Operator´s Manual
CS629 Bench Top Sealer

Qseal® • multi

CONROY
Medical

Every effort has been made to ensure that the information in this document is correct, but we make no guarantee to this effect and would appreciate any observations regarding the contents of this document. We may make improvements and alterations to the instrument and these changes will be incorporated in new issues of this publication when practicable.

Layout and design: Fantasiskafferiet, Sollentuna
Print: Uffe Tryckare, Upplands Väsby, 2024
Version 4.0 November 2024

Warnings and Cautions

The general safety information in the manual is for operating personnel. Specific notes, cautions and warnings are found throughout the manual where applicable. Please read the Operator's manual carefully before use.

Note! Identifies conditions that should be noted carefully.
Caution! Identifies conditions that could result in damage to the equipment.
Warning! Identifies conditions that could result in personal injury or loss of life.

Warning! Qseal-multi must be used in compliance with all specifications and operational procedures listed in this manual.

Warning! When in use, Qseal-multi must be used under the control of trained personnel.

Warning! Follow the operating instructions while operating Qseal-multi.

Warning! Cables and accessories, others than those specified, may result in increased emission or decreased immunity of the equipment or system. Only accessories designed for use with Qseal-multi should be used.

Warning! The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Warning! The device emits RF energy during the seal procedure and movement of electrode.

Warning! Disconnect the device from power source before performing any maintenance and cleaning procedure.

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

Warning! If any of the components of Qseal-multi are exposed to blood, they must be cleaned with an appropriate disinfectant solution.

Warning! The instrument must always be connected to a grounded outlet and with appropriate alternating current mains source, 100 or 240 V ~.

Warning! Do not modify this equipment without authorization of Conroy Medical or Conroy Medical authorized representative.

Warning! Qseal-multi is not intended for use in an oxygen rich environment.

Warning! Qseal-multi is not intended to be used with flammable anaesthetics and not intended for use in conjunction with flammable agents.

Caution! ELECTROMAGNETIC INTERFERENCE REGULATIONS
This equipment fulfils EN 60601-1-2:2015 Standards (Electromagnetic Compatibility). Nevertheless this equipment uses radio-frequency (RF) energy to generate heat while the tube is being sealed and can affect other Medical Electrical Equipment. If installation and use is not performed in accordance with this operator manual, it could cause interference with radio, television and instrument communications.

1. Scope

This chapter contains a description and specifications of the Qseal-multi, a Bench top sealer from Conroy Medical AB.

1.1 Introduction

The intended clinical benefit of Qseal-multi is safe sealing of tubes and bags. Intact seals minimize the risk for contamination and discards of blood component and provide safety for the user and patient.

Qseal-multi is a fully automatic system for sealing PVC and EVA tubes, especially for tubes in blood pack systems. Following the sealing procedure the tube is easily pulled apart, due to the distinct sealing pattern, with no damage to the blood inside the tubes. Segments are formed by advancing the tubing through the slot of the Sealing head to create a series of seals. Up to 8 units can be linked together for simultaneous sealing of segments.

Qseal-multi is complete with inbuilt sealing head and is ready to operate. The electrode cover can be easily removed for cleaning. Different types or sizes of tubes can be used and the necessary sealing time is self-adjustable to suit the tubes that are being used.

Qseal-multi works with radio frequency (RF) energy to generate heat for sealing. Users are requested to be cautious of potential electrical shocks or hazards while handling this sealer. Always turn the power switch off before disconnecting cables or cleaning.

1.2 Performance and Specifications

The table below lists the physical specifications.

