal strength, which the Handheld scanner indicates, audibly and visually.

Handheld Features and Benefits

- Equipped to read Core2Scan tags, as well as 1D and 2D Barcodes
- Designed with the ability to write and password protect information
- Ergonomic, easy to use touchscreen and keyboard
- Offered in regional frequency options including Europe, China, and others
- Durable and drop resistant
- Available with two batteries for extended usage

Fixed Reader Features and Benefits

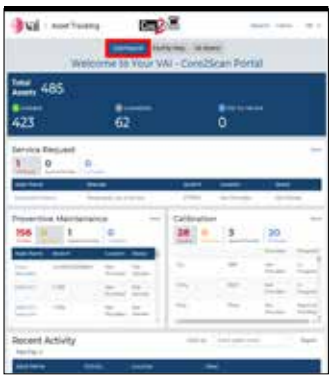
- Reads tags without any operator action
- Equipped to capture large quantities of data accurately and quickly
- Equipped to read RFID Inlays at a rapid rate
- Cleanroom enclosure, mounting kit, and additional antennas are available

Order Number	*Description*	*Qty/Cs*
C2S-HH-001	Core2Scan Handheld Reader Includes wireless connectivity, Alien app, and Strategic app Core2Scan Software and Handheld Software sold separately	1
C2S-FRP-NEMA-002	Core2Scan Fixed Reader for Classified Area Includes Cleanroom Enclosure and Antenna Core2Scan Software sold separately	1
C2S-FRP-TM-001	Core2Scan Fixed Reader for Unclassified Area Includes Antenna Mounting Kit and Core2Scan Software sold separately	1
C2S-MTI-MT-001	Core2Scan Mounting Kit For use with Fixed Reader in Unclassified Area (C2S-FRP-TM-001)	1
C2S-ANT-TM-001	Core2Scan Additional Antenna For use with Fixed Readers (C2S-FRP-TM-001 and C2S-FRP-NEMA-002)	1

Other Technical Data Available Upon Request

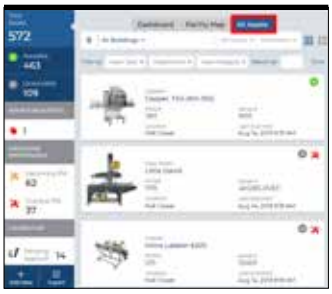
Product Technical Data Report • Specific Test Reports (Consult VAI)

Core2Scan Software



Dashboard

Facility Map



All Assets

Asset Detail

Core2Scan Software is the final step in the Core2Scan Solution.

Paired with Core2Scan Tags and Readers, the Core2Scan Software provides the ability for operators to manage Asset location, information, service workflows, preventative maintenance workflows, and calibration workflows in a compliant, accurate manner.

The Core2Scan Software is user friendly. At login the system authenticates the operator's credentials and allows or limits access to functionality based on the operator's role. The Dashboard presents a clear overview of asset status and workflow activity.

Reporting provides the users access to critical data on assets in the system. The history of all location tracking and user processes are tracked and maintained for every asset in Core2Scan. This information can be exported or organized into reports.

The Core2Scan Software makes users accountable for each task in the workflow. It tracks who, what, and when: Who performed the task, What the task was, and When the task was performed. Tasks include preventive maintenance, calibration, and service requests. Users are notified by email when key steps are upcoming, completed, or overdue. These workflows can be customized to meet your facility needs.

The Core2Scan Software is compliant with industry regulations. The data contained within the Software can be leveraged to support audits, internal reviews, and data integrity assessments.

