HISTOSONICS™

en

FLUIDICS SYSTEM

USER GUIDE
Software Version 1.0

REF

HISFL1001 FLUIDICS CART

HISFK2001 FLUIDICS DISPOSABLE KIT



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1 Introduction

Introduction to the HistoSonics Fluidics System.

General Description and Purpose

The HistoSonics Fluidics System (system) is designed to prepare the ultrasound medium needed to support a histotripsy procedure using the HistoSonics Histotripsy System.

Ultrasound medium acoustically couples the Histotripsy System transducers with the patient during a histotripsy procedure.

The system draws water from a temperature-controlled clinical water source into its system check container, degasses the water, and subsequently transfers it to and from a patient membrane (membrane), a component of the Histotripsy System.

To transfer fluid, peristaltic pumps are paired with single-use cartridges attached to the sides of the system. The cartridges are provided in the Fluidics disposable kit. Each cartridge is part of a larger assembly of various components (for example, hoses and hose guides). The system degasses water by cycling it under a vacuum through the degassing filter for a specified duration.

Although the system is not designed to control water temperature, it monitors the temperature of the ultrasound medium in the system check container and displays it on the control panel.

Additionally, the Fluidics System is used when the Histotripsy System user performs a system check. During the system check, the treatment head is submerged in the system check container filled with ultrasound medium and tested before a histotripsy procedure.

Important

Use of the Fluidics System is not mandatory to support use of the Histotripsy System provided that a site meets the following criteria:

- Uses a calibrated dissolved oxygen (DO) meter with temperature reading
- Has access to a clinical water source between 15°C and 25°C that has been degassed to less than 50% dissolved oxygen
- Is equipped to safely collect, transport, and transfer ultrasound medium as needed to support a histotripsy procedure
- Is equipped with a container suitable for submerging the treatment head when performing a system check of the Histotripsy System

User Training

HistoSonics recommends that physicians and assisting staff receive training prior to using the Fluidics System.

Contact Information

Additional technical and customer service information is available from HistoSonics. Please visit www.histosonics.com or contact HistoSonics at:

Manufacturer	**HistoSonics, Inc.**
Address	16305 36th Avenue North, Suite 300 Plymouth, MN 55446-4273 USA
Customer Service	612-351-0361 Toll-free (US only) 877-740-0543
Email	info@histosonics.com
European Union Authorized Representative	Obelis S.A. Boulevard Général Wahis, 53 1030 Brussels BELGIUM

About This User Guide

Software Version

This user guide is specific to software version 1.0.

Navigating the PDF

- **Contents:** Select any entry in the table of contents to go directly to the corresponding page.
- **Bookmarks:** This PDF is equipped with bookmarks to help navigate through the user guide.
- **Cross-references:** Selecting cross-references will take you directly to the corresponding page.
- **Search Function:** To quickly find specific information, you can utilize the search function in your PDF reader. Press **Ctrl + F** (or **Cmd + F** on macOS) to open the search bar.

Printed User Guides

Printed versions of this user guide are available upon request at no charge.

Conventions Used

The following conventions are used to draw attention to safety information and other types of important information.

Warning

Indicates a potentially hazardous situation that, if not avoided, could result in death or severe injury.

Caution

Indicates a potentially hazardous situation that, if not avoided, could result in minor to moderate injury or product damage.

Important

Used to draw attention to important information and to provide additional context, details, and operational tips.

Symbols

Definitions for symbols used in Fluidics System labeling.


Manufacturer


Use-by date



Lot number



Catalog number



Serial number



Country and date of manufacture


This side up (indicates the correct upright orientation for transport and storage)


Fragile (handle with care)


Temperature limitation


Humidity limitation


Do not re-use (single use)


Consult electronic instructions for use



Caution — Consult instructions for use for specific warnings or precautions associated with the medical device



Medical device



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician



Alternating current



Non-ionizing electromagnetic radiation



Emergency stop



Waste from Electrical and Electronic Equipment (WEEE) indicates the product should be collected separately and not disposed of as unsorted municipal waste



System degree of protection against ingress



Follow instructions for use



Identifies the fill pump and fill cartridge



Identifies the waste pump and waste hose assembly



European Union representative



CE mark

Terminology

Key terminology and concepts.

fill cartridge	Magnetically attaches to the Fluidics cart and is part of an assembly of disposable fluidics components. It pairs with the fill pump and vacuum pump and is used to fill, degas, and transfer ultrasound medium.
fluidics disposable kit	Contains the two disposable cartridges (fill and waste) that are coupled with the Fluidics cart.
hose guides	Used to secure hoses in designated locations during preparation and transfer, each hose guide is color-coded: blue, white, or gray. This color coding is mirrored in the graphical user interface (GUI) to ensure easy identification and correct placement.
membrane	A component of the Histotripsy System that conforms to the patient and holds ultrasound medium.
membrane frame	Holds the membrane and serves as the attachment point for the Fluidics System hose guides during the filling and draining processes. The blue hose guide is used to fill the membrane, and the gray hose guide is used to drain it.
peristaltic pump (pump)	A positive displacement pump that moves fluids by squeezing a flexible hose.
system check container	The removable basin, located near the top of the Fluidics cart, designed to collect water and temporarily store ultrasound medium.
ultrasound medium	Water prepared to the required specifications (dissolved oxygen level and temperature) for a histotripsy procedure. Creates efficient acoustic coupling between the Histotripsy System treatment head and patient.
waste basin	A removable waste basin with lid, positioned near the bottom of the Fluidics cart, used to collect waste (used or extra) ultrasound medium from the membrane above the patient.
waste cartridge	Magnetically attaches to the Fluidics cart and is part of an assembly of disposable fluidics components. It pairs with the waste pump to drain ultrasound medium from the membrane and the waste basin.

Quick Reference



Ensure battery is sufficiently charged before a procedure

- Keep the system plugged in with the power switch in the on (**I**) position to charge the battery
- Never rely on a low battery (indicated by red battery icon)



Schedule at least 1-hour before a histotripsy procedure to:

- Verify that parts and supplies are present and that no parts are damaged
- Visually inspect the system for cleanliness and clean it if needed
- Check the Fluidics disposable kit's use-by date located on its label or packaging
- Install the disposable cartridges provided in the Fluidics disposable kit
- Prepare ultrasound medium—filling and degassing requires approximately 45 minutes



Ultrasound medium must have a temperature between 15°C and 25°C

- Control water temperature from the source (faucet controls) when filling the system
- The control panel displays the temperature of the water collected in the system check container



Ultrasound medium must have less than a 50% dissolved oxygen level

- Do not interrupt the degassing cycle
- Use within 4 hours of completing the degassing process
- Keep the lid on the system check container to slow regassing from the atmosphere
- Do not supplement with unprocessed water



Disposables (fill and waste cartridges) are single-use only

- Dispose after use to prevent mold and mildew growth
- Always use new cartridges to maintain optimal system performance



Clean and dry the system as instructed

2 Safety and Standards

General use information, summary of safety notices, and information about manufacturing and testing.

Intended Use

HistoSonics' Fluidics System is intended to degas, transport, and transfer ultrasound medium.

Indications for Use

HistoSonics' Fluidics System is indicated for preparing ultrasound medium to support a histotripsy procedure.

Contraindications

None known.

Caution

Rx ONLY Federal law (USA) restricts this device to sale by or on the order of a physician.

Reporting of Incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to HistoSonics and to your national authority.

Summary of Safety Notices

This section contains important information about the safe use of the Fluidics System. Read and understand this section prior to setting up and using the Fluidics System.

Warnings

The following warnings apply to the Fluidics System and its use.

Warning

All Fluidics System users must read and fully understand the information in this user guide, including all warnings, precautions, and instructions.

Only HistoSonics service personnel can perform preventive maintenance and service the Fluidics System. The Fluidics System contains internal components such as a lead-acid battery. Unauthorized modification is prohibited and may result in electric shock, fire or explosion, and chemical burns, causing serious harm to the user or damage to the device.

Warning

Do not use a power cord if it shows visible signs of damage or if you suspect internal damage, such as from being crushed by a heavy object. Both visible and concealed damage can create hazardous conditions, including the risk of fire and electrical shock.

To avoid the risk of electric shock, only connect the Fluidics System directly to an earthed, hospital-grade power outlet.

Only use the power cord provided by HistoSonics, as alternative power cords may lead to increased emissions or decreased system immunity.

To meet electromagnetic compatibility (EMC) requirements, avoid using the Fluidics System adjacent to other equipment. Do not place other equipment on top of the Fluidics cart.

Do not use the Fluidics System outside of the EMC specifications provided in this user guide.

The Fluidics System is not compatible with an MRI environment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fluidics cart. Otherwise, the degradation of system performance could result.

Precautions

The following precautions apply to the Fluidics System and its use.

Caution

Follow the instructions in this user guide to ensure that ultrasound medium is sufficiently degassed for use with the Histotripsy System. Delivering energy with the Histotripsy System treatment head through ultrasound medium that is insufficiently degassed can:

- Prevent the bubble cloud from generating and/or prevent a sustained bubble cloud
- Cause damage to the treatment head

Allocate at least 1 hour to set up the Fluidics System and prepare ultrasound medium. Failure to prepare ultrasound medium will prevent the ability to perform the Histotripsy System system check and potentially delay the start of a histotripsy procedure. Well in advance of a histotripsy procedure, verify that:

- All system components are present.
- A water source is available.
- A power source is available in all use locations, or the Fluidics System battery is adequately charged (indicated by the green battery icon).

