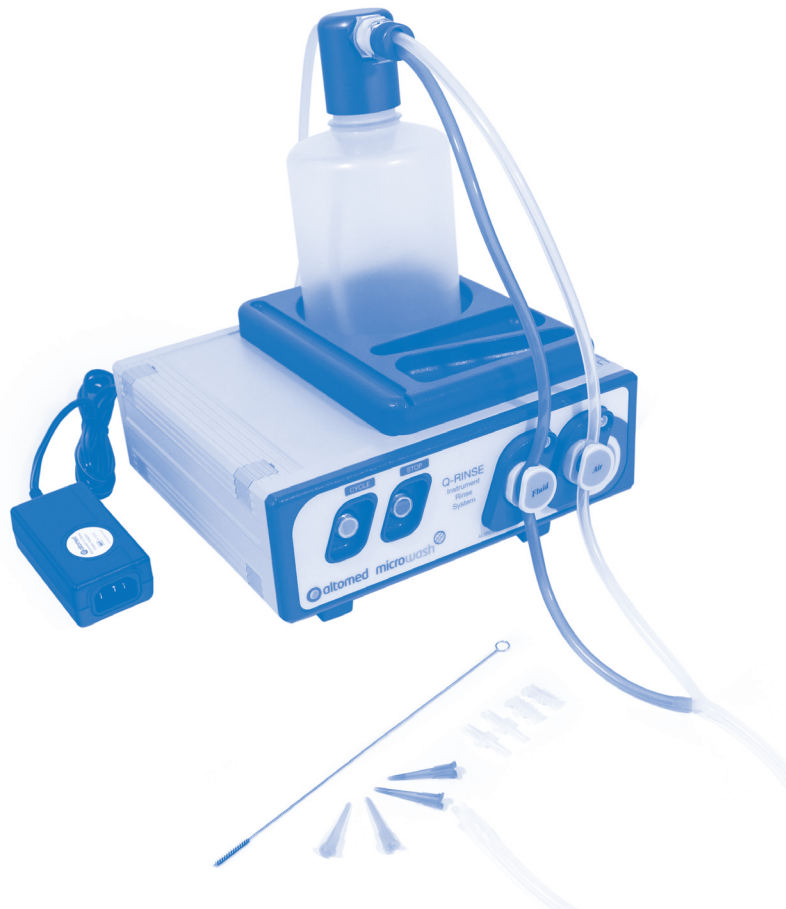




Microwash Q-Rinse System





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1. Introduction

Altomed supports the surgical community with superior products, technical support and customer service.

The Microwash Q-Rinse System is built by Altomed in the UK.

- The Microwash Q-Rinse system will help you standardise the rinsing procedure of reusable surgical instruments and tubing after surgery and prior to processing.
- Its time saving design is an efficient alternative to the manual syringe rinsing method.
- The 15 second automated cycles regulates the necessary flow of fluid and air.
- The manual mode allows for easy transition between cycles at any time if required due to narrow lumen.
- The Microwash Q-Rinse system is recognized globally among the surgical community and is becoming the standard rinsing procedure for many surgical centres.

2. Warning, Cautions and Symbols

Carefully read all warnings, cautions and instructions before use. See also Section 11 for electrical information.

The following warnings and cautions and notes apply to all Microwash Q-Rinse components unless otherwise specified:

General Warnings

- DO NOT attempt to modify the Microwash Q-Rinse system in any way. Modifying the Microwash Q-Rinse System may affect the device operation and user safety. Modification will also void the warranty.
- DO NOT interchange any other manufacturer's equipment or accessories with the Microwash Q-Rinse system unless the Altomed Quality Department confirm otherwise. Only use an Altomed Foot Pedal. The warranty is exclusive to Microwash Q-Rinse System parts and accessories only.
- DO NOT use the Microwash Q-Rinse in the presence of explosive gases or other flammable substances.
- DO NOT open any panels on the machine while the Microwash Q-Rinse is plugged in to avoid electric shock. There are no serviceable parts inside the machine. Contact Altomed Limited Repairs Department or approved Distributor for repair information. A list of Approved Distributors is available from Altomed.
- DO NOT aim the tubing at any part of the body while the Microwash Q-Rinse System is plugged in. The Microwash Q-Rinse operates under pressure.
- DO NOT disconnect the bottle cap or any tubing lines while the system is ON and pressurized. (If the pressure is not allowed to be safely released, disconnecting the tubing lines can cause pressurized fluid to spray.)
- DO NOT carry the machine by the tubing or the cap.
- DO NOT sterilize the bottle in a peel pouch or with the cap on as it may collapse and be rendered unusable.
- In the event the fluid and air do not pass from the tubing during use. Stop the machine by pushing the Stop button and contact Altomed for advice on +44 (0) 191 519 0111.
- Return the machine to Altomed for inspection if the machine has been dropped and does not function correctly. Damaged casings need to be replaced to prevent fluid ingress. If a drop has resulted in the case being damaged, return to Altomed or Authorised Distributor for inspection.

General Cautions

- Carefully read this manual before initial operation of this system or if an untrained user. If in any doubt contact Altomed or Authorised Distributor.
- The Microwash Q-Rinse System must only be connected to a grounded electrical receptacle.
- Use of the Microwash Q-Rinse System does not absolve user from following your facility's policies and procedures for cleaning or decontamination of surgical instruments. All items rinsed with the Microwash Q-Rinse should be inspected for cleanliness and integrity prior to further processing. This is not a disinfection machine.

Special Instructions / Notes regarding the Q-Rinse System and Electromagnetic compatibility (EMC) testing to EN 60601-1-2: 2015

The Q-Rinse system is suitable for use in a professional healthcare facility, except near HF surgical equipment or outside the RF shielded room of a medical system for magnetic resonance imaging where the intensity of EM disturbances is high, or in a home healthcare environment.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 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 Q-Rinse system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Symbols Used On The Machine



Name and address of manufacturer.



Altomed catalogue number used for device identification.



Device lot number used for traceability.



Consult instructions for use for important cautionary information (e.g. warnings and precautions) unable to be printed on the device.



WEEE Symbol. Waste electrical electronic Equipment. Do not dispose of as general waste. Return to Altomed or Authorised Distributor for recycling after end of life



CE mark. Medical device meets the current regulatory and legislative requirements.



Instructions for use. Refer to the Instruction Manual enclosed with the device.

