HIGHPOWER
Validation Testing & Lab Services

Validating reusable
medical and dental devices
for over 30 years

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Pharma-ceutical Market

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"I've seen many changes in the complexities of medical devices and validation testing over the past 30 years, but our commitment to provide the highest level of client service and complete customer satisfaction will never change."

Gary Socola, President

History

We began in 1987, as part of SPS Medical Supply Corp. and have been serving the medical device community for over 30 years. Initially focused on sterilizer validations, our testing quickly expanded to other Class II and III medical devices at the request of our clients. Over the years we grew by word of mouth, and in 2012 we moved into a newly remodeled 16,000 square foot facility. HIGHPOWER then became a stand-alone company performing a broad array of medical device validations and testing services.

The attention to detail and commitment to the highest levels of customer service that were learned under SPS Medical are still core values of HIGHPOWER today.

Who We Are Today

HIGHPOWER has become a leading validation and testing laboratory, focusing on the increasingly complex and highly regulated world of **reusable medical devices** that require cleaning, packaging and sterilization procedures to complete their instructions for use.

With a broad global customer base and extensive regulatory experience with the FDA and regulatory bodies around the globe, our knowledgeable team works diligently to provide full service support to our clients throughout each phase of device design, validation and regulatory approval.

Believing that an educated client will develop the safest medical devices, HIGHPOWER sits on over 25 committees and working groups within the AAMI, ISO and ASTM organizations while using a consultative approach with all clients.

Site Visits/Audits

We encourage potential and existing clients to meet our staff and tour our spacious facility to see our full scope of testing capabilities and discuss project needs. Our facility mimics instrument reprocessing departments within healthcare facilities. Please contact our Quality Department at ext. 1933 to schedule a tour or facility audit.

Certifications/Quality

- Lab Accreditation: ISO 17025
- ISO Registrar: A2LA
- Certificate No. 3718.01
- Conformance to the Requirements of 21 CFR Part 820, Quality System Regulation

ISO 17025 ACCREDITATION

GLP/GMP

With the increased scrutiny of the FDA concerning sterilization, packaging, and cleaning validation studies, our clients require their testing to be performed according to the appropriate regulatory guidelines. Many clients request studies be performed following the GLP's. However, under most circumstances GLP compliance is not required for a laboratory to perform these types of studies. We perform these tests following documented best practices according to the GMP guidelines and the ISO 17025 quality system.

Contact Us

HIGHPOWER
Validation Testing & Lab Services

125 HIGHPOWER Road
Rochester, NY 14623, USA

Phone:	1.585.743.1930
Toll-Free:	1.888.722.1529
Fax:	1.585.697.1506
Website:	highpowervtls.com
Email:	info@highpowervtls.com

Follow Us on LinkedIn

linkedin.com/company/highpowerlabs

Request Quote/Pricing

Our experienced Client Services team will discuss your specific project needs and provide a custom quote that encompasses the full scope of the testing recommended. Rush service (STAT) is available for most services, lab schedules permitting.

Purchase Order

Each PO should reference the applicable quote number(s). This will expedite order setup in our system.

Note: We must receive the completed sample submission form, samples, and purchase order to begin working on any project.

Protocols

Client test protocols follow the most current national or international standards and are tailored to each individual medical device.

> *Our methodology has a long history of acceptance by the FDA and our staff stays current regarding changes to industry standards or regulatory requirements.*

Once generated, protocols are sent to clients for their review and final approval. Testing cannot begin until protocols have been approved and signed off by clients.

Study Completion

A technical review is performed on all data, methods, test procedures, and final reports at completion of the study. After this review, the quality department (QA) performs a review of the project. The original final report and a copy of the signed test protocol (if required) are then provided to the client via fax, email or mail.

A copy of the final report and supporting data remain in the project study folder and are archived along with an electronic copy of the final report for a minimum retention period of seven (7) years.

Sample Disposition

Samples will promptly be returned (if requested) or discarded upon study completion. Please indicate on Sample Submission Form if there are any special instructions regarding handling of samples after testing.

