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SONICLEAN IRRIGATOR

User Manual

Models S2800, S2800MRS, S2800MRS-HCR

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Safety Precautions

Before First Use

Please read and familiarise yourself with this manual prior to first use.

Ultrasound Pressure

Ultrasonic equipment under test generates high amplitude ultrasonic sound which can be harmful to ears. Ensure adequate ear protection is worn while this unit is in use.

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Table of Contents

1. Introduction

Thank you for purchasing a Soniclean ultrasonic irrigator. Soniclean irrigators are designed to improve the quality and consistency of cleaning for laparoscopic instruments using a combination of ultrasonics and irrigation. The irrigator flushes cleaning solution through the cannulae of hollow instruments whilst delivering ultrasonics for a precision clean. The irrigator is equally effective for cleaning non-cannulated instruments. It is intended that the instruments shall be gross-cleaned prior to loading into the irrigator, and be sterilised in the usual manner after ultrasonic cleaning

Soniclean provides several irrigator models: S2800, S2800MRS and S2800MRS-HCR. This manual covers all models. The S2800MRS and S2800MRS-HCR models include Soniclean's Machine Report System (MRS). The MRS logs data of each clean for future reference which can be printed via a dedicated printer (optional) or stored for electronic retrieval via an ethernet interface. The MRS is described in the separate MRS User Manual.

The Soniclean irrigator is a medical device. It is expected that customers use only the recommended settings to maintain the performance required of a medical device.

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2.   Requirements

The customer shall ensure the following requirements are met prior to installation. This is essential for the machine to perform at optimum level and to fulfil Australian Standards. If the customer fails to provide this information, Soniclean will provide the information for a fee.

2.1.   Environmental

1. The water supply (S2800, S2800MRS) or cold water supply (S2800MRS-HCR) should be at ambient temperature.

2. Dedicated taps or inlets are required for the irrigator.

3. A drain outlet must be dedicated to the irrigator.

4. Water Quality for cleaning as per AS/NZS 4187:2014 shall be used. Water hardness will determine the type of detergent to be used. It will also determine the amount of detergent to be used in the cleaner.

2.2.   Plumbing

1. **For S2800 and S2800MRS irrigators**: the water pressure must be between 350 kPa (50 psi) and 1000 kPa (150 psi).

   For S2800MRS-HCR irrigators: the hot or cold water pressure must not exceed 350 kPa. If the water pressure is higher than 350 kPa, a pressure reducer rated to 350 kPa must be connected in series with the affected inlets.

2. The flow rate must be between 10 litres/minute and 20 litres/minute.

3. This is a high hazard application and the inlet water supplies shall be fitted with an approved reduced pressure zone device and a line filter. Please check with your local water authority for the correct installation information for your area.

4. The water inlet connections with ½" male BSP fitting must be within 600 mm of the machine.

5. Do not use any aeration devices in the mains water supply.

6. An outlet pipe of 25 mm diameter for waste water must be located within 600 mm of the machine.

2.3. Electrical

1. A GPO power socket supplying 240 VAC 50-60 Hz rated at 10 amps must be located within 600 mm of the machine.

2. The power supply circuit shall not be shared with life threatening or life support electrical systems.

3. The power supply circuit shall not be shared with computer electrical system or other excessively large power devices such as sterilisers, washers and disinfectors.

4. Earth leakage protection shall be provided by user.

Note: The unit contains a MOV surge arrestor. When carrying out an insulation resistance test, the test MUST be carried out 250v as per AS/NZS 3760-2022 or Class 1 equipment with MOV surge arrestor.

2.4. Machine Reporting System (MRS models only)

1. A Local Area Network (LAN) outlet must be located within 1000 mm of the machine.

2.5. Machine Location

1. Place the machine on a flat and horizontal surface. Maximum tilt is 2º.

2. Position at operator's convenient height. Soniclean recommends the top of the lid be at elbow height.

3. The bench top shall be strong enough to support the fully loaded machine (approximately 60 kilograms).

4. The unit requires a bench area of 590 mm $\times$ 880 mm.

5. Allow minimum 100 mm clearance at the rear to enable plumbing access. This may be reduced by fitting elbows to both the inlet and the outlet.