3. Description

The Microwash Q-Rinse system provides a consistent method for rinsing patient fluids and debris from surgical tubing and instruments. A pressurised stream of air follows the rinse cycle to make sure that the majority of rinsing fluid is cleared from the inner channels. The contaminated surgical tubing or instruments should be rinsed immediately after use to prevent debris drying inside the lumen, preferably no later than 30 minutes.

Note: Residual moisture is desired within the inner channels of the medical device and tubing to prevent any remaining biofilm from drying in the lumen. If the medical device to be rinsed is not being sent for processing straight away fill the lumen with a pre-cleaning solution such as Ruhof Prepzyme XF or similar. Rinse this out with sterile water for irrigation (or similar) prior to processing.

3.1 Features

Some of the features of the Microwash Q-Rinse system are summarised below.

- One automatic cycle has a fluid run of 15 seconds followed by an air cycle of 15 seconds.
- There is a manual override feature to allow the user to select fluid or air depending upon the device being processed
- Positive pressure delivery system
- Selection of adaptors for variety of instrument interfaces, some of which can be cut to size
- 1000ml bottle
- Single connection instrument interface
- Compact countertop-sized unit

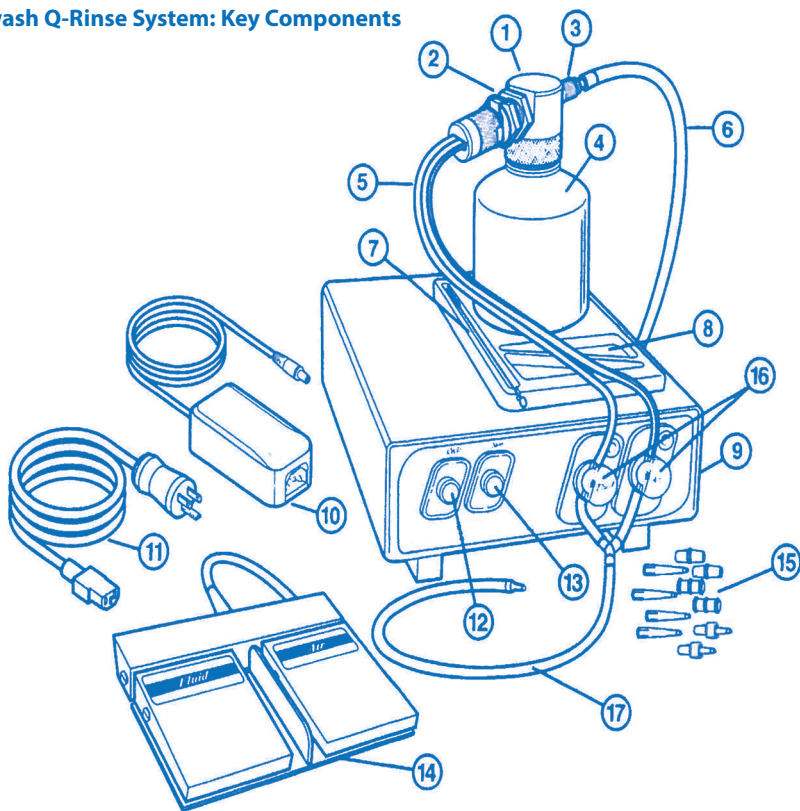
3.2 Function Modes

- Automatic Mode: Fluid followed by air
- Manual Override
 - Fluid Only
 - Air Only
- Foot Pedal (Optional)

3.3 Key Components

Microwash Q-Rinse System: Key Components

Figure 1



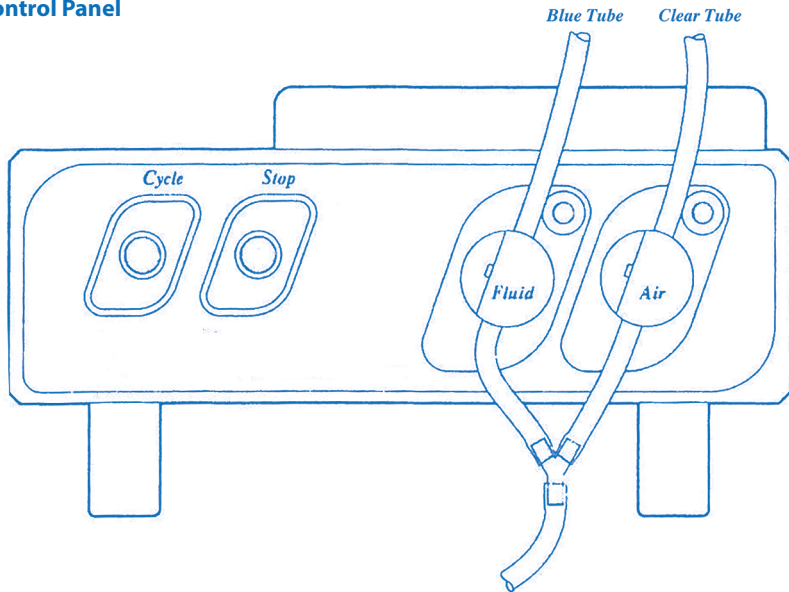
Key

- | | |
|------------------------------|----------------------------------|
| 1. Bottle cap | 10. Power supply |
| 2. Quick disconnect (dual) | 11. Power lead |
| 3. Quick disconnect (single) | 12. Cycle switch (on) |
| 4. 1 litre bottle for fluid | 13. Stop switch |
| 5. Air/fluid tubing | 14. Footpedal (Optional) |
| 6. Air supply tubing | 15. Accessory pack |
| 7. Wire brush | 16. Pinch (air and fluid) valves |
| 8. Storage tray | 17. Instrument interface tubing |
| 9. Front bezel | |

3.4 Front Control Panel

Front Control Panel

Figure 2



The front control panel contains both the automatic and manual control (cycle) switches in addition to the Fluid and Air Valves. The front panel functions are described in the order indicated in Figure 2, from left to right:

Cycles:

Automatic Cycle

Pushing the Cycle switch once will operate the automatic program which consists of two cycles, each lasting a minimum of 15 seconds, first fluid then air. After completing the Automatic Cycle, the system will reset itself for the next program

Manual Override Function

To manually override the Automatic Cycle, push the Cycle button a second time. Repeated pushing of the Cycle button will continue to alternate between fluid and air.

Note: If manually overriding the Automatic Cycle, YOU MUST press the Stop Button before operating the unit again in order to properly reset the Automatic Cycle mode.