Caution
If the Fluidics System was not plugged in and charged before use or during filling and degassing, verify that the Fluidics System battery is adequately charged (indicated by the green battery icon). For uninterrupted operation, immediately connect the Fluidics System to a power outlet when the battery is low (indicated by the red battery icon). To charge the Fluidics System battery, plug the system into a power outlet and ensure that the power switch is in the on (**I**) position. To avoid a low battery, HistoSonics recommends keeping the system plugged in with the power switch in the on (**I**) position: • When preparing the system • During the fill system and degas process • Whenever the use of the power cord will not cause an inconvenience or a tripping hazard Note: The battery only charges when the system is plugged in and the power switch is on (**I**). Plugging in the system alone—with the power switch off (**O**)—does not charge the battery.
Always keep the hose guides attached to their designated attachment points to prevent spills as this could create a slip hazard or other workplace hazard. Exception: When draining the membrane, hand-holding the gray hose guide is necessary to remove the last remaining fluid.
Always carefully align the degassing filter outlet port with the vacuum inlet during both insertion and removal. Misalignment can cause the outlet port to break off.
Failure to insert the hose into the pump as instructed could damage the hose, preventing use of the system.
To prevent burns or discomfort to the operator or patient, do not fill the Fluidics System with hot water. To be within specification, water must be between 15°C and 25°C. Refer to the control panel for the temperature reading.
Before transporting the Fluidics cart, inspect the wheels for damage. Do not transport if the wheels are damaged as there is a risk of tipping and potential injury. When transporting, use care and move slowly to avoid damage. The wheels are designed for smooth surfaces; rough surfaces can damage the wheels.
Always push the Fluidics cart instead of pulling it to minimize the risk of tipping and potential injury.
The cartridge assemblies provided in the Fluidics disposable kit are single use only. Failure to dispose of the cartridges after use can lead to mold and mildew growth and a loss of effectiveness in the degassing filter, resulting in reduced degassing performance.
To prevent hair or loose clothing entanglement and avoid pinch point injuries, operate the pumps only when they are closed (levers in the locked position). When moving a pump lever to the locked position, keep your fingers clear of the opening to avoid injury.
Do not use the Fluidics disposable kit beyond its use-by date. An expired use-by date may indicate that the contents have degraded.

Caution
Clean and dry the system as instructed in this user guide. Failure to clean and dry the system may lead to mold and mildew growth.
The use of cleaning agents or use of cleaning products other than those specified may damage equipment and void the warranty.
Clean the control panel with a soft, non-abrasive cloth. Do not use paper towels as they may cause light scratches.
Do not allow liquids to come into contact with power cord connections.
Avoid exposing the Fluidics System to flammable liquids or gases, corrosive substances, strong electrical or magnetic fields, and equipment that emits high-frequency waves.
HistoSonics cannot guarantee the performance of the Fluidics System if stored or used outside of the specified environmental conditions.
Do not attempt to use the Fluidics System with components other than those provided or specified by HistoSonics.
When connecting the Fluidics cart to a power outlet (mains connection), connect the power cord directly. Do not use extension cords or power strips. Additionally, ensure that the Fluidics cart is positioned so that the power cord can be easily disconnected.
Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.
Federal law (USA) restricts this device to sale by or on the order of a physician.

Safety Features

Cycle Time

The Fluidics System employs a preprogrammed cycle to automatically degas water to the required specification, eliminating the need for manual testing with a dissolved oxygen (DO) meter. The cycle ensures consistent and reliable results below the 50% dissolved oxygen requirement.

Temperature Monitoring

The Fluidics System continuously monitors the temperature of the ultrasound medium in the system check container. The control panel displays the current temperature. Verify that the temperature is between 15°C and 25°C. An alert icon appears on the control panel if the temperature falls outside this range.

Battery

The Fluidics System houses a battery to enable use when a power outlet is not available or convenient. Avoiding the need to plug in the system in a congested procedure room reduces the risk of trip hazards and helps expedite setup when filling and draining the membrane above a patient. Additionally, the battery functions as an uninterruptible power supply, providing backup in case of unexpected power loss.

Important
The battery is not user-accessible and can only be accessed and replaced by HistoSonics service personnel. Always follow the preventive maintenance schedule to maintain battery health.
The system must be plugged in to an outlet to power on. It will remain operational when unplugged, provided that the battery is not depleted.
For battery maintenance, keep the system plugged in with the mains power switch in the on (**I**) position, especially during storage.

Emergency Stop Button

Pressing the emergency stop button instantly stops peristaltic pump operation, thereby stopping fluid flow. To reset the emergency stop condition, twist the emergency stop clockwise until it releases.

Important

Use the emergency stop only in an emergency. Under normal conditions, use the control panel to stop an operation.



① Emergency stop button

Medical Electrical Equipment—International Standard

The Fluidics System is classified and certified in accordance with IEC 60601-1 Medical Electrical Equipment for basic safety and essential performance by a credentialed third-party medical device testing facility as follows:

Type	Classification/Certification
Medical electrical equipment standard	IEC 60601-1 Edition 3.2
Type of protection against electrical shock	Class I
System degree of protection against ingress	IP20

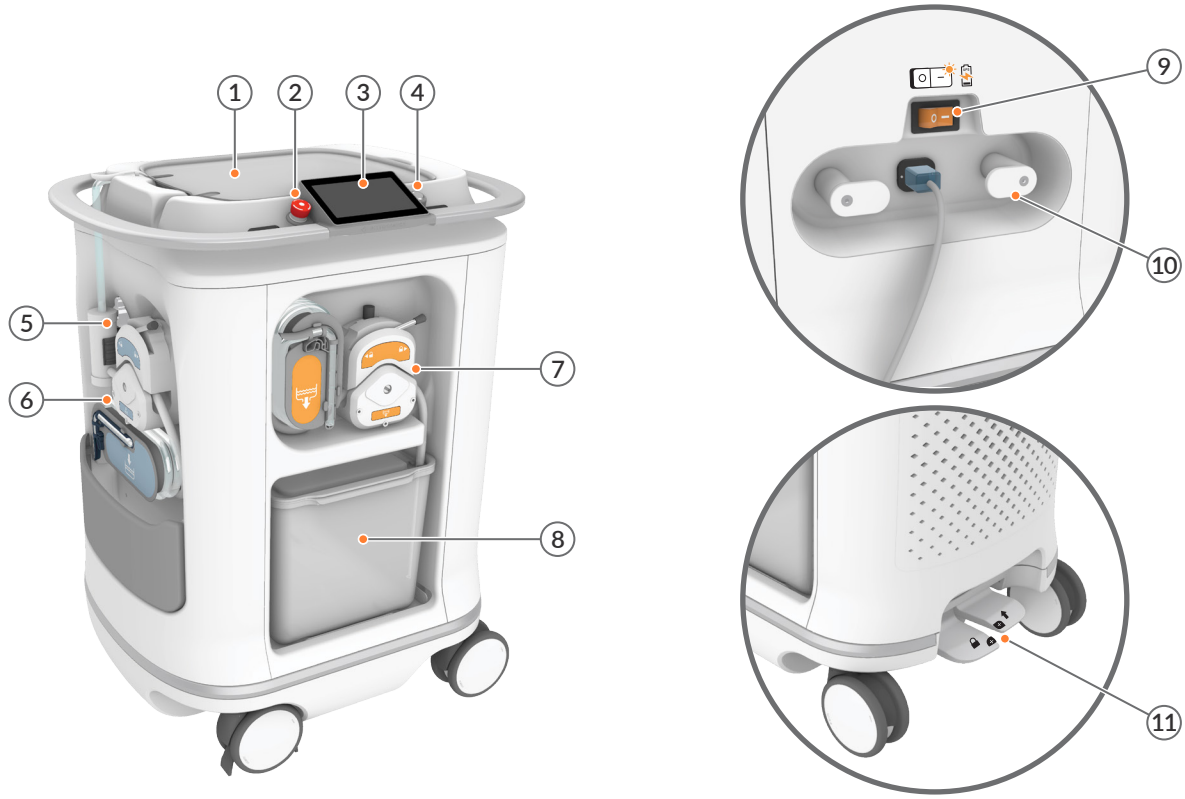
3 Overview

An overview of Fluidics System components and user interface.

Fluidics System

The Fluidics System is an inclusive term that refers to the Fluidics cart and the cartridges provided in the Fluidics disposable kit.

The Fluidics cart is designed to be mobile, enabling it to be conveniently positioned near a clinical water source, and also be placed next to a procedure bed both before and after a histotripsy procedure. To facilitate maneuvering, a wrap-around handle encircles the cart.



1. System check container with lid
2. E-stop
3. Control panel
4. Power button
5. Vacuum pump inlet and degassing filter
6. Fill pump with fill cartridge
7. Waste pump with waste cartridge
8. Waste basin with lid
9. Power switch
10. Power cord keeper
11. Wheel controls

Wheel Controls

Use to:

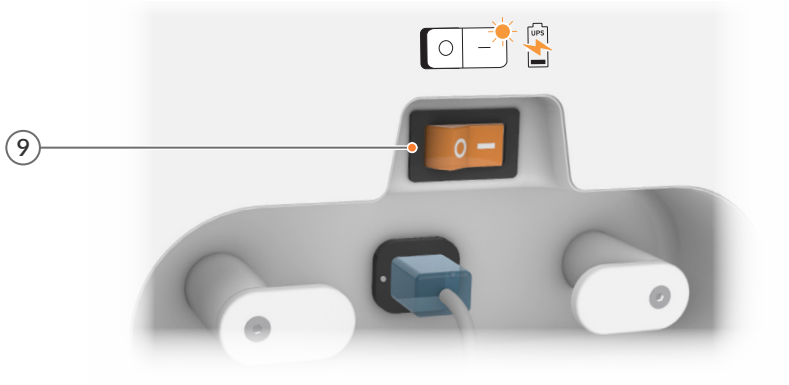
- Lock all four wheels in their current orientation (lock mode)
- Prevent the drive wheels from swiveling during transportation (drive mode)
- Enable all wheels to roll and swivel (full mobility mode)

Desired Operation	Left Pedal Position	Right Pedal Position	Mode Icon
Full mobility mode • All wheels roll • All wheels swivel	Neutral	Neutral	Full mobility mode is engaged when the mobility icons align (both pedals in neutral position). 
Drive mode • All wheels roll • Drive wheels swivel locked	Up	Down	Drive mode is engaged when the pedal with the arrow icon is down. 
Lock mode • All wheels roll locked • All wheels swivel locked	Down	Up	Wheel locks are engaged when the pedal with the lock icon is down. 