Parameter	Value/ Description
REF CS629:	Qseal-multi, a complete sealing system, which includes built-in Sealing head, Power cord, Rail and Operator's manual.
Type of PVC tube:	Different types and sizes of tubes up to 6.2 mm outer diameter can be sealed due to a sophisticated sensing system, which automatically adapts sealing time.
Sealing capacity:	Max. 1000 seals/hour with PVC tubes up to 5 mm outer diameter (wall thickness 0,56 mm) at 20°C (68°F). For information concerning EVA tubes, contact your local Conroy Medical representative.
Sealing time:	0.6 up to 3 sec. depending on tubing.
Intended purpose:	Intended for sealing tubes and bags in blood component sets. Qseal-multi is intended to be used by trained medical pro-fessionals.
Input Power:	100 / 240 V ~ - 50-60 Hz
Consumption:	250 W
Power cord:	Three wire (10 A), 2.5 meter long cable with female plug, (IEC320).
RF Output:	80 W max. / 50 Ω / 40.680 MHz

Size (W x H x D) Weight kg (lb):	70 x 140 x 275 mm (2.8 x 5.5 x 10.3 in) 1.3 kg (2.95)
Temperature:	Operating: 0 - 35°C (32 - 95°F) Storage: - 20 - 70°C (- 4 - 158°F)
Humidity:	Operating: 10 - 90% Rh (non-condensing) Storage: 10 - 90% Rh (non-condensing)
Altitude:	Operating: maximum 3000 meters (9842 feet)
In compliance with:	- EN 60601-1: 2006, General Requirements for basic safety and essential performance. - EN 60601-1-2: 2014, Collateral standards for Electromagnetic Compatibility.
Electrical safety:	Class I The Qseal-multi is used in the same environment as medical equipment (hospitals and blood banks). It must be used by highly qualified personnel.
Manufacturer according to MDR:	Conroy Medical AB Haesthagsvaegen 14A SE-194 52 Upplands Vaesby SWEDEN

Table 1:

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The CS629 Qseal-multi Bench Top Sealer is intended for use in the electromagnetic environment specified below. The customer or the user of the CS629 Qseal-multi should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11	Group2	The CS629 Qseal-multi must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emission CISPR 11	Class B	The CS629 Qseal-multi is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table 2:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS629 Qseal-multi is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-multi should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	6kV 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	2kV Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	1kV 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% Uτ (> 95% dip in Uτ) for 0.5 cycle 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles < 5% Uτ (> 95% dip in Uτ) for 5 sec	< 5% Uτ (> 95% dip in Uτ) for 0.5 cycle 40% Uτ (60% dip in Uτ) for 5 cycles 70% Uτ (30% dip in Uτ) for 25 cycles < 5% Uτ (> 95% dip in Uτ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS629 Qseal-multi requires continued operation during power mains interruption, it is recommended that the CS629 Qseal-multi be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Uτ is the a.c. mains voltage prior to application of the test level.			

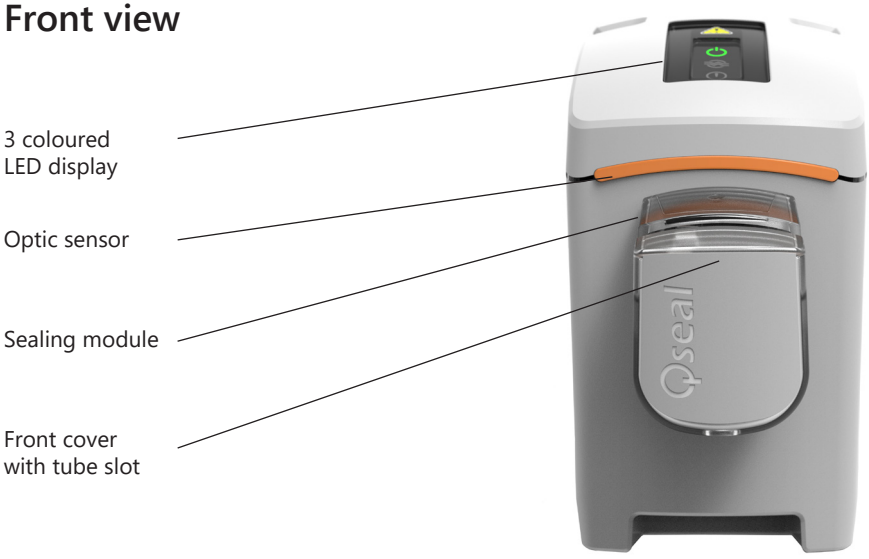
Table 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS629 Qseal-multi is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-multi should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the CS629 Qseal-multi including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CS629 Qseal-multi is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CS629 Qseal-multi. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