Customs Information

We provide the following recommendations for our international clients. All shipments should include a Commercial or Pro Forma Invoice which has the following information:

- Company contact information.
- The name and address, including country of origin of the product manufacturer.
- A detailed description of the items being shipped with the estimated value of each item.
- The product's Medical Device Listing (MDL) or 510K number, or state "Samples not marketed in the U.S."
- The Harmonized Tariff Code.
- The FDA Product Code and FDA Registration Number, or state, "Do not have an FDA registration number."
- Employer Identification Number (EIN), or state, "Do not have an EIN number."
- Statement that samples are for testing purposes only. For example, "Test articles for research. Assigned value provided for Customs purposes only. Product has no commercial value, and no clinical application."
- Instructions for the disposal or return of test samples. For example, "Samples will be disposed of following testing" or "Samples will be returned to manufacturer following testing."
- Reference International Commercial Term (Incoterm) and Delivery Duty Paid (DDP). Also, include a statement that all U.S. and international Customs fees, taxes, tariffs and related costs are your company's responsibility.
- Include three (3) copies of the following executed documents in your shipment:
  - HIGHPOWER Sample Submission Form
  - Commercial or Pro Forma Invoice
  - Certificate of Origin
  - Packing List

International Shipping

For best results we recommend shipping through U.S. based carriers such as FedEx, UPS, or DHL. The Customs Broker used by HIGHPOWER is:

Mohawk Global Logistics
400 Air Park Drive, Suite 80
Rochester, NY 14624, USA

Phone: 1.585.426.0340
Fax: 1.585.426.5249
Email: rocimport@mohawkglobal.com

Your chosen carrier should contact Mohawk Global Logistics to route packages through Rochester's Customs portal, which can alleviate a majority of potential holdups.

Sample Submission Form

This form should be included with all shipments of client provided samples and devices to allow us to properly identify, track, and store samples prior to testing. Clients should also note any other special considerations that are required for the samples and indicate their disposition upon the completion of testing.

Additional questions regarding this form can be directed to Client Services.

Upon receipt of samples, all items are inspected and verified against those listed on the included sample submission form. Please send exact quantities as listed on the form. Next, a unique study number is assigned to each client project.

Notes:

- We must receive the completed sample submission form, the samples and a purchase order prior to performing any work on projects.
- Samples that have been clinically used must be cleaned/desinfected/sterilized prior to being sent to HIGHPOWER.

The sample submission form can be downloaded at:

- highpowervtls.com/services/sample-submission-form

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Validation Testing & Lab Services

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Revision Date: 06/2021
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Authorized by: Eric Mgua

SAMPLE SUBMISSION FORM

Quote #: _____ **PO #:** _____

FINAL REPORT ☐ .pdf ☐ mailed (hard copy shipping charges apply)

Sponsor Information		**Billing Information** ☐ Same as Sponsor	
Contact:		Contact:	
Title:		Title:	
Company:		Company:	
Phone:		Phone:	
Address:		Address:	
City:	State:	City:	State:
Country:	Zip:	Country:	Zip:
Email:		Email:	

Sample Information & DEVICE or PROJECT name as it will appear on final documentation

Part #	Cat. / Ref. #	Lot #	Serial #	Quantity

If additional space is needed or there are more samples than available rows you must include a BOM with the shipment

Sample Storage	**Sample Disposition**	**Shipping Account #**
Choose one	Choose one	

Check all that apply

☐ Samples have been submitted sterile. Description of sterilization:
☐ Samples clinically used, in contact with potential pathogenic substances (exposed to blood/tissue/fluids)
☐ Samples non-sterile & non-clinically used.
☐ Samples are to be shared between HIGHPOWER studies (list study #'s if known):

Special Instructions (e.g., sterilization parameters, special handling, additional information, future analysis):

Additional Device Specific Details (Cleaning and biocompatibility ONLY, contact clientservices@highpowervtls.com with questions)

Part # / Ref. #	Body Contact	Contact Duration	Surface Area to be Tested (patient contacting)	Total Device Surface Area
			cm^2	cm^2
			cm^2	cm^2
			cm^2	cm^2
			cm^2	cm^2
			cm^2	cm^2

Completed by: _____ Date: _____

Laboratory Use ONLY

Sales Order #:	Received by:
Study #:	Date:
Shared Samples:	

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Device Cleaning

With the increased scrutiny of regulatory bodies concerning medical device cleaning and recent FDA warning letters to manufacturers, it's crucial to follow test methodology outlined in AAMI TIR 30, AAMI TIR 12, AAMI ST-98 and the FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*. Cleaning instructions for reusable medical devices require validation in order to assure proper, reproducible and safe reprocessing of the devices by healthcare facility personnel.