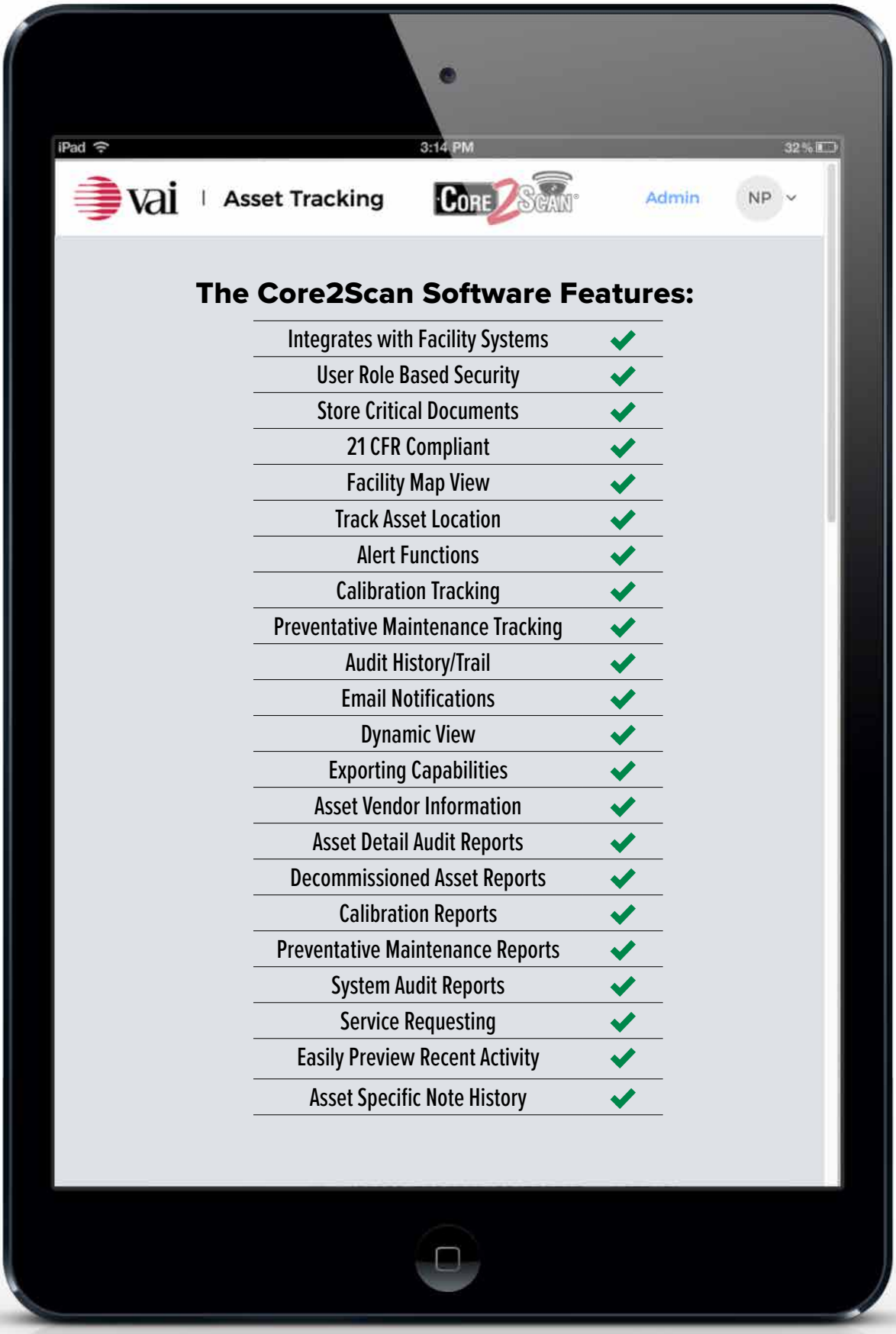
The Core2Scan Software:

- **Dashboard –** Provides an overview of Asset status, service requests, preventive maintenance, calibration, and recent activity
- **Facility Map –** Use to track the physical location of Assets
- **All Assets screen –** Use to search, add, export, and view Asset information
- **Asset Detail screen –** Use to edit and view detailed Asset information, as well as perform service, maintenance, and calibration workflows
- **Reports –** Use to create Audit, Asset Detail Audit, Decommissioned Assets, Calibration, and Preventive Maintenance Reports
- **Administration –** Use to manage vendors, departments, Asset categories, Asset types, and Asset document types
- **Email Notification –** Use to communicate service request, calibration, and preventative maintenance status

Order Number	*Description*
C2S-SWL-001	Core2Scan Software V-2.0, Upgradable, Ten Licensed Users, Administration Privileges Includes Configuration and Setup of Core2Scan Readers
C2S-SWW-001	Core2Scan Handheld Software / Mobile App Use to integrate the Handheld Tag Reader with the Core2Scan Software Includes Configuration and Setup of Core2Scan Readers
C2S-DATA-001	Core2Scan Cloud Data Storage

Other Technical Data Available Upon Request

Product Technical Data Report • Specific Test Reports (Consult VAI)



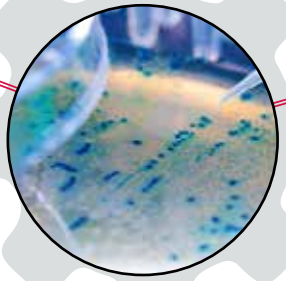
The Core2Scan Software Features:

Integrates with Facility Systems	✔
User Role Based Security	✔
Store Critical Documents	✔
21 CFR Compliant	✔
Facility Map View	✔
Track Asset Location	✔
Alert Functions	✔
Calibration Tracking	✔
Preventative Maintenance Tracking	✔
Audit History/Trail	✔
Email Notifications	✔
Dynamic View	✔
Exporting Capabilities	✔
Asset Vendor Information	✔
Asset Detail Audit Reports	✔
Decommissioned Asset Reports	✔
Calibration Reports	✔
Preventative Maintenance Reports	✔
System Audit Reports	✔
Service Requesting	✔
Easily Preview Recent Activity	✔
Asset Specific Note History	✔

THE CORE2SCAN MODULES

ASSET TRACKING

The backbone of Core2Scan, this module accomplishes asset location tracking and asset management in a single tool. Know where equipment is located and when it is due for calibration, preventative maintenance, and servicing.