If the fluid starts to back up the blue tubing during use, it means the blockage is severe or the lumen very narrow. If there is a blockage use the wire brush or an impregnated sponge designed for cleaning lumen (like a Ruhof InstruSponge); if a narrow lumen, then switch to the Air Cycle on the manual mode to flush away the backed-up fluid. Return to the fluid path if needed.

Stop:

Push the stop button to interrupt the current operation and reset the system.

Fluid Valve/ air Valve:

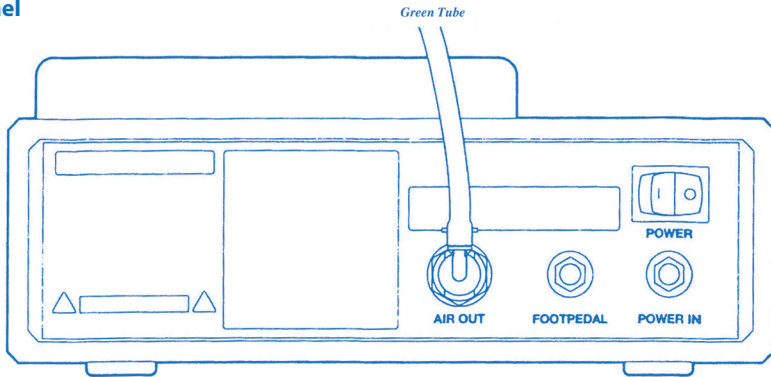
These valves open and close in response to the Microwash Q-Rinse system's timing circuits. The blue tubing segment between the bottle and the "Y" connection is to be placed in the Fluid Valve. The clear tubing segment between the bottle and the "Y" connection is to be placed in the Air Valve.

The amber lights adjacent to the valves illuminate when the valve is open.

3.5 Back Panel

Back Panel

Figure 3



The back panel contains the AIR OUT connector, the POWER IN connector, FOOT PEDAL connector, and the POWER switch. Refer to Figure 3 for locations of the components of the Back Panel.

Power Switch:

The Toggle switch turns the unit on or off. The symbol "I" being On and "O" being off

Air Out:

The Air Out connection delivers approximately 30 psi to the fluid container. The spring lock mechanism prevents accidental disconnection of the rear air supply line.

Foot Pedal:

The Foot Pedal connection is for the optional Foot Pedal.

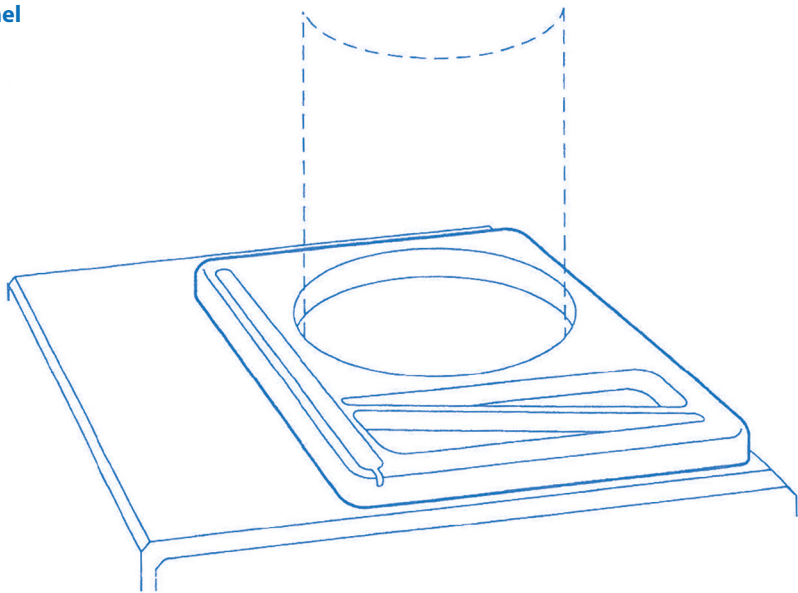
Power In:

Connect the Microwash Q-Rinse Machine to a regulated 12-volt supply by using the Altomed Power supply REF: A11074 (see Section 9).

3.6 Top Panel

Top Panel

Figure 4



Top Panel

The top panel features storage compartments for the wire brush and various connectors used to adapt the Microwash Q-Rinse system to various instruments and tubing. See Figure 4.

A deep well is provided to hold the 1000ml bottle.

4. Set up and Operation

This section details the recommended set up and operational procedures for the Microwash Q-Rinse System.

If in any doubt, contact Customer Services at Altomed Limited on:

Tel: +44 (0) 191 519 0111 or E-mail admin@altomed.com

The Microwash Q-Rinse System is designed to interface with a variety of surgical instruments by using standard luer adaptors. A storage tray is provided on the top of the unit to keep these adaptors available. A smaller diameter cleaning brush is included to assist in clearing blockages in metallic lumens.

CAUTION #1

Follow your facility's *Standards of Practice* for personnel working in the decontamination, preparation and sterilization area.

Personal protective equipment (PPE) including gloves, apron, sleeves and visor or protective eyewear must be worn when cleaning contaminated medical instruments to reduce the risk of cross contamination.

Users of the Microwash Q-Rinse System must still adhere to the facility's *Standards of Practice* for sterilization and sterility assurance for cleaning medical devices. In the UK this includes compliance with recommended practices covering the preparation and decontamination of instruments, see "Choice Framework for Local Policy and Procedures" issued by the Department of Health.

First Use

- Unpack the Microwash Q-Rinse System, place all the parts on a clean flat surface and check to make sure all the items as in Figure 1 (page 8 above) are present and correct; the Foot Pedal is an optional extra and is not supplied as part of the System.
- Check to make sure there has been no shipping damage. Contact the Quality Department at Altomed or the Authorised Distributor in the case of any problems. DO NOT USE ANY DAMAGED PARTS.
- Remove the short protective segments of silicone tubing from the pinch valves and discard in the general waste.
- Place the adaptors into the storage compartment on the top panel.
- Place the wire brush alongside the container in the appropriate storing compartment.