> *A device which has not been properly cleaned may inhibit the ability of the sterilization process to achieve the proper sterility assurance level.*

Validated cleaning procedures must remove gross amounts of soil from the test devices in order for them to be determined as clean and safe for further processing.

Our laboratory staff can validate any device's cleaning Instructions for Use (IFU) or if required, we can use our proven cleaning protocols to develop an IFU for the cleaning of the device. Our protocols include a wide variety of clinically relevant soils and use a quantitative analysis to determine residual soil analytes such as protein, hemoglobin, and TOC. Protocols can also include simulated use processing and can include other clinically relevant reprocessing steps such as high-level disinfection (HLD) and/or sterilization.

Test Code	Test Name
MAN-3LOG	Manual Cleaning Validation—3 Log Reduction
MEC-3LOG	Mechanical Cleaning Validation—3 Log Reduction
MAN-HEM	Manual Cleaning Validation—Hemoglobin Analyte
MAN-PRO	Manual Cleaning Validation—Protein Analyte
MAN-TOC	Manual Cleaning Validation—TOC Analyte
MEC-HEM	Mechanical Cleaning Validation—Hemoglobin Analyte
MEC-PRO	Mechanical Cleaning Validation—Protein Analyte
MEC-TOC	Mechanical Cleaning Validation—TOC Analyte
MAN-HEMO3	Manual Cleaning Validation—Hemoglobin Analyte w/8 Repetitive Cycles
MAN-PRO3	Manual Cleaning Validation—Protein Analyte w/8 Repetitive Cycles
MAN-TOC3	Manual Cleaning Validation—TOC Analyte w/8 Repetitive Cycles
MEC-HEMO3	Mechanical Cleaning Validation—Hemoglobin Analyte w/8 Repetitive Cycles
MEC-PRO3	Mechanical Cleaning Validation—Protein Analyte w/8 Repetitive Cycles
MEC-TOC3	Mechanical Cleaning Validation—TOC Analyte w/8 Repetitive Cycles
MAN-HEMO6	Manual Cleaning Validation—Hemoglobin Analyte w/18 Repetitive Cycles
MAN-PRO6	Manual Cleaning Validation—Protein Analyte w/18 Repetitive Cycles
MAN-TOC6	Manual Cleaning Validation—TOC Analyte w/18 Repetitive Cycles
MEC-HEMO6	Mechanical Cleaning Validation—Hemoglobin Analyte w/18 Repetitive Cycles
MEC-TOC6	Mechanical Cleaning Validation—TOC Analyte w/18 Repetitive Cycles
MEC-PRO6	Mechanical Cleaning Validation—Protein Analyte w/18 Repetitive Cycles
SIM-USE	Simulated Use Testing
IN-USE	In Use Testing

Did You Know?

> *Our facility has most FDA cleared sterilization processes and is ASP factory trained to perform STERRAD® functionality and efficacy validation testing. We also provide sterilizer efficacy, materials compatibility and package integrity testing services.*

Packaging Systems & Shelf Life

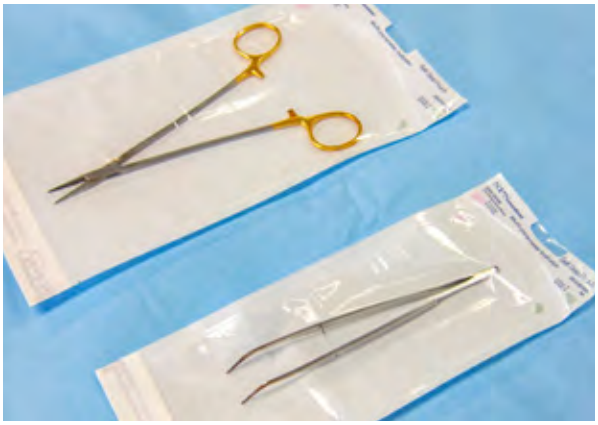
Our test methodology follows the methods outlined in ISO 11607, AAMI ST-77, ASTM F1980 and a number of other recognized standards.

> *Our simulated decontamination, sterilization, and storage areas are used in all packaging validation studies including: maintenance of packaging integrity (MPI), whole package integrity test, real time and accelerated shelf life testing.*

Event related real time shelf life testing is required by the FDA (minimum of 30 days) for all packaging systems. Testing demonstrates that the packaging system is effective at maintaining sterility of the internal contents following the proposed real time shelf life storage period.