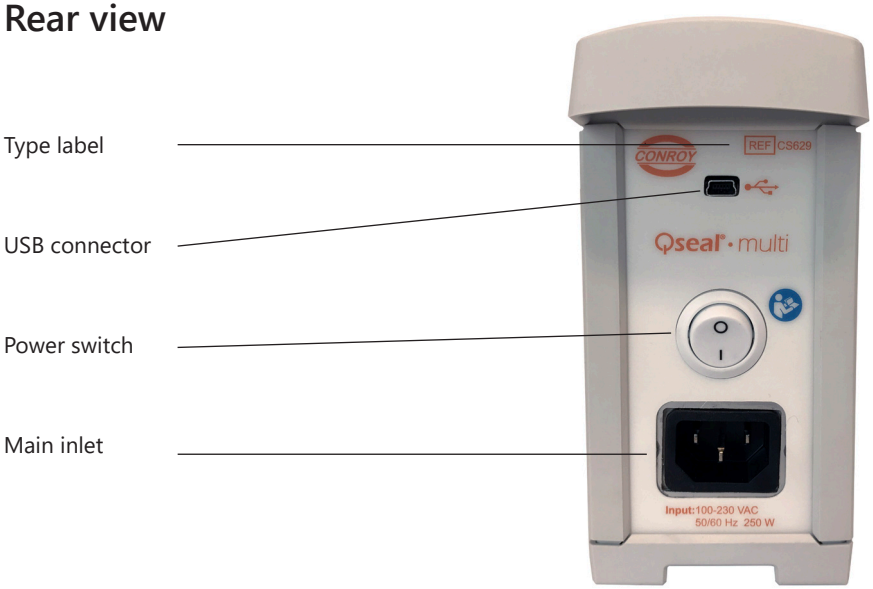
Table 6:

Recommended separation distance between portable and mobile RF communications equipment and the CS629 Qseal-multi			
The CS629 Qseal-multi is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS629 Qseal-multi can help prevent electro-magnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS629 Qseal-multi as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer **NOTE 1** At 80MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Front view



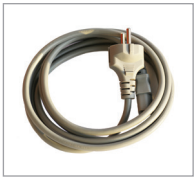
Rear view



1.3 Qseal-multi parts and spare parts

1.3.1 Qseal-multi, REF CS629

Qseal-multi comprises the parts listed below:



Description	Sealing unit	Power cord, 2.5 m
Part No.	64900000	82098100

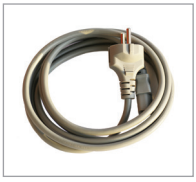
Power cord available for the following countries, order separately:

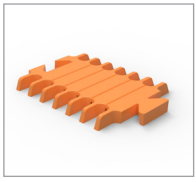
Description	USA/Japan	UK	Australia/NZ
REF	879011252	879011253	879011254

List of all cables and maximum lengths of cables, transducers and other accessories with which the manufacturer claims compliance (cables, accessories used other than those listed may impact emission/immunity):

Part	Reference	Specification
Power cord	879011251	Three-wire (10A), 2.5 m long, (female plug).

1.3.2 Qseal-multi spare parts (user interchangeable parts)





Description	Front cover	Power cord, 2.5 m	Rail (pack of 10)
REF	962921100	979011251	962921200

1.4 Symbols/Markings Description

On instrument and labels:

This marking reflects compliance with the Council Directive 93/42/EEC on Medical Devices.

Symbol for “CATALOGUE NUMBER”.

Symbol for “CONSULT USER MANUAL”.

Symbol for “WARNING”.

Symbol for “CONSULT OPERATOR MANUAL”.

Symbol for “SERIAL NUMBER”.

Symbol for “DATE OF MANUFACTURE”.

Symbol for “MANUFACTURER”.

Symbol for “TEMPERATURE LIMIT”.

Symbol for “RELATIVE HUMIDITY LIMITATIONS”.

Symbol for “ATMOSPHERIC PRESSURE LIMITATIONS”.

Symbol for “KEEP DRY”.

Symbol for “HANDLE WITH CARE / FRAGILE”.

Symbol for “NON-IONIZING RADIATION”.