Power Switch

Regulates electrical power to the system. The switch illuminates when the system is receiving power from an outlet and is in its on (**I**) position. Whenever the system can be plugged into a power outlet, it is recommended that the power switch remain on, allowing the system to charge its battery when necessary.

A diagram adjacent to the power switch indicates that battery charging can only occur when the switch is in the on (**I**) position.



9 Power switch

Battery

Powers the system should an outlet not be available or convenient to use.

Power Button

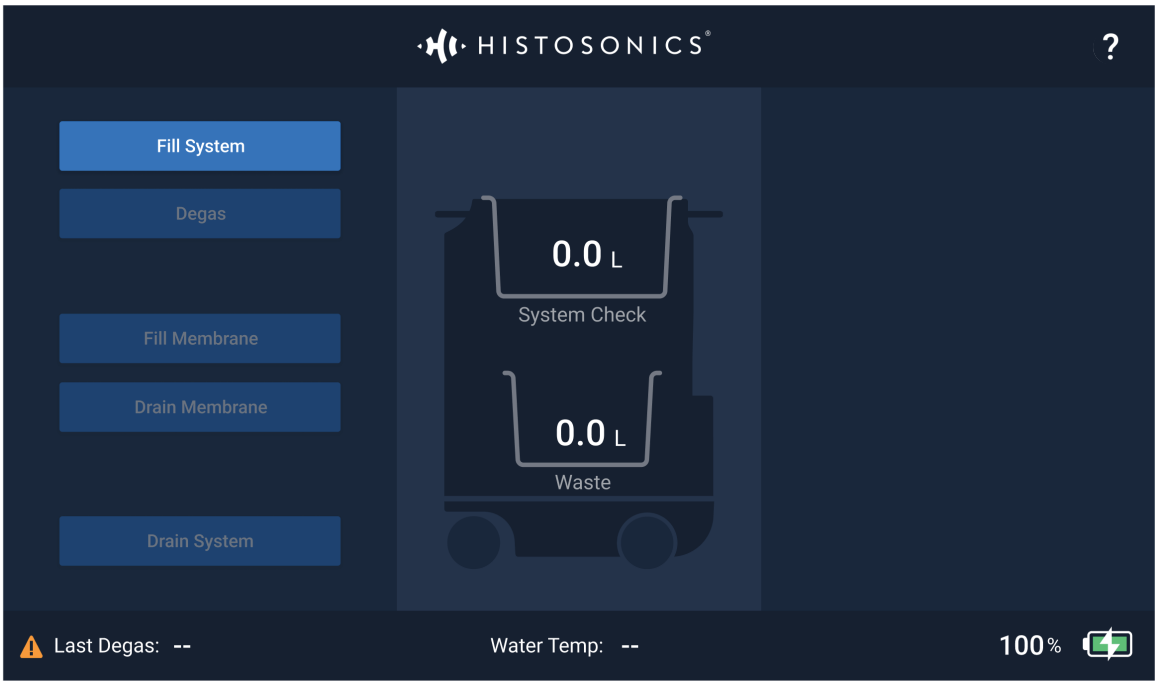
Located to the right of the control panel, this button is used to power the system on and off. The button is slightly recessed when in the on position.



4 Power button

Control Panel

The user interacts with the Fluidics cart via a touchscreen control panel. This interface features dedicated screens and buttons tailored for each operational task, visually guiding the setup process. It displays the current temperature of the ultrasound medium, time since the last degas, and the approximate volume (in liters) of ultrasound medium in each basin, including the approximate volume transferred to the membrane. Additionally, the interface shows the power status and battery charge level.



Key GUI Elements

Help Icon

? Tap the question mark icon to access help content.

- When tapping from the main menu, all help topics display. Select the topic you wish to explore.
- When tapping from within a task, only the guidance that is specific to that task displays.

Temperature

Displays the temperature of the ultrasound medium in the system check container.

- An alert icon displays if the temperature is not within 15°C and 25°C.



Last Degas Timer

Displays the elapsed time since the ultrasound medium was degassed, in hours and minutes.

- A green check mark icon displays when the duration is within the 4-hour maximum use limit.
- An alert icon displays if the duration has exceeded the 4-hour limit.



Charge State

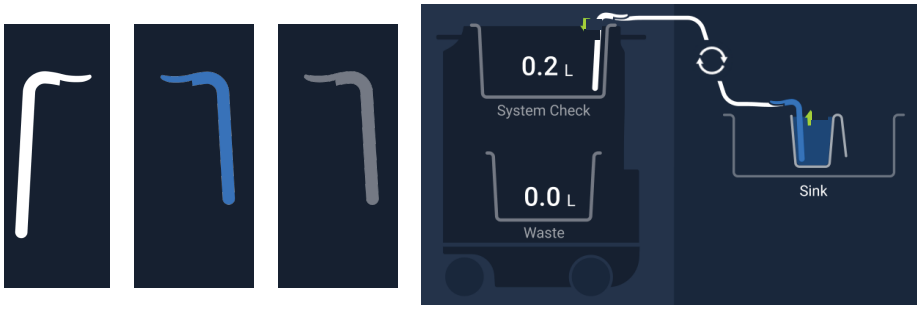
Shows the battery charge and charging status.

- The lightning bolt displays when the system is plugged in.
- Green battery icon indicates that the battery charge is full or adequate for battery use, the red battery icon indicates that the battery charge is too low for battery powered operation.



Hose Guide Icons

The hose guide icons are color-coded: white, blue, and gray, indicating their required attachment point for the current task. In the example screen below, the white hose guide is shown attached to the system check container, while the blue hose guide is shown attached to the pitcher in the sink. Note that the gray hose guide is not displayed as it is not needed for this task.



System Check Container

The system check container is used to collect water for the degassing process and for temporarily storing the degassed water (ultrasound medium) before the histotripsy procedure. Its lid helps prevent spills during transport and slows regassing from the atmosphere. The system check container is removable to facilitate cleaning.

The image below illustrates how the white and blue hose guides are clipped to their respective attachment points on the system check container to facilitate the degassing process by cycling the ultrasound medium.



1. System check container with lid
2. White hose guide
3. Blue hose guide

Important

The software will automatically fill the system check container with 30 liters of water. Typically, a single histotripsy procedure requires 13–15 liters.

The system check container name derives from an additional function it supports, where a Histotripsy System treatment head is partially submerged in it when performing a Histotripsy System system check.

The mirror at the bottom of the system check container is not used for ultrasound medium preparation; it helps the Histotripsy System user inspect for air pockets beneath the Histotripsy System treatment head when it is submerged during a Histotripsy System system check.

Waste Basin

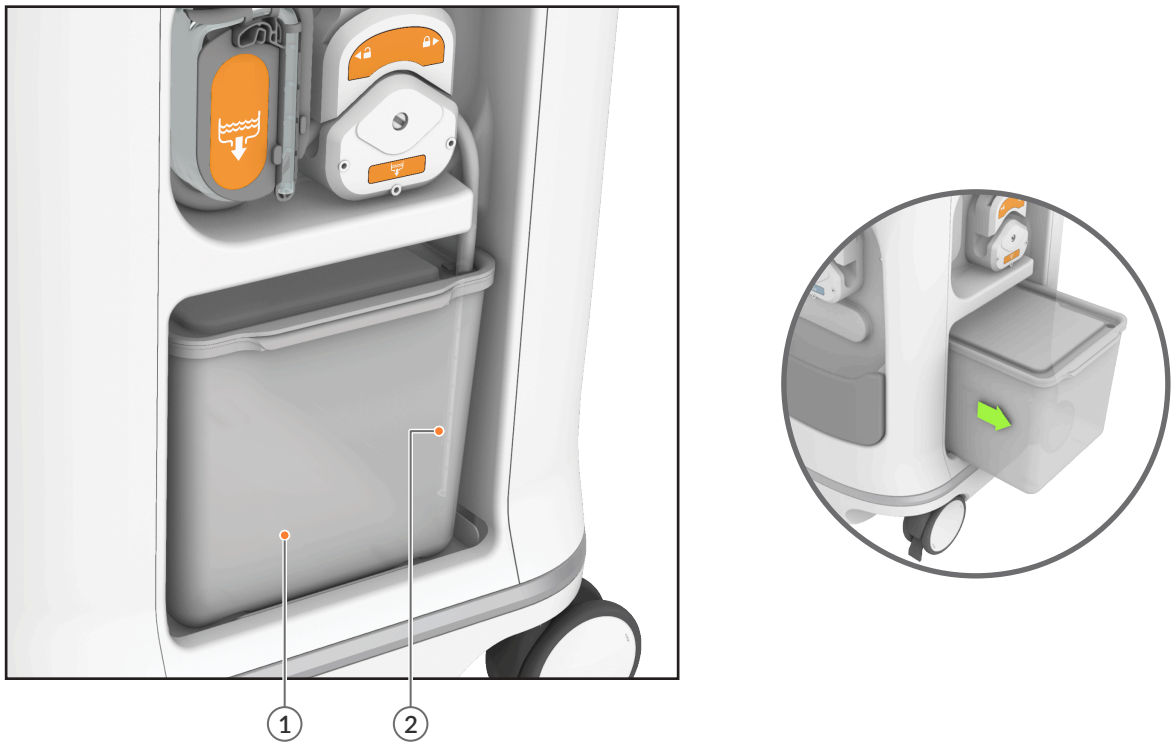
After a histotripsy procedure, ultrasound medium is transferred from the membrane into the waste basin. Later, when draining the Fluidics System, the ultrasound medium is transferred from the waste basin to the pitcher in the sink. The waste basin lid helps prevent spills during transport.

The waste basin is removable to facilitate cleaning.

Important

The waste basin can also be removed to be used as an emergency evacuation container in the event of a patient emergency during a histotripsy procedure. Refer to the Histotripsy System User Guide for more information.

For the system to accurately detect the volume of water in the waste basin, it must be fully inserted. When inserting, push it in until it contacts the back wall.



1. Waste basin
2. Gray waste downspout

Peristaltic Pumps

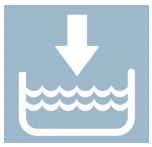
The Fluidics cart is equipped with two peristaltic pumps for managing fluid transfer in the system. Selecting an operation in the user interface activates the appropriate pump to manage fluid transfer—this includes the direction, duration, and volume or time until completion—all automated by the system.