Accelerated shelf life testing is effective in determining the ability of a packaging system to maintain the sterility and functionality of its internal contents if the system was to be exposed to a real time shelf life storage period. This study is limited in scope and does not test the effects of real time storage conditions on the devices but it can provide valuable information to assess the packaging system's capabilities while it concurrently undergoes a real time shelf life study.

Test Code	Test Name
AC- STERRAD	STERRAD Whole Package Integrity Test (Aerosol Challenge Test)
AC-ETO	EO Gas Whole Package Integrity Test (Aerosol Challenge Test)
AC-STEAM	Steam Whole Package Integrity Test (Aerosol Challenge Test)
AC-VPRO	V-PRO® Whole Package Integrity Test (Aerosol Challenge Test)
BE-ISO	Bubble Emission (ASTM F2096)
BT-ISO	Burst Test (ASTM F1140)
DM-ISO	Dye Migration (ASTM F1929)
SL-ACCEL	Accelerated Aging Shelf Life Study (ASTM F1980)
SL-ETO	ETO Real Time Shelf Life Study for: 30 days, 90 days, 180 days, 365 days or 2 years
SL-STEAM	Steam Real Time Shelf Life Study for: 30 days, 90 days, 180 days, 365 days or 2 years
SL-STERRAD	STERRAD Real Time Shelf Life Study for: 30 days, 90 days, 180 days, 365 days or 2 years
SL-VPRO	V-PRO Real Time Shelf Life Study for: 30 days, 90 days, 180 days, 365 days or 2 years
SL-SZ	STERIZONE® Real Time Shelf Life Study for: 30 days, 90 days, 180 days, 365 days or 2 years
SP-ISO	Seal Peel (ASTM F88)
AC-SZ	STERIZONE Whole Package Integrity Test (Aerosol Challenge Test)
BFE	Bacterial Filtration Efficiently (ASTM F2101)



Sterilization Efficacy & High Level Disinfection

Our test methodology follows the methods outlined in AAMI TIR 12, ANSI/AAMI/ISO 14937, ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO TIR 17665-2, ANSI/AAMI ST81, and ANSI/AAMI ST79 standards.

> *Reusable medical devices require sterilization efficacy validation in order to assure proper and safe reprocessing by health care personnel.*

The Overkill Method is typically selected to validate the sterilization efficacy of the challenge devices when exposed to the various sterilization process as indicated in the AAMI standards. In this method, sterilization is accomplished by demonstrating that a minimum of 1.0 x 10^6 highly resistant spores are killed in a half-cycle. A full cycle would therefore result in a 12-log reduction of spores and produce a 10^{-6} SAL, which reflects a one in a million chance of a non-sterile item and shows the device(s) can safely and effectively be sterilized in the process.

Disinfection studies are typically performed to validate a manufacturers' instructions for use when a semi-critical medical device is not amenable to physical sterilization processes (e.g., steam, dry heat, radiation) or gaseous chemical sterilization processes (e.g., ethylene oxide, hydrogen peroxide, ozone). Validations are performed in compliance with AAMI TIR12, ANSI/AAMI ST81, ANSI/AAMI ST58 and FDA guidelines.

High Temperature Sterilization

Test Code	Test Name
DT-STEAM	Steam Dry Time Study
SE-STEAM	Sterilization Efficacy Validation for Steam (gravity or dynamic air removal)
TP-STEAM	Steam Thermal Profile Study
TP-DRY	Dry Heat Thermal Profile Study
SE-DRY	Sterilization Efficacy Validation for Dry Heat

Low Temperature Sterilization

Test Code	Test Name
SE-ETO	Sterilization Efficacy Validation for Ethylene Oxide
SE-100S	Sterilization Efficacy Validation for STERRAD 100S Cycles
SE-100NX-STD	Sterilization Efficacy Validation for STERRAD 100 NX Standard
SE-100NX-DUO	Sterilization Efficacy Validation for STERRAD 100NX Duo
SE-100NX-EXP	Sterilization Efficacy Validation for STERRAD 100NX Express
SE-100NX-FLX	Sterilization Efficacy Validation for STERRAD 100NX Flex
SE-NX-STD	Sterilization Efficacy Validation for STERRAD NX Standard
SE-NX-ADV	Sterilization Efficacy Validation for STERRAD NX Advanced
SE-VPRO	Sterilization Efficacy Validation for STERIS V-PRO Low Temperature Sterilization Systems
SE-SZ	Sterilization Efficacy Validation for the STERIZONE VP4 Sterilizer

