Science-Based Solutions for Ultrasound Probe Reprocessing

Clean • Disinfect • Transport • Store

CS Medical

About CS Medical

Founded in 2003, CS Medical LLC is a leader in developing, manufacturing, and marketing medical devices that are designed to clean and high-level disinfect ultrasound probes. Our focus is on delivering science-backed solutions that help healthcare professionals to minimize patient risk that could be associated with improperly reprocessed ultrasound probes.

Since our inception, CS Medical has pioneered the automated disinfection process. Our first product was designed to automate the high-level disinfection of transesophageal ultrasound probes. In 2005, the TD 100® was the first FDA cleared automated disinfection process with printed verification for transesophageal ultrasound probes.

For more than 15 years and over 8.7 million high-level disinfections, the TD 100 Automated TEE Probe Disinfector has eliminated manual high-level disinfection of delicate and expensive TEE ultrasound probes while also providing a repeatable and FDA cleared disinfection process. Continuing our quest to innovate, CS Medical designed, developed and obtained FDA clearance for TEEClean® automated cleaner disinfector in 2019. TEEClean continues TD 100's work by automating the manufacturer's required cleaning of the TEE probe before high-level disinfection. TEEClean, with electronic record data logging, printed verification reporting, FDA cleared cleaning and high-level disinfection is the standard of care for TEE ultrasound probes.

Setting the Standard for Reprocessing Ultrasound Probes

About CS Medical

In 2023, CS Medical obtained FDA clearance for the latest cleaner disinfector for ultrasound probes. Ethos® automated cleaner disinfector is designed to work with endocavity and surface ultrasound probes. Ethos was designed to remove the risk that exists when reprocessing endocavity and surface ultrasound probes per the Spaulding classification.

CS Medical's TEE Complete Care® and Complete Probe Reprocessing® products provide quality device care and storage by minimizing healthcare operational costs, improving service readiness, and increasing regulatory compliance. Both offerings are designed for compliance with manufacturer IFU's as well as both governmental and industrial standards for reprocessing of endocavity, surface, and transesophageal ultrasound probes.

Today, CS Medical provides science-based reprocessing solutions for endocavity, surface, and transesophageal ultrasound probes that include point-of-care or bedside cleaning, the automation of cleaning and disinfection, drying, storage, and transportation. CS Medical has now set the standard for complete probe reprocessing with Ethos automated cleaner disinfector and TEEClean automated cleaner disinfector.

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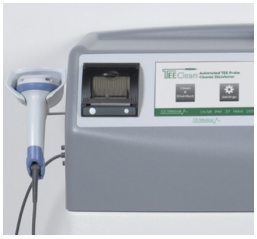
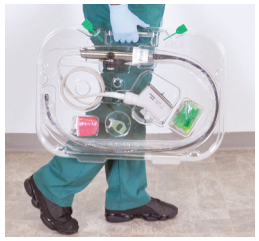
Clean and High-Level Disinfect in One Device Through Automation

Table of Contents





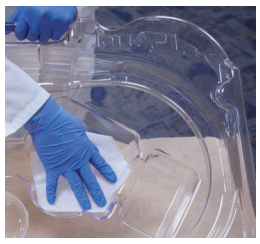
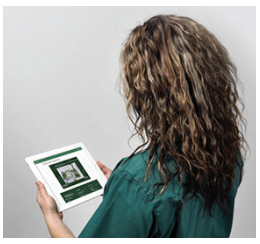


Table of Contents



Complete Probe Reprocessing®

Point-of-care Cleaning

Automated Probe Reprocessing

Probe Transport

Complete Probe Reprocessing®

Probe Storage

Disinfectants

Point-of-care Cleaning

Automated Probe Disinfection

TEE COMPL

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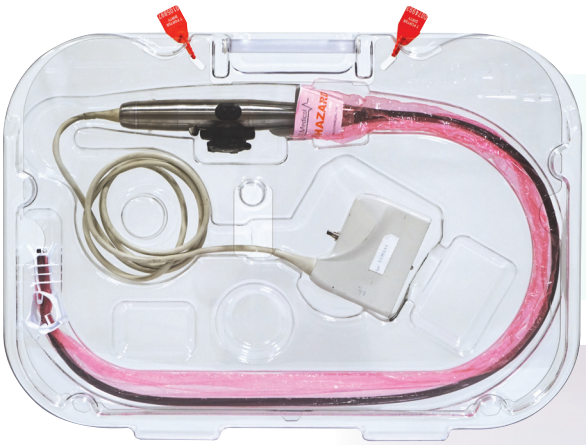

Probe Storage and Transport

Disinfectants

A User's Guide to kNOw the Risks Associated with Reprocessing Ultrasound Probes

Tami Gomez, Jessica Tharrington, Kendall Ashe, Tom Fischer, PhD.

It is not always obvious, but before embarking on almost any task, people undertake a risk assessment. One weighs the possible risks against the potential rewards and bases their decision on what happens on that scale. Unfortunately, humans are not the best at risk assessment[1]; too many people use their intuition to determine the best path forward, as opposed to taking a scientific approach. The problem lies in the fact that one's knowledge is limited and both sides of the scale are missing valuable data that could impact the outcome of the assessment.

When it comes to reprocessing transesophageal echocardiogram (TEE), Transvaginal (TV), Transrectal (TR) and surface ultrasound probes, one cannot afford to base decisions on gut feelings. The right way to determine what a facility's standard procedure for reprocessing these ultrasound probes is by gathering all the available data, analyzing each piece, and weighing the options. One must first know all the risks in order to ensure that there is no risk. This is not just important for a facility's integrity and bottom line, but for the patients it serves.

It may seem simple, but reprocessing ultrasound probes is quite an involved process, especially when trying to go about it the right way. There are ten individual elements that need to be examined carefully to determine and mitigate risk when reprocessing probes: transportation to and from the procedure room, bedside cleaning, cleaning, rinsing, high-level disinfection, electrical leakage testing (related to TEE probes), the drying method employed, storage of the probe, material compatibility, and staff.

Each one of these elements requires a significant amount of attention to every detail. If one step is skipped or inadequately performed, then the entire reprocessing procedure will be inadequate. This can result in serious and even life-threatening consequences. Failure to precisely carry out each step of the procedure can bring about risks to the ultrasound probe, the patient, and the facility.

When performing any step in the reprocessing procedure, it is possible to damage the probe handle, insertion tube, or distal tip. Damage to any of these components can result in different risks. For example, damage to the handle or the distal tip can result in the TEE probe malfunctioning, degraded images, or becoming nonfunctional. A puncture in the transducer lens can lead to fluid immersion or distorted image quality.

If the ultrasound probe's insertion tube is scraped or cut, it can harbor bacteria. Over time, that bacteria can form a biofilm, which is nearly impossible to remove from the insertion tube without causing further damage. Biofilms have been described as cities for microbes, enhancing and fostering growth and development. The Centers for Disease Control and Prevention (CDC) describe biofilms as, "Microbial communities that are tightly attached to surfaces and cannot be easily removed… Bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than are the same bacteria in suspension."[2] Because it can withstand high-level disinfection, biofilm presents a very real danger to patients who are immunocompromised.

When an ultrasound probe is damaged or its safety is compromised in any way, it must be either repaired or replaced. Not doing so jeopardizes patient health and safety and can even put your own staff at risk. Unfortunately, repairs can cost thousands of dollars and replacements can be tens of thousands of dollars. Anything you can do to prevent damaging these delicate and costly probes is worthwhile.

Reprocessing failures can also result in risks to patients. If an ultrasound probe is not fully and properly reprocessed, then it can harbor dangerous bacteria which can harm subsequent patients. The CDC estimates that about three percent of all hospital patients contract infections during their stay in the hospital; these are called healthcare associated infections (HAIs).[3] In one of the most staggering statistics provided by the CDC from their most recent hospital survey, "About 72,000 hospital patients with HAIs died during their hospitalizations."[4] An improperly reprocessed TEE probe leads to significant risk for a facility. In this social media age, a facility's reputation cannot afford mistakes. The Health Research Institute conducted a survey in which they found that about 25% of consumers have posted online about their healthcare experiences while 42% have used social media to access reviews of treatments, physicians, or facilities.[5] These reviews posted by patients impact the reputation of a facility or doctor's office significantly. As a result, each facility must constantly be providing the best service or risk ruining their name and standing in the community.

Failures in reprocessing can also lead to significant financial risk for a facility. Becker's Hospital Review reports that, "The total direct, indirect and nonmedical social costs of HAIs are estimated at around $96 billion to $147 billion annually, including loss of work, legal costs and other patient factors."[6] Due to changes in the law, the Centers for Medicare and Medicaid Services (CMS) will no longer pay for certain preventable complications, which includes many HAIs.[7] Now the entire financial burden will rest on the shoulders of each facility responsible for the transmission of an HAI.

Additionally, a facility may be held legally responsible for the transmission of an HAI. This could result in lawsuits and years of trouble ahead. In fact, Becker's Hospital Review reports, "The typical hospital is the target of seven HAI-related lawsuits per year with an average settlement of $1.5 million."[8] The financial hazard associated with reprocessing ultrasound probes is avoidable if steps are taken to mitigate the risks, but first, one needs to be aware of the risks. By carefully analyzing each of the ten elements previously mentioned, best practices can be incorporated into standard operating procedures, the best equipment for each job can be utilized, and risk can be significantly diminished. Ultimately, the goal of all this effort is improved outcomes for a facility's reputation, finances and, most importantly, patients. By adding a science based approach with full automation of both cleaning and high-level disinfection you can reduce the potential for improperly reprocessed ultrasound probes coming into contact with future patients.

kNOw RISK

References

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3 https://www.cdc.gov/hai/eip/antibiotic-use.html
4 https://www.cdc.gov/hai/data/portal/index.html
5 https://www.pwc.com/us/en/health-industries/health-research-institute/publications/pdf/health-care-social-media-report.pdf
6 https://www.beckershospitalreview.com/quality/how-hais-lead-to-direct-indirect-and-unintended-hospital-costs.html
7 https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond?redirect=/hospitalacqcond/01_overview.asp#TopOfPage
8 https://www.beckershospitalreview.com/quality/hospital-acquired-infections-by-the-numbers.html

Ethos®
CLEAN • DISINFECT

Exceeding expectations, reducing risk, and improving patient outcomes by performing cleaning and high-level disinfection in a single device.

Ethos Automated Ultrasound Probe Cleaner Disinfector is the first product of its kind to be cleared by the US FDA. Ethos provides both manufacturers recommended cleaning and high-level disinfection of soiled endocavity and surface ultrasound probes in the same device.

Once the ultrasound probe is placed into Ethos and data is entered into the microprocessor, reprocessing begins. The probe is first rinsed free of any gel or debris while the cleaning and disinfection liquid is being prepared and MRC is being validated automatically.

Features:

- Validated and FDA cleared cleaning method for endocavity and surface probes
- Validated and FDA cleared high-level disinfection method for endocavity and surface probes
- High-level disinfection in 3 minutes
- Automatic MRC testing, no manual strip or chip to read
- 7" Color Touch Screen LCD with vivid user icons for easy operation
- 5 nanometer filtered rinse water (0.005 micron) — FDA cleared Class II medical device
- Advanced vapor management system
- Data entry with integrated barcode scanner or manual keyboard entry
- Printed disinfection and maintenance record with integrated printer
- Tracking of maintenance events with reminders to improve device readiness and uptime
- Electronic record logging of all cleaning, disinfection, and maintenance events for download, retention of over 15,000 records held in memory

Benefits:

- Validated and repeatable cleaning and high-level disinfection
- Reduced handling of ultrasound probe
- Electronic record retention
- Simplified workflow

U.S. Patent No. 11,660,362

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ethos®
CLEAN · DISINFECT

Clean and disinfect in 3 minutes!

Record Retention

Ethos provides electronic records retention of the clean and disinfection cycle and records device maintenance events. A printed record is provided with the built-in thermal printer.

Water Filter

5 nanometer (0.005 micron) water filter that removes bacteria, viruses and endotoxins from the facility water supply for the rinse cycles.

QwikCheck™ Liquid Chemical Indicator

Ethos performs an automatic MRC test to ensure the AquaCide cleaner high-level disinfectant has the minimum required concentration to achieve high-level disinfection in 3 minutes.

LCD Touchscreen

A 7-inch color LCD touch display with animated help screens and simple process steps and status during operation.

HLD Disinfection

Ethos utilizes a single-use granulated PAA formulation named AquaCide®. AquaCide is mixed within the device and MRC is determined automatically. The PAA formulation generates a cleaner disinfectant that has a pH range between 8.5 and 9.0. Ethos achieves high-level disinfection in 3 minutes.

Clean and disinfect in one device!

Ethos®: Setting Standards — Exceeding Expectations

Actual size shown

Current methods require manual cleaning to be completed so as to achieve proper high-level disinfection. Ethos allows the healthcare professional to simply place a point-of-care cleaned endocavity/surface probe into the device, removing the potential of an ineffectively cleaned probe being high-level disinfected. Ethos provides both a scientifically verified and repeatable method for cleaning of soiled probes.

A large, 7-inch color LCD touchscreen provides the healthcare technician with vivid icons to operate Ethos. The LCD prompts the user, step by step, how to set up the Ethos in order to properly clean and disinfect the soiled probe.

Ethos will incorporate this data as part of the electronic record that is retained in system memory and later printed out on the verification report generated at the conclusion of a successful reprocessing cycle. The electronic log contains all data entered into the device, as well as all parameters that are maintained during the cleaning and disinfection cycles of the process. The electronic record can be downloaded onto a computer and saved or printed for later reference or audit. Ethos can manage over 15,000 disinfection logs within the system memory.

The healthcare technician, once all the necessary information has been entered into Ethos, can walk away and allow the microprocessor controlled device to begin the process of cleaning, disinfecting, and rinsing the inserted soiled probe without any additional interaction.

Ethos® Automated Ultrasound Probe Cleaner Disinfector

The RESULTS-

Adding Ethos to your workflow takes the guesswork out of reprocessing ultrasound probes. No more wondering if the probe was properly cleaned prior to high-level disinfection. Ethos maintains an electronic record of the process. The electronic records are stored with over a 15,000 record capacity maintained in system memory. Additionally, at the conclusion of a successful cleaning and disinfection cycle the printed receipt will provide an immediate visual confirmation of the process.