MICROLAB TRACKING

Have confidence in knowing where all items used in studies are located within your facility. Track and document release dates, lot #, expiration date, and so much more.

CHEMLAB TRACKING

Understand where testing materials are and where you are in the study cycle.

CLEANING TRACKING

Know that SOPs are being followed by tracking cleaning procedures. Core2Scan time and date stamps the flow related to equipment, cleaning supplies, and personnel, and creates an automatic audit trail for further evaluation.

VIAL TRACKING

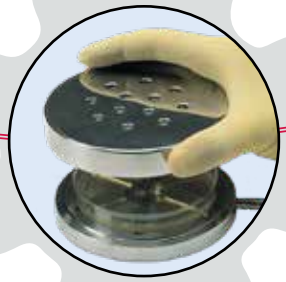
Core2Scan can track all activity related to vials in your facility. From the staging lab to the depyrogenation tunnel, Core2Scan collects data needed for aseptic product manufacturing.

PROCUREMENT TRACKING

Know where supplies are within your facility and have a better understanding of inventory needs. Proactively manage critical supplies before fire drills are needed.

R&D TRACKING

Track Phase 1/2/3 manufacturing and testing data, expiration sample data, ingredient data, and much more.



EM ICS AIR TRACKING

Track the location of key portable samplers and personnel to validate SOPs, locate expensive equipment, and insure process adherence.

EM COMPLETE TRACKING

Integrate and visualize viable and non-viable air sampling activity and results with critical process location data from Core2Scan RFID tracking for validation, investigation, and process improvement.

INVESTIGATIVE TRACKING

When you're involved in an investigation, this is the one source that helps you piece together who was in an area and where they came from, what material and supplies entered the area, and see what other factors may have contributed to the issue.

PERSONNEL TRACKING

Understand workflow patterns so you can implement process improvements to increase productivity. Rest assured that tracking only takes place in areas where the information is important to your facility's success.

WAREHOUSE TRACKING

Supplies coming in and finished product going out need to be tracked in every facility. Furthermore, Core2Scan can even track RFID tags from every company that affixes RFID tags to their products that you use.

COMPOUNDING PHARMACY TRACKING

Personalized medicines are becoming increasingly more complex and numerous. Know what ingredients you're working with and exactly who is getting which dose with Core2Scan Compounding Pharmacy module.

BATCH RECORD TRACKING

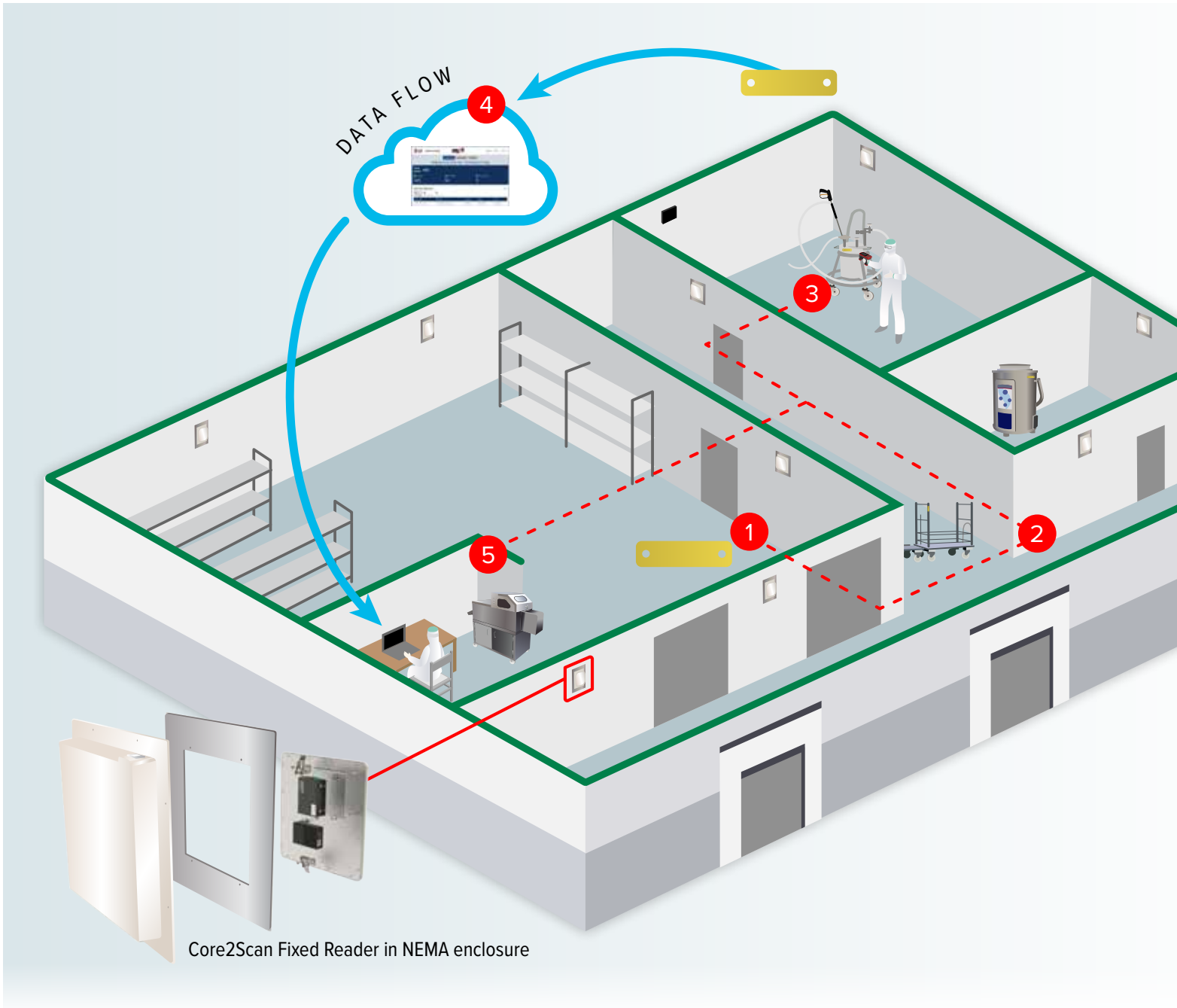
Prevent the misplacement or accidental loss of batch records with this Core2Scan module. Every batch should have its own RFID tag along with a corresponding RFID tag that accompanies the batch record, to always connect them together.