6. Allow 1000 mm clearance above unit to allow the lid to open fully.

2.6. Printer (optional)

1. Allow room on the left hand side of the machine for the printer unit.

2. An additional GPO power socket is required for the printer.

3.   Installation

3.1.   Plumbing

Inlet Mains Supply

1.   Screw the supplied braided hose on to the machine and inlet mains water supply (hand tighten only).

2.   Screw and hand tighten the supplied grey sink hose onto the machine and insert into drain.

Outlet Waste Supply

1.   Screw and hand tighten the supplied black sink hoses onto the machine and insert into drain.

2.   Ensure that the black sink hoses fall evenly away from the machine to the drain.

✓ Correct   ✗ Incorrect   ✗ Incorrect
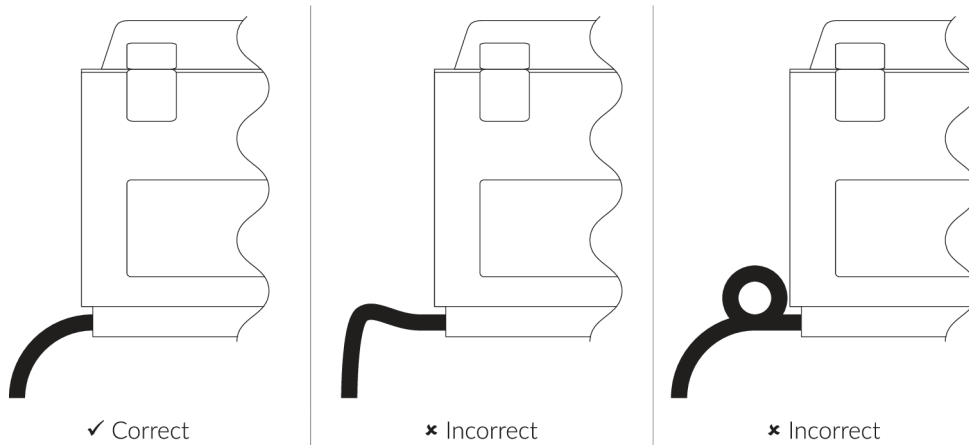
3.2.   Electrical

1.   Plug machine into the mains supply. The machine's power socket is on the right hand side near the rear.

2.   Switch on when ready to operate.

Note: The unit contains a MOV surge arrestor. When carrying out an insulation resistance test, the test MUST be carried out at 250 V as per AS/NZS 3760-2022 for Class 1 equipment with MOV surge arrestor.

3.3. Machine Reporting System (MRS models only)

For connection to a Local Area Network (LAN):

1. Use the LAN cable provided and push the black plug into the MRS socket provided on the irrigator. Plug the other end (RJ45) into the LAN wall outlet.

2. Contact your IT department and hand them the Machine Reporting Manual. The appropriate information for connecting the machine to the Local Area Network is found in the "Network Hardware and Configuration" section of the Machine Reporting System Manual.

To connect directly to a PC or laptop without using a LAN:

1. Use the PC cable provided and push the black plug into the MRS socket provided on the irrigator. Plug the other end (RJ45) into the appropriate outlet on the PC.

2. Consult the MRS User Manual for information about connecting to the MRS from the PC or laptop.

Caution: Only use designated cables for accessing data from the irrigator. The cable marked `PC' should be used for direct connection to computers ethernet port. The cable marked `LAN' should be used for connection to a LAN wall outlet.

Refer to the MRS User Manual for further detailed information about the MRS.

3.4. Printer (optional)

1. Plug the printer cable into the machine and the printer.

2. Plug the printer into the mains supply and turn on at the switch.

3. Press the feed button to progress the paper.

3.5. Detergent

1. Connect detergent hose to the left hand side socket of machine.

2. Place the filtered end of detergent hose into container.

3. Ensure there is sufficient detergent in bottle at all times.

4. The detergent bottle must located within 1.5 m of the machine and placed at the same level as the base of the machine.

Soniclean Sonic 1 detergent (ARTG No: 141350) is a hospital grade medial alkaline detergent concentrate compliant with AS/NZS 2773-2019 and AS/NZ 4187-2014. It has been specifically formulated to give the best results in Soniclean ultrasonic irrigators and is also used for Soniclean's validation and testing

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procedures. Soniclean recommends the use of Sonic 1 detergent at a dosage concentration of 0.5%. Soniclean cannot be held responsible for degraded cleaning action or poor Performance Qualification (PQ) results if using other detergent concentrations or detergents not approved by Soniclean.

If the detergent bottle must be more than 1.5 m from the machine or is connected via a dispensing system, contact Soniclean before installation to ensure the delivery of detergent is reliable and within specification.

Please note Chemical Type: _____(Sonic 1), Dosage Setup: _____(0.5%)

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4. Operation

4.1. Prior to Operation

Position machine on bench top or table. Ideally the lid of the machine should be at elbow height. Ensure the machine is horizontal and the water inlet tap is turned on.

4.2. How to Operate

Start Process

1. Turn on at power point. Switch machine on using the switch on the side of the machine.

2. **For HCR model only**
   If the bath temperature needs to be changed:

   i. Press and hold the "Clean Values" button *before* turning the machine on.

   ii. When the machine enters "Program" mode and displays "ct", release the "Clean Values" button.

   iii. Press the "Enter" button repeatedly until "F°" is displayed. Setting "F°" is the bath temperature selection.

   iv. Select desired temperature as shown in section 8.2 (Program Parameters), table iii.

      Press "Enter" repeatedly until the machine beeps to indicate that programming mode has been exited. The selected temperature will be stored.

   HCR machines ship with the temperature set to "Cold".

3. The machine will display "8.8.8.8", then "SCx.y" where x.y is the machine's firmware version.

4. The machine will automatically, drain, flush, prime the detergent delivery system (HCR model only), drain the flush, fill with water and detergent and perform a degassing cycle.

5. When the degassing cycle is complete, the machine is ready for use.

6. During the above cycle, the machine with display the following:

Display	Function
8.8.8.8	Internal program.
SCx.y	Internal program process. x.y is the machine's firmware version.
Drn	Draining the water.
Drnf	Tank is flushing. (Drain is open.)
Drn	Tank is draining the flush.
FILL	Tank is filling with water and detergent is automatically added at the programmed quantity (0.5%). The detergent pump (HCR model only) will run as required.
De-gas	The solution is degassing. This takes approximately 10 minutes.
----	The machine is ready to be loaded with instruments.