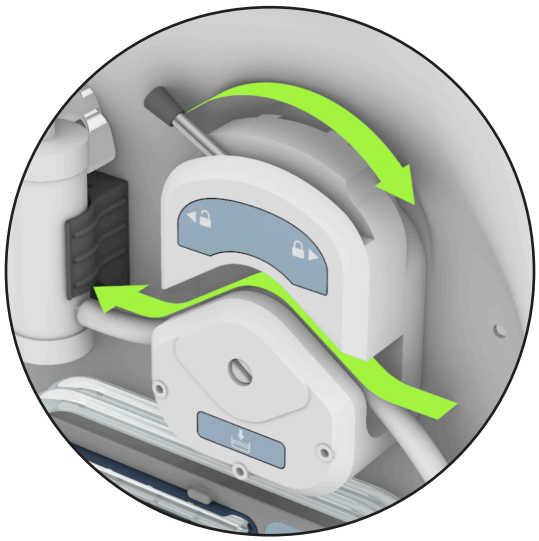
A peristaltic pump includes a rotating roller that compresses the tube when the pump lever is in the lock position. When the roller operates, the pump transfers fluid through the tubing.

- The pumps transfer fluid at a rate of 3–4 liters per minute.
- When filling the membrane, the system enforces a 4.0 liter reserve in the system check container. For example, if 15 liters are displayed, only 11 liters are available for transfer to the membrane. This reserve prevents introducing air into the system. The system displays a prompt if the setting exceeds the available volume.

The two cartridges are labeled with a unique color and symbol that corresponds to the respective pump, ensuring correct pairing and orientation of the cartridges. The cartridges have a unique size corresponding to their magnetic attachment point.

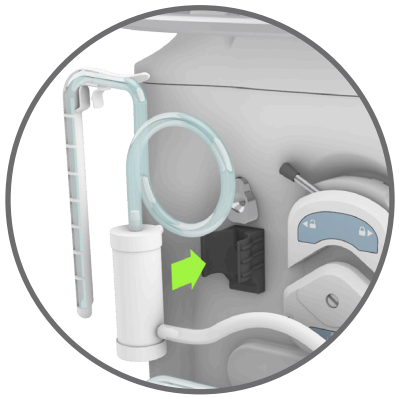
Additionally, each pump is labeled with an unlocked and locked icon, corresponding to the required lever position for inserting or removing the hose (unlocked) and preparing for fluid transfer (locked). The softer, white (opaque) section of the hose is routed through the pumps.

Component	Color and Symbol
Fill pump and fill cartridge	
Waste pump and waste cartridge	



Vacuum Pump

The Fluidics cart contains a vacuum pump, with only the vacuum pump inlet port visible on the side of the cart. A clip on the side of the cart holds the degassing filter, a component of the fill cartridge. The degassing filter outlet port connects to the vacuum pump inlet port. The vacuum pump extracts dissolved oxygen from the water as it passes through the filter.

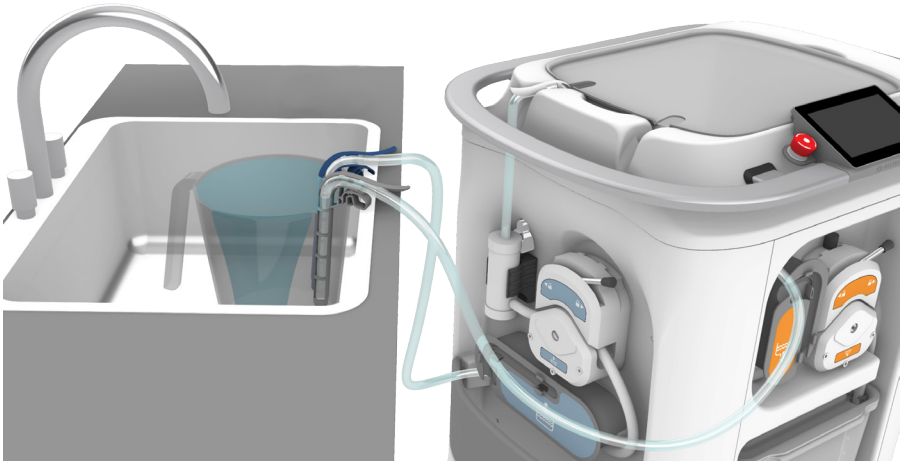


Pitcher

To facilitate the filling and draining of the system, place the shatter-resistant plastic pitcher (provided) in a sink. This approach removes the need for special faucet adapters and makes it easier to regulate the initial water temperature.

Securing the blue hose guide to the pitcher during the fill system task helps prevent it from falling out, which helps avoid accidental spills and unwanted air introduction.

The accompanying image illustrates proper attachment of the blue and gray hose guides to the pitcher during the drain system task. This allows for the simultaneous draining of both the system check container and waste basin into the pitcher, which then simply overflows into the sink.



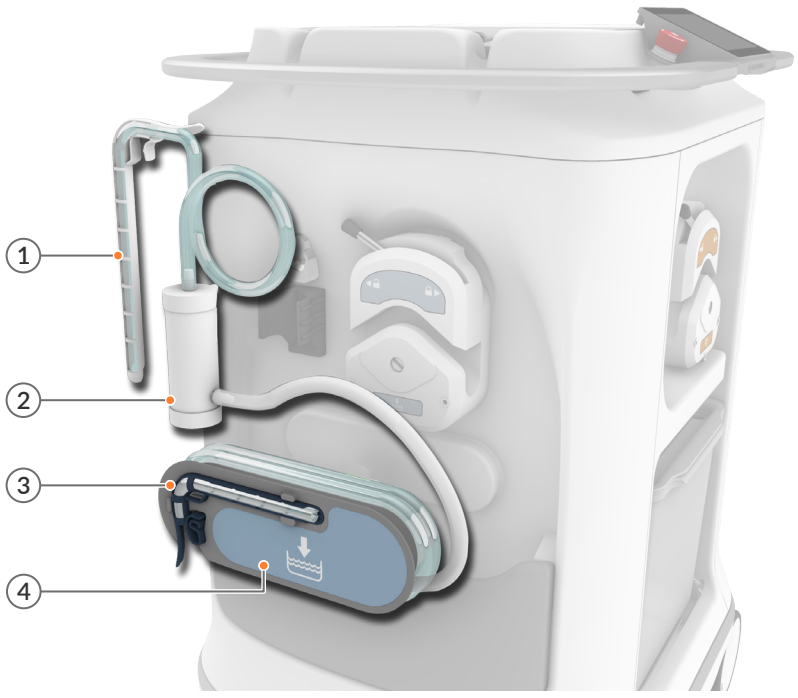
Fluidics Disposable Kit

The Fluidics disposable kit includes two single-use cartridges: the fill cartridge and waste cartridge. The cartridges are magnetically attached to the Fluidics cart during initial setup. Each cartridge is part of a larger assembly of various components detailed in the subsequent sections.

Fill Cartridge

In conjunction with the fill pump, use the fill cartridge to perform the following operations:

- **Fill the Fluidics System:** Transfers water from a pitcher that is actively being filled in a sink to the system check container.
- **Degas:** Cycles the water in the system check container through the degassing filter under vacuum for a preprogrammed length of time (30 minutes).
- **Fill membrane:** Transfers a user-determined volume of degassed water (ultrasound medium) from the system check container into the membrane above the patient.
- **Drain system check container:** Transfers remaining ultrasound medium from the system check container to the pitcher in a sink.



1. White hose guide
2. Degassing filter
3. Blue hose guide
4. Cartridge

Waste Cartridge

Magnetically attaches to the dedicated attachment point. Insert the gray downspout into the waste basin upon initial setup. It secures the gray hose guide when it is not needed.

In conjunction with the waste pump, use the waste cartridge to perform the following tasks:

- **Drain Membrane:** Transfers water from the membrane above the patient into the waste basin.
- **Drain Waste:** Transfers water from the waste basin to a pitcher placed in a sink.



1. Gray hose guide
2. Cartridge
3. Gray downspout

4 Operation

Step-by-step instructions for operating the Fluidics System from setup to preparing for storage.

Prepare and Coordinate

Caution

Allocate at least 1 hour to set up the Fluidics System and prepare ultrasound medium. Failure to prepare ultrasound medium will prevent the ability to perform the Histotripsy System system check and potentially delay the start of a histotripsy procedure. Well in advance of a histotripsy procedure, verify that:

- All system components are present.
- A water source is available.
- A power source is available in all use locations, or the Fluidics System battery is adequately charged (indicated by the green battery icon).

Proper timing is crucial for preparing the ultrasound medium used for both the Histotripsy System system check and the subsequent histotripsy procedure. To ensure the ultrasound medium meets specifications by remaining degassed to less than 50% oxygen, it should not sit for more than 4 hours after the degassing process. This necessitates careful coordination with Histotripsy System users to schedule the preparation timing, aligning with both the system check and the procedure.

The degassing cycle itself takes 30 minutes, with an additional setup and fill time of approximately 15 minutes. Therefore, a good practice is to start the preparation process at least one hour before the system check is scheduled.

Gather Equipment, Accessories, and Supplies

Caution

Do not use the Fluidics disposable kit beyond its use-by date. An expired use-by date may indicate that the contents have degraded.

The cartridge assemblies provided in the Fluidics disposable kit are single use only. Failure to dispose of the cartridges after use can lead to mold and mildew growth and a loss of effectiveness in the degassing filter, resulting in reduced degassing performance.

Do not attempt to use the Fluidics System with components other than those provided or specified by HistoSonics.

Ensure that the following equipment and supplies are available well in advance of a histotripsy procedure.

REF **HISFL1001** **Fluidics Cart**	Includes the following subcomponents: • System check container and lid • Waste basin and lid • Pitcher
REF **HISFK2001** **Fluidics Disposable Kit**	Includes: • Fill cartridge • Waste cartridge

Other Supplies (not supplied by HistoSonics)

- CaviWipes™ germicidal wipe or equivalent
- Soft non-abrasive cloth for cleaning and drying

Clean

Caution

Clean and dry the system as instructed in this user guide. Failure to clean and dry the system may lead to mold and mildew growth.