PATIENT CARE TRACKING

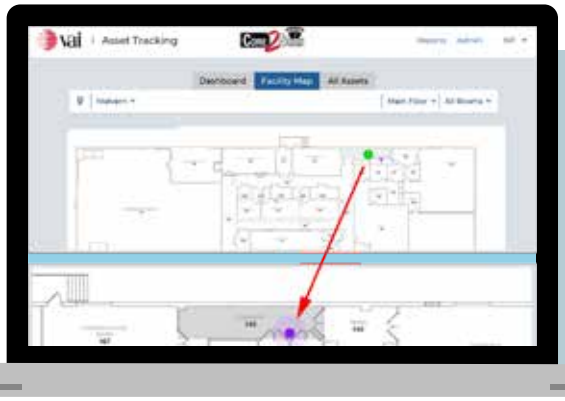
Prevent patients from receiving the wrong dose or someone else's medicine, with Core2Scan's Patient Care module. Core2Scan can help identify the patient and the medicine so errors are reduced.

Core2Scan®: Asset Tracking and Workflow

1. Assets are tagged with cleanroom ready RFID tags.
2. Assets move throughout a facility.
3. Asset information is read by strategically placed RFID readers.
4. Asset data is transfered to the Core2Scan software.
5. User is able to see asset status and location.

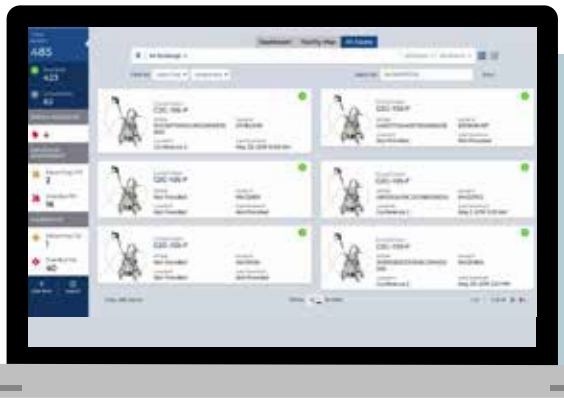


Core2Scan Fixed Reader in NEMA enclosure



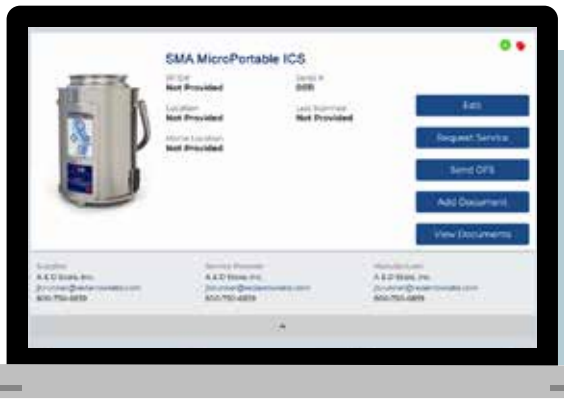
ASSET TRACKING

Track the physical location of assets.