7. It is recommended that you perform a foil test daily to check the performance of your irrigator. Refer to Section 5, Foil Test.

Confirm Parameters

To check or change the settings or parameters of your irrigator:

1. Press the "Shift" and "Program" keys together and hold for 3 seconds.

2. Beep will sound when command has been recognised.

3. The machine display will alternate between "ct" and the configured clean time.

4. Scroll through the parameters using the "Enter" keys.

5. The parameters may be changed as required. (Refer Section 8, "Program Mode".)

Loading the Machine

Refer to Appendix A ("Cleaning Cannulated Instruments") for suggestions about the care of your laparoscopic instruments.

1. Instruments may be loaded into the tray with the tray located in the irrigator tank, inside the machine, or resting above the bath.

2. Dismantle the instruments and insert the nozzle end of the cannulated instrument (standard sizes 2, 5 and 10 mm) into the connector provided.

3. With the ports vertical, place the connector, with instrument loaded, into the port.

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4. Gently lay the instruments down and rest them on the movable plastic rack. Adjust the rack to support the instruments. The other parts of the instruments may be placed on the bottom of the tray or in the instrument holders provided.

5. The unused ports should be left in vertical position. This turns the irrigator function off for these ports.

6. Lower the tray into the cleaning bath. Ensure the "T" handle is on the right hand side.

7. Ensure that the spigot in the bath docks onto the instrument tray.

Note – with twin manifold baskets it is important to load the lower of the two manifolds first with the lower of the two instrument supports in place. The taller of the instrument supports can now be fitted and the higher manifold can be loaded.

Start Cleaning Cycle

1. Close the lid and press "Clean".

2. The machine will perform a cleaning cycle according to its program.

3. The following table explains the various parameters of the clean function, which are displayed during cleaning and are programmable to suit your requirements.

Cleaning Activity	Display	Parameters[1]	Explanation
Clean No.	C-01	10	Current clean cycle no.
Ultrasonics	P-03	3	Displays power level.
Time Remaining	09.48	10 minutes	Time remaining to complete current clean, displayed in minutes and seconds (mm:ss).

Pause Cleaning Cycle

1. Lift the lid to pause the cleaning cycle.

2. This feature allows for any adjustments the instruments may require.

Stop Cleaning Cycle

1. Press "Clean" again during cycle. This will stop the cycle and clear current clean.

2. To start new cycle, press "Clean" again.

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1 As set by the manufacturer.

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Completion of Single Clean Cycle

1. The machine will emit five (5) beeps and display "----".

2. Lift the lid.

3. Raise the instrument tray and rest it above the bath using the "T" handle.

Automatic Drain and/or Shutdown

The irrigator can be programmed to automatically drain after a selected number of cleaning cycles.

1. The manufacturer's programmed number of cleans between draining is ten (10).

2. When the tenth clean cycle is completed the machine will display "End".

3. The tank will automatically drain.

Irrigation

For HCR models, irrigation also activates re-circulation.

1. To turn on, press the "Irrigate" key. The machine will irrigate as programmed.

2. To stop irrigating, press the Irrigate key again.

Degas Function

1. The machine will automatically degas as programmed when started.

2. If further degassing is required, press the "Degas" key.

3. The red indicator light will light, indicating the machine is degassing.

4. To stop degassing, press the "Degas" key again, the red indicator light will extinguish, indicating the machine has stopped degassing.

Draining the Tank

1. Press the "Shift" key and "Drain" key together and hold for three (3) seconds.

2. The machine will emit a beep.

3. Release the keys and the machine will drain.

4. When drain complete display will show "off".

Draining and Refilling the Tank

1. Press the "Shift" key and "Refill" key together and hold for three (3) seconds.

2. The machine will emit a beep.

3. Release the keys. The machine will drain, refill with water and detergent, and perform a degas cycle.

Manual Shutdown Procedure

Use this procedure to shut down the machine. It is recommended that this be done at the end of each day.

1. Press "Shift" and "Drain" together, and hold for 3 seconds.

2. The machine will drain.

3. The machine will display "OFF".

4. Turn off the power at the power point.

5. Wipe down surfaces of machine with detergent or disinfectant.

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5. Foil Test

Tip: Remove tray to ensure foil test is accurate.

5.1. Performing a Foil Test

1. Complete the usual start process.

2. Use a strip of `home' brand aluminium foil about 150 mm long × width of roll

3. Suspend foil from wire stretched between tray handles.

4. Press the "Test" Key to switch on ultrasonic and unit will run for 30 seconds as programmed.

5. Remove the foil and compare the number and distribution of perforations with the sample foil test provided with your machine.

Refer to AS/NZS 2773-2019 for more details.

NOTE: It is important to always use the same type of foil. It is suggested that a test is performed, on receipt of the machine, of such duration as to give a result similar to the sample provided. This will then become the foil test time for that type of foil.

5.2. Foil Test Problem Solving

If you are having difficulty getting a foil test to perform to standard, work through the following items, then try foil test again.

Machine may require further degassing.

