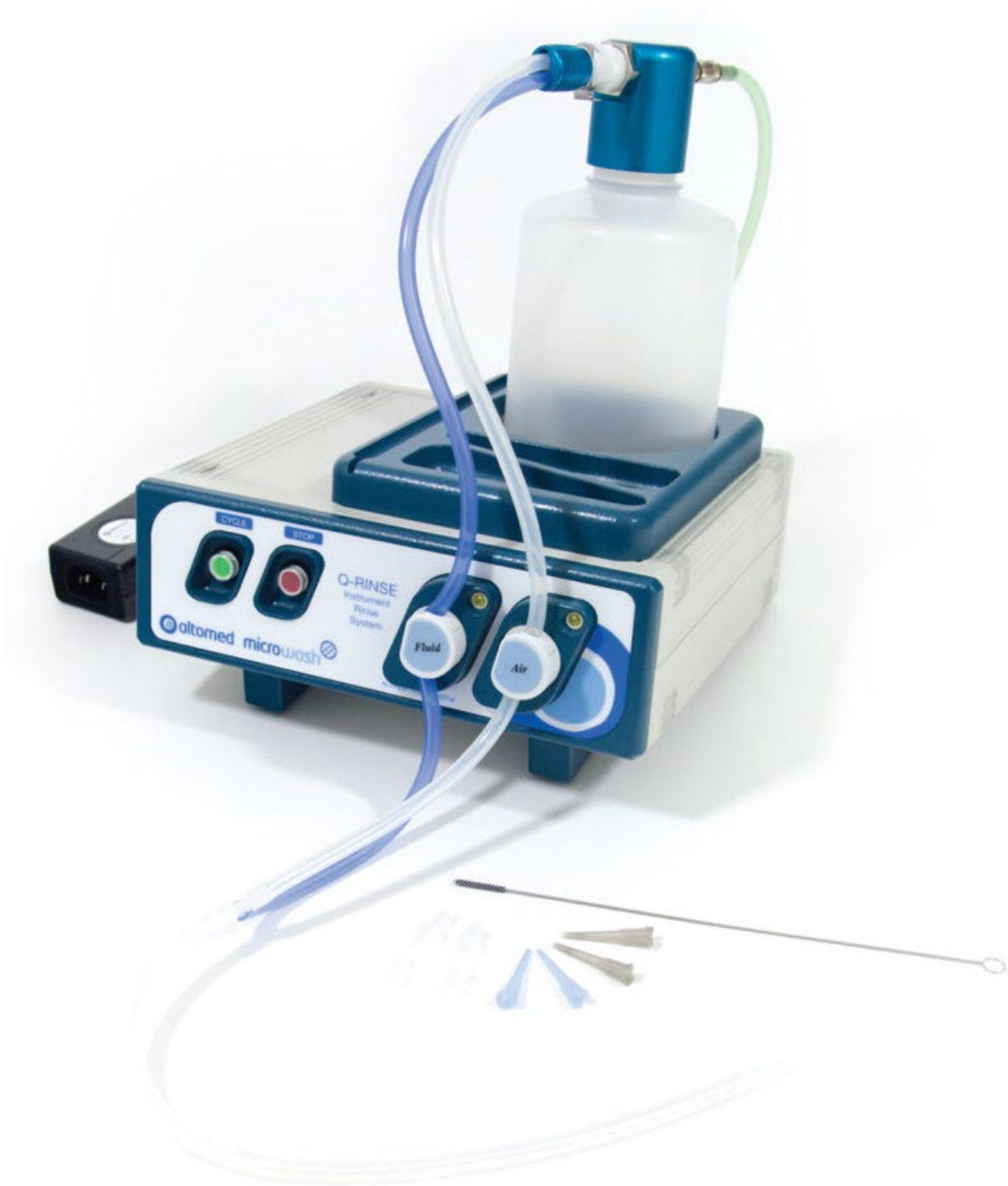
altomed

Q-Rinse System



All in one place, always at hand

All in one place, always at hand

Contents

1. Introduction

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

The Q-Rinse is classified as a medical device.

The Q-Rinse is built by Altomed in the United Kingdom.

- The Q-Rinse will help you standardise the rinsing procedure of reusable ophthalmic 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 Q-Rinse is recognized globally among the surgical community and is becoming the standard rinsing procedure for many surgical centres.

Intended Use

The Q-Rinse is intended to rinse the lumen of an ophthalmic medical device (such as a phacoemulsification handpiece or irrigation / aspiration handle), straight after its use in a surgical procedure. It is used to help rinse out any contaminants from inside the lumen and prevent them from drying on the inner wall in preparation for the washing, disinfection and sterilization stages carried out later.

Notes:

The lumen is kept damp after rinsing, ready for the application of a suitable preparation solution such as Ruhof Prepzyme XF or similar.

This is not a disinfection device. The devices rinsed must go through the decontamination instructions provided by their manufacturers.