Table 1: Pre-Use Checks

* See Page 8 for “Item” References

Part Description	Item Numbers*	Checks to be carried out
Tubing Set	5 and 6	Check all silicone tubes for signs of wear or physical damage such as holes, stretches, splits or squashing. If damaged replace.
	5	Ensure the “Y” connector is secure in the tubes and not damaged. If damaged replace.
	2 and 3	Ensure the joints around the male connections are all secure and that the connectors themselves are not damaged. Check for cracks or chips etc. If damaged replace.
	2	Ensure the hexagonal nut on the air/fluid tubing connector is secure, if loose tighten or replace bottle cap.
	2 and 3	Ensure the 1 x black gasket on the elbow connector is present and undamaged and that the 2 x black gaskets on the air/fluid tubing cap connector are also present and not damaged. If missing or damaged replace.
Bottle Cap	17	Ensure the luer connector is present and secure in the end of the interface tubing. If it is missing replace it.
	1	Ensure the white gasket is secure inside the cap and that it is not damaged. Check for wrinkles, splits, snaps or squashing. If damaged replace.
	2 and 3	Ensure both the female connectors are secure in the cap and are not loose or damaged. Check for cracks or chips. If damaged replace.
	2	Check that the metal pin in the air/fluid connector is not damaged and that the metal plate slides down and springs back up. If damaged replace.
	2	Ensure the PTFE (white) tape is secured around the metal air input connector on the cap. If damaged replace.
Bottle Cap Complete	1	Ensure there is no damage to the silicone tube, especially around the connector, and that it is securely on the connector inside the cap. If damaged replace.
	1, 2 and 3	Ensure the male and female connectors are fastened together and secure. If unable to secure replace bottle cap.

Part Description	Item Numbers*	Checks to be carried out
Bottle	4	Ensure there is no physical damage to the bottle, cracks, splits, holes etc., and that the threads are not damaged and that the structure is not deformed. Dispose of any failed bottles and replace with new ones.
	4	Ensure the bottle is clean and dry and does not have residues in the bottom. If dirty clean, may be sterilized if deemed necessary.
Power Supply and Lead	10 and 11	Check the grommets, connectors, plugs and wire for any signs of physical damage, e.g. exposed wires, splits in the cable, cracks in casing etc. Do not use if there is any sign of damaged
	10 and 11	Make sure the connection between the lead and power supply unit is secure, if loose push together to ensure the connection is secure.
Q-Rinse Machine	N/A	Check for any physical damage to the casing e.g. cracks, chips etc., or other physical damage to the valves or switches or connectors. If damaged replace.
	N/A	Ensure the four rubber feet are in place and secure to prevent movement of the machine. If missing replace.
	15	Check to make sure the 10 adaptors are present and ready for use if needed. If missing replace.
Assembled Q-Rinse System	N/A	Ensure the waste receptacle is designed to accept contaminated fluid waste. If not designated for contaminated waste, source a suitable receptacle approved by your facility.
	6 and 16	Ensure the blue tubing goes into the Fluid Valve and the clear tubing goes into the Air Valve. Ensure the elbow connector on the green tubing has clicked securely into place. If not set up accordingly and re-read the Instruction Manual.
	10 and 11	Ensure the Power Supply and lead cannot be splashed or exposed to water. Use splash protection over sockets if present.
	N/A	Run an automatic cycle to ensure fluid and air flow is correct and that the switch over between fluid and air takes place. Do not use if the cycle fails, send for repair.

4.1 Set Up

* See Page 8 for “Item” References

STEP 1

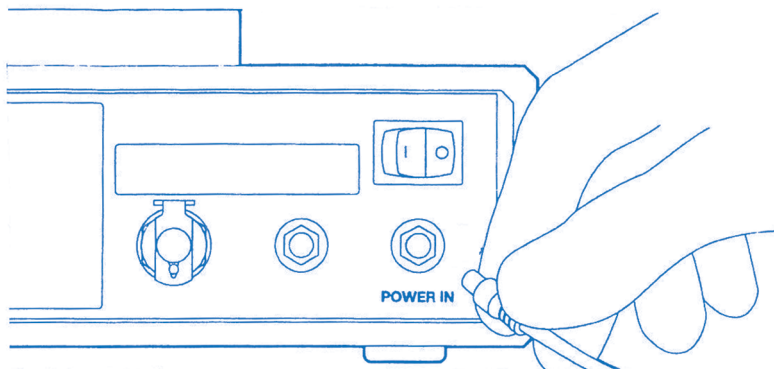
See Caution #1 and complete all pre-use checks as advised in Table 1 (page 14 above). Position the machine on a flat surface near a grounded wall outlet and close to the facilities waste receptacle for disposing of contaminated fluids (e.g. sink). Ensure there is sufficient free space around the machine to permit proper connection, use and dismantling procedures. Do not position the device in a way that will make it difficult to readily access the plug.

Plug in the A11047 Altomed power supply (*Item 10*) into the hospital grade power cord (*Item 11*) supplied, (this may differ from the picture in Figure 1 depending upon which country you are in.) Ensure the machine is not pushed up against a wall or other solid surface causing the power connector and lead to bend at the back of the machine.

Plug the A11047 Altomed power supply (*Item 10*) into the back of the Microwash Q-Rinse System (Figure 5a). Make sure the plug is fully engaged. Plug the power cord (*Item 11*) into a grounded wall outlet. A standard wall plug has been supplied to allow the use of splash protection covers if required.

Power Supply Connection

Figure 5a



STEP 2

Fill the bottle (*Item 4*) with sterile water for irrigation (or similar) leaving one inch of space from the top for proper operation. DO NOT OVER FILL. Screw the metal cap (*Item 1*) onto the bottle (*Item 4*). **The bottle cap must be securely on the bottle BEFORE it is put into the well!**

Place the bottle (*Item 4*) into the well located on the top of the machine. Position so that the quick disconnect (single) fitting (*Item 3*) faces the rear of the unit.

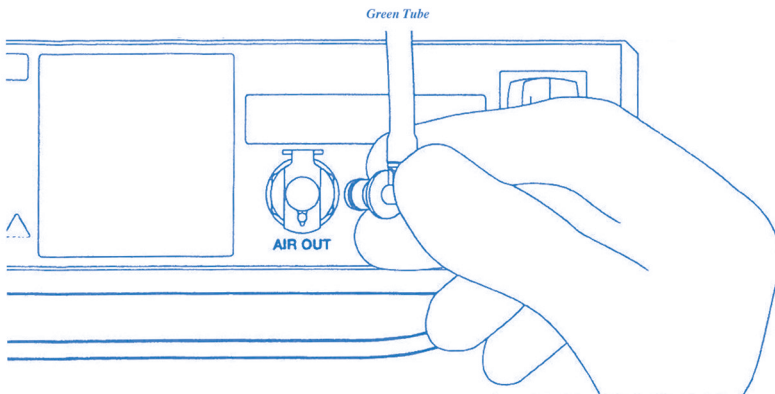
Connect the air supply tubing (*Item 6*) to the metal female connector on the bottle cap. The tubing will “click” into place when the connection is secure.