1. Remove any load from the machine.

2. Press "Degas" to degas the machine.

Detergent Type and Dilution

Tip: Check detergent bottle is full, check that same brand is being used, and check bottle and hose are connected and that there are no kinks in the line.

1. Always use a pH neutral or slightly alkaline detergent (pH 8 to 10.8) that is made specifically for ultrasonic machines.

2. Extra detergent may be added to overcome water quality issues.

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Contact your service agent if you cannot achieve a satisfactory foil test.

Note that as per AS/NZS 2773-2019, it is acceptable to use alternative methods of testing the performance of your ultrasonic machine. Examples such as aluminium disc and pencil test, Soniclean Ultrasonic Performance Meter (UPM) must be used as per manufacturer's instructions.

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6.   Keypad Description

Item	Function
1.7 segment display	Provides feedback, incl. error messages, clean status, etc.
2. Irrigate (⊑)	Initiates irrigation.
3. Clean Values (∿)	Change selected settings during operation which are used until power is turned off.
Program (secondary)	Initiates "program" mode: change operation parameters and store them so they persist after turning the irrigator off.
4. Up (▲)	Increases values in "program" mode.
Shift (hold)	Secondary function key. Hold, then press required key, eg. Drain.
5. Enter (⤶)	Comfirms changes to parameters in "program" mode. Initiates machine in "operate" mode.
Drain (secondary)	Drains machine (press while holding shift).
6. Down (▼)	Decreases values in "program" mode.
Refill (secondary)	Drains machine, then refills with fresh water. (press while holding shift).
7. Test	Tank is draining the flush.
8. De-gas (☄)	Removes gas from solution. Press again to cease degassing.
9. Clean (∿)	The solution is degassing. (This takes approximately 10 minutes.)
Reset (secondary)	Immediately aborts current operation (press while holding shift).
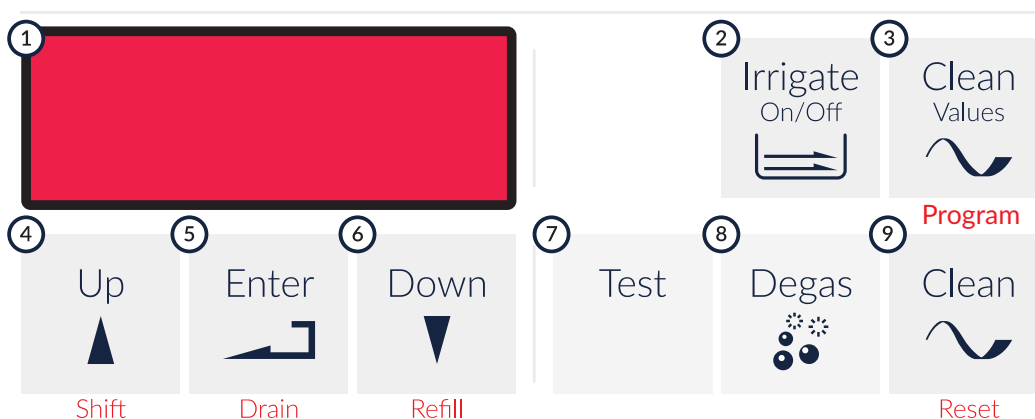
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7.   Programmable Features

When you receive your Soniclean irrigator it will be set to function automatically. The parameters are set in the factory. The features described below may be altered as you require. The list includes the display you will see on the machine when you are programming.

Parameter	Description
Ct	Length of cleaning times.
PO	Ultrasonic power levels.
Cn	Clean number. This determines the number of cleaning cycles your machine will perform before automatically draining.
F°	Wash fill temperature.
SP	Detergent concentration. Displayed but not used on the HCR model.
G1	Start up degassing time.
G2	Pre-wash degassing time.
tt	Test time. Set time for foil test.
Id	Irrigation default - 1= irrigation on at start up.
Ir	Number of (5 second) rest periods between flushes. Displayed but not used on the HCR nodel.

To alter these parameters see Section 8, "Program Mode".

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8. Program Mode

The parameters can be altered by entering the program mode. There are three (3) methods to enter this mode.

8.1. Program Entry Points

Alternative 1 Program at Start Up

1. Press the "Clean Values" key then turn on the machine.

2. Hold the "Program" key down until the machine displays "Ct.nn".

3. Release the "Program" key.

Alternative 2 - Program during Operation

1. The machine will display "- - . - -".

2. Hold down the "Shift" key and then press the "Program" key and hold for three (3) seconds.

Alternative 3 - Program during Operation

1. The machine will display "- - . - -".

2. Hold the "Program" key for three (3) seconds.

3. "Ct", "PO" & "rt" parameters may be reset.