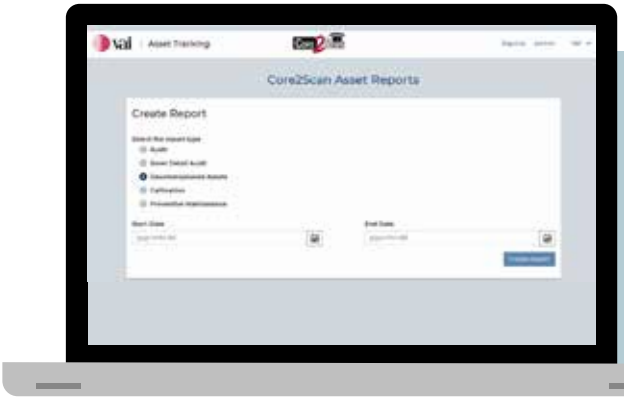
ALL ASSETS

Search, add, export, and view asset information.



ASSET DETAIL

Manage asset workflows such as service, maintenance, and calibration.



REPORTS

Create Audit, Asset Detail Audit, Decommissioned Assets, Calibration, and Preventive Maintenance Reports.


VAI LABS

AET
2°-8°C
aseptic
25+ years
disinfectants
End User Surfaces
Laboratory Testing
Final Report Writing
justification carrier
done in triplicate
User Isolates
ambient
wipers
ATCC
GMP

Welcome to VAI® Laboratories

Laboratory Testing Services

VAI Laboratories closes the gap of required regulatory documentation by providing contract microbial identification and antimicrobial effectiveness studies. These studies are performed either with one's internal environmental isolates or ATCC cultures against the chosen array of disinfecting agents.

As time and personnel within GMP firms may be unavailable to conduct these extremely important studies, one can have VAI Laboratories complete these items on a contract basis.

The identification of microbial contaminants is completed, per the customer's specifications, either by fatty acid or genetic sequencing techniques. Identification of the organism is the first step to designing a corrective action plan to destroy its existence in controlled environments.

Subsequently, the need to verify the antimicrobial effectiveness of disinfecting agents used in controlled environments is a critical step to assuring a documented disinfection system is in place. VAI Laboratories conducts either time contact kill studies on standard or user surfaces and AOAC protocol testing studies. All tests are performed in triplicate and done at three specified contact (dry time) time periods. A complete report of the study is presented to the end user to complete their documentation file for internal or external audit requirements.

VAI Laboratories is a value-added service available through Veltek Associates, Inc. that not only completes required testing but also provides an invaluable source of information from experienced laboratory and disinfection professionals who are involved daily in GMP settings.

VAI® Laboratories

VAI Laboratories was established to assist our customers by providing microbiological testing services ranging from the identification of microorganisms to antimicrobial effectiveness studies to prove the effectiveness of selected disinfectants.

The successful operation of a cleanroom environment is dependent on the exactness of the information available and the implementation of a plan of action from such information. Pharmaceutical, biotechnology, and healthcare professionals have been required by the FDA to address known contamination within their facility and develop a validated plan of action to remove such contamination. This requirement will not change in the future. In fact, qualifications for cleanroom operations will only become more stringent as time progresses.

The importance of addressing existent contaminants is a situation that requires guaranteed effort. Complete and documented efficacy performance testing and in-situation testing to prove the removal of existent contamination is a very costly and time-consuming task. To date, there has been no completely encompassing alternative provided in the marketplace that can provide services from identification of an organism to effective destruction of the organism from the environment. Thus, microbiologists are continually forced to focus efforts on basic laboratory services that are costly and time-consuming.

VAI has responded to the needs of our clients by installing laboratories focusing in the area of microbiological testing services. Customized to the users requests, VAI laboratory testing division is capable of performing the following services in conjunction with the use of VAI products:

Time Contact Kill Studies

ATCC cultures and/or cultures obtained from the customer (environmental isolates) will be tested over a specified contact time. The results obtained will demonstrate the effectiveness of the disinfectant tested against the suspended organism culture or coupon study. All data is then compiled into a report per organism.

Disinfectant Validation Services

An expanded and more encompassing service than the time contact kill studies listed above is the Disinfectant Validation Service. In conjunction with the customer's needs, VAI will test specified disinfectants against a variety of ATCC cultures and cultures obtained by the customer (environmental isolates). Testing will specify a contact time. The results obtained will demonstrate the effectiveness of the disinfectant tested against the suspended organism culture or coupon study. All data is then compiled into one report and will provide an effective means to address regulatory concerns for addressing contamination within one's operations.