The printed receipt contains the following information:

- PASSED Probe Cleaned and Disinfected
- Run number
- Date of cleaning and disinfection
- Time of cleaning and disinfection
- Indication that point-of-care cleaning occurred and within 1-hour of extraction from patient
- Operator number and name
- Probe number, serial number, and description
- Chemical indicator lot number and expiration date used to verify MRC of AquaCide®
- AquaCide lot number and expiration date used to clean and high-level disinfect endocavity or surface probe
- Time and temperature of the cleaning and high-level disinfectant during the reprocessing cycles
- Required maintenance time for QwikCheck chemical indicator, water filter, debris filter, and vapor filter
- Days until annual verification and cycles until PM is printed

ETHOS SN: 30100010

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PASSED

PROBE CLEANED AND DISINFECTED

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RUN NO: 00000158

DATE: 21 JUN 2023
TIME: 09:56:42 AM

POINT OF CARE CLEANING PERFORMED: YES
MANUFACTURER'S CLEANING: N/A

OPERATOR NO: 15
OPERATOR NAME: LORETTA KILLON

PROBE NO: 10
PROBE SN: 123456
PROBE DESC: RIC5-9

QWIKCHECK LOT NO: 1234
QWIKCHECK EXP DATE: JUN 2023

AQUACIDE LOT NO: 23674
AQUACIDE EXP DATE: SEP 2024

MRC: PASSED

AVG CLEAN & DISINF TEMP: 051.0
RANGE: > 45.0 C
CLEAN & DISINF TIME: 0185
RANGE: > 180 Sec.

MAINTENANCE REQUIRED IN:

QWIKCHECK USES LEFT: 53
QWIKCHECK DAYS LEFT: 10
WATER FILTER DAYS LEFT: 84
DEBRIS FILTER DAYS LEFT: 23
VAPOR FILTERS DAYS LEFT: 358

DAYS UNTIL YEARLY VERIFICATION: 355
CYCLES UNTIL PM: 4969

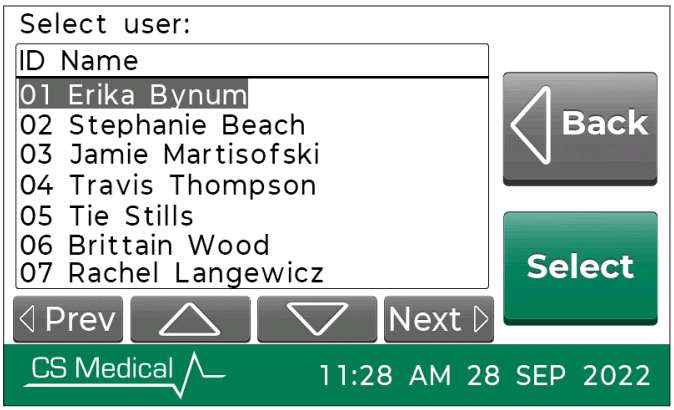
REMARKS:

1 **ONE DEVICE**
Clean and Disinfect with confidence

Using Ethos® is simple

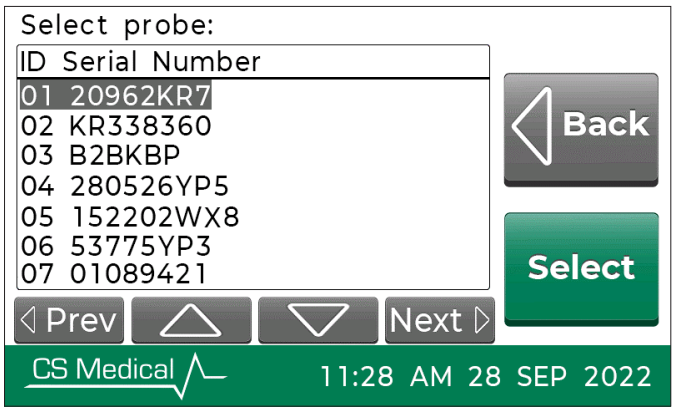
One minute of the technician's time to interact with Ethos will begin the process of cleaning and high-level disinfecting soiled ultrasound probes. Simple data input in one of three ways allows for quick and accurate setup. Ethos allows for either scanning input, selecting from a list, or manual entry.

An added advantage to Ethos is the MRC testing is fully automated — no end user interaction required.



Select User

Ethos stores user names and assigns user numbers to all trained technicians that use the device. Selection of user is done with scanning of a barcode associated with the user number or through a manual lookup on the LCD touchscreen. Users can be easily added or deleted for administrative purposes. The user name and number are printed on each verification report. Ethos will manage up to 99 unique users.



Select Probe

Ethos stores a list of all probes that could be cleaned and disinfected with the device. The reprocessing technician can simply scan a barcode for the soiled probe or select the correct probe from the list via the color touchscreen. Ethos will manage up to 99 individual probes.

Automated Ultrasound Probe Cleaner Disinfector

AquaCide® Cleaner Disinfectant

CS Medical's AquaCide is a granulated peracetic acid based cleaner disinfectant used with the Ethos® cleaner disinfector. Ethos is a microprocessor-controlled high-level disinfection method for endocavity and surface ultrasound probes.

The cleaner disinfectant is peracetic acid based with an anticorrosive agent, detergent, and other inactives supplied in a single-use container. The container is punctured at the time of use, immediately prior to closing the door and initiating the cycle. The AquaCide solution has an at use concentration of 3,500 ppm of peracetic acid, with a pH of 8.5 to 9.0, within the Ethos disinfection chamber at a temperature of at least 47°C. The peracetic acid solution is circulated within the system of the device for 3 minutes, cleaning and high-level disinfecting the ultrasound probe.

CATALOG NUMBER	DESCRIPTION
CS-AQ-3	AquaCide Cleaner Disinfectant, 50 bottles per case

QwikCheck™ Liquid Chemical Indicator

CS Medical's QwikCheck Liquid Chemical Indicator provides a rapid, convenient means of indicating the concentration of peracetic acid (PAA) of AquaCide when used in the Ethos cleaner disinfector.

QwikCheck liquid chemical indicator solution is designed exclusively for Ethos automated ultrasound probe cleaner disinfector and provides an effective and clear indication of concentration of the cleaner high-level disinfectant solution, AquaCide. Ethos samples the AquaCide solution by mixing a measured quantity of QwikCheck with AquaCide to determine if the minimum recommended concentration of 1750 ppm is exceeded prior to allowing Ethos to move into the cleaning and high-level disinfection stage.

Through automation and advanced electronics Ethos automatically determines if AquaCide is ready to achieve high-level disinfection of the soiled ultrasound probe in just 3-minutes. Ethos cleaner disinfector removes the potential failure points of manual test strips or chips that require the end user to read a color change or to remember to complete the step all together.

Automated MRC

The QwikCheck Liquid Chemical Indicator is an automated solution to determine whether the concentration of peracetic acid, the active ingredient in CS Medical's AquaCide cleaner disinfectant, is above minimum recommended concentration (MRC) of 1750 ppm.

CATALOG NUMBER	DESCRIPTION
CS-202790	QwikCheck Liquid Chemical Indicator, 4 bottles per case

TEEClean®

AUTOMATED TEE PROBE CLEANER DISINFECTOR

TEEClean® Automated TEE Probe Cleaner Disinfector is the first product of its kind to be cleared by the US FDA. Designed exclusively for transesophageal echocardiogram ultrasound probes (TEE), TEEClean accomplishes both the manufacturers recommended cleaning and high-level disinfection of soiled TEE probes in the same device.

U.S. Patent No. 10,238,760

Features:

- Validated and FDA cleared cleaning method for TEE probes
- Validated and FDA cleared high-level disinfection method for TEE probes
- 5-minute high-level disinfection of TEE probes
- TEEZyme® enzymatic cleaning solution
- 7" LCD color touchscreen display with vivid user icons for easy operation
- Data entry with integrated barcode scanner or manual keyboard entry
- Printed disinfection and maintenance record with integrated printer
- Electronic record logging of all cleaning, disinfection, and maintenance events for download, retention of over 15,000 records held in memory
- 5 nanometer filtered rinse water (.005 micron) — FDA cleared Class II medical device
- Advanced vapor management system
- Full system high-level disinfection for added preventative maintenance

Benefits:

- Validated and repeatable cleaning and high-level disinfection
- Reduced TEE probe handling
- Electronic record retention
- Simplified workflow

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Clean and High-Level Disinfect

User Interaction
TEEClean® offers the ability to scan user, disinfectant, probe, cleaner, filters and maintenance activities into system memory or manually type with a full sized key pad on the 7 inch color LCD touchscreen

Record Retention
TEEClean provides electronic records retention of the clean and disinfection cycle and records device maintenance events. A printed record is provided with the built-in thermal printer

LCD Touchscreen
A 7-inch color LCD touch display with animated help screens and simple process steps and status during operation

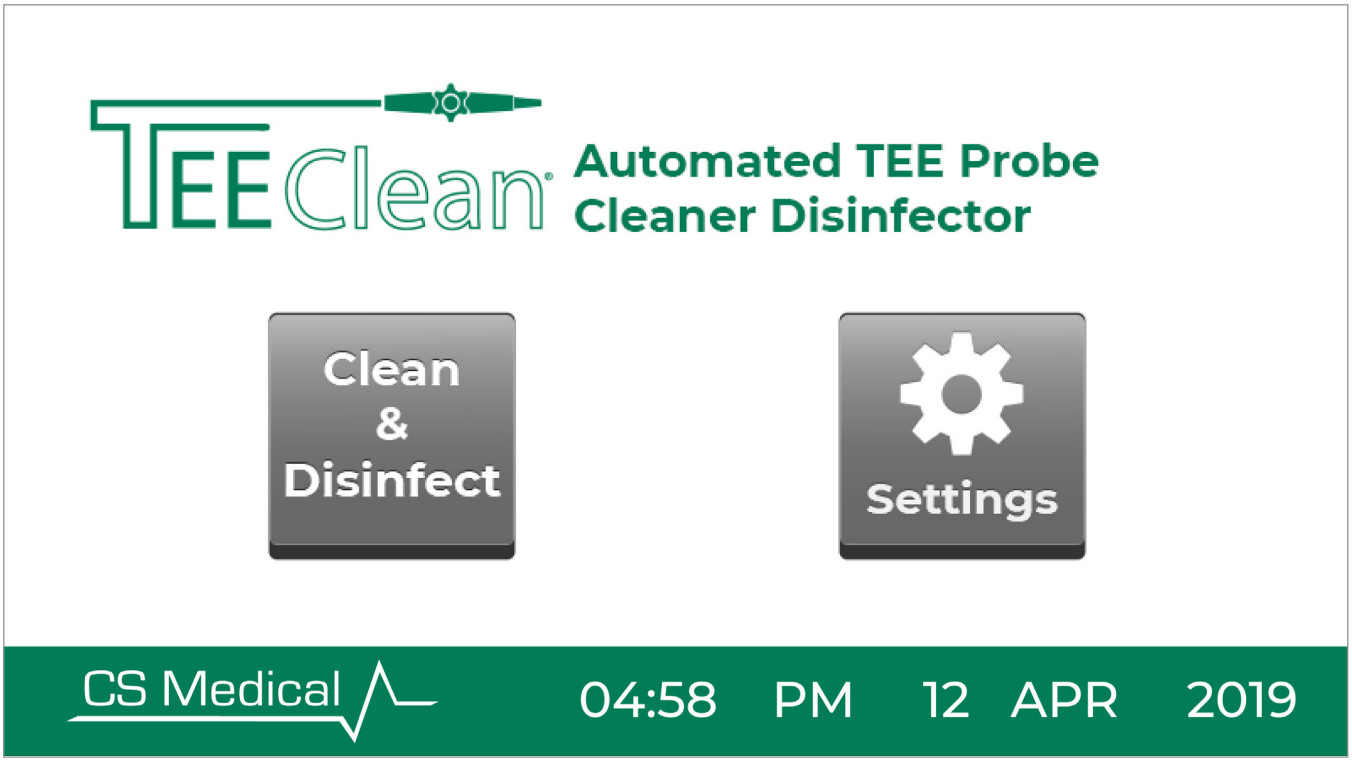
Water Filter
5 nanometer (.005 micron) water filter that removes bacteria, viruses and endotoxins from the facility water supply for the rinse cycles

HLD Disinfectant
Single-use high-level disinfectant eliminates the use of test strips to confirm MRC- no added hassle or objective determination of pass or fail- removes risk of disinfectant efficacy

TEEZyme®
An enzymatic solution to remove soil from inserted TEE ultrasound probe

TEEClean: Setting Standards — Exceeding Expectations

Current methods require manual cleaning to be completed so as to achieve proper high-level disinfection. TEEClean allows the healthcare professional to simply place a bedside cleaned TEE probe into the device, removing the potential of an ineffectively cleaned TEE probe being high-level disinfected. TEEClean provides both a scientifically verified and repeatable method for cleaning of soiled TEE probe.



7-inch color LCD touchscreen

A large, 7-inch color LCD touchscreen provides the healthcare technician with vivid icons to operate TEEClean. The LCD prompts the user, step by step, how to set up the TEEClean in order to properly clean and disinfect the soiled TEE Probe. The user will scan or manually enter the following data for each cycle.

- TEE probe identifier
- User identifier
- Disinfectant type and lot number
- Electrical leakage test results

TEEClean will incorporate this data as part of the electronic record that is retained in system memory and later printed out on the verification report generated at the conclusion of a successful reprocessing cycle. The electronic log contains all data entered into the device, as well as all parameters that are maintained during the cleaning and disinfection cycles of the process. The electronic record can be downloaded onto a computer and saved or printed for later reference or audit. TEEClean can manage over 15,000 disinfection logs within the system memory.

The healthcare technician, once all the necessary information has been entered into TEEClean, can walk away and allow the microprocessor controlled device to begin the process of cleaning, disinfecting, and rinsing the inserted soiled TEE probe without any additional interaction.