4. Values will be held until changed or until machine is restarted.

8.2. Program Parameters

To program the parameters, enter program mode per section 8.1 above, then:

1. The machine will display a variety of parameters that you may reconfigure.

2. Press the arrow "Up" key to increase the parameter and the arrow "Down" key to decrease the parameter.

3. To accept a value press "Enter" The display will scroll through the parameters.

4. Refer the table on the next page for parameters and default values.

Default Parameter Values

    i.   Key to Programming Display

Parameter	Display	Unit	Min	Max	Default
Clean time.	Ct	mins	1	99	5
Ultrasonic power level.	PO		1	6	3
Clean number.	Cn		0	99	10
Detergent concentration.	SP	%	0.0	5.0	0.5
Start-up degas time.	G1	mins	0	99	5
Pre-wash degas time.	G2	mins	0	99	1
Test time.	tt	sec	0	99	30
Irrigation default.	Id		0	1	1
Irrigation rest periods.	Ir	1/per 5 sec	5	50	5

    ii.   Ultrasonic Power Level

Parameter	Power
1	Low
2	Medium
3	Full
4	Full power at 25% duty cycle
5	Full power at 50% duty cycle
6	Full power at 75% duty cycle

    iii. Fill Temperature

Parameter	Temperature
0	Cold
1	Warm
2	Very warm

To alter these parameters see Section 8, "Program Mode".

9. Display Messages

These messages are displayed on the keyboard at various times. This table explains their meanings.

Display	Explanation
----	Together with 5 beeps indicates that a process has been completed. (The operator does not need to wait for the beeps to complete before starting another process.)
04:58*	Shows the time remaining of the degas or clean function that is currently operating.
C-01*	Indicates the current cleaning cycle number.
P-03*	Indicates power level selected (P-02, P-03, etc.)
dGAS	Indicates the machine is degassing.
drn	Machine is draining.
drnf	Bottom of the wash tank is flushed with clean water, and then drained.
FILL	The machine is filling the wash tank.
OFF	The machine has completed operation and needs to be turned off at power point.
END	End of final clean.
tESt	When the lid is open to maintain ultrasonic (foil/UPM) performance test.
Drnb	This indicates sensors detect liquid when wash tank supposed to be empty.
FAIL	Indicates that the operator programmed values have been lost and will need to be re-programmed.
HOT	Indicates an excessive heat condition.
LO	Indicates a low level in the wash tank.
OFLO	Indicates that liquid has been detected in an area of the machine that should always be dry.
rtc	Indicates the Real Time Clock (RTC) date/time in the system is considered invalid. (MRS function only.)
P-UP	Indicates a clean process was interrupted and did not complete the full cycle.
H2OL	Indicates a water leak in the system or circuit/wiring failure.
IP-?	Indicates the configuration of the machine is not known. (MRS function only.)
SLid	Lid has been opened during operation.

* Displayed when cleaning.

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10. Error Diagnosis

IMPORTANT: When the following messages (except for the first) are detected, they are flashed on the display together with rapid intermittent beeps. Power to the machine must be removed when this occurs.

10.1. Program Values Lost (FAIL)

This message indicates the operator programmed values have been lost and will need to be re-entered. This error occurs when the machine loads the programmed values stored in memory and an error is detected in the data. This error may be caused by:

1. The memory device has not been programmed or programming has been erased.

2. An error in the memory device.

3. Electrical noise causing corruption of data.

Corrective Action

1. Press the "Program" key to re-program the machine.

2. If the "FAIL" message is displayed again it may a faulty memory device.

3. Contact service agent.

10.2. Low Level in Tank (LO)

1. This message may occur after a Fill Wash Tank Operation has completed and a low level is detected in the wash tank (below minimum level).

2. This fault may be caused by a leaky drain valve or faulty minimum level sensor.

3. This error will not be detected while the wash lid is up as the operator may cause wave action in the wash tank causing a false indication.

Corrective Action

1. Turn off at power point.

2. Contact service agent.

10.3. Drain Blocked (drnb)

1. This message occurs if the top, minimum, or empty level sensors detect liquid.

2. This may be caused by a blocked drain, or a faulty level sensor.

3. This may be caused by an incorrectly installed drain hose.

Corrective Action

1. Turn off at power point.

2. Check for blocked drain.

3. Remove blockage if found.

4. Re-start machine.

5. Check drain hose installation

6. If no blockage present contact service agent.

10.4. Overflow Detection (OFLO)

1. This message occurs when liquid is in danger of overflowing tank.

2. When this condition occur all power to the machine shall be shut down.

Corrective Action

1. Turn off the machine

2. Scoop out the water manually from the tank.

3. Turn on the machine, machine will operate again.

4. Contact a service agent.

10.5. Ultrasonics Overheating (HOT)

This message occurs when the ultrasonics board indicates an excessive temperature condition.

Corrective Action

1. Turn off the machine at power point.

2. Allow to cool for at least one hour.

3. Re-start machine.

4. If "HOT" display persists, contact a service agent.

10.6. Real-Time Clock (rtc)

This message occurs if the Real Time Clock (rtc) date/time in the system is considered invalid. This may be caused by the machine not being used for a long period of time.

Corrective Action

1. Replace the backup battery for the clock if discharged.

2. Reset the date/time through the Web interface. (Read the Machine Reporting Manual).

3. Contact a service agent.

10.7. Power-up warning (P-UP)

This message occurs at boot up time if a clean process was interrupted and did not complete its cycle. This alerts the operator that instruments being cleaned in the machine may not be completely clean. A power failure is the most likely cause.

Corrective Action

1. Press enter and continue with the clean cycle.

10.8. Water leak (H2OL)

Water may have entered the internal red control box or blue ultrasonic box, or there may be a circuit/wiring failure.