Microbial Identification Services

Sequence based genetic microbial identification. The 16S rRNA sequencing capitalizes on state-of-the-art technology to identify both bacteria and fungi.

Consulting

The design of a biodecontamination system warrants experience and familiarization with disinfection systems that have proven success in the control of microbial and particulate contamination in cleanroom environments. VAI has the experience and the personnel to completely evaluate operations and address the necessary requirements for operation of the controlled areas.


CORE LABS

CIP
COP
ATCC
User Product
Process2Clean
Final Report Writing
CIP Validation
Product Contact Surfaces
Process Cleaners
User Surfaces
Pre-Validation
planchettes
justification
25+ years
carrier

What is the CORE® Program?

While years have gone by and technology has changed, many GMP firms have not re-evaluated the effectiveness of their process cleaning detergents. At the same time, the industry grows and new operations manufacturing new products blossom each day. In both scenarios, the need for routine evaluations to be conducted is essential to achieve overall site optimization. In the competitive world, cleaning down time costs operations enormous amounts of overhead, time, and money. Normally these costs can be dramatically reduced by the use of more efficient and state-of-the-art detergents that work specifically against residues in current times. At the same time, firms also find that combination cleaning, not in present scopes, reduce the amount of cleaning time, cleaning chemicals used, and the level of personnel required to clean critical surfaces.

The proper selection of optimal detergents can also positively effect: substrate integrity, effluent concerns, overall chemical usage, storage, and inventory issues. **The CORE (Critical Ongoing Residue Evaluation®) program** is a service offered within the VAI® Laboratories division of VAI. The focus of the division is to provide our clients with a specialized laboratory service that can assist them in performing product contact cleaning evaluation studies as an external service.

With our Process Cleaning Detergents, Process2Clean, our Biomedical Research Detergents, Cage2Wash, and our CORE Program, operations can be assured the correct and most effective product is being used.

Testing is designed around the client's product residues and detergent choice to provide the client with a sound scientific rationale in your process cleaning detergent selection. CORE ultimately helps the end user implement the necessary internal and external regulatory expectations and choose the correct detergent by performing and providing analytical methods of detection, process cleaning compatibility, TOC curves, conductivity curves, toxicological reports, and controlled documents to assist in validation.

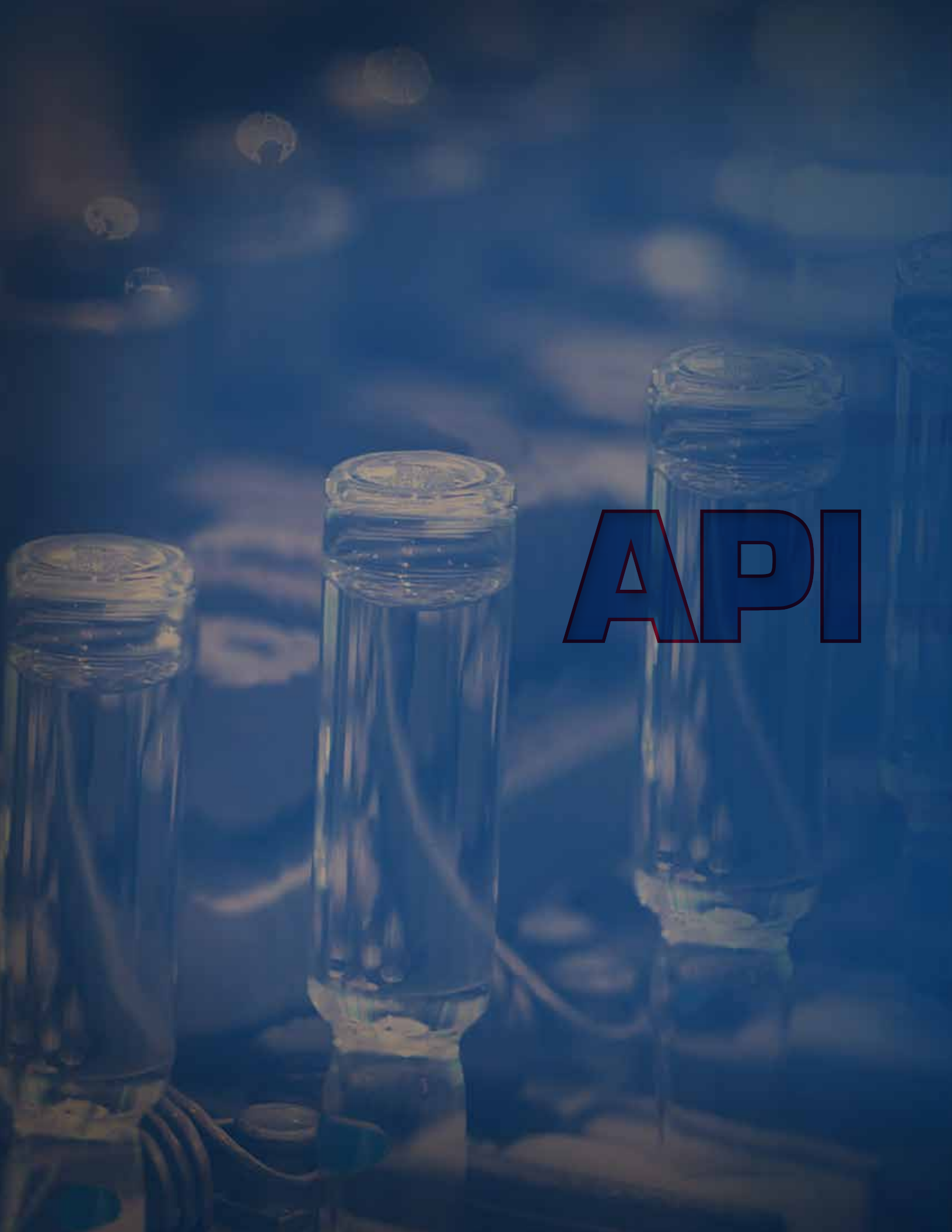
The CORE program provides an excellent means to define where present systems are and where they want to be in the future. May it be older operations or a new operation, the CORE program provides the development of consistent and dependable cleaning procedures.