Fast and Easy to Use

To use TEEClean simply place the bedside enzymatically treated, soiled TEE Probe directly into TEEClean, no additional steps required. Then, by following simple prompts on the color LCD display, the healthcare professional will enter information about the probe, disinfectant chemistry used for high-level disinfection and if the probe passed electrical leakage testing. This data in addition to other system data will be printed on the reprocessing report at the conclusion of a completed cleaning and disinfection cycle. For the healthcare facility and technician TEEClean removes the unknowns that exists with manual enzymatic cleaning and provides an added level of confidence that each TEE probe is receiving the same care during cleaning and disinfection.

Soiled TEE Probe is placed directly into TEEClean

Electrical Leakage Testing

Incorporated into the TEEClean workflow is the function of electrical leakage testing. The healthcare professional can elect to perform electrical leakage testing within the TEEClean reservoir or skip electrical leakage testing if not required by their healthcare facility. If elected to conduct the electrical leakage testing the healthcare professional will insert the conductive probe into the TEEClean reservoir and follow the steps for electric leakage testing provided by the manufacturer. Once complete, TEEClean will ask for the results of the test and will then record them in the electronic record file as well as incorporating the results on the printed record at the conclusion of the cleaning and disinfecting cycle.

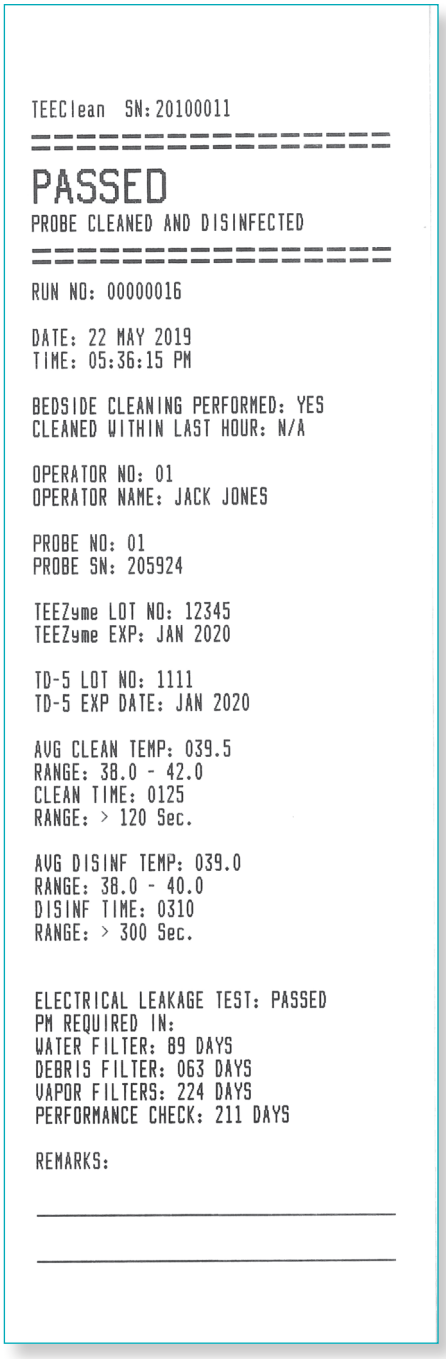
Electrical leakage testing can be performed while inside TEEClean

The RESULTS-

Adding TEEClean to your workflow takes the guess work out of reprocessing TEE ultrasound probes. No more wondering if the probe was properly cleaned prior to high-level disinfection. TEEClean maintains an electronic record of the process. The electronic records are stored with over a 15,000 record capacity maintained in system memory. Additionally, at the conclusion of a successful cleaning and disinfection cycle the printed receipt will provide an immediate visual confirmation of the process.

The printed receipt contains the following information:

- PASSED Probe Cleaned and Disinfected
- Run number
- Date of cleaning and disinfection
- Time of cleaning and disinfection
- Indication that bedside cleaning occurred and within 1 hour of extraction from patient
- Operator number and name
- Probe number and serial number
- Lot number and expiration date of TEEZyme used to clean the soiled TEE probe
- Disinfectant type, lot number, and expiration date used to high-level disinfect cleaned TEE probe
- Time and temperature of TEEZyme during the cleaning process
- Time and temperature of the high-level disinfectant during the disinfection process
- Electrical leakage test results
- Required PM time remaining for water filter, debris filter, and air filter



TEEClean Automated TEE Probe Cleaner Disinfector is the new standard in TEE Probe reprocessing and care.

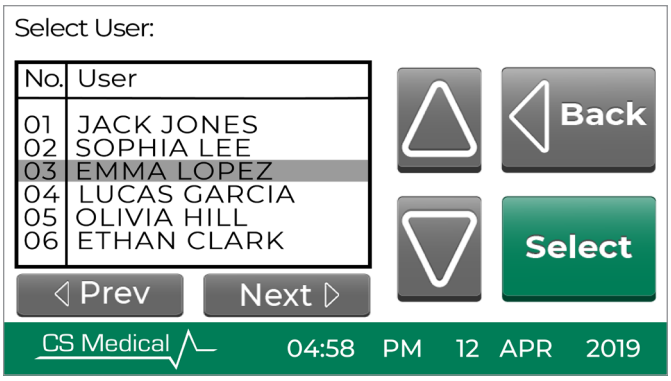
Why wouldn't you TEEClean when it is this simple and validated to ensure your TEE probes are cleaned and high-level disinfected each and every time, the same way!

Using TEEClean is simple.

One minute of the technician's time to interact with TEEClean will begin the process of cleaning and high-level disinfecting a soiled TEE ultrasound probe.

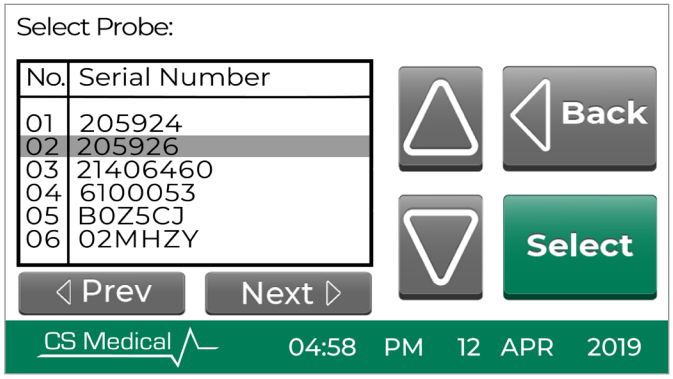
Select User

TEEClean stores user names and assigns user numbers to all trained technicians that use the device. Selection of user is done with scanning of a barcode associated with the user number or through a manual lookup on the LCD touchscreen. Users can be easily added or deleted for administrative purposes. The user name and number are printed on each verification report. TEEClean will manage up to 99 unique users.



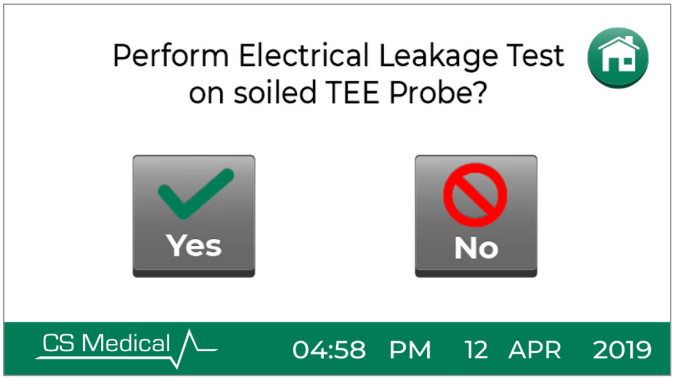
Select Probe

TEEClean stores a list of all TEE probes that could be cleaned and disinfected with the device. The reprocessing technician can simply scan a barcode for the soiled TEE probe or select the correct probe from the list via the color touchscreen. TEEClean will manage up to 99 individual TEE probes.



Perform Electrical Leakage Test

TEEClean provides prompts to reprocessing technician for completion of electrical leakage testing. Electrical leakage testing results are then recorded in TEEClean by the technician and then printed on the verification record as well as stored in system memory. These records can be retrieved later, if desired.



*TEEClean® is the first **A**utomated **U**ltrasound **R**eprocessor cleared by the US FDA.*

TD 100®

TEE PROBE DISINFECTOR

The TD 100® Automated TEE Probe Disinfector is designed to provide high-level disinfection of transesophageal (TEE) ultrasound probes. The TD 100 disinfects each TEE probe with either TD-5 or TD-8 disinfectant. These disinfectants are single-use and require NO MRC test strip to validate efficacy.

Features:

- 5 minute high-level disinfection cycle
- Microprocessor-controlled for ease of use by medical professionals
- Advanced vapor management system that captures and neutralizes disinfectant fumes
- Five individual rinse cycles after disinfection cycle is complete
- Single-use, 16 oz. high-level disinfectant
- No down time waiting for high-level disinfectant to reach temperature
- Repeatable, verified disinfection cycle
- Printed record of successful disinfection cycle
- Full diagnostic check of each disinfection cycle
- NO MRC testing necessary for high-level disinfectant

24/7
365

On demand web-based training

www.csmedicalllc.com info@csmedicalllc.com

High-Level Disinfect TEE Probes in 5 minutes!

Over 11.87 million successful high-level disinfections to date

Printed Verification
Upon a successful disinfection cycle, a printed confirmation is provided that includes the average disinfectant temperature, disinfectant contact time, disinfectant lot number, operator and probe ID, and time and date of disinfection.

Touch Pad Interface
Vividly labeled keypad with clear prompts on the LCD guiding the user through the process in less than one minute.

Automatic Waste Disposal
Upon completion of the disinfection cycle, the TD 100 automatically pumps disinfectant to drain and eliminates the potential for over-soaking the TEE probe.

Probe and High-Level Disinfectant Holder
Custom, form fitted holders safely and securely hold the TEE probe to minimize potential probe damage. The high-level disinfectant container is held securely to deliver the exact measured dose for proper high-level disinfection.

Gas Phase Bonded Filter
Chemisorptive bonded gas phase filter eliminates exposure to harmful fumes and vapors associated with the high-level disinfectant.

U.S. Patent No. 7,641,873

Cost Saving

The TD 100 generates significant savings both in labor time and cycle time. The device setup requires less than one minute of operator interaction, while the whole disinfection and rinse cycle is completed in less than 17 minutes. The TEE ultrasound probe is held within the disinfection reservoir and once the cycle starts the staff member can resume other duties while the TD 100 reprocesses the probe.

The TD 100, with the advanced vapor management system, can be installed near the TEE procedure room. This will allow for minimal transportation of the delicate probes for reprocessing. When compared to manual reprocessing, the TD 100 allows more procedures with the same probe, while reducing stress and potential damage to probes.

TD-5 and TD-8 reduce cost and concerns of efficacy as no MRC test strip is required.

Protects Your Probes

The TD 100 dramatically reduces the amount of stress and the potential for damage to TEE probes. The system was designed with every aspect of the TEE probe taken into consideration. The control handset is held securely within the TD 100, while strain and stress is minimized from the cable and electronic pack adapter with a specially designed hanger and mounts for both.

The TD 100 suspends the TEE probe in a custom fitted bracket that holds the control handle securely while the insertion shaft of the probe is placed within the disinfection reservoir for high-level disinfection. The TD 100 is designed to prevent oversoaking as this is the second leading reported damage to TEE probes beyond being dropped or struck by another object.

Manual reprocessing can expose your TEE probes to this type of expensive damage.

The following is a manufacturer's warning for TEE probes:

"Do not use a transducer that has been dropped or struck against another object. The transducer is fragile and will break ….this is not covered by the probe warranty or service contract."

Automated TEE Probe Disinfector

Protects Your Staff

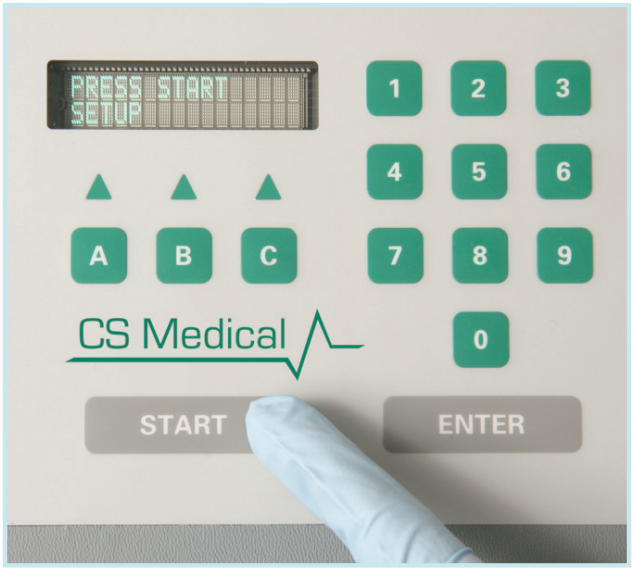
The TD 100 utilizes a dedicated single-use 16 oz. bottle of disinfectant. The high-level disinfectant container seal is opened inside the machine. The TD 100 was engineered with an advanced vapor management filtration system that adsorbs and neutralizes vapors released during the high-level disinfection process. Splashes and spills are trapped within the disinfectant reservoir while the fumes are captured by the advanced vapor management system to minimize operator exposure. The TD 100 uses a fresh bottle of high-level disinfectant each cycle eliminating the need for a healthcare professional to conduct MRC testing and have the potential of exposure to the high-level disinfectant vapors. The TD 100 was engineered to provide unsurpassed operator safety from exposure to high-level disinfectant vapors.

Printed Verification

The TD 100 performs continuous self-diagnostic tests that confirm the result in a printed report after each cycle. The successful disinfection record contains the date, time, disinfectant type, disinfectant lot number, disinfectant contact time, average disinfectant temperature, and both the operator and probe identification. The verification ticket can be recorded in the HLD TRACKER™ provided by CS Medical for audit purposes. If needed, additional copies of the record can be printed directly from the device and used to accompany the disinfected TEE ultrasound probe to the procedure room. The HLD TRACKER, found on page 49, can also be used to document electrical leakage testing results as well as pertinent patient information.