Miscellaneous

Test Code	Test Name
SE-COLD	Chemistry Immersion Efficacy (High Level Disinfectant/Sterilant)
TP-WASH	Thermal Disinfection—Ao Study
HLD	High Level Disinfection Study
ILD	Intermediate Level Disinfection Study
LLD	Low Level Disinfection Study

Materials Compatibility & Biocompatibility

We provide materials compatibility testing and reusability studies for a myriad of sterilization processes including: Steam, EtO, STERRAD, V-PRO, STERIZONE and High Level Disinfectants/Sterilants.

Our test methodology is based on methods outlined in AAMI TIR 12, AAMI TIR 17, and ANSI/AAMI ST79 standards. Materials Compatibility testing can also be referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse.

The device or material is subjected to one or more repetitive processing cycles. The cycles can include simulated cleaning, handling, packaging, and exposure to worst case sterilization parameters. The objective of this testing is to ensure the device can effectively maintain functionality and/or to identify any device degradation following repeated processing cycles.

After device exposure, biocompatibility testing according to ISO 10933-1 can be performed on the device for cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity and other applicable tests.

Test Code	Test Name
BIO-CYTO	Cytotoxicity Test—MEM Elution
BIO-CYTO-NRU	Cytotoxicity Test—Neutral Red Uptake
BIO-GENO	Genotoxicity Test
BIO-IRRI	Irritation Test, Intracutaneous Reactivity, 2 extracts
BIO-SENS	Sensitization Test, GPMT, 2 extracts
BIO-SYST	Systemic Toxicity Test, Acute Systemic Injection, 2 extracts
BIO-HEMOL	Blood Hemolysis Test, ISO 10993-4, (NIH Method)
BIO-TESTING	Custom Biocompatibility Test
MC-100NX	Materials Compatibility for STERRAD 100NX Cycles
MC-100S	Materials Compatibility for STERRAD 100S Cycles
MC-ETO	EtO Concentration run @ 446 mg/L, 567 mg/L, 735 mg/L or 759 mg/L
MC-NX	Materials Compatibility for STERRAD NX Cycles
MC-STEAM	Materials Compatibility for Steam Cycles
MC-VPRO	Materials Compatibility for V-PRO Cycles
MC-SZ	Materials Compatibility for STERIZONE Cycles
MC-COLD	Chemical Immersion Cycle (High Level Disinfectants)
RESID-H2O2	Residual Testing of Hydrogen Peroxide
RESID-ETO	Residual Testing of Ethylene Oxide
MC-WASH	Materials Compatibility Testing, Mechanical Washer—Repetitive Cleaning
MC-MANUAL	Materials Compatibility Testing, Manual Wash—Repetitive Cleaning