Corrective Action

1. Contact a service agent.

10.9. Setting default IP values (IP-?)

Only for MRS models and IT staff use.

Corrective Action

1. Contact the facilities IT department.

2. Refer to the Machine Reporting Manual.

3. Contact a service agent.

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11. Optional modules

11.1. Remote Diagnostic Interface (RDI)

A Remote Diagnostic Interface (RDI) was an optional module supplied by Soniclean which allowed a remote technician to access low level machine functions for diagnostic and servicing purposes. It was discontinued in 2014. Customers who purchased an RDI can find information about setup in the Remote Diagnostic Interface User Manual.

11.2. MRS Monitor

The MRS Monitor module connects to the ethernet port of irrigators fitted with the MRS option. It automates the delivery of MRS data to Soniclean which uses it to monitor machine performance. Please refer to the MRS Monitor User Manual for full details or contact Soniclean if there is interest in utilising an MRS Monitor. Module.

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12. Ongoing Maintenance Requirements

12.1. Product Validation & Calibration

Soniclean offers validation, calibration and electrical safety testing ("Test and tag") services for all Soniclean products. We recommend that re-validation and calibration of Soniclean equipment be performed on an annual basis to ensure your machine continues to meet our original specifications.

Our validation and calibration services meet AS/NZS 4187:2014, which states in clause 7.1.2 that "Validation of the cleaning, disinfecting, packaging and sterilising processes shall be documented in a validation report".

12.2. Servicing and Maintenance

Soniclean offers 12 month service contracts for planned preventative maintenance to ensure the equipment is performing at its peak. Our Preventative Maintenance Contracts (PMC) comply with AS/NZS 4187:2014, which states in clause 10.3.1 that "Preventative maintenance of all equipment shall be planned and undertaken in accordance with documented procedures by the equipment manufacturer. This shall be carried out by the manufacturer or a competent person."

Soniclean has not authorised any other third-party or service provider to undertake validation, calibration and maintenance of Soniclean products and cannot be held liable for any malfunction or adverse cleaning results caused by a validation and performance qualification (PQ) undertaken by a third-party.

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A.   Cleaning Cannulated Instruments

Cannulated instruments are difficult and time consuming to clean. This information is designed to assist you in the cleaning of your instruments. It provides suggestions only and needs to be used in conjunction with your hospital procedures and protocols, the instrument manufacturers' instructions and the Australian Standards (AS/NZ). In particular, AS/NZS 4187-2014 and AS/NZS 2773-2019.

> *"The aim of cleaning is to remove microbial, organic and inorganic soil. The way in which this is done varies with the material composition of the instrument as well as its design."*

(AS/NZS 4187-2014)

There are hundreds of different types of rigid cannulated instruments. These instruments are made by many different manufacturers from a variety of materials. By checking the manufacturer's instructions for each instrument you are cleaning, you will ensure the best result.

Water used for cleaning and rinsing needs to be of good quality (as per AS/NZS 4187-2014). Some practitioners choose to use demineralised, distilled or sterile water for rinsing of instruments.

A.1. Cleaning Process

Before you use your Soniclean S-2800 Ultrasonic irrigator, it is suggested that you:

1. Process your instruments as soon after use as possible. (Once soil has dried on an instrument it is more difficult to decontaminate and the bioburden will increase).

2. It is recommended that initial treatment of used instruments is done as close to place of use as possible (that is, near the operating table).

3. Disassemble instruments as recommended by the manufacturer.

4. Remove visible soil by rinsing under running water and flush the internal lumens of instruments with a syringe (or pressure gun) via flushing ports.

   Some practitioners may choose to add the following steps:
5. If not cleaning immediately, soak instruments in enzymatic detergent. Ensure you flush channels of instrument again with enzymatic detergent.

6. After soaking, rinse enzymatic detergent off instrument including flushing the internal lumens of the instrument with a syringe via flushing port.

A.2. Using your Soniclean Ultrasonic Irrigator

1. Prepare irrigator for use as per summarised operating instructions on front panel of irrigator (refer to operating instructions if required).

2. Place instruments into the Soniclean Ultrasonic irrigator ports. Instruments may be loaded outside, above or inside machine. (This is done with the ports in the upright position. Then, position ports so instruments are lying down in the irrigator bath).

3. Clean for desired time, ensuring irrigator function on. (Recommended time is 5-15 minutes depending on size, type, and numbers of instruments to be cleaned).

4. Remove instruments from irrigator.

5. Visually check for any contamination. If this occurs, start cleaning process again.

A.3. After using your Soniclean Ultrasonic Irrigator

1. Rinse instruments outside and inside, flushing internal lumens with water using syringe. (This will remove detergent used in ultrasonic irrigator.)

2. Check for any signs of contamination while rinsing: if present, repeat cleaning process.

3. Dry instrument using compressed air (air gun) if available. If any soil seen, repeat cleaning process.

4. Pre-pack and sterilise as per usual procedure.

A.4. Performance Testing

Foil Test

As per AS/NZS 2773-2019 it is recommended that you undertake a performance test on your irrigator regularly. Your machine has been supplied with a sample foil test to assist you with this testing.

Other Options

Some practitioners may choose to use additional tests for checking the performance of the Soniclean ultrasonic irrigator.