Fast & Easy to Use

After inserting an enzymatically cleaned and dried TEE probe into the TD 100, you simply follow the clear prompts on the display. This takes less than one minute to enter operator and probe details that will be printed on the verification report along with the contact time and average disinfectant temperature at the completion of a successful disinfection cycle. The TD 100 automatically continues the process of high-level disinfection followed by five cold water rinses for a total of 17 minutes of total reprocess time. When comparing that to the labor intensive manual process for disinfection and rinsing the TD 100 is extremely efficient and provides a repeatable result. Additionally, the high-level disinfectant used in the TD 100 is single-use and does not require the staff member to perform a MRC test on the solution to confirm efficacy prior to high-level disinfection.



TD 200®

TEE PROBE DISINFECTOR

In only 3 minutes, the TD 200® delivers high-level disinfection to clean TEE ultrasound probes. The TD 200 automated TEE probe disinfector uses a propriety granulated biocide, TD-12®, which is constituted in the TD 200. The process is self-contained and simple to operate allowing the technician to reprocess a TEE probe with confidence. Total cycle time of the TD 200 is 12 minutes once the probe and TD-12 container has been inserted into the device.

Features:

- High-level disinfection complete in 3 minutes
- Microprocessor-controlled for ease of use by medical personnel
- Single-use high-level disinfectant, granulated formula
- Repeatable, verified disinfection cycle
- Built-in advanced vapor management system captures disinfectant fumes
- Printed record includes TD 200 serial number, disinfection cycle count number, time/date, contact time of TD-12, and temperature of TD-12 during HLD

24/7
365

On demand web-based training

www.csmedicalllc.com info@csmedicalllc.com

High-Level Disinfection in 3 minutes!

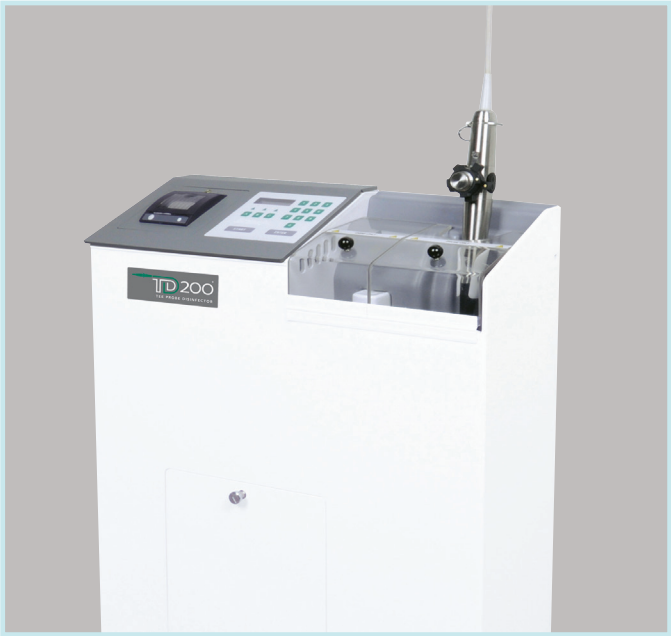
Printed Verification
Upon a successful disinfection cycle, a printed confirmation is provided that includes the average disinfectant temperature, disinfectant contact time, disinfectant lot number, operator and probe ID, and time and date of disinfection.

Touch Pad Interface
Vividly labeled keypad with clear prompts on the LCD guiding the user through the process in less than one minute.

Automatic Waste Disposal
Upon completion of the disinfection cycle, the TD 200 automatically pumps disinfectant to drain and eliminates the potential for over-soaking the TEE probe.

Probe and High-Level Disinfectant Holder
Custom, form fitted holders safely and securely hold the TEE probe to minimize potential probe damage. The high-level disinfectant container is held securely to deliver the exact measured dose for proper high-level disinfection.

Gas Phase Bonded Filter
Chemisorptive bonded gas phase filter eliminates exposure to harmful fumes and vapors associated with the high-level disinfectant.



Cost Saving

The TD 200 generates significant savings both in labor time and cycle time. The device setup requires less than one minute of operator interaction, while the whole disinfection and rinse cycle is completed in less than 12 minutes. The TEE ultrasound probe is held within the disinfection reservoir and once the cycle starts the staff member can resume other duties while the TD 200 reprocesses the probe.

The TD 200, with the advanced vapor management system, can be installed near the TEE procedure room. This will allow for minimal transportation of the delicate probes for reprocessing. When compared to manual reprocessing, the TD 200 allows more procedures with the same probe, while reducing stress and potential damage to probes.

Protects Your Probes

The TD 200 dramatically reduces the amount of stress and the potential for damage to TEE probes. The system was designed with every aspect of the TEE probe taken into consideration. The control handset is held securely within the TD 200, while strain and stress is minimized from the cable and electronic pack adapter with a specially designed hanger and mounts for both.

The TD 200 suspends the TEE probe in a custom fitted bracket that holds the control handle securely while the insertion shaft of the probe is placed within the disinfection reservoir for high-level disinfection. The TD 200 is designed to prevent oversoaking as this is the second leading reported damage to TEE probes beyond being dropped or struck by another object.

Manual reprocessing can expose your TEE probes to this type of expensive damage.

The following is a manufacturer's warning for TEE probes:

"Do not use a transducer that has been dropped or struck against another object. The transducer is fragile and will break ….this is not covered by the probe warranty or service contract."

Automated TEE Probe Disinfector

Protects Your Staff

The TD 200 utilizes a dedicated single-use granulated high-level disinfectant tht is prepared inside the device. The high-level disinfectant container seal is opened inside the machine. The TD 200 was engineered with an advanced vapor management filtration system that adsorbs and neutralizes vapors released during the high-level disinfection process. Since the HLD is generated inside the reservoir, fumes are captured by the advanced vapor management system to minimize operator exposure. The TD 200 was engineered to provide unsurpassed operator safety from exposure to high-level disinfectant vapors.

Printed Verification

The TD 200 performs continuous self-diagnostic tests that confirm the result in a printed report after each cycle. The successful disinfection record contains the date, time, disinfectant type, disinfectant lot number, disinfectant contact time, average disinfectant temperature and both the operator and probe identification. The verification ticket can be recorded in the TD 200 Log Book provided by CS Medical for audit purposes. If needed, additional copies of the record can be printed directly from the device and used to accompany the disinfected TEE ultrasound probe to the procedure room. The TD 200 Log Book, found on page 49, can also be used to document electrical leakage testing results as well as pertinent patient information.

Fast & Easy to Use

After inserting an enzymatically cleaned and dried TEE probe into the TD 200, you simply follow the clear prompts on the display. This takes less than one minute to enter operator and probe details that will be printed on the verification report along with the contact time and average disinfectant temperature at the completion of a successful disinfection cycle. The TD 200 automatically continues the process of high-level disinfection followed by a single cold water rinse for a total of 12 minutes of total reprocess time. When comparing that to the labor intensive manual process for disinfection and rinsing the TD 200 is extremely efficient and provides a repeatable result. The high-level disinfectant used in the TD 200 is single-use.

TD-5® and TD-8® Single-Use Disinfectant

When determining the right disinfectant for your TD 100® or TEEClean®, remember that both the TD-5® (2.65% glutaraldehyde formula) and TD-8 ®(0.59% Ortho-phthalaldehyde (OPA) formula) have the same exact indications for use and perform identically inside the TD 100 or TEEClean. Both TD-5 and TD-8 chemistries are heated and held in contact with the TEE probe for 5 minutes. Both TD-5 and TD-8 have been cleared by the FDA for use in the TD 100 or TEEClean to high-level disinfect TEE probes by a trained professional.

The packaging design is simple and safe to use as the single-use, one-pint container is pierced inside the machine. Chemical splashes, spills, and vapors are contained through an advanced vapor management system within the TD 100 or TEEClean.

MRC Test Strips NOT REQUIRED

TD-5

The TD-5 disinfectant is a single-use, 2.65% glutaraldehyde based, high-level disinfectant that when used with the TD 100 or TEEClean provides a five minute high-level disinfection of TEE probes. TD-5 has been tested to effectively kill potentially harmful microorganisms without damaging the TEE probe. Since the TD 100 or TEEClean uses a fresh TD-5 bottle for each disinfection cycle; the need for continuous MRC testing is eliminated.

TD-8

The TD-8 disinfectant is a single-use, 0.59% Ortho-phthalaldehyde (OPA) based, high-level disinfectant that when used with the TD 100 or TEEClean provides a five minute high-level disinfection of TEE probes. TD-8 has been tested to effectively kill potentially harmful microorganisms without damaging the TEE probe. Since the TD 100 or TEEClean uses a fresh TD-8 bottle for each disinfection cycle; the need for continuous MRC testing is eliminated.

Features:

- Single dose packaging - NO MRC testing required
- High-Level Disinfection in 5 minutes when used with the TD 100 or TEEClean
- Over 8.7 million successful high-level disinfection and counting

TD 100 and TEEClean Testing and Approvals

TD-5 and TD-8 have been tested by TEE probe manufacturers for material compatibility. Both disinfectants have been approved by these companies for use in the high-level disinfection of their individual TEE probes. Please contact your probe manufacturer for full details and compliance documentation.

TD-12® Single-Use Disinfectant

TD-12® PAA High-Level Disinfectant

TD-12 is a granulated peracetic acid based high-level disinfectant used with the TD 200® automated TEE probe disinfector. The TD 200 is a microprocessor-controlled, low-temperature high-level disinfection method for TEE ultrasound probes. The disinfectant and an anticorrosive agent are supplied in a single-dose container. The container is punctured at the time of use, immediately prior to closing the lid and initiating the cycle. The 3000 ppm peracetic acid solution, with a pH of 8.5 to 9.0, is created within the TD 200 disinfection reservoir at a constant temperature of 38°C. The peracetic acid solution is circulated within the disinfection system of the device for 3 minutes, high-level disinfecting the TEE probe.

TD-12 has been evaluated and approved for use to high-level disinfect TEE probes by various manufacturers.

TD 200 and TD-12 Testing and Approvals

TD 200 and TD-12 have been tested by TEE probe manufacturers for material compatibility. Both disinfectants have been approved by these companies for use in the high-level disinfection of their individual TEE probes. Please contact your probe manufacturer for full details and compliance documentation.

QwikCheck™ Chemical Indicators

QwikCheck Chemical Indicators provide a rapid, convenient means of indicating the concentration of peracetic acid (PAA) in TD-12® disinfectant when used in the TD 200® Automated TEE Probe Disinfector.

QwikCheck Chemical Indicators are single use devices for use exclusively with TD-12 disinfectant in the TD 200 Disinfector.

QwikCheck Chemical Indicators cannot be used to verify the efficacy or completeness of the disinfection process. Chemical indicators can only establish that a specific factor exists within the specified limits or performance of the indicator. These indicators are not intended to replace microbiological determinations.

Indications for Use

The QwikCheck Chemical Indicator is a chemical indicator for use in determining whether the concentration of peracetic acid, the active ingredient in CS Medical's TD-12 Solution, is above or below the manufacturer's established minimum recommended concentration (MRC) of 1750 ppm.

TPorter® TEE Transport Device

TPorter® TEE Transport Device

TPorter® TEE Ultrasound Probe Transportation and Procedure Case was designed to effectively and securely move high-level disinfected TEE ultrasound probes to the procedure area and then return the biologically soiled TEE ultrasound probe for reprocessing. TPorter is a complete delivery system that allows healthcare personnel to move delicate TEE ultrasound probes throughout the healthcare facility and deliver them in a manner that creates a standardized operating procedure. TPorter, as a dedicated transportation device, will help minimize the risk of probe damage and reduce staff exposure to potentially hazardous biological material. CS Medical engineers created TPorter to be more than just a transportation case; TPorter is an engineered solution for the healthcare professional that cleans, high-level disinfects, stores, and delivers TEE ultrasound probes for patient care.

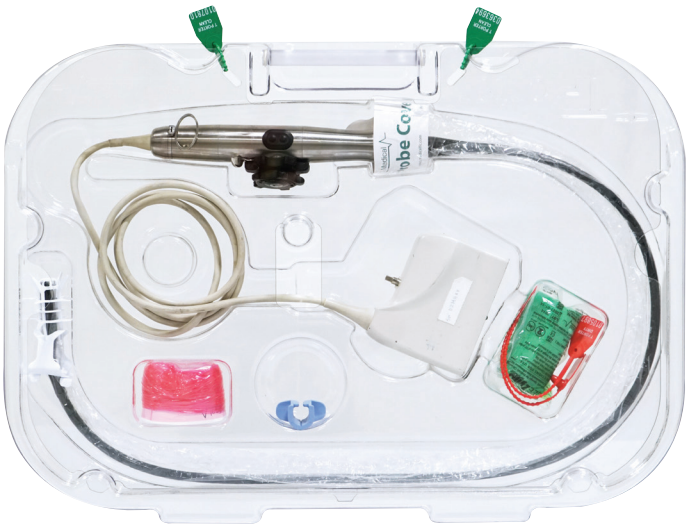
TPorter is designed with a variety of molded compartments to accommodate the TEE ultrasound probe, bite block(s), a PullUp™ Bio-Barrier Sleeve, and a TEEZyme® enzymatic sponge. Carried just like a suitcase or placed into a multiple compartment utility cart, TPorter solves the current issues associated with TEE ultrasound probe transportation. The TPorter transport case provides a standardized method for delivering the necessary components to the procedure room. It then promotes the proper point-of-care bedside cleaning, as described by the TEE ultrasound probe manufacturers and allows for the secure transport of the biologically soiled ultrasound probe to the reprocessing area.