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 Q-Rinse components unless otherwise specified:

General Warnings

- DO NOT attempt to modify the Q-Rinse in any way. Modifying the Q-Rinse may affect device operation and user safety. Modification will also void the warranty.
- DO NOT interchange any other manufacturer's equipment or accessories with the Q-Rinse unless Altomed confirm otherwise. The warranty is exclusive to Q-Rinse parts and accessories only.
- DO NOT use the Q-Rinse in the presence of explosive gases or other flammable substances.
- DO NOT open any panels on the machine while the Q-Rinse is plugged in to avoid electric shock. There are no serviceable parts inside the machine. Contact Altomed repairs repartment or approved distributor for repair information. A list of approved distributors is available from Altomed. Any attempt to open the machine may invalidate warranty.
- DO NOT aim the tubing at any part of the body while the Q-Rinse is plugged in. The Q-Rinse operates under pressure.
- DO NOT disconnect the bottle cap or any tubing lines while the 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 refer to the trouble shooting guide.
- Return the machine to Altomed for inspection if the machine has been dropped and does not function correctly. If a drop has resulted in the casing being damaged, return to Altomed or authorised distributor for inspection.
- Keep power adaptor away from water sources
- Clean the handpiece separately and after immersion in any bath.
- It recommended to use water for irrigation (deionised water). It is not recommended to use saline

General Cautions

- Carefully read this manual before initial operation or if an untrained user. If in any doubt contact Altomed or authorised distributor.
- The Q-Rinse must only be connected to a grounded electrical outlet.
- Use of the Q-Rinse does not absolve the user from following your facility's policies and procedures for cleaning or decontamination of ophthalmic surgical instruments. All items rinsed with the 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 and Electromagnetic compatibility (EMC) testing to EN 60601-1-2: 2015

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

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. This will also invalidate the warranty.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30 cm (12 inches) to any part of the Q-Rinse, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

IMPORTANT!
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Power Adaptor
The power adaptor is only intended for use with the Q-Rinse and is for indoor use only. Keep dry. It is not protected against ingress of water. Protect from excessive force or shock. Do not pull out plug with excessive force. No user serviceable parts inside. Use only rated input range as indicated on the bottom of the equipment. Locate near an accessible, properly grounded outlet.

Description of Symbols Used

Name and address of manufacturer.

Altomed catalogue number used for device identification.

Device lot number (batch code) 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.

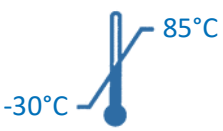
This is a Medical Device.

Fragile handle with care.

Keep dry (shipping).

This way up.

Non-sterile



Temperature limit

3. Description

The used ophthalmic device should be rinsed **immediately after use** to prevent debris drying inside the lumen, preferably within 30 minutes. Carry out initial cleaning on the outer body by following the Handpiece manufacturer's instructions for use.

The Q-Rinse provides a consistent method for rinsing residual fluids and debris from ophthalmic surgical devices. A pressurised stream of air follows the rinse cycle to make sure that the majority of water is cleared from the inner channels.

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, then follow manufacturers instruction prior to processing

3.1 Features

Some of the features of the Q-Rinse 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 (e.g. narrow lumen devices)
- Positive pressure delivery
- 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

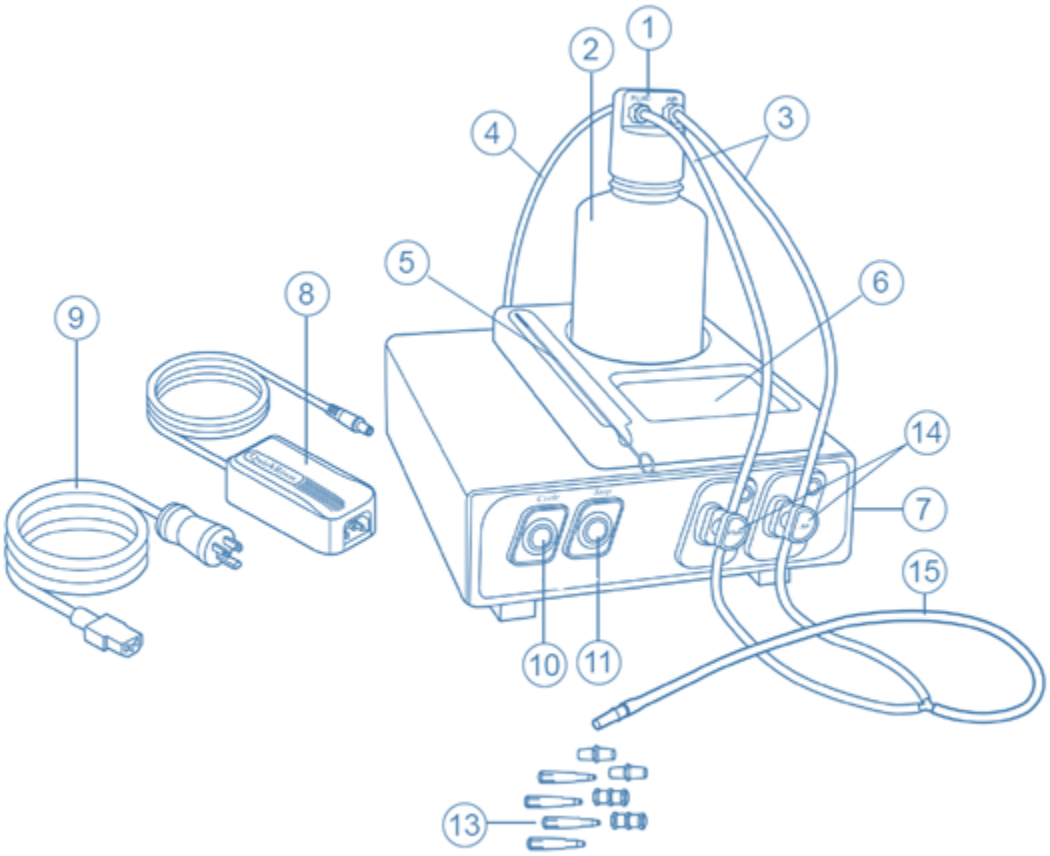
3.2 Function Modes

- Automatic Mode: Fluid followed by air
- Manual Override
    - Fluid Only
    - Air Only