Specific Testing Services and Program Features

- Analytical methods of detection
- Process cleaning compatibility
- TOC curves
- Conductivity curves
- Toxicological reports
- Controlled documents to assist in validation

Industries Served

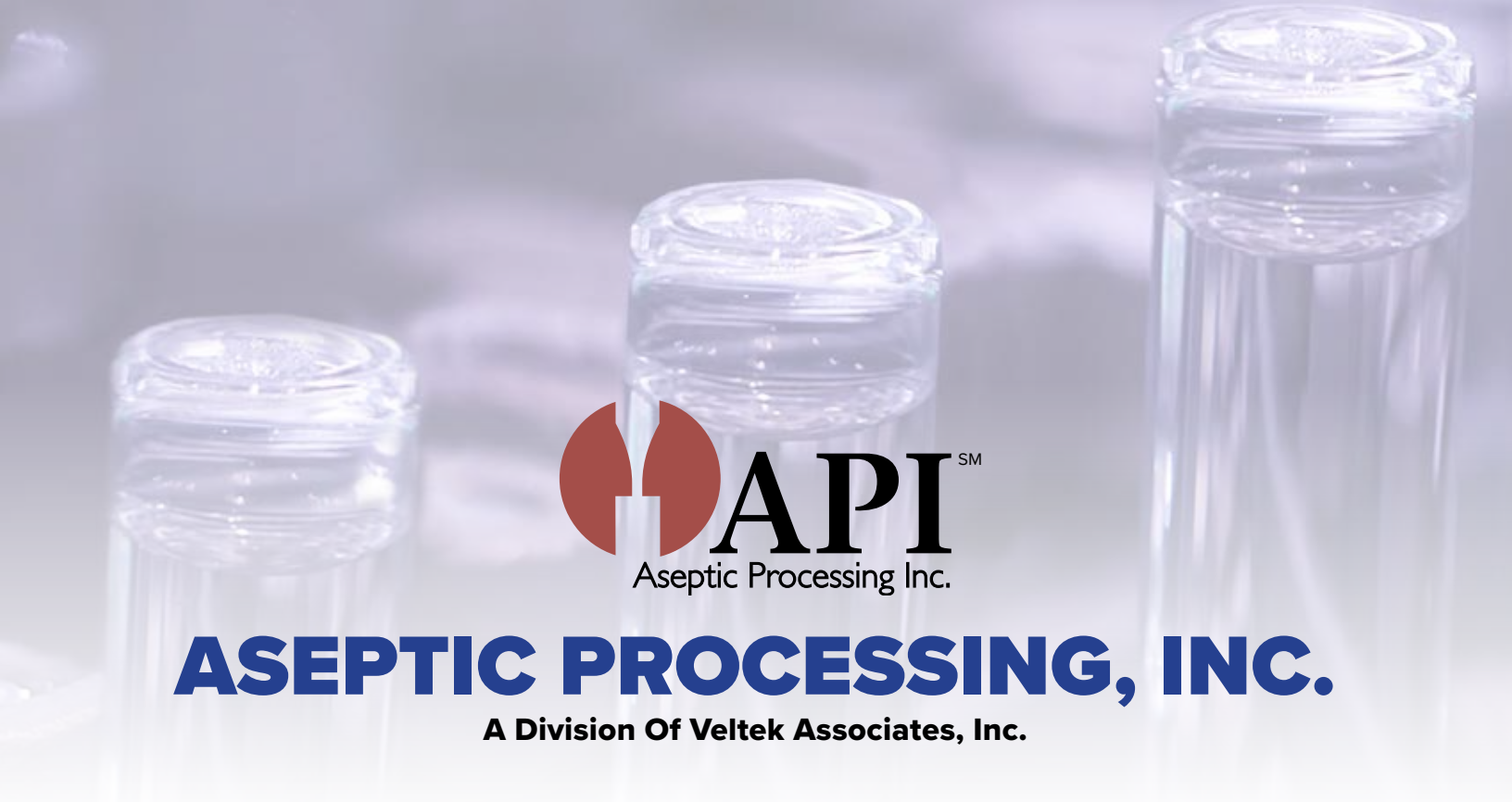
- Lab Animal Research
- Pharmaceutical
- Biotechnology
- Cosmetic
- Medical Device
- Food and Beverage Industry