TransPorter™ mobile cart

CATALOG NUMBER	DESCRIPTION
CS-200950	TPorter® TEE Transport Device, 27.5" W x 19" D x 3.75" H
CS-200980	TransPorter™ Mobile Cart, holds 4 TPorter® cases

TPorter® TEE Transport Device

Transporting to the Procedure Room using TPorter



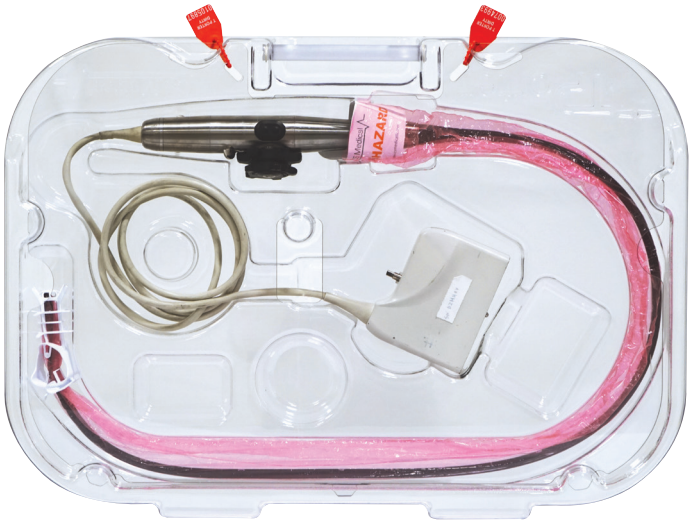
Procedure Transportation Case

TPorter should be placed on a flat and stable area, like a counter top or mobile procedure cart, to allow the high-level disinfection technician to insert the following items into the molded compartments: one TEEZyme enzymatically pre-saturated sponge, one PullUp Bio-Barrier Sleeve, bite blocks, two red tie bands, and one dried and high-level disinfected TEE ultrasound probe with the insertion tube covered by a PullUp TEE Probe Cover. Prior to placement into TPorter, the TEE ultrasound probe should have been stored in a vertical position and within a HEPA clean environment. The CleanShield® TEE Ultrasound Probe Storage Cabinet, is one option available to healthcare professionals and it complies with current TJC (The Joint Commission) standards for care.

Once TPorter is loaded with the necessary components, the clear transportation lid should be placed over the molded transportation device and slid into the lock position. Green tie bands should be placed on TPorter for added security and identification during transportation to the point of use within the healthcare facility.

"By implementing TPorter, we reduced mechanical failures of our TEE probe by greater than 50%."
— Dale S., Duke University Medical Center

Reprocessing the TEE Probe using TPorter



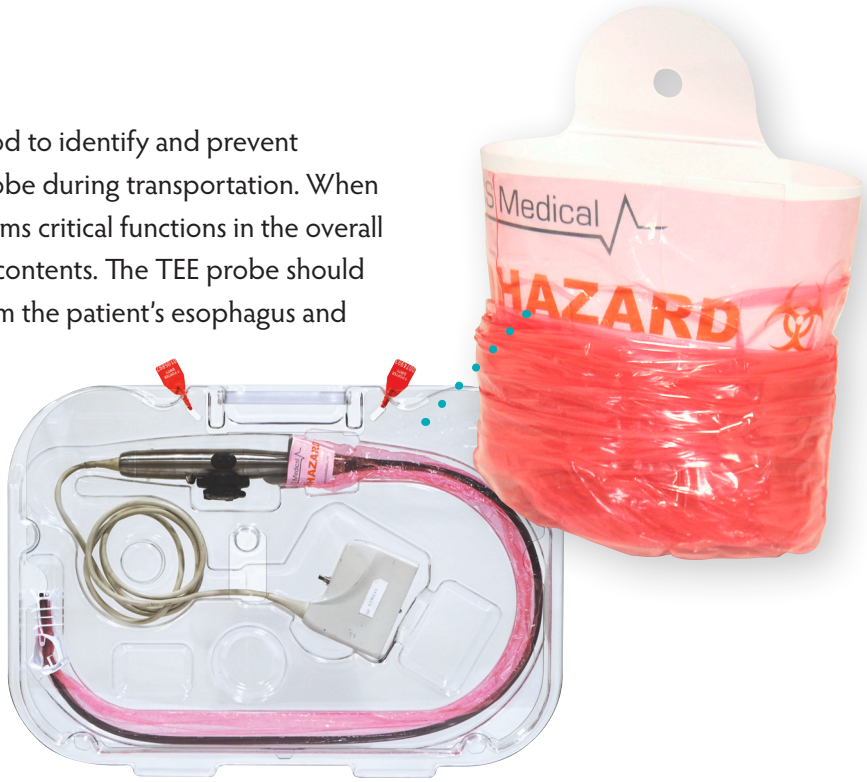
Soiled Transportation Case

Once the TEE ultrasound probe has been enzymatically pre-cleaned, the healthcare professional should place the PullUp Bio-Barrier Sleeve, located within the TPorter case, onto the TEE ultrasound probe insertion tube. The purpose of the PullUp is to prevent the enzymatic and non-HLD components of the TEE ultrasound probe from contacting each other. The PullUp is designed to completely cover the insertion tube of the TEE ultrasound probe. The unique cone shaped receiver allows healthcare professionals to place the insertion tip of the TEE ultrasound probe into the PullUp Bio-Barrier Sleeve and easily pull the cover over the complete distance of the enzymatically cleaned TEE ultrasound probe. The receiver cone also provides another identification label of the potential biohazard in the sealed, red tagged TPorter transportation case.

Once TPorter arrives at the point of reprocessing the high-level disinfection technician will physically remove the red tags and slide the lid for removal and access to the soiled TEE ultrasound probe. The ultrasound probe should be removed from TPorter and reprocessing should begin per TEE ultrasound probe manufacturer's recommendation.

PullUp™ Bio-Barrier Sleeve

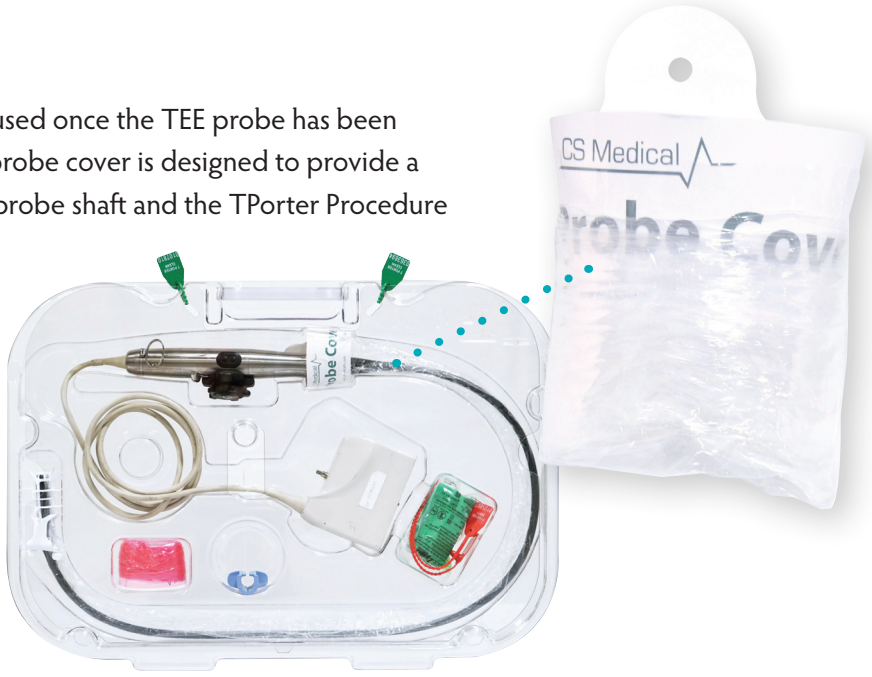
The PullUp Bio-Barrier Sleeve provides a method to identify and prevent exposure to a potentially biohazardous TEE probe during transportation. When used in the TPorter® Transport Device it performs critical functions in the overall safe handling and identification of the TPorter contents. The TEE probe should be enzymatically pre-cleaned after removal from the patient's esophagus and the PullUp correctly identifies the contents of the cover as potentially biohazardous. The biohazard cover prevents the enzymatic solution from coming into contact with other components of the TEE Probe that are not able to be high-level disinfected. The biohazard cover completely encases the insertion tube of the TEE probe.



CATALOG NUMBER	DESCRIPTION
CS-200905	Pull-Up™ Bio-Barrier Sleeve, 100 per case

PullUp™ TEE Probe Cover

The PullUp TEE Probe Cover is designed to be used once the TEE probe has been properly high-level disinfected and dried. The probe cover is designed to provide a barrier between the high-level disinfected TEE probe shaft and the TPorter Procedure Case. A new PullUp cover should be used for each procedure case set up and delivery to the examination room. The PullUp probe cover can be used within the CleanShield® TEE Probe Storage Cabinet as an added barrier during storage.



CATALOG NUMBER	DESCRIPTION
CS-200915	Pull-Up™ TEE Probe Cover, 100 per case

PullUp™ is a trademark of Aspen Surgical

TPorter® Tie Bands

TPorter Tie Bands are used to secure the case lid of the TPorter. Red tie bands are to identify a "DIRTY" or soiled TEE probe. The green tie band is to identify a high-level disinfected TEE probe within the case. The green tie band is labeled with "CLEAN". The tie bands are designed to be secured into place and only removed when cut off.

CATALOG NUMBER	DESCRIPTION
CS-200920	TPorter® Tie Bands, 200 per pack (100 clean, 100 dirty)

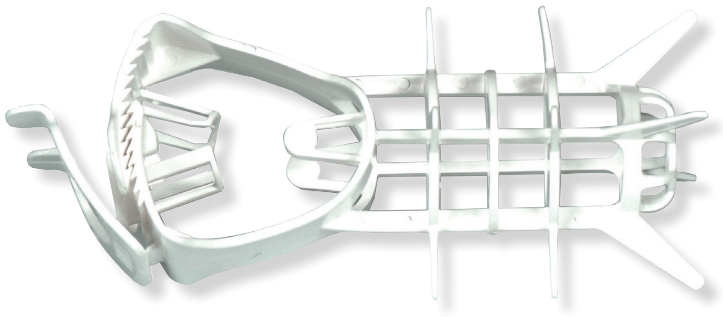
TDefender™ Disposable Distal Tip Protector

When it comes to handling transducers, damage can occur during the storing and transporting process. TEE probe protection is critical for patients' health and safety, and repairing and replacing ultrasound probes is a lengthy and costly expense for a facility.

The TDefender™ Disposable Distal Tip Protector is a single-use device that protects the distal tip of a TEE ultrasound probe from shock damage during transportation and storage.

The following is a manufacturer's warning for TEE probes:

"Do not use a transducer that has been dropped or struck against another object. The transducer is fragile and will break ….this is not covered by the probe warranty or service contract."



CATALOG NUMBER	DESCRIPTION
CS-202630	TDefender™ Disposable Distal Tip Protector, 100 per case

PROBE Valet™ Clean AND BIOHAZARD

Safe and Secure Transport Bags for Endocavity and Surface Ultrasound Probes

Probe Valet ™ transportation bags are designed to provide a secure and properly identifiable method of moving soiled and clean Endocavity and Surface Ultrasound Probes throughout the healthcare facility.

Biohazard Transport Bag

Clean Transport Bag

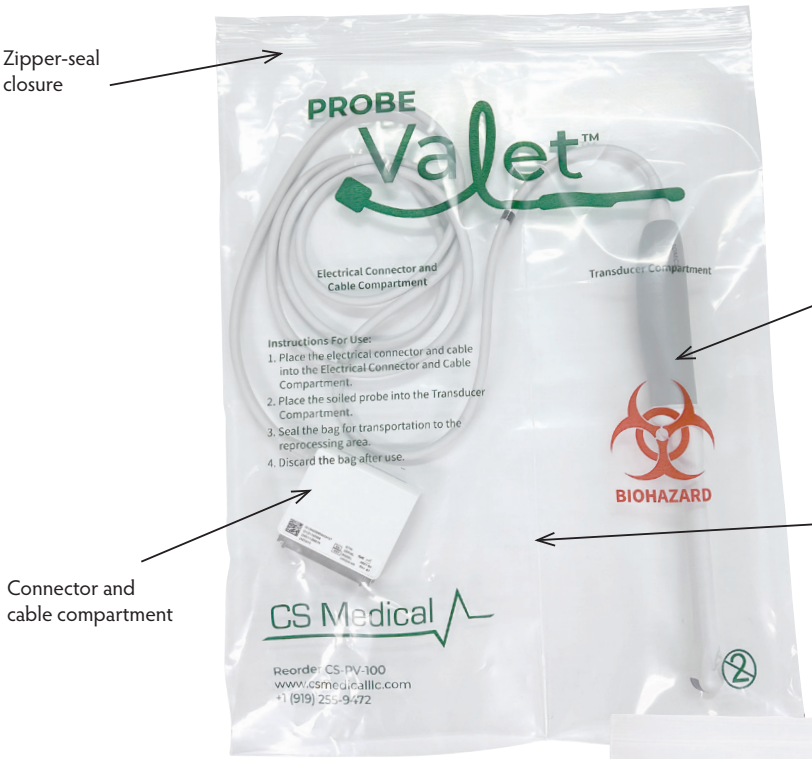
Designed with input by healthcare professionals that allows for compliance to applicable standards and guidelines currently used by healthcare facilities. Proper handling of ultrasound probes can improve patient safety and reduce costly probe damage. Both Probe Valet and Clean Probe Valet are constructed from 4 mil polyethylene to ensure a safe environment. During transport the probe is secure as the Probe Valet and Clean Probe Valet bags will not rip or tear to maintain the integrity of the environment in which the probe is placed. Probe Valet transport bags manage the complete probe from transducer to power pack and cabling. Once the ultrasound probe is placed inside, it is sealed to prevent the probe or contaminants from escaping, or the environment from encountering the probe.

Probe Valet and Clean Probe Valet are each separated into two distinctive compartments, one compartment is for the power pack and cabling while the other compartment is for the insertion or scan portion of the ultrasound probe. This feature is critical as it maintains separation of LLD (low-level disinfection) and HLD (high-level disinfection) sections of the ultrasound probe during transport.

Probe Valet, Clean or Biohazard are single-use and sold in boxes of 100.

Probe Valet™ Probe Transportation Bags

Probe Valet is labeled with the necessary diagrams and information to easily identify the state of the ultrasound probe.



Probe Valet specifications:
16" Width x 20" Length

Closure type:
Reclosable, Zipper-Seal

Clean Probe Valet specifications:
16" Width x 20" Length

Closure type:
Sealed top for integrity with perforation for easy opening

CATALOG NUMBER	DESCRIPTION
CS-PV-100	Probe Valet Transport Bag for Endocavity and Surface Ultrasound Probes (100 per box)
CS-PV-200	Clean Probe Valet Transport Bag for Endocavity and Surface Ultrasound Probes (100 per box)

CleanShield® TEE Probe Storage Cabinet

CleanShield® TEE Probe Storage Cabinets are designed for storing disinfected TEE probes. Constructed from natural-white, thermally-fused polypropylene, the storage cabinet is easy to clean with any hard surface disinfectant. Polypropylene does not absorb moisture and will not breakdown when exposed to harsh cleaning solvents making it the ideal construction material for the TEE probe storage cabinet.