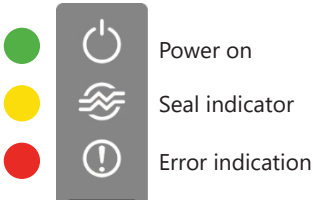
Symbol (WEEE 2002/96/EC) - Do not dispose Product as municipal waste. Collect Product separately. Use collection and return systems available to you. Product brought to EU market after August 13th, 2005.

MD

Symbol for “MEDICAL DEVICE”.

LED indications

Sealing module



Power on

Seal indicator

Error indication

2. Installation

This chapter involves unpacking, temperature requirements and installation of the instrument.

2.1 Unpacking and Inspection

1. Visually inspect the cardboard box for damage. Report any damage immediately.
2. Lift the instrument out of the cardboard box and place it on a flat surface.

   The instrument is shipped in one cardboard box that includes:
   1 Sealing unit
   1 Power cord
   1 Rail
   1 Operator's manual

3. The above list is subject to change, refer to the packing list for accurate description of contents.
   If any parts are missing or if the parts are damaged, report it immediately.
4. Please keep all shipping and packaging materials, as they may be required for later transportation, at least during the warranty time.

2.2 Environmental Requirements

To keep the instrument operating at its best, please observe the following:
• The instrument should be placed on a flat surface free from dust, solvents and acidic vapor.
• Use the instrument in an area free from vibration and with a room temperature of 0 - 35°C (32 - 95°F), and relative humidity 10 - 90% non-condensing.
• Handle the components with care in a clean environment.

2.3 Installation Procedure

2.3.1 Stand alone

Preparing the sealer for use

1. Connect the power cord to the receptacle at the rear of the Sealing unit.
2. Plug the power cord into a grounded outlet.
3. Perform a test seal on an empty or water filled tube to ensure proper operation.

2.3.2 Multi set-up

1. Ensure rails positioning and number of units dependent on the number of segments required. See picture.
2. Fix the segment length by positioning the Qseal-multi devices in the correct rail slot. Minimum segment length is 7 cm (2.75”).
3. The master can be placed on the left-hand side or right-hand side.
4. Connect the Qseal-multi master to the power supply by connecting the AC power cord to the AC power inlet and then to an earthed AC socket.
5. Connect the following Qseal-multi devices also to earthed socket. Make sure the power switch is in the ‘I’ position on all devices.
6. When the status LED is green on all devices, the devices are ready to make segments. (Connection between Qseal-multi devices is automatic through bluetooth connection).
7. Place the tubing in the tube slot and slide the tubing downwards into the slots. Be careful not to stretch the tubing or to put any stress on it.
8. Each sealing head will separately detect its piece of tubing and multi sealing will only be activated when all the individual tube sections are detected. If tubing is not correctly detected in one or more of the sealing heads, the error LED will be illuminated on the actual device and on the master. In this case, remove the tubing out of all the heads and start the procedure again.
9. All the Qseal-multi devices will seal one by one.
10. During the sealing process the LED will turn yellow on each device. When the process is finished, they will turn green again.
11. Remove the tubing when all the LED have turned green.

2.3.3 Programming for Single or Multi Use

All units should be turned off and front covers removed.

2.3.3.1 Programming for Multi Use

Programming Master: Cover the optic sensor and turn on the unit. Wait until the red error LED stops blinking and the unit goes to Master mode by lighting 1 yellow and 1 green LED.

Programming Slave: Cover the optic sensor and turn on one slave unit at the time. Wait until the red error LED stops blinking and the unit goes to Slave mode by lighting 2 yellow and 1 green LED.

For every Slave that is programmed, the Master should blink with the middle yellow LED the same number of times as number of Slaves.

When all units are ready, attach the front covers on all units, including the Master. Restart all units. The system is now ready to use.

2.3.3.2 Programming for Single Use

Make sure that the unit is not in reach for another turned on Qseal-multi.

Cover the optic sensor and turn on the unit. Wait until the red error LED stops blinking and goes to Master mode by lighting 1 yellow and 1 green LED. Attach the front cover and restart the unit. The unit is now ready to use.