Clean the Fluidics cart before each use. Refer to *Cleaning* on page 5-1.

Inspect

Perform the following inspection tasks before every use.

Warning

Do not use a power cord if it shows visible signs of damage or if you suspect internal damage, such as from being crushed by a heavy object. Both visible and concealed damage can create hazardous conditions, including the risk of fire and electrical shock.

Caution

Before transporting the Fluidics cart, inspect the wheels for damage. Do not transport if the wheels are damaged as there is a risk of tipping and potential injury. When transporting, use care and move slowly to avoid damage. The wheels are designed for smooth surfaces; rough surfaces can damage the wheels.

Always push the Fluidics cart instead of pulling it to minimize the risk of tipping and potential injury.

1. Inspect the power cord for signs of damage.
2. Inspect the wheels for damage or excessive tread wear that could affect stability. Do not use if the wheels are damaged to the point that stability could be affected.
3. Verify the wheel lock function, and do not use if the wheels do not lock.

Position and Plug In

Warning

To avoid the risk of electric shock, only connect the Fluidics System directly to an earthed, hospital-grade power outlet.

Caution

When connecting the Fluidics cart to a power outlet (mains connection), connect the power cord directly. Do not use extension cords or power strips. Additionally, ensure that the Fluidics cart is positioned so that the power cord can be easily disconnected.

Do not allow liquids to come into contact with power cord connections.

Caution

If the Fluidics System was not plugged in and charged before use or during filling and degassing, verify that the Fluidics System battery is adequately charged (indicated by the green battery icon). For uninterrupted operation, immediately connect the Fluidics System to a power outlet when the battery is low (indicated by the red battery icon).

To charge the Fluidics System battery, plug the system into a power outlet and ensure that the power switch is in the on (**I**) position.

To avoid a low battery, HistoSonics recommends keeping the system plugged in with the power switch in the on (**I**) position:

- When preparing the system
- During the fill system and degas process
- Whenever the use of the power cord will not cause an inconvenience or a tripping hazard

Note: The battery only charges when the system is plugged in and the power switch is on (**I**). Plugging in the system alone—with the power switch off (**O**)—does not charge the battery.

1. Position the Fluidics cart near a sink.
2. Plug the Fluidics cart directly into an outlet.

Important

The system must be plugged in to an outlet to power on. It will remain operational when unplugged, provided that the battery is not depleted.

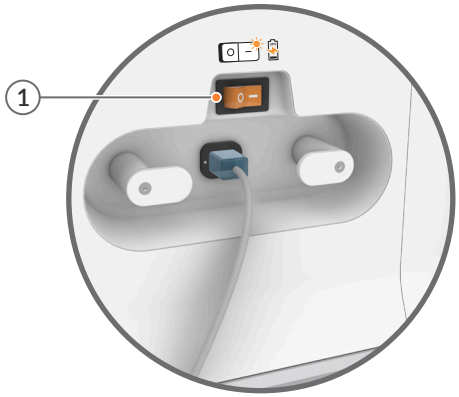
To avoid a low battery, HistoSonics recommends keeping the system plugged in with the power switch in the on (**I**) position:

- When preparing the system
- During the fill system and degas process
- Whenever the use of the power cord will not cause an inconvenience or a tripping hazard

Note: The battery only charges when the system is plugged in and the power switch is on (**I**). Plugging in the system alone—with the power switch off (**O**)—does not charge the battery.

Power On the System

1. If not already on, set the power switch to the on (**I**) position.
2. Press the power button on the control panel.





① **Power switch**

② **Power button**

Prepare Ultrasound Medium

Caution

Follow the instructions in this user guide to ensure that ultrasound medium is sufficiently degassed for use with the Histotripsy System. Delivering energy with the Histotripsy System treatment head through ultrasound medium that is insufficiently degassed can:

- Prevent the bubble cloud from generating and/or prevent a sustained bubble cloud
- Cause damage to the treatment head

Set Up System

Caution

To prevent hair or loose clothing entanglement and avoid pinch point injuries, operate the pumps only when they are closed (levers in the locked position). When moving a pump lever to the locked position, keep your fingers clear of the opening to avoid injury.

Failure to insert the hose into the pump as instructed could damage the hose, preventing use of the system.

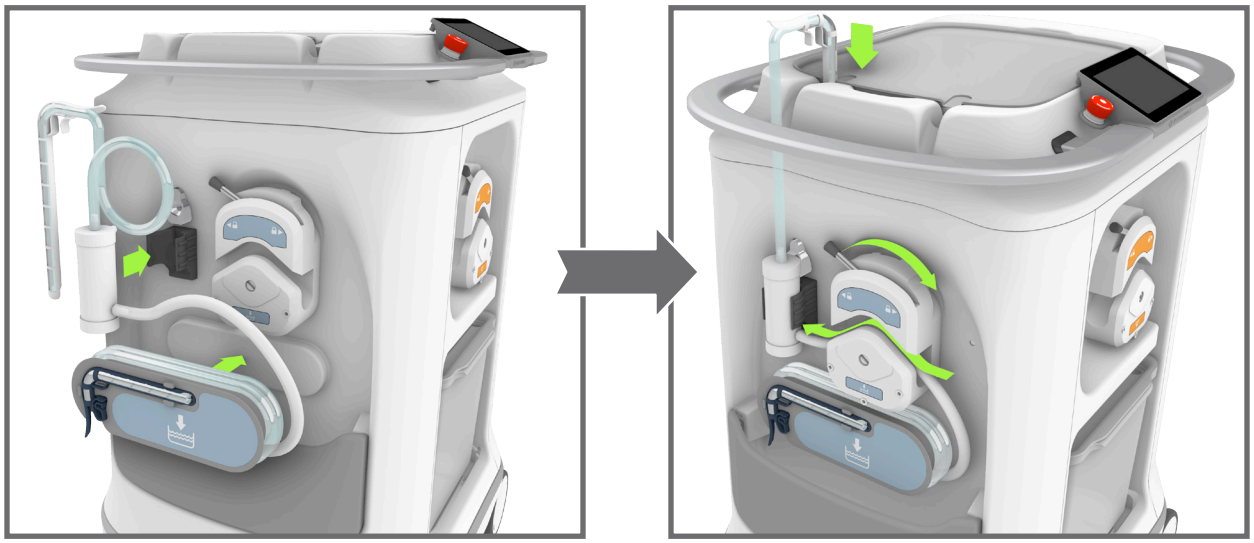
Always keep the hose guides attached to their designated attachment points to prevent spills as this could create a slip hazard or other workplace hazard. Exception: When draining the membrane, hand-holding the gray hose guide is necessary to remove the last remaining fluid.

Install Fill Cartridge

Caution

Always carefully align the degassing filter outlet port with the vacuum inlet during both insertion and removal. Misalignment can cause the outlet port to break off.

1. Place the fill cartridge over its magnetic attachment point. Refer to the matching blue labels and fill symbols to ensure that you are using the correct attachment point and orientation.
2. Route the soft white tube through the fill pump.
3. Align the degassing filter outlet port with the vacuum inlet, then press the degassing filter into the clip. Ensure the outlet port is fully inserted in the vacuum inlet.
4. Move the fill pump lever to the locked position.
5. Attach the white hose guide onto the system check container.

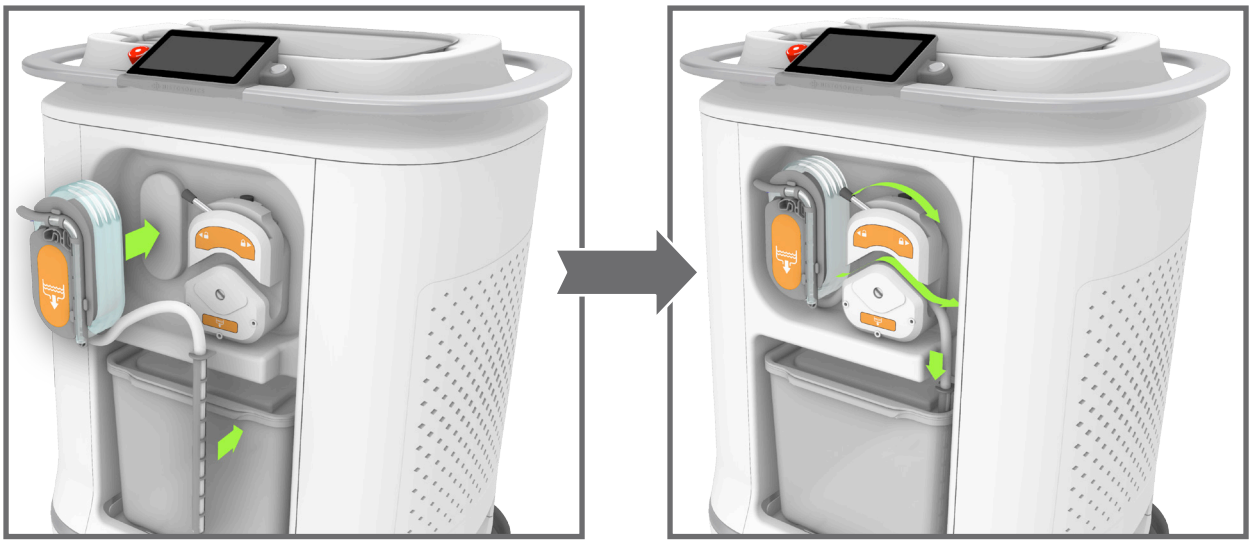


Important

The white hose guide will remain attached to this location for the entire duration of system use.

Install Waste Cartridge

1. Place the waste cartridge over its magnetic attachment point.
2. Insert the gray downspout into the waste basin.
3. Route the soft white tube through the waste pump.
4. Move the waste pump lever to the locked position.



Important

For the system to accurately detect the volume of water in the waste basin, it must be fully inserted. When inserting, push it in until it contacts the back wall.