CleanShield TEE Probe Storage Cabinets are designed to safely and securely store disinfected TEE probes.

Features:

- Thermally-fused polypropylene construction
- Positive-pressure HEPA-filtered clean air
- Specially-designed hanging crescents and shelves
- Locking front door for securing TEE probes
- Specially designed for TEE probes ONLY
- Clear viewing panel in door
- Padded lower section to protect delicate TEE probe distal tip

CleanShield TEE Probe Storage Cabinets are available in 110V or 220V configurations

The Joint Commission outlines best practices for probes and scopes once they have been high level disinfected. They indicate "scopes should be vertically hung in a manner that prevents contamination and in a clean, well ventilated and dust-free area." CleanShield fully complies with this recommendation.

CleanShield® TEE Probe Storage Cabinet

Positive-pressure HEPA-filtered clean air bathes the disinfected TEE probes to minimize the potential of airborne contaminants entering into the cabinet. The TEE probe storage cabinet is designed with hanging crescents and shelves to allow for easy and secure placement of the disinfected TEE probe. The TEE probe is allowed to hang freely inside the TEE probe storage cabinet while the TEE probe handset and cable are held in secure positions. Once the TEE probe has been safely placed inside the storage cabinet the door can be closed and locked for added security.

Hang Time Tag

CS Medical's Hang Time Tag is designed to provide a quick, easy, and visible method for healthcare professionals to know when a probe has been placed in the HEPAfiltered storage cabinet. Tags are single-use and simple to use.

Use Hang Time Tags to track HLD details for probes

CATALOG NUMBER	DESCRIPTION
AC-TE-03	3 Probe CleanShield TEE Probe Storage Cabinet
AC-TE-06	6 Probe CleanShield TEE Probe Storage Cabinet
CS-203155	Hang Time Tag, Package of 100

CleanShield® is a registered trademark of AirClean® Systems

CleanShield® Ultrasound Storage Cabinet

The CleanShield® Ultrasound Storage Cabinet is designed to effectively and securely store disinfected ultrasound transducers and semi-critical devices by suspending each disinfected probe in a vertical position that minimizes stress on the connection cable, strain relief, and electrical pack of the probe.

To ensure a high degree of protection the cabinet is configured with three separate hanging platforms to securely and effectively hold each probe without strain to cables or added stress to the probe. A contoured cradle, located in the center of the cabinet, securely nests the probes while the other two brackets support and suspend the probes minimizing the potential for damage or touching each other.

Features:

- Thermally-fused polypropylene construction — NO chemical compatibility issue
- Two stage filtration — electro-statically charged pre-filters and 99.97% at 0.3 micron HEPA filtered clean air
- Specially designed hanging mounts
- Locking front door for securing ultrasound probes
- Specially designed for endocavity and general purpose ultrasound probes
- Clear polycarbonate viewing panel in door

CATALOG NUMBER	DESCRIPTION
CS-VR06	CleanShield® Ultrasound Storage Cabinet
CS-VR06W	CleanShield® Ultrasound Storage Cabinet, Wall Mount

CleanShield® Ultrasound Storage Cabinet

CleanShield® has a unique two stage filtration incorporated in the design of the CleanShield Ultrasound Probe Storage Cabinet to remove potential airborne contaminants from entering the cabinet and contacting disinfected ultrasound probes. An electrostatically charged pre-filter is positioned in series to remove gross particulate from entering the blower and HEPA filter. The cabinet blower then pushes positive pressure HEPA filtered clean air into the chamber to bathe the disinfected ultrasound probes. This process minimizes the potential of airborne contaminants entering into the cabinet.

The ultrasound probes are allowed to hang vertically inside the CleanShield Ultrasound Probe Storage Cabinet while the probe connector and cable are held in secure positions. Once the endocavity or general purpose ultrasound probes have been safely placed inside the storage cabinet the door can be closed and locked for added security. The CleanShield Ultrasound Probe Storage Cabinet was designed to accommodate up to six endocavity or general purpose ultrasound probes.

CleanShield has built-in HEPA filter monitoring to alert the healthcare professional when HEPA filter replacement is required.

Features:

- Wall mount for direct placement in procedure room
- Two stage filtration — electro-statically charged pre-filters and 99.97% at 0.3 micron HEPA filtered clean air
- Clear polycarbonate viewing panel in door
- Thermally-fused polypropylene construction — NO chemical compatibility issue
- Safely and effectively accomodate up to 6 ultraound probes

CleanShield Ultrasound Probe Storage Cabinets are available in 110V or 220V configurations

The Joint Commission outlines best practices for probes and scopes once they have been high level disinfected. They indicate "scopes should be vertically hung in a manner that prevents contamination and in a clean, well ventilated and dust-free area." CleanShield fully complies with this recommendation.

Clean and Sanitize Ultrasound Probes

Medi-Fect™ Disinfectant Wipes

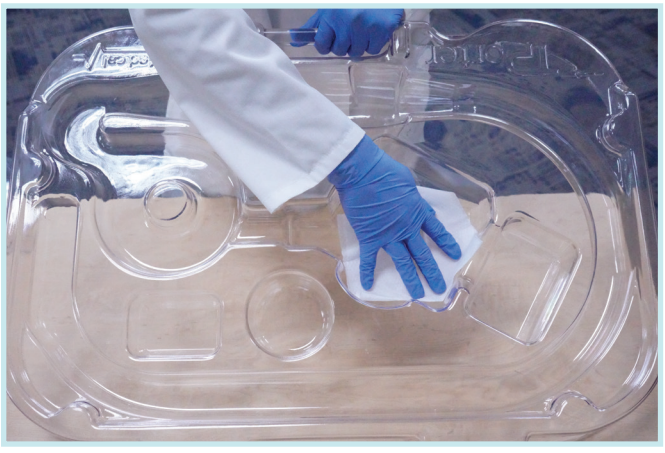
CS Medical's Medi-Fect disinfectant wipes provide one-step disinfection/sanitization that starts killing on contact.
Medi-Fect will eliminate 99.9% of bacteria in 15 seconds and surface disinfects in just 4 minutes. It is effective against a broad spectrum of pathogens, including HIV, Influenza Type A, MRSA, SARS-CoV-2 virus, (the cause of COVID-19), and many others. They are effective in surface disinfecting ultrasound transducers and probes, mammography compressor plates, vinyl exam tables, countertops, and other hard, non-porous, non-critical surfaces.

Medi-Fect wipes have been tested for material compatibility on a variety of surfaces and equipment.

Features:

- Eliminates 99.9% of bacteria in 15 seconds
- Surface disinfects in just 4 minutes, starts killing on contact
- Kills the virus that causes COVID-19 (SARS-CoV-2)
- Disinfects AND sanitizes in one easy step. Not a replacement for high-level disinfection of semi-critical medical device surfaces
- Alcohol, bleach, and solvent FREE
- Accepted for use by manufacturers of ultrasound equipment
- Fully material compatible with all CS Medical products

Medi-Fect being used to clean TEEClean.



Medi-Fect disinfecting TPorter between uses.

CATALOG NUMBER	DESCRIPTION
CS-203100	Medi-Fect Disinfectant Wipes, 75 count canister/6 canisters per case

Medi-Fect™ is a trademark of Medical Chemical Corporation

QwikDry® Ultrasound Probe Drying Cloth

A properly dried ultrasound probe, prior to storage, is critical in minimizing the possibility of water-borne bacterial contamination during storage. QwikDry Ultrasound probe drying cloths have been developed to give healthcare professionals the added confidence of properly dried ultrasound probes prior to re-use or storage.

QwikDry used in conjunction with transvaginal probe after high-level disinfection

QwikDry used for removing a high-level disinfected TEE probe from the TD 100® or TEEClean®

QwikDry used for drying a surface probe after high-level disinfection

Features:

- Single-use
- Non-abrasive surface for easy glide on ultrasound probe
- Individually packaged, gamma irradiated cloth
- Engineered textile with internal high absorbent membrane

QwikDry removes the current issues associated with other drying methods employed in today's healthcare facilities. QwikDry is an individually packaged, irradiated cloth with a super absorbent matrix and ultra-smooth textured surface that effectively removes moisture and slides freely over the ultrasound probe shaft. Each cloth is designed for single-use, thus removing the potential for cross-contamination and potential microbiological growth.

The QwikDry ultrasound probe drying cloths are the next solution for healthcare professionals that are tasked with minimizing healthcare associated infections.

CATALOG NUMBER	DESCRIPTION
CS-200880	QwikDry® Ultrasound Probe Drying Cloth, 100 per case
CS-200890	QwikDry® Drying Cloth Caddy

Bedside Cleaning for TEE Probes

TEEZyme® TEE Probe Enzymatic Sponge

TEEZyme has a neutral pH, multi-tiered enzymatic detergent, specifically formulated to remove gross contaminants while targeting insoluble polysaccharides that encase biofilm, exposing them to the high-level disinfectant utilized in the TD 100® Automated TEE Probe Disinfector or TEEClean® Automated TEE Probe Cleaner Disinfector.

TEEZyme super absorbent sponges are designed to hold the enzymatic detergent in, so that it guarantees to disperse the detergent over the probe surface and distribute it more evenly. This will provide longer contact time with biofilm and contaminants so the detergent can help break them down.

Features:

- The only TEE probe specific sponge on the market
- TEEZyme enzymatic detergent aids in the solubilization of polysaccharides and removal of biofilm allowing for high-level disinfectants to kill
- Proprietary blend of enzymes designed to break down all bio burden — blood, carbohydrates, protein, polysaccharides, fats, oils, uric acid, and other nitrogenous compounds
- Pre-cleans inanimate surfaces where biofilm, germs, allergens or microorganisms can hide, thrive, and grow
- Individually-wrapped for single use to help decrease cross-contamination
- Latex-Free/Dust-Free
- The sponges have been treated with a preservative to inhibit and protect the product from mold and fungus
- The product is preserved against the growth of bacteria

TEEZyme caddy for easy wall dispensing

TEEZyme allows for simple and effective enzymatic cleaning of dirty TEE probes.

Individually pre-packaged enzymatic sponge, sold 100 sponges per case.

CATALOG NUMBER	DESCRIPTION
CS-200750	TEEZyme® Enzymatic Sponges, 100 per case
CS-200780	TEEZyme® Sponge Caddy

Nephros Water Filter

The risk of healthcare-associated infections has become a focal point in many facilities throughout the United States, as well as other parts of the world. One potential source of contamination is the water that is used to rinse scopes and probes that have been high-level disinfected. High-level disinfection is only one component, regardless of manual or automated method, when healthcare workers are reprocessing semi-critical medical devices. The high-level disinfection process is defined by individual disinfectant manufacturers as well as the multiple large volumes of water recommended to remove residual disinfectant.

Waterborne bacteria is an ever-growing challenge in healthcare facilities. The effects of these contaminants continue to cause an increasing rise in healthcare costs. Rinse water quality can affect a properly high-level disinfected medical device by introducing bacteria, viruses, and endotoxins.

CS Medical has partnered with Nephros to provide a solution that provides ultrapure bacteriologically-filtered water during the rinse cycles of the TD 100® or TD 200®. The Nephros DSU-H filter is a patented dual stage hollow fiber ultrafilter that retains bacteria, viruses, and endotoxins found in water.

Why did CS Medical choose Nephros DSU-H ultrafilter to provide a solution to the growing water quality concern in hospitals? It's simple, the technology has been cleared by the FDA with the indication for use to aid in infection control and produce filtered water that is suitable for cleaning of equipment used in medical procedures. The DSU-H ultrafilter has been tested and validated to retain bacteria, viruses, and endotoxins. The expected life span of a DSU-H ultrafilter is up to 6 months and is easily installed in-line between the TD 100/TD 200 and the hospital water supply.

Specifications:

Filter Membrane	Medisulfone®
Material	Polysulfone
Pore Size	5 nm
Bacteria Retention	> 10^{11} (B.diminuta)
Virus Retention	> 10^{8} (PhiX-174)
Endotoxin Retention	> 10^{5} EU/ml
Dimensions	13" L x 2.5" D
Expected life	up to 6 months

Medisulfone® is a registered trademark of Medica S.p.A.

For use with the TD 100 or TD 200®Automated High-Level Disinfector

CATALOG NUMBER	DESCRIPTION
CS-200895	DSU-H Ultrafilter installation kit. (Kit consists of mounting hardware, tubing, DSU-H protective cover and two DSU-H filters.)
CS-200900	Replacement DSU-H Ultrafilter replacement pack contains 2- DSU-H filters.

Transducer Leakage Tester

CS Medical electrical leak testers provide a safe and effective method in conducting the electrical leakage test within the disinfectant reservoir of the TD 100®/ TD 200® Automated TEE Probe Disinfector and TEEClean® Automated TEE Probe Cleaner Disinfector.

The ULT-2000 Series is specifically designed to test the electrical safety of all types of diagnostic ultrasound transducers, totally independent of the ultrasound machine on which they are typically used. The ULT-2000 Series tests the integrity of the outer insulation barrier of the transducer as well as the capacitive leakage currents that exist.

The ULT-PC-31 flexible conductivity probe is exclusively designed for use with the TD 100/ TD 200 Automated TEE Probe Disinfector and TEEClean Automated TEE Probe Cleaner Disinfector. The ULT-PC-31 probe is designed to be placed in the disinfection reservoir and allows the electrical leakage test to be conducted prior to high-level disinfection.

IAC (Intersocietal Accreditation Commission) recommends the structural and electrical integrity of the transducer be checked between each use, using an ultrasound transducer leakage tester.