3. Functional Description

This chapter describes how Qseal-multi works, where the connectors and the indications are placed on the unit and their functions.

3.1 Description of Sealing

The indication for use of Qseal-multi is a need for seal and separation of tubing or bags in blood component sets during blood and plasma donation or other blood component preparation. The target population is determined by the intention of the blood components as determined by the trained medical professionals operating the device. The use of Qseal-multi does not limit the initial target population or intended use of the blood components.

The tube to be sealed is placed in the slot of the Front Cover, in between the electrodes. When the sensor detects the tube, the sealing procedure will commence automatically. The radio frequency (RF) generator starts and the energy is transferred from the fixed electrode to the tube, which melts to a welding pattern.

During the whole sealing process the yellow Seal light on the display of the Sealing unit is lit. When the light goes out, the seal indicator is complete, the electrode will open and the tube may be released. The Sealing unit detects, controls, and adjusts the necessary sealing activity to give the best sealing quality for the type of tubes that are being used.

4. Operating Instructions

This chapter describes the use of the instrument.

Warning! Qseal-multi uses radio frequency (RF) energy to generate heat for sealing. Users should be cautious of potential electrical shocks or hazards while handling this sealer. Always keep your fingers away from the electrodes in the slot. Never place any object other than the PVC tube between the electrodes.

Warning! This instrument emits a low level of electromagnetic (non-ionizing) radiation while sealing. It should not be used near high frequency sensitive electronic equipment. *See table 1 for guidance.*

Caution! Inspect all parts of the instrument for defects before use.

4.1 Preparation before Use

1. Place the instrument on a flat surface near the working place. Ensure that it is placed so the front of the unit is visible during seal procedure. Ensure also that the power inlet of the unit is accessible so that the unit can be easily disconnected from the mains supply.
2. Connect the power cord according to chapter 2.3 "Installation procedure".
3. Check that the ⏻ Power on LED lights up green when the power switch is turned on.

4.2 How to Seal Tubes

Note! The tube must be dry on the outside.

1. Put the tube to be sealed in the slot ❶ of the Front cover.

2. The tube activates the sealing process. The sealing electrodes press the tube together and the "Seal Indicator" on the Sealing unit lights up. The sealing time is normally 0.5 to 3 seconds. Avoid stretching the tube during the sealing process.

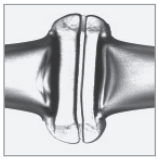
Note! Keep the tube in position until the light goes out.

3. When the light goes out, the sealing is finished and the electrodes move back to release the tube.
4. Lift up the sealed tube and check the pattern below.
5. The center of the sealed pattern is very thin and pulling both sides will divide the tube into two pieces.

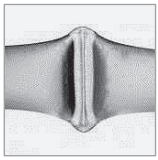
Caution! If you should make two or more seals, they should not be within 1 cm (½") of each other, otherwise the resulting pressure in the tube may cause microscopic cracks and holes in the seals.

Caution! In case of sealer malfunction (intermittent operation, poor seal quality, the sealing time seems too long or too short) contact your local C.M. representative for assistance.

Caution! Periodically check the pattern of the sealing visually (see picture below).



Good sealing pattern



Bad sealing pattern

4.3 If the Sealer Doesn´t Start

The Sealer has several safety functions. Before sealing, these functions control and identify whether it is possible to seal the tube. The table below covers the common probable causes for problems and suggests some recommended actions.

Probable cause	Recommended action
Wet tube	Dry the tube and try again
Tiny arcs between the electrodes	Dry the electrodes and try again
No seals	Check Sealing unit and that the Front Cover is in place

If the sealer still doesn't start, see chapter 6 for further information.

5. Cleaning

This chapter gives information on the cleaning (procedure, frequency) for the Sealing unit. The Sealer requires minimal maintenance for efficient operation. Follow the cleaning procedure below.

Warning! For you own safety always turn off the power switch and disconnect the Power Cord.

Warning! Blood and blood products must be treated as potentially infectious at all times. In the event of blood spillages, appropriate protective clothing should be worn during cleanup procedures.