Important: This document provides suggestions only and needs to be used in conjunction with your hospital procedures and protocols, the instrument manufacturers' instructions and the standards applicable in the user's jurisdiction.

B. Operating Instructions Summary (Irrigator)

B.1. Typical Operation

1. Remove tray.

2. Turn on at power point. Turn the irrigator's power switch on.

    The machine will display "8.8.8.8", followed by "SCx.y" (where x.y is the machine's software version number). The machine will automatically drain, flush, drain the flush, fill, and degas. This will take approximately 25 minutes.

3. Machine will display "- - - -"

4. Check program settings.

    The machine is now ready for use.

5. Load the machine and close the lid.

6. Press "Clean".

    Display shows "C-01" (number of cleans), "degas", "01.52" (time remaining), then "C-01" (number of cleans), "P-03" (power level), "09.48" (time remaining). HCR irrigators will activate recirculation.

7. To stop cleaning at any time, press "Clean" again or lift lid.

8. When cleaning cycle is complete, machine will display "- - - -"

9. Lift lid and remove tray.

B.2. Automatic Shutdown

1. When the programmed number of cleaning cycles are completed the machine will automatically drain, and display "End".

2. Press and hold the "Shift" and "Refill" keys to continue cleaning or;

3. Switch the irrigator's power switch off. Turn off at power point.

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B.3. Manual Shutdown

1. Press "Shift" and "Drain".

2. When machine has drained the display will show "OFF".

3. Switch the irrigator's power switch off. Turn off at power point.

C.   Specification

Soniclean ultrasonic irrigator models S2800, S2800MRS, S2800MRC-HCR

Tank Size	650 mm (W) $\times$ 336 mm (D) $\times$ 180 mm (H)
Tank Capacity	39 L
Ultrasonic Power	350 W (typical)
Overall Size	742 mm (W) $\times$ 483 mm (D) $\times$ 420 mm (H)
Weight	~35 kg
Benchtop Footprint	880 mm (W) $\times$ 590 mm (D) $\times$ 790 mm (H)

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D.   S2800/MRS Preventative Protocol (Recommended)

Soniclean recommended the following protocol to be carried out (daily and weekly by your authorities; annually by your service agent) to ensure the machine is performing at the optimum performance.

Daily

Remove and clean strainer	Ensure strainer is clean.
Drain machine at end of day/session	Ensure the contaminated water is not stored in tank.
Check cleaning efficacy	Visual examination of all load items.

Weekly

Safety checks	Check condition of lid hinges and tray.
Lid interlock test	Ensure safety to operator.
Drainage test	Ensure free-flowing drainage.
Detergent dosing test	Ensure the detergent can flow into the tank.

Annually

Verification of calibration e.g. plumbing system, detergent intake, level sensor, electronic boxes, MRS.
Completion of all validation & performance tests.
A service reminder sticker and Test Certificate will be provided after each calibration.
Where to obtain service? Return your machine to Soniclean for a full overhaul and service.
Preventative maintenance contract recommendations--please contact Soniclean for more information.
Re-ordering information for SONIC 1 detergent.

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E.   Recommended Irrigator Disinfection Protocol

It is Soniclean's protocol to disinfect every irrigator supplied for trial at the end of every trial and immediately prior to commencing the next trial. Soniclean or their distributors/agents will ensure this is undertaken unless the trial organisation prefers to conduct the disinfection themselves.

The protocol to be followed:

1. Drain irrigator and turn off at power point.

2. Apply protective gloves (disposable non sterile latex gloves are suitable).

3. Remove tray; thoroughly wipe down all visible surfaces of the irrigator including the lid, tank, all outside surfaces, hoses and attachments with disinfectant solution1.

4. Remove detergent hose and replace with disinfectant hose connected to bottle with slightly more than required amount of disinfectant1.2. Insert tray.

5. Turn irrigator on at power point whilst holding down the "Program" key (this will allow you to reprogram the parameters).

6. Change soap % parameter to required amount of disinfectant. Ensure irrigate function on.

7. Press "Clean". The irrigator will now add appropriate amount of disinfectant to tank and in doing so will disinfect the internal plumbing fittings as well as irrigator ports.

8. Once clean is complete, disconnect disinfectant bottle and replace with bottle filled with clean water.

9. Press "Shift" and "Refill" keys, hold for three seconds. This will cause irrigator to empty of water and disinfectant and then to fill with water. This will rinse disinfectant out of the unit.

10. Repeat steps 5 and reprogram soap parameter to factory setting (that is, 0.5)

11. Dry all external surfaces and pack unit ready for transport.

Note on disinfectant solutions: The recommendation is to use a TGA approved medical grade disinfectant which is recommended for use in hospital settings for disinfecting horizontal and vertical working surfaces.

Soniclean currently uses a product called LCC (supplied by Dominant Chemicals). For disinfecting the irrigator it is recommended that you dilute LCC, 1:35. That is: To disinfect surfaces you will need 6 ml disinfectant to 200 ml water; for plumbing, set soap % parameter to 5 (800 ml/30L tank).

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F.   Warranty

Note: For goods purchased in Australia after 1 January 2012.

Soniclean goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The benefits under our warranty described below are in addition to other rights and remedies under a law in relation to the goods.