STEP 3

At the back of the unit, click the white elbow connector on the air supply tubing (*Item 6*) into place (Figure 5b). The elbow connector will “click” when secure. The air supply tubing (*Item 6*) MUST be in place before operating the Microwash Q-Rinse System otherwise the pressure will not build in the container.

Air Supply Connection

Figure 5b



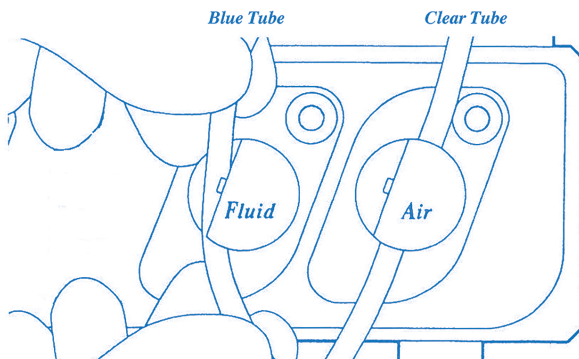
STEP 4

Connect the air/fluid tubing (*Item 5*) to the quick disconnect (dual) fitting (*Item 2*) on the bottle cap. It will “click” when the connection is secure.

At the front of the unit, install the rinse lines through the pinch valves (see Figure 5c below). The BLUE tubing line MUST run through the *Fluid* valve. The CLEAR line MUST run through the *Air* valve.

Installing Fluid and Air Lines

Figure 5c

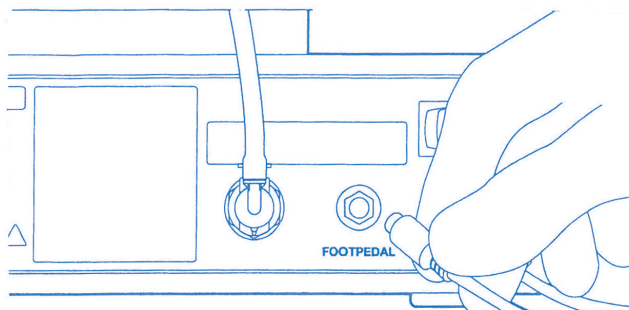


STEP 5

(Optional footpedal) Only use an Altomed footpedal.

Connection of Optional Footpedal

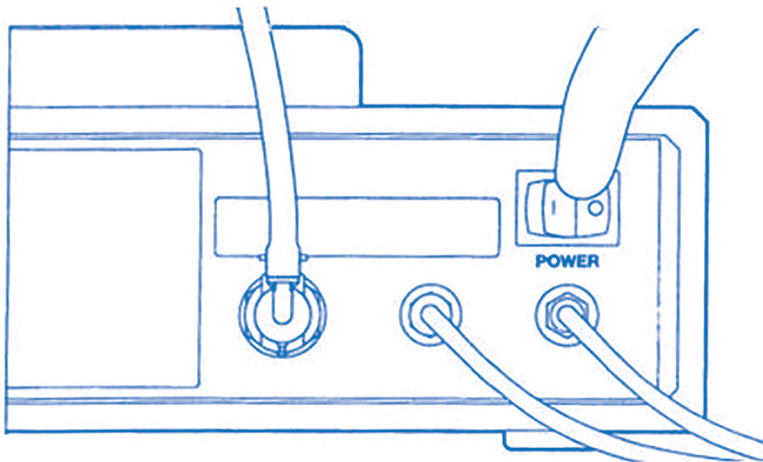
Figure 5d



At the back of the Microwash Q-Rinse System, plug in the Foot Pedal connector (see Figure 5d). Place the Foot Pedal on the floor in a location which is convenient for use. Be constantly aware of a possible trip hazard.

Switch on the machine

Figure 5e



Turn on the Microwash Q-Rinse System by pressing the power switch on the rear panel (Figure 5e). The symbol "I" being On and "O" being off.

4.2 Operation: Automated Cycle

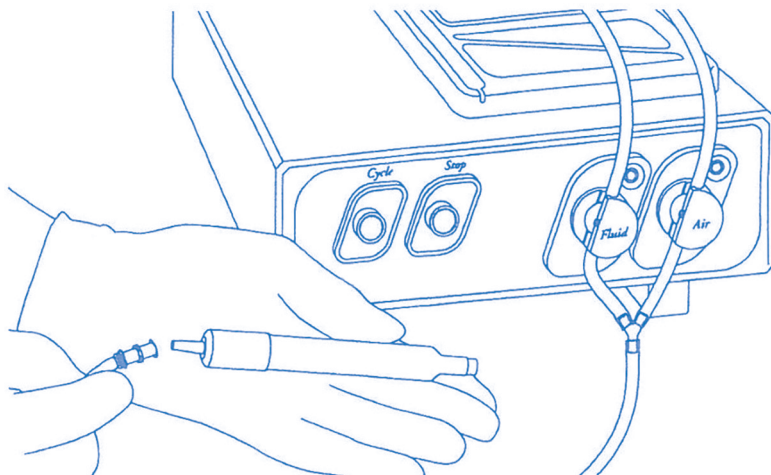
* See Page 8 for “Item” References

STEP 1

See Caution #1 and complete all pre-use checks as advised in Table 1 (see page 14 above). Connect the instrument interface tube (Item 17) to the item to be rinsed (Figure 6), use the adaptor pack (Item 15) and/or A11047 “Y” Dual Rinse Fitting if necessary.

Device Connection

Figure 6



STEP 2

Press the Cycle button (Item 12) once to begin the automated rinse cycle. The amber light next to the fluid valve will light up indicating that the valve is open. After 15 seconds the fluid valve will close and the air valve open. The amber light next to the air valve will now be illuminated. After 15 seconds the air valve will close, the machine will stop and both amber lights will be turned off. This completes the automated cycle. See Table 2 (page 26 below) for Troubleshooting if necessary.

STEP 3

Repeat Steps 1 and 2 for any further lumen on the device.

STEP 4

Inspect the rinsed device for cleanliness and function prior to further processing, e.g. disinfection or sterilization.

4.3 Operation: Manual Cycle

* See Page 8 for “Item” References

STEP 1

See Caution #1 and complete all pre use checks as advised in Table 1 (see Page 14 above). Connect the instrument interface tube (*Item 17*) to the item to be rinsed (Figure 6), use the adaptor pack (*Item 15*) and/or A11047 “Y” Dual Rinse Fitting if necessary.