◀ *Optional wall mounting bracket (CS-200844) for the ULT-2020 and printer also available.*

ULT-2020 - Leakage tester

CS-200806 - Print Kit

ULT-PC-31 - Flexible Conductivity Probe

Transducer Adapater

HLD TRACKER™

CS Medical developed the HLD TRACKER as an aide to the healthcare professional in maintaining a continuous documentation log of successful high-level disinfections. The TD 100®, at completion of a successful disinfection cycle, provides a print out that records the following data: disinfectant contact time, average disinfectant temperature, probe and operator ID, disinfectant lot number, and time and date of the disinfection cycle. Many healthcare facilities SOPs require maintaining this data for extended period of time and the HLD TRACKER is the solution. The HLD TRACKER will maintain 200 individual disinfection events as well as document the necessary pre-care steps required prior to high-level disinfection of a TEE probe. Current IAC guidelines require a TEE probe to be electrical leakage tested prior to high-level disinfection. The HLD TRACKER allows the healthcare professional to document the successful completion of this activity. The HLD TRACKER can serve as a permanent record for each TEE probe high-level disinfected by the TD 100. The reprocessing technician will attach the printed verification report to the HLD TRACKER and then record any additional pertinent details of the individual case.

CATALOG NUMBER	DESCRIPTION
CS-200870	HLD TRACKER™
CS-202570	TD 200 Log Book

TEEClean® and Ethos® Log Books

TEEClean and Ethos log books are designed as a manual records log that serves as a back up to the electronic files retained within the system memory. TEEClean and Ethos produce a printed verification report that outlines the successful cleaning and disinfection of the soiled ultrasound probe. The log book can serve as a permanent written record for each reprocessed ultrasound probe by either TEEClean or Ethos. The reprocessing technician will attach the printed verification report to the log book page and then record additional pertinent details of the individual case.

CATALOG NUMBER	DESCRIPTION
CS-201870	TEEClean® Log Book
CS-203870	Ethos® Log Book

TEEZyme®MC Dual Enzymatic Cleaner

TEEZyme®MC is a dual enzymatic cleaner that removes blood, protein, mucus, vomit, and fecal matter. This formulation of protease and amylase enzymes, with buffers and non-ionic detergents, is perfect for all scopes and instruments and extends usable lifetime. TEEZyme®MC will solve any problem with clogged channels, sticky forceps, or clouded lenses and will leave both scopes and instruments free of any unpleasant odors or baked-on blood.

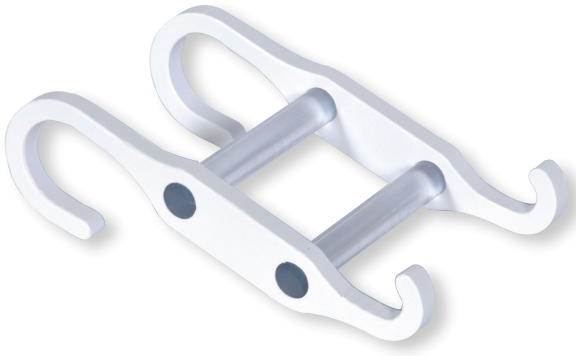
Features:

- Dual enzymatic cleaner – Protease and Amylase
- Designed for universal applications: For use in all endoscope washers, washer disinfectors, ultrasonics, and for manual cleaning
- Safe for use on all instruments and scopes
- Neutral pH, non-abrasive, free rinsing, and biodegradable
- Will not harm any metals, plastics, rubber, or corrugated tubing
- Works in all temperatures.

CATALOG NUMBER	DESCRIPTION
CS-201910	TEEZyme®MC Dual Enzymatic Cleaner

TPorter® Carrier

The CS Medical TPorter Carrier is designed to aid healthcare professionals in transporting the TPorter by permitting it to be hung from an ultrasound console handle. The TPorter Carrier is intended to be used with the TPorter (CS-200950) only.



CATALOG NUMBER	DESCRIPTION
CS-201240	TPorter® Carrier

Aldehyde Clean-Up Kit

The Aldehyde Clean-Up Kit is compact and can be placed near the point of use as The Joint Commission Hazardous Material Plan requires. Each kit contains materials to effectively neutralize and clean-up small spills.

Kit contains:

- 5 oz. bottle of Green Z solidifier
- Nitrile gloves
- 2 oz. pouch of ACX4400
- Ventilated goggles
- Aldehyde respirator mask
- Scoop/scraper (2)
- 30 gallon bag
- Instructions

CATALOG NUMBER	DESCRIPTION
CS-200850	Aldehyde Clean-Up Kit

Peracetic Acid Clean-Up Kit

The Peracetic Acid Clean-Up Kit is compact and can be placed near the point of use as The Joint Commission Hazardous Material Plan requires. Each kit contains materials to effectively neutralize and clean-up small spills.

Kit contains:

- Bottle of Acid Lock
- Nitrile gloves
- Scooper
- Scraper
- Twist tie
- 30" x 36" black disposal bag
- 9" x 12" plastic bag
- Respirator
- Instructions

CATALOG NUMBER	DESCRIPTION
CS-200990	Peracetic Acid Clean-Up Kit

Solucide® Hard Surface Cleaner

Solucide is an EPA registered hard surface cleaner, disinfectant, and deodorizer. Solucide is a broad-spectrum disinfectant spray that is effective in the presence of organic soil. Solucide contains no alcohol or glutaraldehyde, and has a fresh lemon scent.

Effectively Kills:

- Norovirus (Norwal Virus)
- Fast Parvo Virus
- SARS associated Coronavirus
- Hepatitus A Virus
- Hepatitus B Virus
- Hepatitus C Virus
- Fast TB Kill
- HIV
- Bactericidal (MRSE, MRSA, VRE, VISA, Strep pyogenes)
- Virucidal
- Fungicidal
- Pseudomonacidal

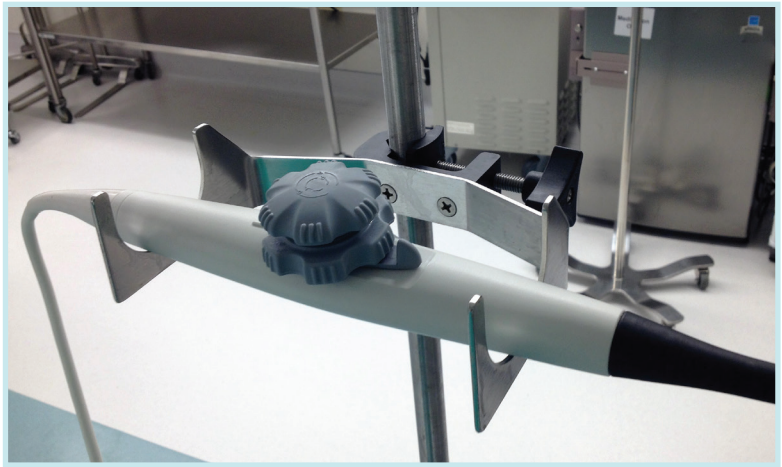
Approved for use when cleaning TPorter®, TD 100®, TD 200®, TEEClean®, Ethos®, CleanShield®, Brooker Probe Holder, and TransPorter™.

Solucide® is a registered trademark of Medical Chemical Corporation

CATALOG NUMBER	DESCRIPTION
CS-200710-4	Solucide®, 16 oz. pump spray bottle, 4 per case

Brooker TEE Probe Holder

The Brooker Probe Holder addresses handling and manipulation issues that have faced cardiologists working with transesophageal ultrasound probes for years. An integral mounting clamp attaches the Brooker Probe Holder directly to a standard IV pole. The crescent bracket securely holds the control handle of the TEE probe during transesophageal echocardiography procedures, making manipulation and adjustment of the TEE probe simple.



CATALOG NUMBER	DESCRIPTION
CS-200970	Brooker Probe Holder

Neutralization Station

Safely neutralize Glutaraldehyde and OPA before disposal

The AC-DS-03 Neutralization Station is a semi-automated neutralization system designed to neutralize spent high-level disinfectants and residue-laden rinse water prior to disposal into facility drains.
The AC-DS-03 Neutralization Station, when used in conjunction with the TD 100® Automated TEE Probe Disinfector or TEEClean® Automated TEE Probe Cleaner Disinfector will effectively neutralize spent TD-5 or TD-8 and the rinse water.

Features:

- Automatically pumps reservoir empty once filled
- User-friendly operation
- Holds up to 4 gallons of solution
- Vapor management filter

CATALOG NUMBER	DESCRIPTION
AC-DS-03	Neutralization Station
ACF-DS-03	Vapor Management Filter

Glycinex is required for operation of AC-DS-03.

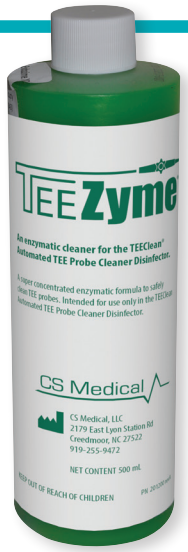
Glycinex™

Glycinex completely neutralizes disinfectant in 5 minutes. No overnight waiting to dispose of waste. Glycinex packets contain a pre-measured volume of neutralizer. Simply open the packet and pour Glycinex crystals into your disinfectant. A noticeable color change will occur during deactivation. Glycinex converts glutaraldehyde and OPA into a non-toxic, pH-neutral compound in 5 minutes. Glycinex has no corrosive acids or unstable oxidizers. Heating is not required. Larger volumes of glutaraldehyde and OPA based products can be safely neutralized without dangerous heat build-up. Glycinex and the neutralized product that is formed are not harmful to active bacteria used in treating sewage and sewer sludge.

CATALOG NUMBER	DESCRIPTION
ACX-4400	Glycinex Neutralization Powder, 24 pouches per case

Glycinex™ is a trademark of AirClean® Systems

TEEZyme® for TEEClean®



TEEZyme for TEEClean is formulated exclusively for use in the TEEClean Automated TEE Probe Cleaner Disinfector. The cleaning agents in TEEZyme, when used with TEEClean, effectively remove soil from TEE ultrasound probes. TEEZyme for TEEClean combines the power of a super-concentrate with the performance of CS Medical's proven multi-enzyme formula to create the ultimate ultrasound probe cleaner. This unique combination gives TEEZyme for TEEClean superior cleaning ability to deliver fast and thorough soil contaminant removal. TEEZyme for TEEClean contains biological additives that speed the process of liquefaction and solubilization, facilitating enzymatic action and contributing to the products overall effectiveness.

CATALOG NUMBER	DESCRIPTION
CS-201200	TEEZyme® 500 ml bottles, Case of 2

Nephros 5 nm Water Filter for TEEClean®

The Nephros 5 nm water filter is integral to the TEEClean design. TEEClean rinses each TEE probe with the Nephros filtered water. The water filter is a Class II medical device that has been tested and validated to retain bacteria, viruses, and endotoxins. The filter is simple to change out when required. Nephros TEEClean water filters are packaged 4 to a case. The expected useful life of each filter, after installation, is 90 days. Filters are shipped with a barcode for easy entry into TEEClean systems memory and this will become part of the electronic record as well as the preventative maintenance record.

CATALOG NUMBER	DESCRIPTION
CS-201340	Nephros Water Filter, Case of 4

Vapor Management Filtration System

Incorporated in the TEEClean are two chemisorptive bonded gas phase carbon filters that effectively remove and neutralize either TD-5® or TD-8® disinfectant fumes. The main vapor management filter is housed inside the TEEClean main housing while the secondary filter is placed on the drain to prevent drain gases from returning into the room. Both filters, the main and drain, are tested for 12 months of useful life after installation. The solid bonded carbon filters have superior residence time and capacity to ensure the safety of healthcare personnel.

CATALOG NUMBER	DESCRIPTION
CS-201900	Main and Drain Vapor Management filter - TEEClean

On-Demand Web-Based Device Training

On-Demand Training is versatile and ready when you are 24-7/365.

As training and proper equipment use is a key component in ensuring patient and staff safety, CS Medical's web-based training provides compliance to The Joint Commission (TJC) for competency and training of staff. The on-demand training is available for all medical devices offered by CS Medical. Training is simple, the staff member will watch a video that is then followed by a competency test and certification upon successful completion of the course and exam for the staff member. Training on the instruction for use (IFU's) is covered in the web-based training program that provides the proper use and preventative maintenance for both our disinfectors and cleaner disinfectors for ultrasound probes. In addition to device training, each video covers the compliance products offered by CS Medical known as TEE Complete Care® and Complete Probe Reprocessing®. The web-based training is accessible by anyone 24 hours a day and 7 days per week. The training portal allows healthcare chains or facilities with multiple individuals to identify a super user that then can review each participant's program status, results, and print a master document showing each participant's successful completion of the web-based training program.

When CS Medical installs one of our devices, our factory trained service engineers perform a device verification to ensure proper operation and then conduct an in-service training to all staff assigned to use the TD 100, TD 200, TEEClean or Ethos. The web-based device training is ideal to address staff turnover or new staff hire since it is available on demand. Certified training is critical to a healthier healthcare system for both patients and staff.

The web-based training program is ideal to meet the TJC requirements outlined in sections IC.02.02.01, LD.03.06.01-EP4, HR.01.05.01 and HR.01.06.01.

The TJC general checklist outlines: "Competency evaluations should be completed for each employee on hire and considerations for annual review as recommended by evidence-based guidelines; also include random observations. Determine frequency of competency and training based on staff turnover, purchase of new equipment and products, or a breach in the process has been identified."

TD 100/TD 200 CATALOG NUMBER	TEECLEAN CATALOG NUMBER	ETHOS CATALOG NUMBER	DESCRIPTION
CS-201800-5	CS-202500-5	CS-203500-05	Five Web-Based User Licenses
CS-201800-10	CS-202500-10	CS-203500-10	Ten Web-Based User Licenses
CS-201800-20	CS-202500-20	CS-203500-25	Twenty Web-Based User Licenses
CS-201800-30	CS-202500-30	CS-203500-30	Thirty Web-Based User Licenses
CS-201800-50	CS-202500-50	CS-203500-50	Fifty Web-Based User Licenses

Device Annual Service Contract

Preventative maintenance is essential to ensure the device provides your healthcare facility with long and continuous service. The TD 100® and TD 200® provide high-level disinfection of a TEE ultrasound probe while the TEEClean® provides both cleaning and high-level disinfection through an FDA 510k cleared method. By heating the single-use high-level disinfectant, the TEE probe can be disinfected in 5 minutes. After the disinfection, our devices continue to care for the TEE probe by rinsing the residual high-level disinfectant from the probe shaft. During disinfection and rinse the probe is securely held inside the disinfection reservoir to prevent stress and shock to the TEE probe.