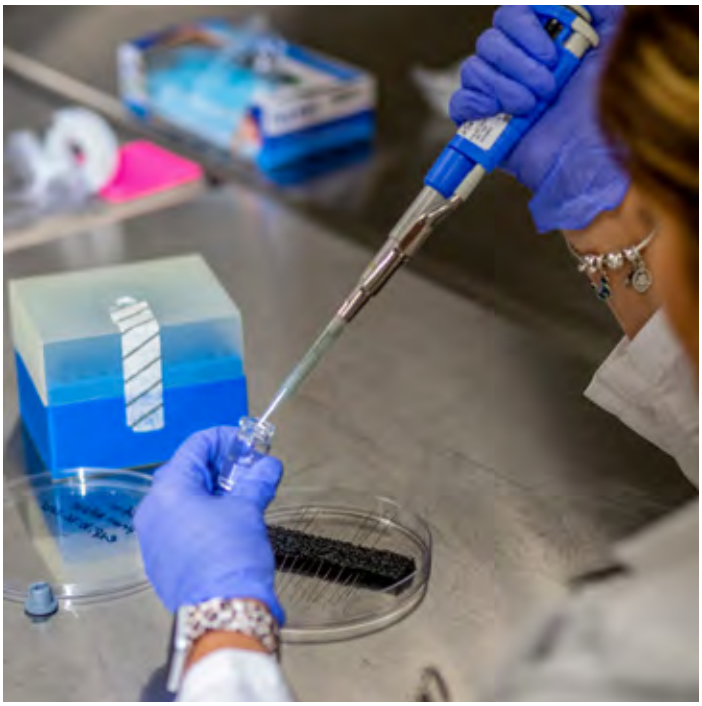
Microbiology

We provide an extensive breadth of microbiology testing including assessing the sterility of processed devices, determining device bioburden counts, and evaluating the performance of biological and chemical indicators using ISO compliant Steam, EtO and VHP resistometers.

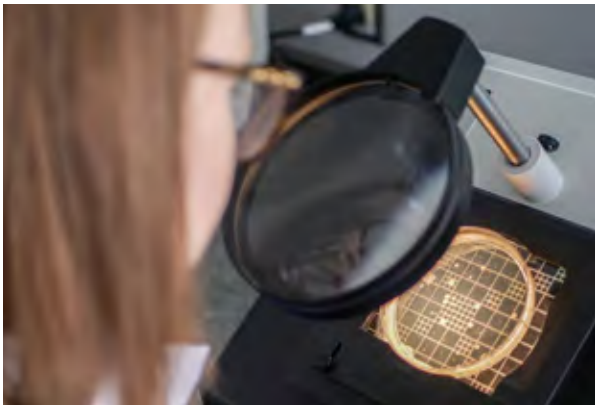
We routinely perform biological indicator testing, including verification for D-value analysis, survival/kill, population assay/viable spore count and purity testing for biological indicators.

We test indicators to Tables 2 through 4, 6 and 7 in ISO 11140-1 as well as individual test cycles for Type 1, 3, 4, 5 and 6 chemical indicators.

Our capabilities also include accessing the effectiveness of a Bowie Dick Test Pack to the ISO 11140-5 standard.



Test Code	Test Name
BI-ASSAY	Biological Indicator Population Verification • *Geo. stearothermophilus* • *B. atrophaeus* • *B. pumilus*
BI-DV-DRY	Dry Heat Biological Indicator D-value Analysis
BI-DV-ETO	EtO Biological Indicator D-value Analysis
BI-DV-STEAM	Steam Biological Indicator D-value Analysis
BIO-BURDEN	Article Bioburden Test
BI-PURITY	Biological Indicator Purity Test
BI-SK	Survival/Kill Test for Biological Indicators
CI-ISO1	Table 2 of ISO 11140-1— Steam Chemical Indicators
CI-ISO2	Table 3 of ISO 11140-1— Dry Heat Chemical Indicators
CI-ISO3	Table 4 of ISO 11140-1— ETO Chemical Indicators
CI-ISO5	Table 6 of ISO 11140-1— Steam/Formaldehyde Chemical Indicators
CI-ISO6	Table 7 of ISO 11140-1— VHP Chemical Indicators
RES-ETO	EtO Resistometer Cycle
RES-STEAM	Steam Resistometer Cycle
RES-VHP	VHP Resistometer Cycle
STERILITY	Article Sterility Test
BI-STERILITY	Sterility Culturing of Biological Indicators
BD-ISO	Bowie Dick Testing to ISO 11140-5



Human Factors Testing

Our test methodology follows the methods outlined in ANSI/AAMI HE: 75 and ANSI/AAMI IEC 62366 and a number of other recognized standards and FDA guidance documents. Successful development of safe and usable medical devices is of the utmost importance to device manufacturers and the FDA. The FDA is increasingly requesting Human Factors testing of devices as device manufacturers seek 510(k) approvals.

> *We have extensive experience in developing, hosting and moderating Human Factors Testing on-site in a controlled setting that simulates a functional central service department.*

This unique set of data can aid device manufacturers in assessing the effectiveness of their risk analysis and subsequent IFU listed in the device labeling. Our facility is set up to mimic instrument reprocessing departments within healthcare facilities and can readily accommodate additional equipment for Human Factors Testing.