STEP 2

Press the Cycle button (*Item 12*) once to begin the automatic rinse cycle. At any time during the automatic cycle, press the Cycle button (*Item 12*) a second time to enter the manual mode.

After pressing the Cycle button (*Item 12*) a second time, the Microwash Q-Rinse System will be in the manual mode and the Cycle button (*Item 12*) will begin to flash.

While in the manual mode, the user can alternate between fluid and air by further pressing of the Cycle button (*Item 12*). The amber light adjacent to the open valve will illuminate.

STEP 3

To end the manual mode, press the stop button (*Item 13*). The Cycle button will stop flashing and the unit will reset for the next use. The manual mode will time out after 60 seconds if no buttons are pressed.

STEP 4

Repeat Steps 1 to 3 for any further lumen on the device. Use the luer adaptors (*Item 15*) as required.

STEP 5

Inspect the rinsed device for cleanliness and function prior to further processing e.g. Disinfection or Sterilization.

Note: After using manually shortened modes, you must press the Stop to reset the internal timers.

4.4 Operation: Foot pedal Operation

The Foot Pedal is an optional accessory. Only use an Altomed Foot Pedal.

STEP 1

See Caution #1 and complete all pre use checks as advised in Table 1 (see page 14 above). Connect the instrument interface tube (*Item 17*) to the item to be rinsed (Figure 6), use the adaptor pack (*Item 15*) and/or “A11047 “Y” Dual Rinse Fitting” if necessary.

Note: The Footpedal is comprised of two foot switches. The left-hand switch controls the **Fluid** valve and the right-hand switch controls the **Air** valve.

STEP 2

Press and hold the desired foot pedal (*Item 17*) switch **Fluid** or **Air**. The pump will run and the appropriate valve will remain open as long as the Foot pedal is in the depressed position.

Release the switch to close the valve. This will turn off the pump and reset the unit.

You may alternate between **Fluid** and **Air** by pressing the appropriate Foot pedal.

Note: The Foot pedal operation overrides all other modes. If one of the Foot pedal switches is pressed during the automatic manual modes, the Microwash Q-Rinse will immediately abort that mode and enter the Foot pedal mode. Once the Foot pedal switch is released the unit will reset and the automatic modes are again available.

STEP 3

Repeat Steps 1 and 2 for any further lumen on the device. Use the luer adaptors (*Item 15*) as required.

STEP 4

Inspect the rinsed device for cleanliness and function prior to further processing, e.g. disinfection or sterilization.

4.5 Operation: Refilling bottle

STEP 1

Slide back the quick disconnect single connector (*Item 3*) to separate the green air supply tubing (*Item 6*) from the bottle cap (*Item 1*). This is done first to release any remaining pressure in the system and to avoid spilling excess fluid.

STEP 2

Depress the silver plate on the quick disconnect dual connector (*Item 2*) to separate the air/fluid tubing (*Item 5*) from the bottle cap (*Item 1*)

STEP 3

Take the bottle from well and remove the cap by turning counter-clockwise.

STEP 4

Fill the bottle with the sterile water for irrigation (or similar), leaving one inch of space from the top of the bottle to ensure proper operation.

STEP 5

Replace the bottle cap. Place bottle back in the well and reconnect the green air supply tubing (*Item 6*) and air/fluid tubing (*Item 5*). Ensure both quick disconnect connectors are secure.

4.6 Operation: Disinfection and Sterilization

As required after inspection or as recommended in your Risk Assessment, disinfect and/or sterilize the Microwash Q-Rinse system as described below.

STEP 1 – Disinfection

- a. Wear the correct PPE (personal protective equipment) gloves, apron, sleeves and visor or protective eyewear) or as recommended in your Risk Assessment.
- b. Switch the machine off by pressing the switch at the back to the “0” position. Switch off the power supply at the wall socket and remove the plug. Unplug power supply from the back of the Microwash Q-Rinse system.
- c. Carefully remove the air/fluid tubing from the pinch valves.
- d. Remove the elbow connector on the air input tubing from the back of the machine by depressing the silver release plate.
- e. Unscrew and remove the cap assembly. Remove bottle from machine.
- f. Disconnect the air/fluid tubing from the cap by depressing the silver release plate and remove the “Y” Dual Rinse Fitting” if attached.
- g. Disconnect the green air input tube from the cap by sliding back the quick disconnect connector.
- h. Mix up a solution of a hospital approved disinfectant (e.g. Ruhof Virusolve) and pour into a disinfectant bath big enough to hold the bottle and cap assembly.
- i. Submerge the bottle fully in the disinfectant bath for the required time as specified by the disinfectant manufacturer (e.g. 5 minutes with Ruhof Virusolve); ensure there is no air trapped inside the bottle.
- j. Place the green air tube into the disinfectant bath for the recommended time (e.g. 5 minutes with Ruhof Virusolve)
- k. Place the cap end of the air/fluid tube into the disinfectant bath. Using a syringe connected to the interface tube by a luer connector, carefully withdraw the disinfectant up the tubes until the lumen is completely exposed to the solution. Remove the syringe then completely submerge the air/fluid tubing in the bath for the required time (e.g. 5 minutes with Ruhof Virusolve).

- l. Wipe exterior of console and the Foot Pedal (if applicable) to remove any visible soil/fluids using a soft cloth moistened with the disinfectant of choice.
- m. Once the bottle assembly has been exposed to the disinfectant for the required time, remove all parts from the disinfectant bath and rinse in sterile water for irrigation (or similar) to remove any chemical residues. Dry using a suitable lint free cloth. Reassembly the bottle assembly.
- n. Carry out all the necessary pre-use checks as described in Table 1 (see page 14 above). Operate a cycle to flush any residues from the tubing.

STEP 2 – Sterilization

As the bottle assembly is a non-contact device, disinfection is deemed sufficient to decontaminate it. The bottle assembly however can withstand exposure to a standard autoclave cycles of 134-137°C for a minimum holding time of 3 to 3½ minutes.

- a. Disinfect the bottle assembly first by following the steps a) to n) outlined in STEP 1 above.
- b. Unscrew and remove the cap assembly from the bottle.
- c. Disconnect the green air tube from the cap; see STEP 1 g) above.
- d. Carefully disconnect the Interface Tube from the “Y” connector.
- e. Place the bottle cap (with the air/fluid tubes attached), the separate green air tube and the interface tube and any luer or cone adaptors into a facility approved and validated peel pouch or wrap and put in the autoclave following facility approved procedures.
- f. Place the bottle directly onto the autoclave shelf upside down to facilitate drainage. The bottle should NOT be put into any package (e.g. peel pouch or wrap) as this may cause the bottle to deform and require replacement. Autoclave following the facility approved and validated cycle as above.