3.3 Key Components

Q-Rinse: Key Components

Figure 1



The Q-Rinse

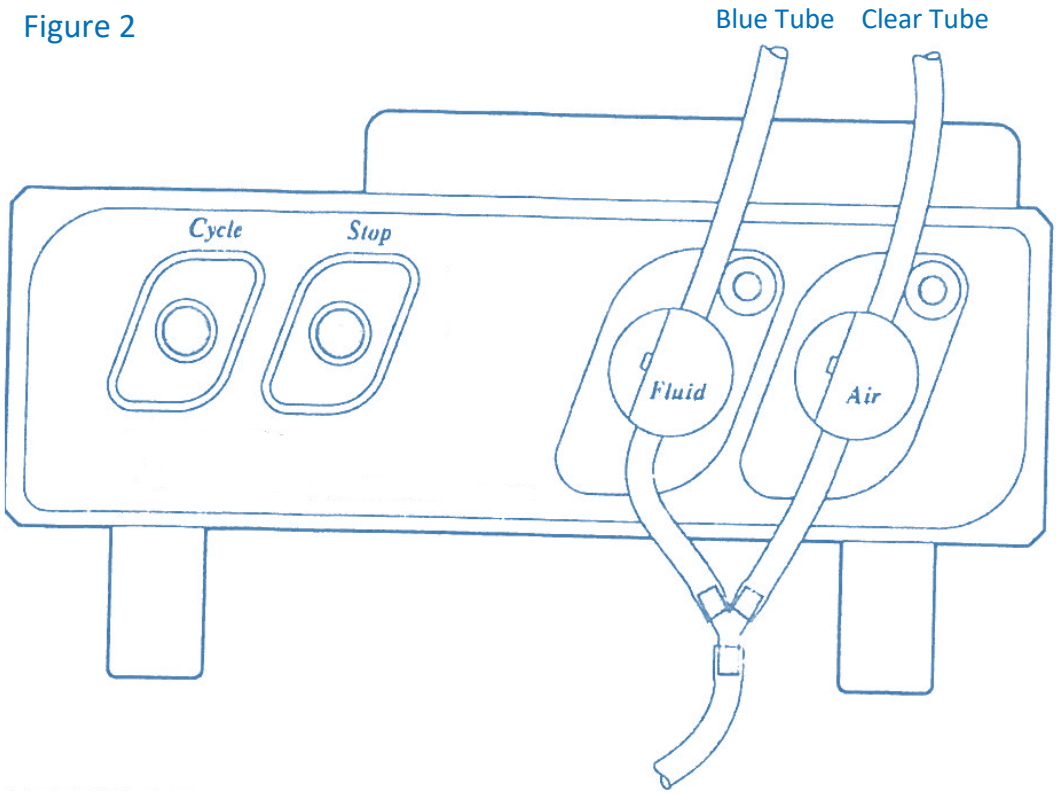
Key

1. Bottle cap (With fittings)
2. 1000ml bottle for fluid
3. Air/fluid tubing
4. Air supply tubing
5. Wire Brush
6. Storage tray
7. Front bezel
8. Power Supply
9. Power Lead
10. Green cycle switch (on)
13. Accessory pack
14. Pinch (air and fluid) valves
15. Instrument interface tubing

11. Blue stop switch

3.4 Front Control Panel

Figure 2



Front Control Panel

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:

Cycle Button:

Automatic Cycle

Pushing the Cycle button 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 unit 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 cycle if needed.

Stop Button:

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

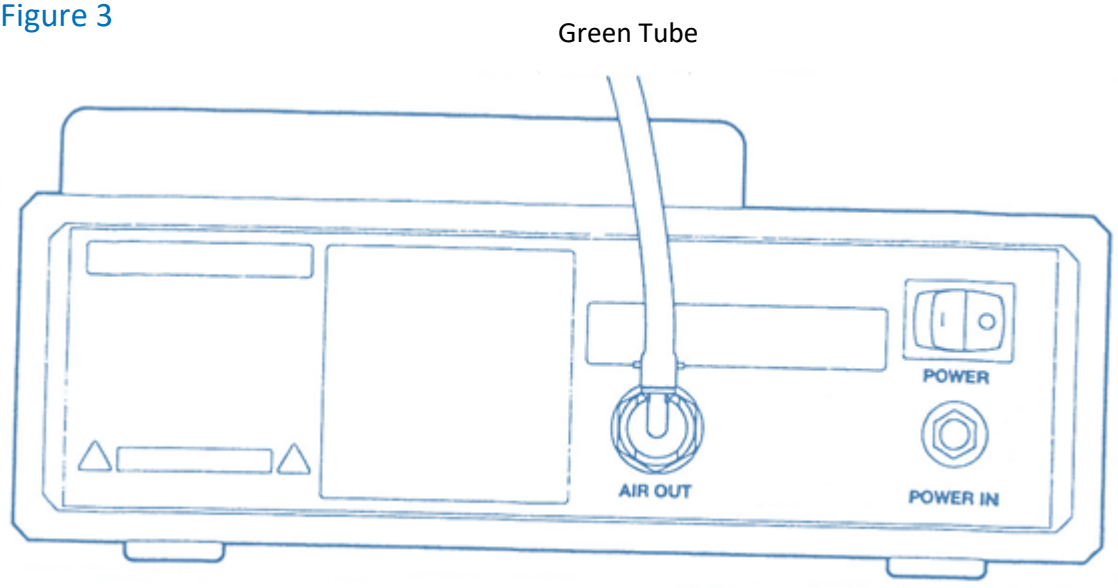
Fluid Valve/ Air Valve:

These valves open and close in response to the Q-Rinse's timing circuits. The blue tubing segment between the bottle and the "Y" connection is to be placed in the Fluid Valve (see Figure 2). The clear tubing segment between the bottle and the "Y" connection is to be placed in the Air Valve (see Figure 2).

The amber light adjacent to the valve illuminates when the valve is open.

3.5 Back Panel

Figure 3



Back Panel

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

Power Switch:

The Power Switch turns the unit on or off. The symbol “▌” being On and “ **O** ” being Off.

Air Out:

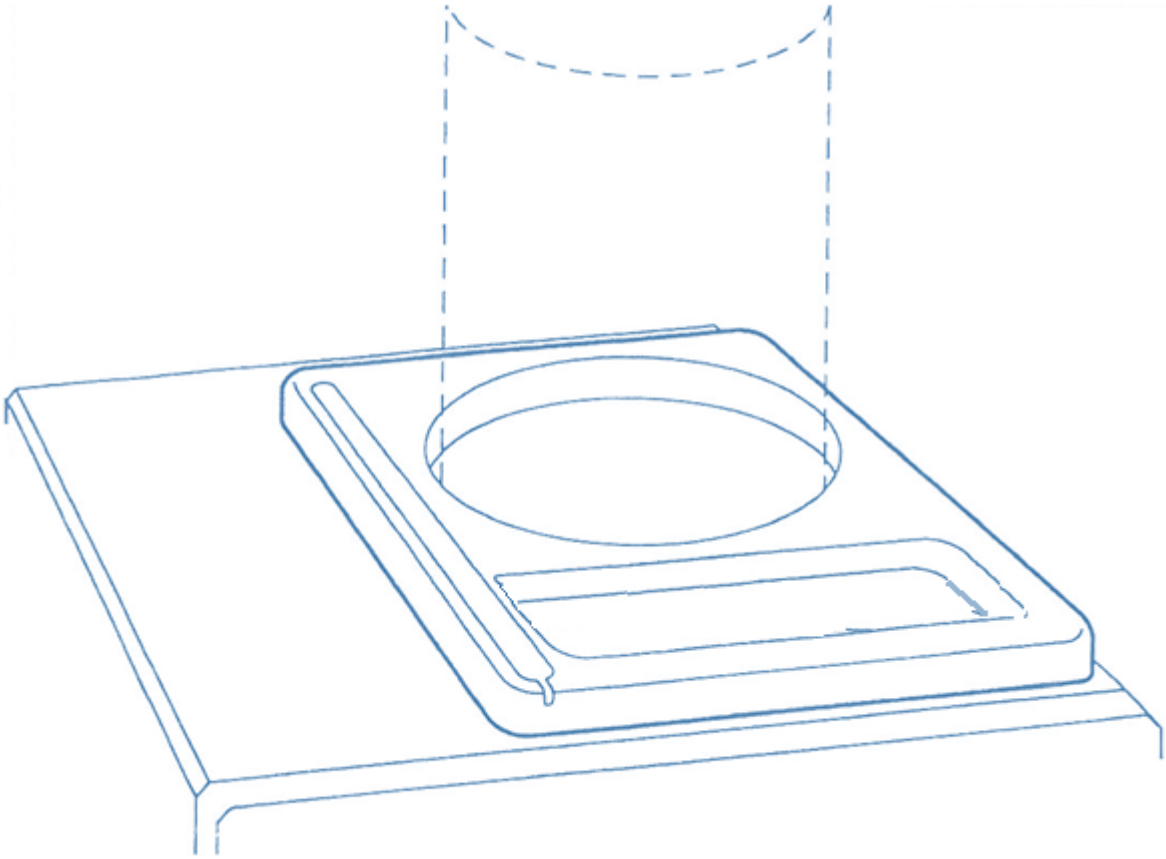
The Air Out connection delivers approximately 30 psi to the bottle. The spring lock mechanism prevents accidental disconnection of the rear air supply line.

Power In:

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

3.6 Top Panel

Figure 4



Top Panel

Top Panel

The top panel features storage compartments for the wire brush and various luer connectors used to connect the Q-Rinse 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 Q-Rinse.

If in any doubt, contact Altomed on:

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

The Q-Rinse is designed to interface with a variety of ophthalmic surgical devices by using standard luer adaptors. A storage compartment is provided on the top of the unit to store these adaptors. A smaller diameter cleaning brush is included to assist in clearing blockages in 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 Q-Rinse 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.

4.1 First Use

- Unpack the Q-Rinse, place all parts on a clean flat surface and check to make sure all items as in Figure 1 (page 9 above) are present and correct.
- Check to make sure there has been no shipping damage. Contact 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 storage compartment.