API

risk
GMP
media fill
35+ years
Regulatory
experience
Disinfection
component entry

Consulting Services

Regulatory Expectations
aseptic manipulation
contamination
guidelines
gowning
cleaning
training
on-site
EM



ASEPTIC PROCESSING, INC.

A Division Of Veltek Associates, Inc.

Since 1981, Veltek Associates, Inc. (VAI®) has played an innovative role to the pharmaceutical, biotechnology, and medical device industries by partnering with clients to develop strategic products and services that have improved operations and reduced costs associated with the ingress of contamination. During the history of the company, VAI has manufactured and developed over 500 strategic and critical contamination control products, systems, and services. These innovative solutions are used by most GMP organizations worldwide.

In over three decades of operations, VAI has not only developed innovative products and services but also the know how to assure successful and compliant systems in order to monitor and control contamination.

In 2001, after many years of refinement and development, VAI introduced a unique and specialized value added advantage for its clientele known as VAI Consulting Services. In 2003, due to its enormous growth, the division was reorganized into Aseptic Processing, Inc. (API). API is the consulting and training division of Veltek Associates, Inc.

The mission and key focus of the division is to lead the industry in specific contamination control and environmental monitoring systems. Unlike many consulting organizations, API® focuses specifically in the areas of Cleaning and Disinfection Systems, Disinfectant Validation Services, Component Entry Systems,

Environmental Monitoring Systems, Aseptic Processing Systems, Media Fills, and Personnel Training Systems. API has assisted a multitude of pharmaceutical, biotechnology, and medical device organizations worldwide. API was also responsible for the cleaning and disinfection training that was conducted by the U.S. Food and Drug Administration's CDER and CBER divisions in 2001-2004.

Uniquely, the division works to combine all contamination control aspects within an organization into one system that is compliant, effective, and assures repeatable success.

Specialized Consulting Services In The Areas Of

- Environmental Monitoring Systems
- Cleaning/Disinfection Systems
- Personnel Gowning Systems
- Aseptic Processing Systems
- Component Entry Systems
- Personnel Training
- Media Fill Trials
- Process Cleaning

API® provides a wide range of technical services to the pharmaceutical and biotechnology industries. Our experience encompasses the following critical areas:

Cleaning and Disinfection Component Entry Systems

Review of current and future practices; advanced technology; cleaning of controlled and non-controlled areas; equipment cleaning and disinfection; disinfectant and sporicidal qualifications and validations; cleaning practices and methods of application; contamination control practices; residue removal; clean in place systems (CIP); sterilize in place systems (SIP); component entry systems; compliance assurance; and training of personnel.

Environmental Monitoring, Media Fills, and Air Flow Studies

Review of current and future technology; development of air, surface and personnel programs; qualification of controlled environments; validation; compliance assurance; conducting investigations; corrective actions; media fills; air flow studies; and training of personnel.

Aseptic Processing

Review of current and future practices; advanced technology; review of aseptic practices; regulatory compliance; facility design; aseptic filling; terminal sterilization; and in-house training of personnel.

Personnel Gowning

Personnel gowning for controlled and non-controlled environments; qualifications; aseptic practices; gown training programs; and training of personnel.

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Website: www.sterile.com
E-mail: vai@sterile.com

Technical Support
VAI® Technical Support Group can be contacted through our main office or by contacting the VAI Technical Support Group via e-mail at sales@sterile.com.

Technical Documentation
Technical documentation for each product is available electronically in Adobe Acrobat PDF format. This includes product specifications, testing and Safety Data Sheets.

Worldwide Distribution
VAI's infrastructure incorporates 120 worldwide stocking distributors. Please contact VAI's Customer Support for your local distribution organization.

In an effort to provide our customers with single lot orders and optimum expiration dates minimum order quantities may be required for some VAI products.

Patents: www.sterile.com/patents

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