The Soniclean irrigator is guaranteed for 12 months from date of purchase. We undertake to repair free of charge or exchange (at our discretion) any part found to be defective due to a manufacturing fault.

As a Medical Device, it is essential your machine is validated and calibrated at least once every 12 months to meet the cleaning performance, subject to mandatory compliance to AS/NZS 2773-2019, AS/NZS 4187-2014, HTM01-05 and HTM2030. See the services page on our website for more information.

A service reminder sticker and a Calibration/Validation Certificate will be provided after each service. For our annual preventative maintenance contract outside warranty period, please contact Soniclean for more information.

This warranty is not transferable and does not cover damage caused by the following: unvalidated installation, misuse, neglect, failure to observe operating instructions, failure to keep the machine clean, accident, use of incorrect power supply, use of incorrect water supply and use of incorrect or non-approved cleaning chemicals.

This warranty does not cover:

- the ultrasonic tank against erosion by chemical, cavitation or ultrasonic actions;

- damage to transducers caused by excess thermal or mechanical shock.

F.1. Warranty Registration

The purchaser agrees to undertake the cost and responsibility of transportation of the machine to and from the premises of the distributor, authorised service agent or manufacturer.

For the warranty conditions to apply, the irrigator must be installed and commissioned by personnel approved by the manufacturer. Any faults or possible doubts arising concerning the effective operation of the machine must be reported to your supplier or Soniclean in writing within 3 working days.

This form, photocopy or facsimile must be returned with the installation checklist (see next page) within 1 month from the date of commissioning the machine.

Personal details collected by Soniclean are treated as confidential and in accordance with our privacy policy.

Retailer / Place of Purchase _____

Model _____ Serial No. _____

Date of Purchase _____

Date of Commissioning _____

Commissioned By _____x

      Position _____

Customer Representative _____x

      Position _____

Soniclean Representative _____x

      Position _____

G.   Installation Checklist

Note: The check-list must be returned to Soniclean (the manufacturer) together with the warranty form from date of commissioning the machine.

Hospital Name _____   Location _____

Serial No. _____   Asset No. _____

Technician _____ x

     Position _____

Customer Representative _____ x

     *Position*_____

Return check-list and warranty form to:

     Soniclean Pty Ltd
     ABN 89 057 730 ACN 057 730 917
     12B Islington Court
     Dudley Park, SA 5008 AUSTRALIA
     Tel: +61 8234 8398
     soniclean.com.au / sales@soniclean.com.au

Technician and Installation Requirements check-lists are found on the following pages.

G.1. For Technician

Please tick relevant boxes. If an item is not applicable, leave blank.

Plumbing

Screw supplied braided hose on to the machine and inlet mains water supply (hand tighten only). ❑

Screw and hand tighten supplied grey sink hose onto the machine and insert into drain. ❑

Ensure that the drain hose falls evenly away from the machine to the drain ❑

Electrical

Wall power socket 240 VAC 50-60 Hz rated at 10 amps ❑

Wall power socket located within 600mm from the machine ❑

Power supply circuit shall not be shared with life threatening or life support electrical systems. ❑

Power supply circuit shall not be shared with computer electrical system or other excessively large power devices (for example, sterilisers, washers or disinfectors). ❑

Earth leakage protection shall be provided by user. ❑

Machine Reporting System (MRS only):

LAN connection: take the LAN provided cable and push the black plug into the MRS socket provided on the irrigator. Plug the other end (RJ45) into the LAN wall outlet. ❑

Contact your IT department and hand them the Machine Reporting Manual. The appropriate information for connecting the machine to the Local Area Network is found in the Machine Reporting System Manual, "Network Hardware and Configuration." ❑

PC Connection: take the PC cable provided and push the black plug into the MRS socket provided on the irrigator. Plug the other end (RJ45) into the appropriate outlet on the PC. ❑

Temperature Sensor: Push the ambient temperature sensor probe into the temperature sensor socket found on the right side of the machine. ❑

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Printer

Plug the machine into mains supply and turn on at the switch ❏

Plug the printer cable into the machine and the printer. ❏

Press the feed button to progress the paper. ❏

Detergent Bottle

Connect detergent hose to left hand side socket of machine ❏

Place filtered end of detergent hose into container. ❏

Ensure there is sufficient detergent in bottle at all times. Explain this to customer that level must be checked regularly. ❏

Please note Chemical Type: (Sonic 1), Dosage Setup: (0.5%). ❏

Machine Location

Place machine on flat and horizontal surface (maximum 2° tilt). ❏

Caution: Explain to the customer the following.

Only use designated cables for accessing data from the irrigator. ❏

The cable marked "PC" should be used with a laptop computer. ❏

The cable marked "LAN" should be used for connection to a LAN wall output. ❏

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![Soniclean® logo]

H.   Further Enquiries

Technical Support

Nominated Service Provider

or

Soniclean Pty Ltd
+61 8 8234 8398

Sales Enquiries

Soniclean Pty Ltd
soniclean.com.au
sales@soniclean.com.au
+61 8 8234 8398

To arrange a service or discuss the terms of your contract, contact our Customer Care Team on +61 8 8234 8398.

All services are provided subject to our Standard Service Terms and Conditions.