4.2 Table 1: Pre-Use Checks

* See page 9 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.
	14	Ensure the luer connector is present and secure in the end of the interface tubing. If it is missing replace it.
Bottle Cap	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.
	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.
Bottle Cap Complete	1, 2 and 3	Ensure the male and female connectors are fastened together and secure. If unable to secure replace bottle cap.
Bottle	4	Ensure there is no physical damage to the bottle, the threads are not damaged and that the structure is not deformed. Dispose of any failed bottles and replace.
	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. Ensure no contact with water or other fluids. 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	N/A	Check for any physical damage to the casing e.g. cracks, chips or other physical damage to the valves, 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	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.
	N/A	Run an automatic cycle to ensure fluid and air flow are correct and that the switch over between fluid and air takes place. Do not use if the cycle fails, return for inspection.

	N/A	Fill bottle. Using a calibrated measuring device, ensure the water output is >140ml for every cycle until the bottle is empty. Check air cycles last 15 seconds. Do not use if the tests fail, return for inspection.

4.3 Set Up

* See page 9 for “Item” references

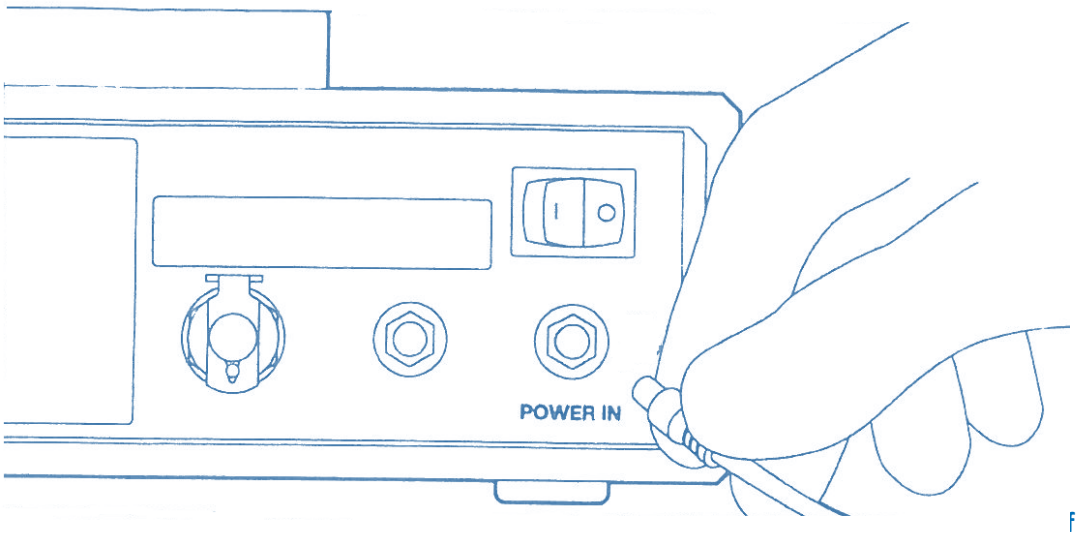
STEP 1

See Caution #1 and complete all pre-use checks as advised in Table 1 (page 13 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 A11074 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 A11074 Altomed Power Supply *(Item 10)* into the back of the Q-Rinse (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.

Figure 5a



STEP 2

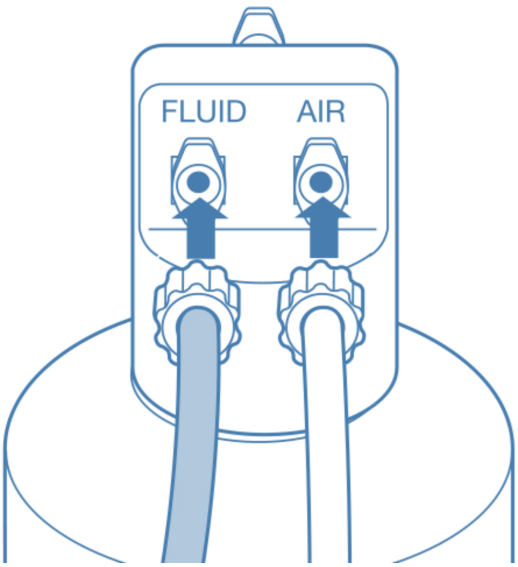
Fill the bottle *(Item 4)* with sterile water for irrigation (or similar) leaving one inch of space from the top for optimum operation. DO NOT OVER FILL. Screw the metal cap *(Item 1)* onto the bottle *(Item 4).* **The bottle cap must be securely screwed onto the bottle BEFORE it is put into the well! Only use the bottle supplied with the Q-Rinse which is specifically designed to withstand the pressures associated with the machine. Use of third party bottles may result in reduced performance and invalidate the warranty.**

Place the bottle *(Item 4)* into the well located on the top of the machine. Position the Poly bottle so that the two fittings on the Bottle Cap face the front of the console.