Leave the gray hose guide attached to the waste cartridge until after the histotripsy procedure when it is used to drain the membrane.

Fill System

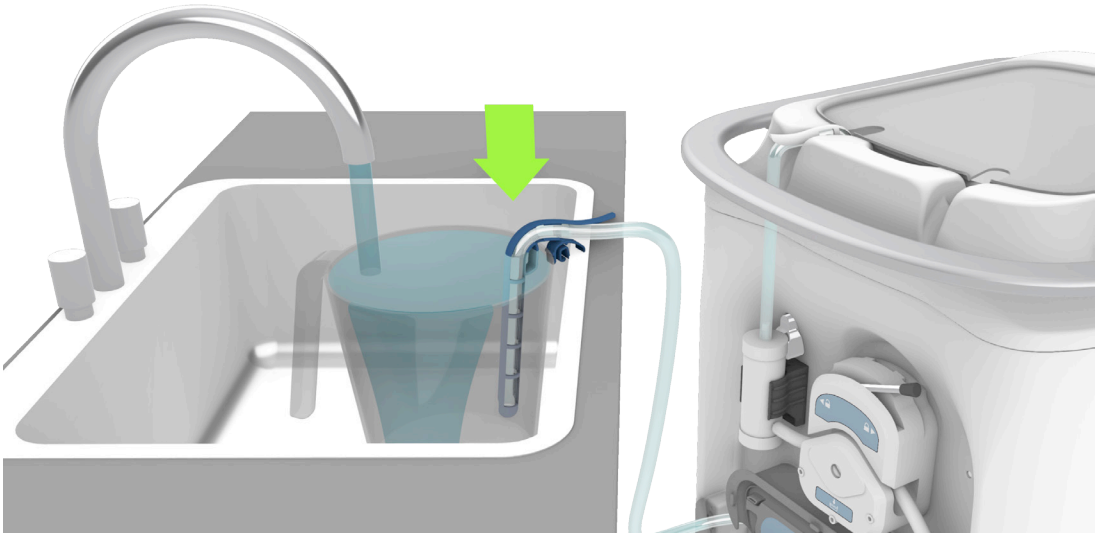
Caution

To prevent burns or discomfort to the operator or patient, do not fill the Fluidics System with hot water. To be within specification, water must be between 15°C and 25°C. Refer to the control panel for the temperature reading.

Important

Do not place any objects on top of the lids. The system measures volume by weighing the system check container and waste basin. Objects on the lids can compromise the accuracy of these measurements.

1. On the main menu, select **Fill System**. The required setup displays.
2. Place the pitcher into the sink.
3. Begin filling the pitcher with cool water, keeping the faucet running. Expect the pitcher to overflow during the fill system task. Adjust the flow as needed to keep the pitcher full during the filling process.
4. Attach the blue hose guide onto the pitcher, avoiding bubbles.
5. Select **Start Fill**.
   - The system transfers 30 liters of water from the pitcher into the system check container. The vacuum pump runs to partially degas water while filling.
   - As the system fills, monitor the temperature displayed on the control panel and adjust the faucet controls as needed to keep water in the system check container between 15°C and 25°C.
   - The system stops automatically. Turn off the faucet after filling is complete.



Degas

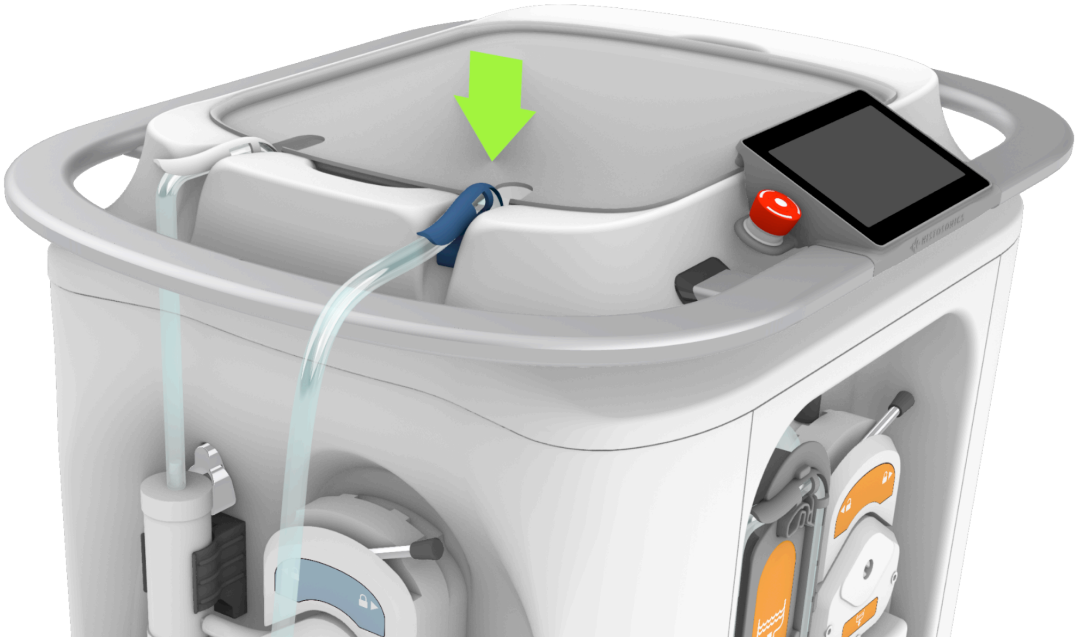
1. On the main menu, select **Degas**. The required setup displays.
2. Attach the blue hose guide onto the system check container.
3. Select **Start Degas**.
   - The degas cycle circulates the water in the system check container through the degassing filter under vacuum.
   - Degassing takes 30 minutes to complete and stops automatically. The remaining degassing time displays on the control panel.

Important

Use the degassed ultrasound medium within 4 hours as it will regas from the atmosphere. If this time limit is exceeded, the system displays an alert. As long as the water temperature remains between 15°C and 25°C, you may repeat this degassing cycle to ensure the medium meets the specification, without repeating the entire preparation process.

Keep the lid on the system check container to slow regassing from atmosphere and to prevent spills during transportation.

Keep the system plugged in and the power switch in the on (**I**) position to ensure the battery is adequately charged before performing the next steps.



Prepare for System Check

Perform this task in advance of a histotripsy procedure.

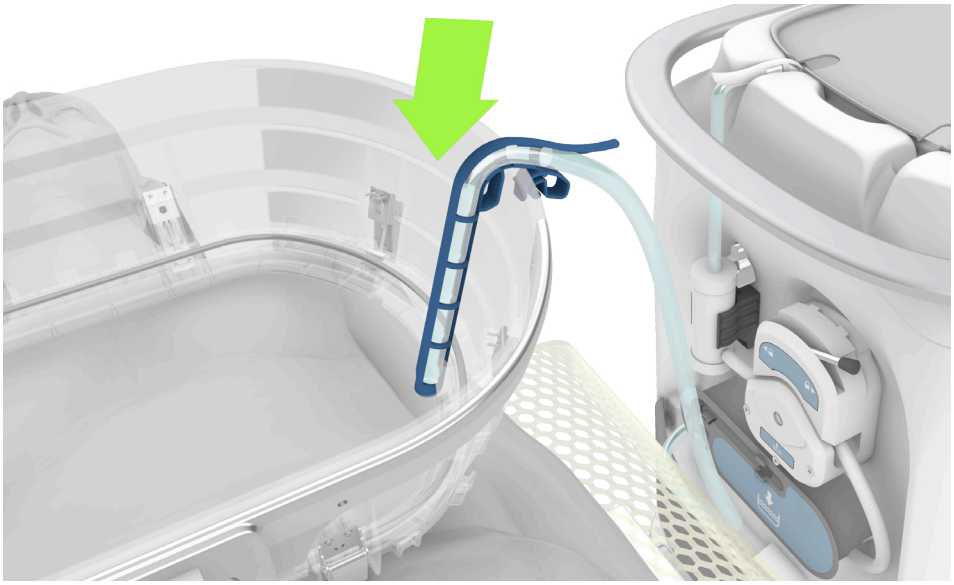
1. Unplug the Fluidics System, then wrap the power cord around the power cord keeper.
2. Position the Fluidics System near the Histotripsy System and adjacent to the treatment arm, or as directed by the Histotripsy System user. Leave enough room to access the Fluidics System wheel controls.
3. Lock the Fluidics System wheels.
4. The Histotripsy System user performs system check(s) in conjunction with the system check container.
5. Unlock the Fluidics System wheels, then move the Fluidics cart away from the procedure area.



Fill Membrane

Perform this task during a histotripsy procedure, at the direction of the Histotripsy System user.

1. On the main menu, select **Fill Membrane**. The required setup displays.
2. Position the Fluidics System near the procedure bed so that the blue hose guide can easily reach the membrane frame.
3. Lock the wheels.
4. Attach the blue hose guide onto the membrane frame.



5. Select **Fill Membrane**. The system transfers the specified amount of ultrasound medium (default setting is 5 liters) from the system check container into the membrane.

Important

Filling with this initial amount of ultrasound medium enables the Histotripsy System user to perform a preliminary check, ensuring correct setup without leaks in or around the membrane and to verify its positioning.

6. Fill the membrane to the required level. Use one or a combination of the following methods:
   - Set the desired volume, then select **Auto Fill**.
   - Press and hold **Manually Fill** until the membrane is filled to the required level.

Important

The amount of ultrasound medium required for the histotripsy procedure is determined by the Histotripsy System user, in accordance with their training and the instructions in the Histotripsy System User Guide. Typically, a histotripsy procedure requires 13–15 liters.

Important

The total amount of ultrasound medium transferred to the membrane displays on the control panel.

When filling the membrane, the system enforces a 4.0 liter reserve in the system check container. For example, if 15 liters are displayed, only 11 liters are available for transfer to the membrane. This reserve prevents introducing air into the system. The system displays a prompt if the setting exceeds the available volume.