Discolouration

Due to presence of various cleaning chemicals that may be used during the decontamination procedure, the user may notice a staining or discoloration of the cap or tubing. Any damaged tubing should be replaced; discolouration of the cap itself will not cause any performance issues.

5. Troubleshooting

Table 2: Troubleshooting

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
No or poor flow of fluid.	1. Bottle empty. 2. Bottle cap is loose. 3. Bottle not pressurized by pump. 4. Gasket inside cap is missing. 5. Black gaskets on tubing are missing or damaged. 6. Fluid valve is not opening.	1. Check bottle fluid level. 2. Check cap tightness. 3. Check green pressure line for secure connection at back of system (figure 5b). 4. Check cap for presence white gasket. 5. Check tubing connectors to make sure black gaskets are present and correct. 6. DO NOT USE. Send machine for repair.
No flow of Air.	1. Bottle cap is loose. 2. Bottle not pressurized by pump. 3. Gasket inside cap is missing. 4. Black gaskets on tubing are missing or damaged. 5. Air valve is not opening.	1. Check cap tightness. 2. Check green pressure line for secure connection at back of system (figure 5b). 3. Check cap for presence white gasket. 4. Check tubing connectors to make sure black gaskets are present and correct. 5. DO NOT USE. Send machine for repair.
Unit fails to switch modes.	1. Cycle not completed from last sequence. 2. Cycle switches have failed.	1. Press STOP to reset the unit. 2. DO NOT USE. Send machine for repair.
Unit starts in wrong mode.	1. Cycle not completed from last sequence.	1. Press STOP to reset the unit.
Fluid is backing up the interface tubing	1. The incorrect cycle is being used	1. Control the flow of fluid by switching to the manual mode

SYMPTOM	PROBABLE CAUSE	CORRECTIVE ACTION
Unit fails to operate.	1. Unit not plugged in. 2. Unit plugged in. 3. Internal parts have failed	1. Check Power connection (figure 5a) 2. Check Power outlet. Check Power switch (figure 5e). Check green pressure line for secure connection at back of unit (figure 5b). Let unit sit unplugged for 10 minutes with green pressure line connected at back of unit (figure 5b). 3. DO NOT USE. Send machine for repair.
Poor pressure of both fluid and air.	1. Bottle not pressurized properly by pump. 2. Leak in green pressure line. 3. Cap or connector gaskets are damaged or missing 4. Pump unit has failed	1. Check green pressure line for secure connection at back of unit (figure 5b). 2. Check line for cracks or leaks. 3. Check inside the cap to make sure gasket is present, check the tubing connectors to make sure black gaskets are present and correct. 4. DO NOT USE. Send machine for repair.
Foot pedal does not operate.	1. Foot pedal not plugged in	1. Plug in Foot pedal (figure 5d)
Tubing connectors do not fit inside the cap anymore	1. The tubing has been disconnected from the bottle at sterilization	1. Replace cap assembly

6. Maintenance

Most problems which may occur can usually be resolved by verifying instrument set up against the step-by-step procedure provided in Section 4.

If this does not result in proper operation of the unit, try to isolate the problem to a major area. Try the checks indicated on the Troubleshooting Chart in Section 6.

If the problem still cannot be resolved, contact the Quality Department at Altomed for assistance on +44 (0) 191 519 0111 or your Approved Distributor.

If the problem cannot be resolved, the instrument must be returned to Altomed or your Approved Distributor prepaid. If necessary, a quotation for the cost of repair will be provided if the instrument is out of warranty.

There are no serviceable parts in the Altomed Q-Rinse System.

7. Warranty

Microwash Q-Rinse Automated Instrument Rinsing system Warranty and disclaimers

Altomed warrants that the Microwash Q-Rinse system when delivered will conform to the manufacturer's then current version of the published specifications for such. The Microwash Q-Rinse system in all material respects shall be free from defects in material and workmanship for a period of one (1) year from date of delivery when properly installed, maintained, and used for the intended purpose. Disposable accessories such as tubing, sleeves and brushes are not covered by this Warranty. An extended warranty is available to purchase at a premium for UK customers only.

The exclusive remedy for any breach of this warranty shall be, at Altomed's sole option, the repair and replacement of the non-conforming Microwash Q-Rinse system or component thereof, which is returned to Altomed during the warranty period. Any claim based upon this warranty must be submitted to Altomed during the applicable Warranty period. All replacement components provided during the warranty period shall be deemed to have been delivered on the original delivery date of the Microwash Q-Rinse system.

This Warranty is non-transferable without Altomed's prior consent.

Any Microwash Q-Rinse system or component thereof returned for any reason must be accompanied by an authorization number obtained by calling the Altomed Quality Department on 0191 519 0111. Any shipping charges incurred shall be paid by the purchaser/ user of the equipment.

This warranty does not apply to normal wear and tear, or to defects, malfunctions or failures that result from the abuse, neglect, improper installation or maintenance or processing, alteration, modification, accident, or misuse of the Microwash Q-Rinse system or its components. Failure to maintain the Microwash Q-Rinse system and its components in accordance with the manufacturer's recommendations shall void the warranty.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALTOMED SHALL NOT BE RESPONSIBLE FOR ANY LOST PROFITS OR OTHER DIRECT, INCIDENTAL, CONSEQUENTIAL OR EXPLANATORY DAMAGES SUFFERED BY ANY PARTY, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

In no event shall Altomed's liability for any claim, whether in contract or tort, exceed the amount paid to Altomed for the Microwash Q-Rinse system. The Warranty set forth herein may not be enlarged, or otherwise modified by any Altomed agent or employee, and Altomed does not assume any liability or make any warranty except as stated herein.

8. Specifications

IEC 60601 classification	Electric shock protection	Class I, powered with dedicate PSU (Ref A11074)	
	Protection against harmful ingress of water and particulate matter	IPx0	
	Applied parts	No applied parts	
	Oxygen rich environment	Not suitable for use in such environment	
	Mode of operation	Continuous	
Dimensions	Height	4.5 inches	11cm
	Length	8.8 inches	22cm
	Width	8.8 inches	22cm
Weight	Unpacked	4.0lbs	2Kg
Environmental limitations	Altitude	10,000 feet	3050 meters
	Temperature	32° - 104°F	0° - 40°C
	Relative Humidity	15% - 95%	
Permissible environmental conditions for transport and storage	Temperature	-30 to +85°C	
	Relative Humidity	5% to 95%, non-condensing	
Electrical Input requirements	100-240VAC	@47 – 63 HZ	
Power supply REF: A11074	SL Power and AULT	12 Volt DC 1.5A	
	MENB1020A1203F01		
Plug fuse	5 Amp, 240 Volts AC, operating speed f.	Size: 25.4mm long x 6.3mm diameter.	Breaking capacity: 6000A, 264VAC, 50 HZ, p.f. 0.3-0.4.