Connect the luer fitting on the clear tube of the Air/Fluid Tubing to the connection on the Bottle Cap labeled AIR with a twisting motion until snug. Connect the luer fitting on the blue tube of the Air/Fluid Tubing to the connection on the Bottle Cap labeled FLUID with a twisting motion until snug. (Refer to Figure 5b)

Figure 5b

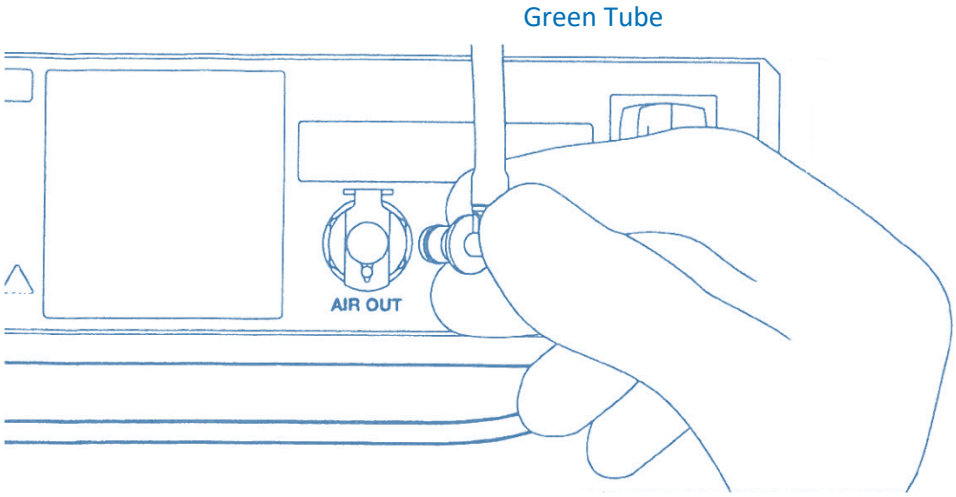
Connecting Air/Fluid Tubing



STEP 3

At the back of the unit, insert the white elbow connector on the green supply tubing *(Item 6)* into place (Figure 5c). The elbow connector will "click" when secure. The green supply tubing *(Item 6)* MUST be in place before operating the Q-Rinse otherwise the pressure will not build in the bottle.

Figure 5c



Air Supply Connection

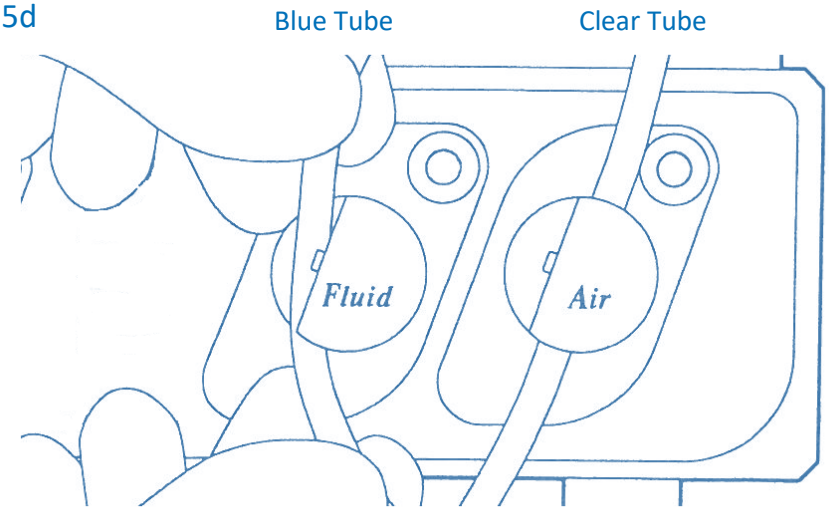
STEP 4

* See page 9 for "Item" references

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 5d below). The BLUE tubing line MUST run through the *Fluid* valve. The CLEAR line MUST run through the *Air* valve.

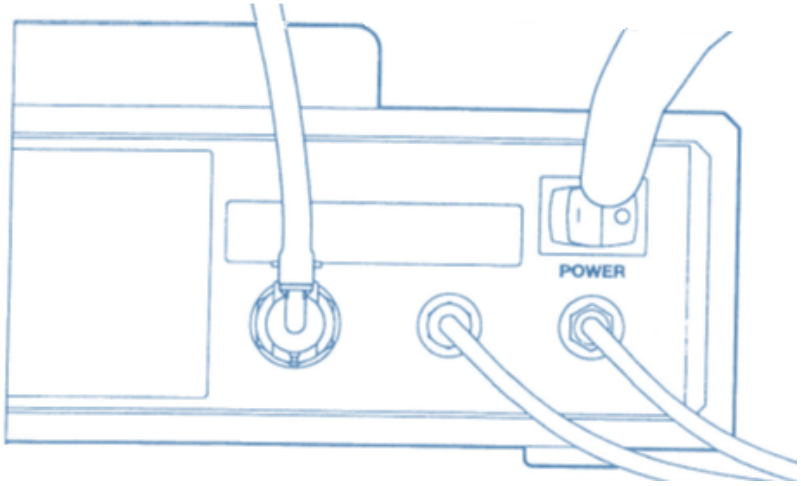
Figure 5d



STEP 5

Turn on the Q-Rinse by pressing the power switch on the rear panel (Figure 5e). The symbol " ▌" being On and " **O** " being Off.