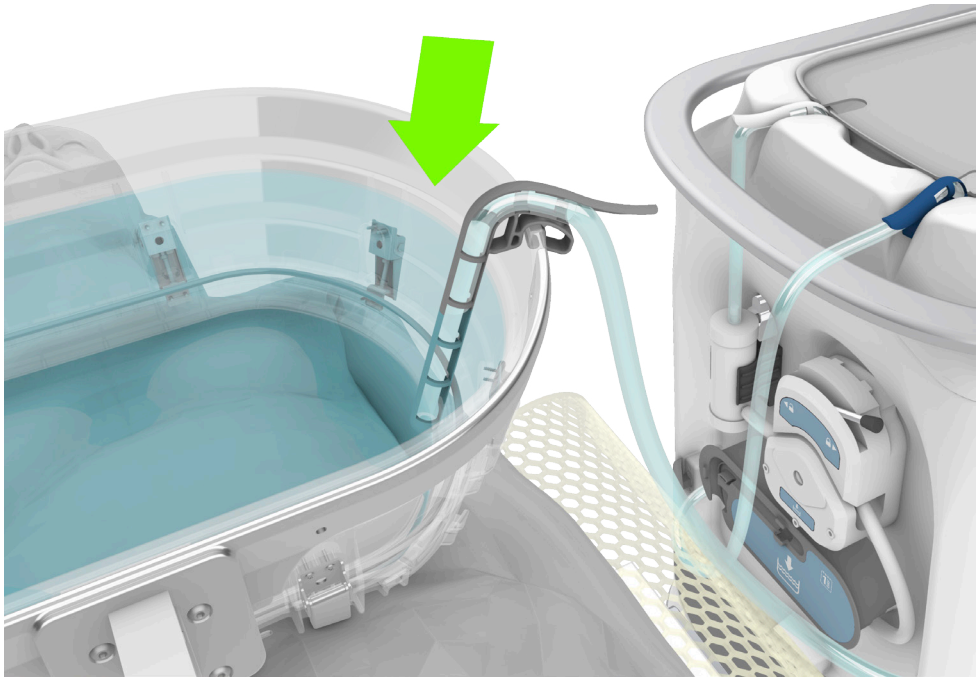
7. Reattach the blue hose guide onto the system check container. If desired, wrap the excess hose around the fill cartridge.
8. Unlock the wheels, then move the Fluidics System away from the procedure area.



Drain Membrane

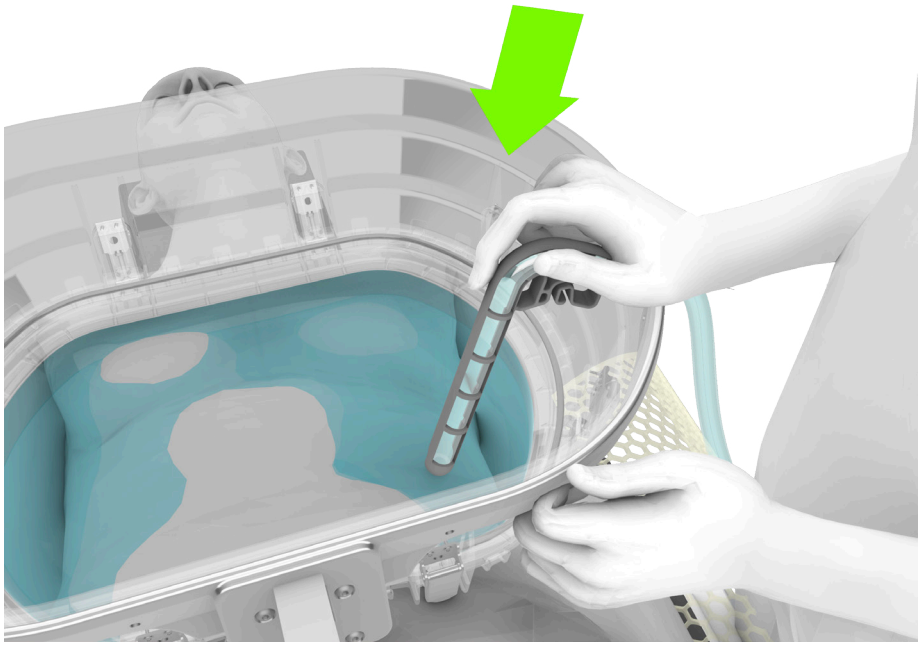
Performed after the histotripsy treatment phase, at the direction of the Histotripsy System user.

1. On the main menu, select **Drain Membrane**. The required setup displays.
2. Position the Fluidics System near the procedure bed so that the gray hose guide can easily reach the membrane frame.
3. Lock the wheels.
4. Attach the gray hose guide onto the membrane frame.



5. Select **Start Drain**. The system transfers the ultrasound medium from the membrane to the waste basin.

6. When the system is no longer removing ultrasound medium, detach the gray hose guide from the frame and guide it by hand to remove as much of the remaining ultrasound medium as possible.



7. Select **Pause Drain**.

Important

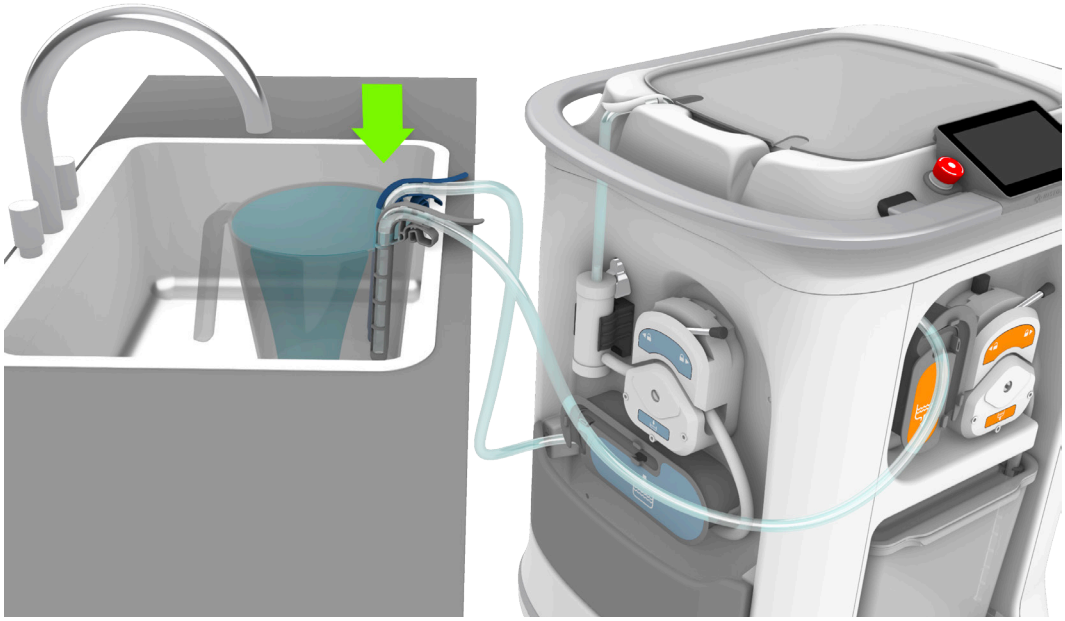
The system automatically stops the pump one minute after detecting no transfer of ultrasound medium to the waste basin. No damage can occur from the running pump when it is not transferring.

8. Wrap excess hose around the waste cartridge, then reattach the gray hose guide to the waste cartridge.
9. Unlock the wheels, then move the Fluidics System away from the procedure area.

Drain System

Perform this task away from the histotripsy procedure area.

1. Position the Fluidics System near a sink.
2. Lock the wheels.
3. On the main menu, select **Drain System**. The required setup displays.
4. Place the pitcher into the sink.
5. Attach the blue hose guide and gray hose guide onto the pitcher.



6. Select **System**. Ultrasound medium is transferred from both the system check container and waste basin into the pitcher.

Important

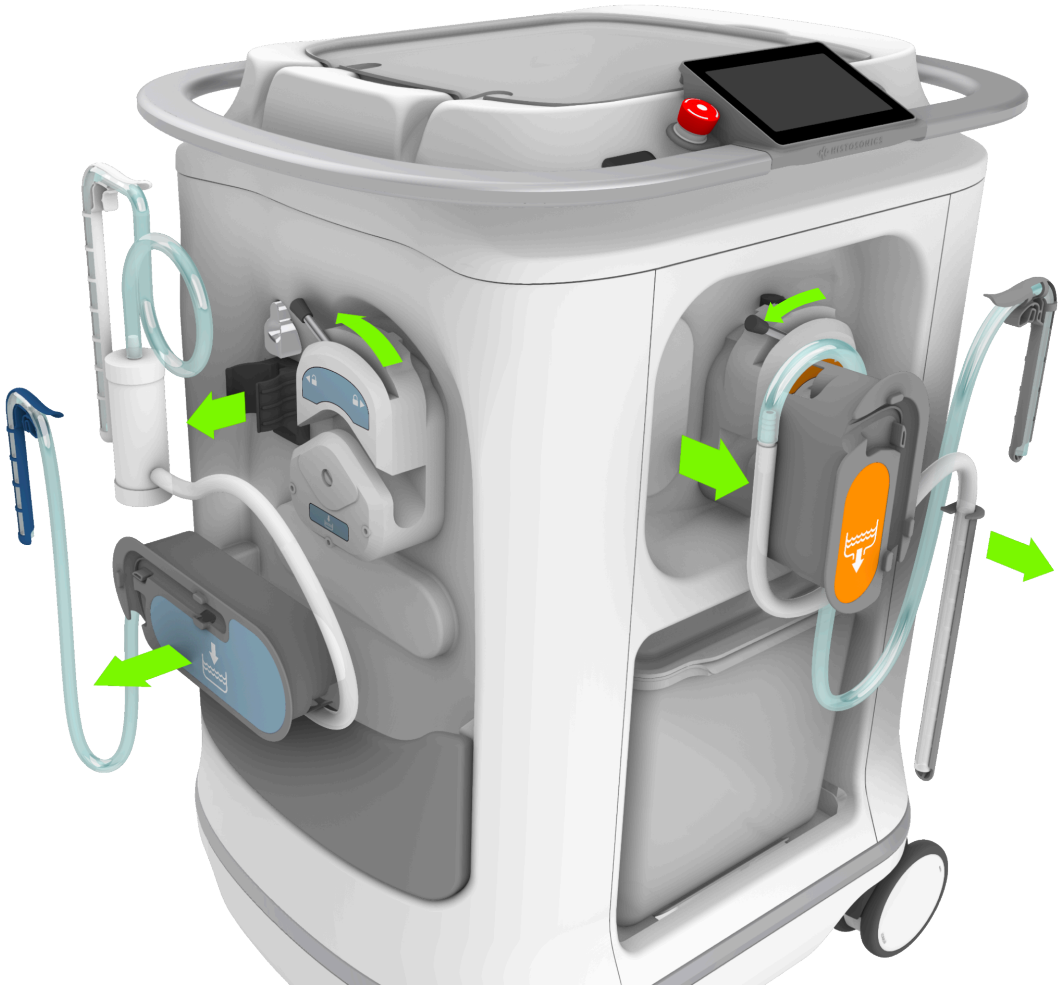
The system also offers the controls to drain the system check container or the waste basin individually. For instance, if ultrasound medium was prepared but not used, only the system check container requires draining.