Test Code	Test Name
HFACTOR	Human Factor Testing of: • Medical Devices • Dental Devices • Washers • Ultrasonic Cleaners • Rigid Containers and Rigid Containment Systems • Sterilizers


HIGHPOWER

CS Managers/Educators Needed — Human Factors Study For Surgical Devices

HIGHPOWER Validation Testing & Lab Services Inc. is recruiting participants for a Human Factors Study involving CS Managers/Educators who are involved with or oversee the reprocessing of reusable medical devices. This study involves the review of an IFU for the reprocessing of reusable medical devices. Qualifying Participants will be asked to complete a demographic/consent form and then complete a questionnaire based on the IFU for the device. If qualified through the Demographics/Consent form, you will be notified about the next steps to complete the study.

The participants in this study should be CS Managers/Educators who work in a Central Service Department within a healthcare setting. However, individuals with the background and/or experience managing and/or supervising a Central Service Department, may also be considered.

Participants should be familiar with the review of IFU's and know how to sterilize medical devices, as well as loading and packaging instruments used during surgery. They should be familiar with the procedures used to decontaminate, clean, process, assemble, store and distribute medical devices as supplies used in a patient care setting.

Participants should be familiar with the principles, methods and control of sterilization processes, the cleaning, processing, packaging, distributing, storing and inventory control of sterile instruments, trays, rigid containers and surgical equipment.

- A total of approximately 1-2 hours of your time is required.
- A total of approximately 1-2 hours of your time is required. Each participant to complete a demographics/consent
- [illegible] will require each participant to complete a demographics/consent and undertake a post interview phone call

Sterilizer Validations

We have a long history of aiding manufacturers in the regulatory approval process by performing a multitude of sterilizer validations. Validation will be performed by following the FDA's Sterilizer 510(k) Guidance document or the applicable American National Standards (ST-08 and ST-55).

Test Code	Test Name
VAL-ST55	AAMI ST-55 Steam Table-Top Sterilizer Validation
VAL-ST8	AAMI ST-08 Steam Hospital Sterilizer Validation
SIM-USE	Simulated Use Testing
IN-USE	In Use Testing

Washer Disinfector Validations

We validate mechanical washers to the American or International Standard (ANSI/AAMI 15883 or ISO 15883).

Test Code	Test Name
VAL-WD	Washer Disinfector Validation

Miscellaneous Tests

If the test you are looking for is not listed in this catalog, please contact Client Services to inquire on its availability. Many times we can perform the required test under one of our miscellaneous test codes. We would like to discuss your project with you and frequently increase our scope of testing work to meet the needs of our customers.

Test Code	Test Name
MS-CLEAN	Miscellaneous Cleaning
MS-MAT	Miscellaneous Materials Compatibility
MS-EFF	Miscellaneous Sterilization Efficacy & High Level Disinfection
MS-PKSL	Miscellaneous Packaging Systems/Shelf Life
MS-MICRO	Miscellaneous Microbiology

Training/Education

A commitment to best practices for instrument reprocessing has always been one of our core values. We have been serving on multiple AAMI committees and presenting at industry conferences for over 30 years. Having acquired a unique set of skills while working in class II medical device production, quality assurance, validation, research & development, and regulatory compliance, we are enthusiastic to share this knowledge and experience with you.

Our laboratory is set up to mimic instrument reprocessing departments within healthcare facilities, providing the ideal training environment for engineers, quality, regulatory, product managers and any personnel new to the industry.

> *We provide an opportunity to learn both in a classroom and in a hands-on setting for training, meetings, and collaboration. Although it's preferred to provide training at our facility, we can customize packages for training at our clients' facilities.*

Our team has developed a myriad of educational programs on reusable device cleaning, packaging and sterilization. These programs are based on industry best practices and can be tailored to meet the specific needs of our clients.

Test Code	Test Name
TRAIN	Educational Topics: • Medical Device Cleaning • Packaging Validations • Cleaning Validation • Sterilization Efficacy • Sterilizer Validations • Human Factors • Biological Indicators • Chemical Indicators

“The MDRAO Delta Chapter Education Day at Highpower was a great success. Our participants walked away with a better understanding of the testing and validation required before reusable instruments can touch the hands of an MDR technician.

Our host’s presentation was thorough and intriguing allowing for an opportunity for questions and answers. We will encourage our other chapters in Ontario to visit Highpower.

Thank you again for allowing us this rare opportunity to see the effort that goes on for testing and validation behind the scenes of the medical device reprocessing industry.”

Tony Leite,
MDRAO Delta Chapter President

HIGHPOWER Validation Testing & Lab Services

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