Figure 5e



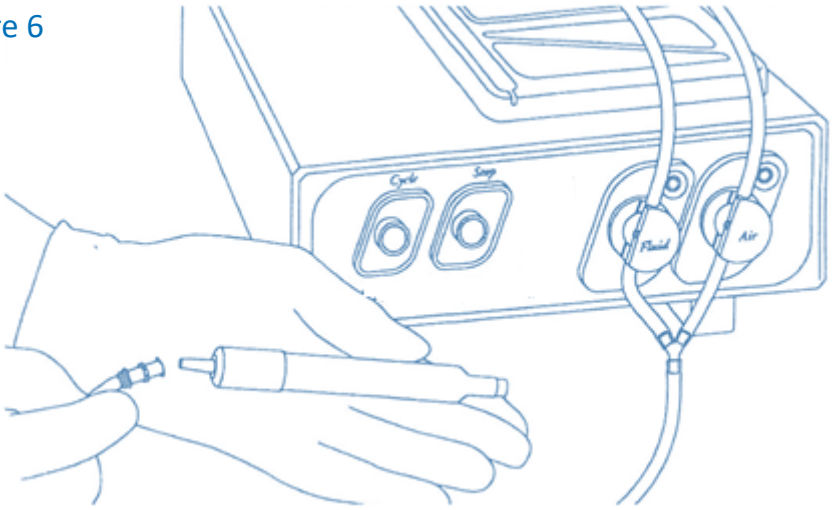
Switch on the machine

4.4 Operation: Automated Cycle.

STEP 1

See Caution #1 and complete all pre-use checks as advised in Table 1 (see page 15 above). Connect the instrument interface tube *(Item 17)* to the item to be rinsed (Figure 6), use the adaptor pack *(Item 15)* if necessary.

Figure 6



Device Connection

STEP 2

Press the Cycle button *(Item 12)* once to begin the automated rinse cycle. The amber light next to the fluid valve will illuminate indicating the valve is open. After 15 seconds the fluid valve will close and the air valve will open. The amber light next to the air valve will now illuminate. 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 27 below) for Troubleshooting if necessary.

STEP 3

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

STEP 4

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

4.5 Operation: Manual Cycle.

* See page 9 for “Item” references

STEP 1

See Caution #1 and complete all pre-use checks as advised in Table 1 (see page 15 above). Connect the instrument interface tube *(Item 17)* to the item to be rinsed (Figure 6), using the adaptor pack *(Item 15)* where necessary.

STEP 2

To initiate manual mode, first press the Cycle button *(Item 12).* 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 Q-Rinse 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.

4.6 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 performed 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 optimum 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.

4.7 Operation: Disinfection and Sterilization

Table 1.1 Processing Summary – See also Steps 1 and 2 below

Manufacturer: Altomed Limited **Device(s): Altomed Q-Rinse and Bottle Assembly**	
WARNINGS	Do not sterilize bottle in a peel pouch. pH neutral detergent is recommended as strong alkalines may cause discolouration
Limitations on processing	It is recommended to replace the bottle assembly after 50 autoclave cycles or if it fails the inspection procedure. It is recommended to replace the Q-Rinse after 10 years.

Initial treatment at the point of use	**Disconnect bottle assembly from machine and dismantle as described in Step 1 below.**
Preparation before cleaning	Mix up a solution of a hospital approved disinfectant (e.g.Virusolve) and pour into a disinfectant bath big enough to hold the 1000ml bottle and cap assembly.
Cleaning: Automated	Bottle Assembly: It is recommended to manually clean the bottle assembly as described below before automated processing due to the narrow lumen of the tubing and connectors. This ensures total exposure of the detergent to the inside of the bottle. The device can go through a washer / disinfector cycle however care should be taken to ensure the gasket does not become separated or damaged. Q-Rinse should not be put in an automated washer and should not be exposed to any liquids unless controlled as specified in the Manual Cleaning section below.
Cleaning: Manual	See Step 1 below for full procedure. Bottle: Submerge the bottle in a detergent bath and ensure there are no air bubbles left in. Ensure the inside surface of the bottle is fully exposed to the detergent for the length of

	time specified in the detergent IFUs e.g. 5 minutes with Virusolve). Rinse in water to remove residues. Bottle cap and tubing: Disconnect all tubing from cap. Using a syringe withdraw detergent inside the lumen of the blue and clear tubing including Y connector, then place in detergent bath along with green tube for the time specified in the detergent IFU e.g. 5 minutes with Virusolve). Q-Rinse: Ensure machine is fully disconnected from the mains and the power adaptor. Apply the CE marked hospital approved disinfectant (e.g. Tristel Duo OPH) to a suitable CE marked wipe (e.g. Tristel Duo Wipe) and apply to the surface of the machine. Wipe off any excess after the recommended time on the detergent IFU (e.g. 30 seconds for Tristel Duo OPH).
Disinfection	The cleaning procedures above will provide adequate disinfection of the bottle and cap assembly.
Drying	Dry the bottle assembly with a suitable dry clean cloth.
Maintenance, inspection and testing.	See Table 1 on page 15 for applicable maintenance and inspection requirements. There are no serviceable parts in the Q-Rinse.
Packaging	The bottle should be put directly into the autoclave. The bottle may deform if placed in a peel pouch. The cap assembly may be put into a hospital approved CE marked peel pouch.
Sterilization	Follow Step 2 below to dismantle the cap assembly. As the bottle assembly is a non-contact device, disinfection is deemed sufficient to decontaminate it. The bottle assembly can withstand exposure to a standard autoclave cycles of 134-137°C for a minimum holding time of 3 to 3½ minutes.
Storage	Store the bottle assembly in a dry location out of direct sunlight. Empty any water inside the bottle if it is being left for prolonged periods of time, e.g. >24 hours. Store the machine in a dry location.
Additional information	Specified throughout the rest of this manual.
End of life	Decontaminate the bottle and cap assembly and dispose of following hospital procedures. Metal cap can be recycled. Contact Altomed for collection of the machine and power adaptors under WEEE regulations for recycling.
Manufacturer contact	Please contact Altomed using the details on page 36.