- To drain only the system check container, select **System Check**.
- To drain only the waste basin, select **Waste**.

7. Select **Pause Drain** when the system is no longer removing ultrasound medium.
8. Remove the system check container and waste basin to dump out any remaining ultrasound medium.
9. Press the power button to shut down the system.

Discard

1. Move the pump levers to the unlocked position.
2. Remove the fill cartridge and waste cartridge and discard them according to hospital or clinical protocol.



Clean and Dry

Caution

Clean and dry the system as instructed in this user guide. Failure to clean and dry the system may lead to mold and mildew growth.

1. After use, inspect the Fluidics cart, its basins and the pitcher and clean if any visual contamination is present. Refer to *Cleaning* on page 5-1.
2. Thoroughly dry all water from the basins, lids, and cart surfaces.

Store and Charge

1. Store the pitcher in the system check container.
2. Ensure the lids are placed on the system check container and waste basin to prevent loss.
3. Unlock the wheels and transport the Fluidics cart to its storage location. Do not store the Fluidics cart in direct sunlight or where the temperature or humidity varies outside of specified storage environmental condition limits. Refer to *Environmental Conditions* on page 7-2.
4. To charge the Fluidics System battery during storage, plug the system into a power outlet and ensure that the power switch is in the on (**I**) position.

   Important

   If the Fluidics cart cannot be plugged in during storage, it may require at least 3 hours of charging before battery-only use. If the battery level is low during use (indicated by the red battery icon), that may require external power (outlet connection) during use until the battery charges.

5 Cleaning

How and when to clean the Fluidics System.

Cleaning Safety

Observe the following precautions when cleaning the Fluidics System.

Caution

Clean and dry the system as instructed in this user guide. Failure to clean and dry the system may lead to mold and mildew growth.

The use of cleaning agents or use of cleaning products other than those specified may damage equipment and void the warranty.

Clean the control panel with a soft, non-abrasive cloth. Do not use paper towels as they may cause light scratches.

Cleaning Protocol

Reusable Equipment

- Fluidics cart
- System check container and lid
- Waste basin and lid
- Pitcher

Frequency

- Before use: Clean all reusable equipment.
- After use: Inspect all reusable equipment and clean if visual contamination is present.

Important

If cleaning is not required after use, dry any residual water from the bottom of the system check container and waste basin with a soft, non-abrasive cloth or sponge to prevent mold and mildew growth.

Approved Cleaning Products

- CaviWipes™ germicidal wipe or equivalent

Cleaning Action

- Use a gentle wiping action.
- Use a scrubbing action only when required to remove stubborn soil.

Cleaning Instructions

1. Wipe all surfaces clean, including all sides of the basins and lids, with a fresh germicidal wipe. Use additional wipes as needed.
2. Soak a soft, non-abrasive cloth with water, then wipe surfaces to remove residual cleaning agents.
3. Use a soft, non-abrasive cloth to dry any residual water from the basins, lids, and cart surfaces.

6 Service

Service and preventive maintenance information and information related to expected service life, warranty, and disposal.

Service and Preventive Maintenance

Warning

Only HistoSonics service personnel can perform preventive maintenance and service the Fluidics System. The Fluidics System contains internal components such as a lead-acid battery. Unauthorized modification is prohibited and may result in electric shock, fire or explosion, and chemical burns, causing serious harm to the user or damage to the device.

The Fluidics System is not designed with any user-serviceable components. Preventive maintenance must be performed by HistoSonics service personnel.

Schedule

Visual inspection, cleaning, and preventive maintenance must be performed as follows.

Task	Frequency	By	Reference
Visual inspection	Daily, prior to every use	User	*Inspect* on page 4-4
Cleaning	Before use	User	*Cleaning* on page 5-1
Preventive maintenance	Annually	HistoSonics	

Replacement Components

Components that can be obtained from HistoSonics and replaced by the user:

- System check container with lid
- Waste basin with lid
- Power cord
- Pitcher

Expected Service Life

The expected service life of the Fluidics System is five years.

Warranty

Refer to your purchase or use contract for warranty information, or contact HistoSonics.

Disposal

Caution

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Contact HistoSonics for disposal information when the Fluidics System reaches the end of its service life and must be removed from service.

7 Specifications

Fluidics System Specifications, Testing, and Performance.

Ultrasound Medium Specifications

Caution

Follow the instructions in this user guide to ensure that ultrasound medium is sufficiently degassed for use with the Histotripsy System. Delivering energy with the Histotripsy System treatment head through ultrasound medium that is insufficiently degassed can:

- Prevent the bubble cloud from generating and/or prevent a sustained bubble cloud
- Cause damage to the treatment head

Water must be degassed to have less than a 50% dissolved oxygen level and have a temperature between 15°C and 25°C.

Fluidics Cart Specifications

Physical Characteristics	
Footprint	76 cm x 61 cm (30 in x 24 in)
Height	107 cm (42 in)
Weight Empty	125 kg (275 lbs)
Weight Full (Safe Working Load)	193 kg (425 lbs)

Environmental Conditions

Caution

HistoSonics cannot guarantee the performance of the Fluidics System if stored or used outside of the specified environmental conditions.

Avoid exposing the Fluidics System to flammable liquids or gases, corrosive substances, strong electrical or magnetic fields, and equipment that emits high-frequency waves.

Fluidics System (Fluidics cart and Fluidics disposable kit)	**Temperature Limit** 	**Humidity Limit** 
Operation	10°C to 40°C (50°F to 104°F)	30% to 75% RH (non-condensing)
Shipping/Storage	-15°C to 50°C (5°F to 122°F)	10% to 75% RH (non-condensing)

Electrical Requirements

Fluidics cart	
Line voltage (must be held within +/- 10% of specified line voltage)	100–240 V
Line frequency	50–60 Hz
Current rating	4.7 A

Electromagnetic Compatibility (EMC) Requirements

Warning

The Fluidics System is not compatible with an MRI environment.

To meet electromagnetic compatibility (EMC) requirements, avoid using the Fluidics System adjacent to other equipment. Do not place other equipment on top of the Fluidics cart.

Do not use the Fluidics System outside of the EMC specifications provided in this user guide.

Only use the power cord provided by HistoSonics, as alternative power cords may lead to increased emissions or decreased system immunity.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Fluidics cart. Otherwise, the degradation of system performance could result.

Caution

Avoid exposing the Fluidics System to flammable liquids or gases, corrosive substances, strong electrical or magnetic fields, and equipment that emits high-frequency waves.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).

The Fluidics System has special precautions regarding electromagnetic compatibility. Contact HistoSonics if additional information or assistance is required relative to the following requirements:

- Always use the Fluidics System according to the EMC information provided in this user guide.
- Portable and mobile RF communications equipment can affect the Fluidics System.

- The Fluidics System has been tested and found to comply with the limits for Class A equipment, pursuant to IEC 60601-1-2 for emissions and immunity for non-life-supporting equipment. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. The Fluidics cart generates, uses, and can radiate electromagnetic energy. If the Fluidics System is not installed and operated in accordance with these instructions, it may cause harmful interference to surrounding equipment.
- The Fluidics System is intended for use in an electromagnetic environment specified in this section. The user of the Fluidics System should ensure that it is used in such an environment.
- If the Fluidics System is suspected of causing harmful interference for other surrounding equipment, try to correct the interference by one or more of the following methods:
  - Shut down the Fluidics cart, check for equipment interference, then turn back on to verify that the interference is coming from the Fluidics cart.
  - Move the other equipment farther away from the Fluidics cart.
  - Connect the other equipment to an outlet on a circuit different from that to which the Fluidics cart is connected.

<table>
<tr><th>Immunity/Test</th><th colspan="3">Electrostatic Environment Requirements</th></tr>
<tr><td>Electrostatic discharge</td><td colspan="3">Compliant to +15 kV. Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.</td></tr>
<tr><td>EFT and surge</td><td colspan="3">Electrical power quality should be that of a typical commercial or hospital environment. See Electrical Power Requirements.</td></tr>
<tr><td>Voltage dips/dropout</td><td colspan="3">Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an external uninterruptible power supply.</td></tr>
<tr><td>Conducted radio-frequency (RF)</td><td colspan="3">Portable and mobile communication equipment should be separated from the Fluidics cart by no less than 6 meters (19 feet).</td></tr>
<tr><td rowspan="6">Radiated RF</td><td colspan="3">The Fluidics cart is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Fluidics cart as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td>Maximum Output Power (watts)</td><td>Separation (150 kHz–800 MHz)</td><td>Separation (800 MHz–2.5 GHz)</td></tr>
<tr><td>0.01</td><td>38 cm (15 in)</td><td>76 cm (30 in)</td></tr>
<tr><td>0.1</td><td>38 cm (15 in)</td><td>76 cm (30 in)</td></tr>
<tr><td>1</td><td>117 cm (46 in)</td><td>2.4 m (8 ft)</td></tr>
<tr><td>10</td><td>3.7 m (12 ft)</td><td>7.3 m (24 ft)</td></tr>
</table>

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