Pump type	Diaphragm		
Pressure output	Fluid 6-15 in ³ /min. auto cycle	100-250 cc/min	
	Air 10-30 psi		
Bottle description	32 fl.oz.	1000ml	
	Fully Autoclavable		
Tubing Sets	Medical grade silicone fully autoclavable		
Fluids to be used	Sterile water for irrigation (or similar)		
Fluid output	Automatic cycle	>140ml and <260ml	
Modes of operation	Automatic, Manual, Foot pedal (Optional)		

Note:

1. Weight and dimensions are appropriate
2. Specifications are subject to change without notice.

9. Supplies and Ordering

Please refer to following part numbers and descriptions when calling for assistance

Part REF	Description – Machine
A11070	Microwash Q-Rinse system complete
A11074	Microwash Q-Rinse power adaptor and lead
A11070W	Extended 24-month warranty to give 36 months in total (UK only)

Part REF	Description – Bottle Assembly
A11072	Microwash Q-Rinse bottle assembly - Complete
A11044A	Microwash Q-Rinse bottle only - No cap or tubing
A11044D	Microwash Q-Rinse bottle cap complete - Includes tubing, no bottle
A11044B	Microwash Q-Rinse bottle cap only - No tubing or bottle
A11044E	Microwash Q-Rinse tubing set - All air/fluid and air input tubing
A11042	Microwash Q-Rinse spare interface tubing pack of 4
A11044C	Bottle cap gaskets pack of 4
A11044F	Bottle cap connector black "O" rings pack of 8

Part REF	Description – Device Connectors
A11046	Microwash Q-Rinse assorted adaptors - Pack of 10
A11047	Microwash Q-Rinse "Y" dual rinse fitting
A11049	Microwash Q-Rinse luer adaptors - Converts male to female
A11049A	Microwash Q-Rinse luer adaptors - Converts female to male

Part REF	Description – Other Connectors
A11047	Microwash Q-Rinse dual rinse tubing with "Y" fitting
A11047C	Microwash Q-Rinse air input tube elbow connector
A11047P	Microwash Q-Rinse "Y" connector for bottle assembly

Part REF	Description – Other Connectors
A11076	Microwash Q-Rinse nylon and wire brush single use

10. Special Instructions / Notes regarding the Microwash Q-Rinse and Electromagnetic compatibility (EMC) testing to EN 60601-1-2:2015

The Q-Rinse has been tested to EN 60601-1-2:2015, regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the Q-Rinse is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the Q-Rinse.

Despite the testing of the Q-Rinse that has been undertaken, normal operation of the Q-Rinse can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment. As the Q-Rinse is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the Q-Rinse is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied. Changes or modifications to the Q-Rinse may result in increased emissions or decreased immunity of the Q-Rinse in relation to EMC performance.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The Q-Rinse should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the Q-Rinse and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN 60601-1-2:2015 the Q-Rinse has essential performance; the pump and valve must continue to operate as intended.

Table 4. EN 60601-1-2:2015 Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Required Test	Compliance	Comments
RF emissions	Group 1	For use in a professional healthcare facility environment only
CISPR 11	Class B	
Harmonic emissions	Class A	
IEC61000-3-2		
Voltage fluctuations / flicker emissions	Complies	
IEC61000-3-3		

Electromagnetic immunity

WARNING: 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 Q-Rinse system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 5. EN 60601-1-2:2015 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity		
Required Test	60601 test level for equipment used in a professional healthcare facility only	Compliance level
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications IEC61000-4-3	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz - 9V/m 745MHz - 9V/m 780MHz - 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz - 9V/m 5.50GHz - 9V/m 5.875GHz - 9V/m	Frequency - Test Level 385MHz - 27 V/m 450MHz - 28 V/m 710MHz - 9V/m 745MHz - 9V/m 780MHz - 9V/m 810MHz - 28 V/m 870MHz - 28 V/m 930MHz - 28 V/m 1.72GHz - 28 V/m 1.845GHz - 28 V/m 1.97GHz - 28 V/m 2.45 GHz - 28 V/m 5.24GHz - 9V/m 5.50GHz - 9V/m 5.875GHz - 9V/m
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines

Table 5. EN 60601-1-2:2015 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity		
Required Test	60601 test level for equipment used in a professional healthcare facility only	Compliance level
Surge IEC61000-4-5	$\pm 0.5, 1, 2$ kV line(s) to earth, $\pm 0.5, 1$ kV line(s) to line(s) for power supply lines ± 2 kV line(s) to earth for input / output lines	$\pm 0.5, 1, 2$ kV line(s) to earth, $\pm 0.5, 1$ kV line(s) to line(s) for power supply lines
Conducted RF IEC61000-4-6	3 V - 150 kHz to 80 MHz 6V - ISM bands between 150 kHz to 80 MHz	3 V - 150 kHz to 80 MHz 6V - ISM bands between 150 kHz to 80 MHz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% UT (100 % dip in UT) For 0.5 cycle 0% UT (100 % dip in UT) For 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) For 250/300 cycles	0% UT (100 % dip in UT) For 0.5 cycle 0% UT (100 % dip in UT) For 1 cycle 70 % UT (30 % dip in UT) for 25/30 cycles 0% UT (100 % dip in UT) For 250/300 cycles
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m

11. Customer and Technical Support

The Technical support of Altomed offers over 40 years of industry expertise with highly skilled technicians and superior customer service.

All servicing and repairs are done at Altomed Limited or at the Authorised Distributor.

Area Sales Managers are available to help you set up and operate your Microwash Q-Rinse System if needed.

If you have any questions that require any Technical Support, please call the Quality Department at Altomed

Telephone: +44 (0) 191 519 0111

Fax: +44 (0) 191 519 0283

Email: admin@altomed.com

Website: www.altomed.com

Office Hours:

Monday - Thursday

9:00AM to 17:00PM

Friday

9:00AM to 16:30PM

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