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 Q-Rinse.

c) Carefully remove the air/fluid tubing from the pinch valves.

d) Remove the elbow connector on the green 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. 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 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 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 draw 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 Virusolve).

l) Wipe exterior of console to remove any visible soil/fluids using a soft cloth moistened with the disinfectant of choice, e.g. Tristel Duo Wipe and OPH solution.

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 clean cloth. Reassemble the bottle assembly.

n) Carry out all the necessary pre-use checks as described in Table 1 (see page 15 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 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) Disconnect the air/fluid tubes from the bottle cap

f) Place the bottle cap, the separate tubes, 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. Do not autoclave the Air Supply tubing (green).

g) 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 slight 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.

Note:

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is actually performed using the equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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 (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 inspection.
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 (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 inspection.
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 inspection.
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
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 inspection.
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 inspection
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 issues 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 correct 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 issue still cannot be resolved, contact Altomed for assistance on +44 (0) 191 519 0111 or your approved distributor.

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

7. Warranty

Q-Rinse

Automated Instrument Rinsing

Warranty and disclaimers

The Q-Rinse when delivered will conform to the manufacturer's current version of the published specifications. The Q-Rinse 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 (UK customers only).

The exclusive remedy for any breach of this warranty shall be, at Altomed's sole discretion. The repair and replacement of the non-conforming Q-Rinse 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 Q-Rinse.

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

Any Q-Rinse 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 Q-Rinse or its components. Failure to maintain the Q-Rinse 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 EXPLANARY 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 Q-Rinse. 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

Table 3: Specifications

IEC 60601 classification	**Electric shock protection** **Protection against harmful ingress of water and particulate matter** **Applied parts** **Oxygen rich environment** **Mode of operation**	**Class I, powered with dedicate PSU (Ref A11074)** **IPx0** **No applied parts** **Not suitable for use in such environment** **Continuous**	
Dimensions	Height Length Width	4.5 inches 8.8 inches 8.8 inches	11cm 22cm 22cm
Weight	Unpacked	4.0lbs	2Kg
Environmental limitations	Altitude Temperature Relative Humidity	10,000 feet 32° - 104°F 15% - 95%	3050 meters 0^{o} - 40^{o}C
Permissible environmental conditions for transport and storage	Temperature Relative Humidity	-30 to +85°C 5% to 95%, non-condensing	
Electrical input requirements	100-240VAC	@47 – 63 HZ	

Power supply REF: A11074	SL Power and AULT MENB1020A1203F01	12 Volt DC 1.5A	
Pump type	Diaphragm		
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.
Pressure output	Fluid 6-15 in^3/min. auto cycle Air 10-30 psi	100-250 cc/min	
Bottle description	32 fl.oz. Fully Autoclavable	1000ml	
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 and Manual		

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.

Table 4. Part numbers and descriptions

Part REF	Description – Machine and Bottle
A11070	Q-Rinse complete
A11070W	Extended 24-month warranty to give 36 months in total (UK only)
A11072	Q-Rinse bottle assembly - Complete
Part REF	**Description – Other Accessories**
A11049	Q-Rinse luer adaptors - Converts male to female, pack of 10
A11049A	Q-Rinse luer adaptors - Converts female to male, pack of 10
A11049B	Q-Rinse luer adaptors – Converts male to male luer lock, pack of 10
A11076	Q-Rinse nylon and wire brush single use
A11078	Q-Rinse assorted adaptors - Pack of 10
Part REF	**Spare Parts**
A11074	Q-Rinse power adaptor and lead
A11044A	Q-Rinse bottle only - No cap or tubing
A11044B	Q-Rinse bottle cap only - No tubing or bottle
A11044C	Bottle cap gaskets pack of 4
A11044D	Q-Rinse bottle cap complete - Includes tubing, no bottle
A11044E	Q-Rinse tubing set - All air/fluid and air input tubing
A11044F	Bottle cap connector black “O” rings pack of 8
A11042	Q-Rinse spare interface tubing pack of 4
A11047C	Q-Rinse air input tube elbow connector

10. Special Instructions / Notes regarding the 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, installed and commissioned 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 5. EN 60601-1-2:2015 Electromagnetic emissions

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

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, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 6. 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
Surge IEC61000-4-5	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines ± 2 kV line(s) to earth for input / output lines	± 0.5, 1, 2 kV line(s) to earth, ± 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% U_T (100 % dip in U_T) For 0.5 cycle 0% U_T (100 % dip in U_T) For 1 cycle	0% U_T (100 % dip in U_T) For 0.5 cycle 0% U_T (100 % dip in U_T) For 1 cycle

	70 % U_T (30 % dip in U_T) for 25/30 cycles 0% U_T (100 % dip in U_T) For 250/300 cycles	70 % U_T (30 % dip in U_T) for 25/30 cycles 0% U_T (100 % dip in U_T) 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 at Altomed has several decades of industry expertise with highly skilled technicians and customer service.

All servicing and repairs are performed at Altomed Limited or at the authorised distributor.

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

If you have any questions that require any Technical Support, please call 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 5:00PM
Friday
9:00AM to 4:30PM

Date: 21/11/2024

Q-Rinse

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