CS Medical service engineer completing the vapor filter maintenance process.

CS Medical offers an extensive service contract for those healthcare facilities wanting to utilize the device manufacturer for ongoing maintenance of the TD 100, TD 200 or TEEClean. Our highly trained service technician will work with appointed healthcare staff to ensure the device is functioning within manufacturer recommended guidelines. The annual device service contract provides parts for any reported device issue during the term of the agreement.

A CS Medical certified technician will visit the device's installation site and provide an annual verification of device functionality to manufacturer specifications as well as conduct a staff training on proper operation and preventative maintenance aspects of the TD 100, TD 200 or TEEClean.

Features:

- 12-month service contract
- Annual device preventative maintenance
- Parts replacement from normal wear and tear
- Loaner device, if required
- Staff training during annual preventative maintenance

CS Medical recommends each device have a preventative maintenance check up to ensure device readiness, reliability, and help reduce operating cost. The staff training is compliant with the Joint Commission Standards.

CATALOG NUMBER	DESCRIPTION
CS-SRL-12	TD 100® or TD 200® Annual Device Service Contract
CS-TCDSC12	TEEClean® Annual Device Service Contract

Verification and Training

Proper operation of the TD 100®, TD 200®, or TEEClean® is essential to ensure each TEE probe receives the correct care and high-level disinfection. CS Medical recommends our devices receive an annual verification to confirm all operational parameters of the device are within manufacturer's specification. The performance check includes a full diagnostic checkup of the device. At the conclusion of the verification, a CS Medical technician will provide the healthcare facility with a written record of the service verification event. Training of staff, using the device, will be conducted by the CS Medical technician to ensure competency of use as well as required preventative maintenance to ensure device readiness. At the conclusion of the training, the service technician will provide a written training record for all staff in attendance.

Pictured is a CS Medical technician confirming device temperature per factory specifications.

CS Medical service engineer conducting hands-on device training for healthcare staff.

CATALOG NUMBER	DESCRIPTION
CS-VT12	TD 100® or TD200® Training and Verification
CS-VTCD12	TEEClean® Training and Verification

Ethos® SelectCare™ Device Management Programs

Ethos® cleaner disinfector is built to deliver the same result each cycle, to clean and high-level disinfect a surface or endocavity ultrasound probe as defined by the Spaulding classification system. Ethos, like any other medical device, requires regularly scheduled maintenance to ensure optimal function and to ensure performance is meeting the necessary parameters related to time and temperature for cleaning and high-level disinfection of an ultrasound probe.

CS Medical has created the Ethos SelectCare™ offering to allow owners of Ethos to determine what works best for them and their respective healthcare system. Ethos SelectCare has four options to pick from that will effectively allow you to have the confidence that Ethos is effectively cleaning and high-level disinfecting your soiled endocavity and surface ultrasound probes. You can elect to have CS Medical trained technicians manage the care of your device or through the CS Medical training program our staff can educate and support your internal biomedical or clinical engineers in the daily and yearly support of your Ethos automated cleaner disinfector.

SelectCare™ Device Management Programs

SelectCare CheckPoint™

SelectCare CheckPoint is to ensure the safety and efficacy of cleaning and high-level disinfection operations with Ethos. This on-site service offering is post-warranty and Ethos will monitor and alert you when your critical component service is required at the 5,000 cleaning and high-level disinfection cycle preventative maintenance event. In addition to the preventative maintenance, a CS Medical field service technician will conduct an in-service for any staff assigned to operate Ethos. This service package includes all parts and labor to ensure Ethos is functioning per manufacturer specification.

CATALOG NUMBER	DESCRIPTION
CS-CP-5000	Critical Component Preventative Maintenance

SelectCare12™

SelectCare12 is designed for annual verification per manufacturer IFUs as well as in-service training with a CS Medical field service technician. The CS Medical employee will visit the healthcare facility where the Ethos cleaner disinfector is installed and perform the manufacturers testing to confirm device conformity to time and temperature. Once this activity is completed, the technician will deliver a single in-service training to any healthcare facility staff member that is charged with the operation of Ethos. This service package does not include any parts required to achieve manufacturer specifications.

CATALOG NUMBER	DESCRIPTION
CS-ESC-12	Ethos Annual Verification and Training

SelectCare365™

SelectCare365 is CS Medical's annual service contract that provides full post warranty coverage just like the original manufacturer's warranty that was delivered with the device. SelectCare365 also offers the healthcare facility the annual verification and training visit, unlimited seats to the 24/7/365 on-demand training portal for staff training, a device loaner if needed, and even full replacement of the device if deemed necessary by CS Medical. If the 5,000 cycle Preventative Maintenance SelectCare CheckPoint service is required while SelectCare365 is in force, all aspects of SelectCare CheckPoint will be included at no additional fee to the healthcare facility.

CATALOG NUMBER	DESCRIPTION
CS-ESC-365	Ethos Annual Service Contract

SelectCare Direct™

SelectCare Direct is designed for those healthcare facilities that wish for their internal biomedical or clinical engineering team to manage the day to day and annual requirement for Ethos automated cleaner disinfector. CS Medical has established a training program, conducted at the corporate headquarters in Creedmoor, NC over the course of 4 days to train and certify healthcare facilities selected biomedical and clinical engineers. The course will provide a hands-on full understanding of how to troubleshoot, repair, and verify Ethos automated cleaner disinfector to meet manufacturer IFU's. At the conclusion of this weeklong training program the biomedical or clinical engineer will be able to support Ethos in all aspects that will allow compliance to the manufacturer's IFU. This training course includes the necessary tools and equipment to perform the annual verification and training, 5,000 cycle preventative maintenance and access to the Ethos service portal.

CATALOG NUMBER	DESCRIPTION
CS-SC-DT	Ethos Biomedical and Clinical Engineering On-site

Probe Reprocessing Checklist

TEE Ultrasound Probes

This checklist is provided as an outline of steps required to successfully reprocess a TEE ultrasound probe when using the TD 100® or TD 200® device. These steps are intended to follow guidelines and recommendations from manufacturers of the ultrasound probe, high-level disinfectants and recognized governmental and professional bodies. This checklist should be used as a reference for individual healthcare infection control professionals.

ALWAYS DON PROPER PPE!

☐ **Step 1: Point-of-Care - Bedside**

At patient bedside, immediately after removal from patient, apply an enzyme to the probe shaft with either a cloth or other applicator to remove organic and inorganic matter. By performing this step, it aids in preventing drying of the gross material on the probe shaft which can lead to biofilm formation.

☐ **Step 2: Transporting to Clean and Disinfect**

Transport the TEE probe to the area designated for performance of the manufacturer's directed enzymatic cleaning steps, i.e. basin with tempered enzymatic solution. Caution should be taken to minimize exposure to the potential biological hazard of the soiled TEE probe as well as to protect the probe from damage. Maintain separation between parts of the probe that receive low-level disinfection and areas that require high-level disinfection. Consult the probe manufacturer's IFU for handling and care.

☐ **Step 3: Manufacturer Cleaning**

Insert probe shaft ONLY into enzymatic solution and follow manufacturer's IFU for soak time. **WARNING:** TEE probes are not liquid sealed, DO NOT submerge handle or cabling.

☐ **Step 4: Manufacturer Cleaning Continued**

Rinse enzymatic solution from TEE probe and dry with a low-linting cloth. Consult probe manufacturer's IFU for type of material to ensure no damage to probe.

☐ **Step 5: Electrical Leakage Testing**

Perform electrical leakage testing per probe manufacturer's guidelines. Each TEE probe has different measurements, so consult your probe manufacturer's IFU.

☐ **Basin Test:**
After electrical leakage test, ensure the probe shaft is dry prior to insertion into high-level disinfectant. **ONLY** insert the probe shaft into the basin for electrical leakage testing and high-level disinfection.

☐ **Automated TEE Disinfector:**
Follow the IFU from the disinfector manufacturer to complete the necessary steps for electrical leakage testing.

☐ **Step 6: High-level disinfection of TEE ultrasound probe**

☐ **Automated Single-Use Chemistry:**
Once the TEE Probe has been placed into the automated disinfector, follow the screen prompts to perform high-level disinfection and rinse of the TEE ultrasound probe. The device will have the operator enter into the microprocessor the following data: operator name or designation, probe name or designation, and chemical lot number. With single-use chemistry, the expiration date on the bottle should be observed and if the expiry date has occurred, the chemical should not be used. NO MRC test strip is required to validate the efficacy of the disinfectant as long as it is used within the shelf life as cleared by the manufacturer with the FDA.

Probe Reprocessing Checklist

☐ **Step 7: Rinsing of HLD Probe**

☐ **Automated Single-Use Chemistry:**
Automatic rinsing is incorporated into the design to ensure removal of disinfectant residue.

☐ **Step 8: Drying of Probe After Removal from High-Level Disinfectant**

☐ **Automated Disinfector:**
Once the final rinse is complete, remove the probe from the device. Apply a low-linting drying cloth to the shaft as you remove the probe from the machine. Care should be observed not to hit or bang the distal tip of the TEE probe as this portion is the most delicate.

☐ **Step 9: TEE Probe Storage**

Place the high-level disinfected and dried TEE probe into a storage cabinet designed to hang the handle, electrical connector, and shaft vertically and freely. Make sure that the handle, cable, and electrical connector remain separate from the insertion shaft. All portions of the TEE, other than the insertion shaft, have only been surface disinfected while the insertion shaft has been high-level disinfected. Attention should be given not to bang or hit the distal tip of the probe as this portion is the most delicate. Per TJC requirements, the storage cabinet should allow the probes to hang vertically and have HEPA filtered air bathe them during storage.

☐ **Step 10: TEE Probe Transport**

Remove the probe from the storage cabinet and transport the TEE probe to the procedure room in a manner that ensures the probe meets the following conditions:

☐ 1) Secure as to not drop or bang the probe in transit

☐ 2) Within an enclosure designed not to allow cross-contaminants to be reintroduced onto the probe

☐ 3) Enclosure designed to transport the probe without damaging due to over coiling or components hitting each other during transit

TEE COMPLETE CARE®

Endocavity and Surface Ultrasound Probes

This checklist is provided as an outline of steps required to successfully reprocess an endocavity or surface ultrasound probe using Ethos®. These steps are intended to follow guidelines and recommendations from manufacturers of the ultrasound probe, recognized governmental agencies, and professional bodies. This checklist should be used as a reference for individual healthcare infection control professionals.

ALWAYS DON PROPER PPE!

☐ **Step 1: Point-of-Care Cleaning**

At the point of use or patient's bedside, use a wipe to remove the procedure cover. This can be accomplished with a Medi-Fect™ disinfectant wipe or a simple wipe. Once the procedure cover is removed, then place probe directly into Ethos. Follow prompts on LCD screen to begin automated cleaning and high-level disinfection.

☐ **Step 2: Cleaning and High-Level Disinfection**

Once the ultrasound probe has been placed into the automated cleaner disinfector, follow the screen prompts to automatically perform cleaning, high-level disinfection, and rinsing of the ultrasound probe. The device will have the operator enter into the microprocessor the following data: operator name or designation, probe name or designation, and AquaCide® lot number. The expiration date on the bottle should be observed and if the expiry date has occurred, the chemical should not be used. Ethos has automated MRC testing to validate the potency of the disinfectant. With automated MCR testing, Ethos will alert the end user in the event the minimum recommended concentration is not achieved and high-level disinfection will not be performed.

☐ **Step 3: Rinsing of HLD Probe**

Automatic rinsing is incorporated into the design to ensure removal of disinfectant residue.

☐ **Step 4: Drying of Probe After Removal from High-Level Disinfectant**

Once the final rinse is complete, remove the probe from the device. Apply a low-linting drying cloth to the insertion portion of the probe as you remove it from the Ethos. Care should be observed not to hit or bang the distal tip or lens area of the ultrasound probe as this portion is the most delicate.

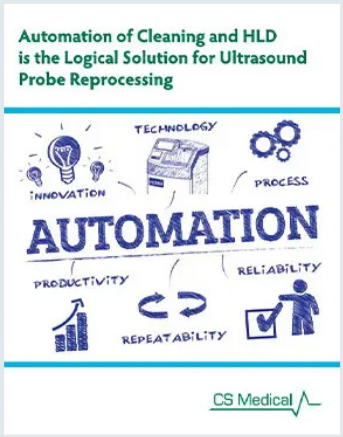
☐ **Step 5: Endocavity and Surface Probe Storage**

Place the high-level disinfected and dried ultrasound probe into a storage cabinet designed to secure the handle, electrical connector, and cable freely. Make sure that the handle, cable, and electrical connector remain separate from the body of the probe. All portions of the ultrasound probe, other than the insertion shaft or scanner head, have only been surface disinfected while the insertion shaft or scanner head has been high-level disinfected. Attention should be given not to bang or hit the distal tip or lens area of the probe as this portion is the most delicate. Per TJC requirements, the storage cabinet should allow the probes to be held securely and have HEPA filtered air bathe them during storage.

Resources

CS Medical Product Resources

CS Medical has numerous resources available to healthcare professionals tasked with reprocessing ultrasound probes, including developing comprehensive programs around ultrasound probe reprocessing and ensuring staff training.



Industry White Papers

Over 20 science-backed papers are available to download for free to ensure your team is up-to-date on industry trends, regulatory standards, and best practices utilizing the latest innovations in automation. View and download all available white papers at csmedicalllc.com/resources or scan the QR code.

Industry Information Sessions

CS Medical is committed to providing the products and support you need to ensure safe and effective ultrasound probe reprocessing. This includes opportunities to earn free continuing education (CE) credits by attending live virtual Industry Information Sessions on topics related to all steps of probe reprocessing from cleaning to storage and transportation.
Find the current schedule of upcoming events at csmedicalllc.com/continuing-education or scan the QR code.

IP Insights

This section is dedicated to educational and informational materials focused to aid infection prevention specialists as they perform audits, write standard operating procedures, and prepare for external audits. Find articles curated for IPs that relate to relevant content in today's healthcare setting and ask questions to subject matter experts on staff at CS Medical. Discover all of the available resources at https://csmedicalllc.com/ip-insights or scan the QR code.

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