After removing residual biological material, surfaces which have been in contact with blood or components must be disinfected using a chemical agent considered to be "sterilizing" (isopropanol 70%,....). Alternatively, a freshly prepared solution of diluted sodium hypochlorite (household bleach) may be used to disinfect surfaces which will not be harmed by the solution. Diluted solutions of 1 part bleach to 10 parts water may be used.

Regardless of the "sterilant" or disinfection solution used, remember to remove any residue to ensure that surfaces of the equipment are not subject to corrosion or discoloration. Discard all materials in contact with blood according to institutional policies regarding disposal of biohazardous materials.

Caution! Do not disinfect or sterilize any part of the Sealer through autoclave, or with ethylene oxide gas. To do so will render the Sealer unusable and invalidate the warranty.
Do not use chemical or abrasive cleaners such as acetone, ammonia or similar.
Do not use sharp edged tools for cleaning, which could damage the finish of the units.

Caution! Do not allow liquid to flow in the electronic part of the machine.

5.1 Sealing Unit

Cleaning may be required as a result of spilled drops of blood or when required after inspection.

If spillage occurs, the unit must immediately be removed from service and cleaned completely before resuming use.

Use a soft lint-free tissue, moistened with a mild detergent to clean the outside of the Sealing head and cover.

For cleaning the electrodes you should remove the front cover of the Sealing module by pressing the grip marks button on the cover.

For cleaning the Optic Sensor use the specified cleaning fluid and Q-tips or lint-free tissue.

Note! The Front Cover can be cleaned separately. Clean both electrodes with a soft lint-free tissue moistened with a mild detergent. Dry carefully and ensure that the electrodes are completely dry to prevent sparks.

Note! After cleaning, inspect the electrodes for damage. Attach the cover, ensuring that it snaps in position.

Note! Some sealing tests can be made before resuming use. Compare the pattern against picture in Section 4.2.

Caution! Do not dip the unit in liquid, as it is not waterproof. Intruding liquid will cause malfunction, tiny arcs and reduce the lifetime use.

6. Troubleshooting

Maintenance performed by the user is limited to changing main unit and power cord. The following information covers common problems and offers suggested solutions.

6.1 Main Unit

Problem	Probable cause	Recommended action
Power on indicator doesn't light up green.	No Voltage.	Check power supply. Check that main switch is on.
	Other cause.	Contact your local C.M. representative.
Power on indicator lights up green, but when the tube is inserted the Seal indicator doesn't light. LED flashes red.		Check that Front cover is correctly in place.
	Sealing unit defective.	Change unit.
	Other cause.	Contact your local C.M. representative.
	The Sealing unit is too hot.	Turn the power switch off and wait about 10 minutes, and then try again. If still flashing, contact your local C.M. representative.
LED doesn't light.	Sealing unit defective.	Contact your local C.M. representative.
The sealing doesn't start.	Wet electrodes.	Dry the electrodes, see Section 5.2
	Blocked optic sensor.	Contact your local C.M. representative.
	Other cause.	
Tube splits or breaks during sealing.	Stretch of tube during sealing.	Do not stretch tube. See Section 4.2
	Seals to close.	Min 1 cm (0.4") between seals. See Section 4.2.
	Moving electrode obstructed.	See Section 5.2
	Wrong adjustment of electrodes.	Contact your local C.M. representative.

7. Warranty and Service

Information on the warranty and the service provided by Conroy Medical is listed below:

7.1 Warranty

Conroy Medical guarantees that the equipment shall be free from defects in material and workmanship when delivered to the original purchaser. Conroy Medical´s sole obligation shall be limited to repair or replacement, at Conroy Medical´s option and expense, of the defective part or unit for a period of two (2) years following the date of initial delivery to original purchaser.

The warranty extends only to the original purchaser and is not assignable or transferable, and shall not apply to auxiliary equipment, or disposable accessories.

Conroy Medical guarantees that the equipment is fit for the purposes and indications described in the labelling when used in accordance with the directions for use. Unless the equipment is used in accordance with such instructions, this warranty is void and of no effect. No other expressed or implied warranty exists, including any warranty of merchantability or appropriateness for a particular purpose. Conroy Medical's sole obligation and original purchaser's exclusive remedy for breach of warranty shall be limited to repair or replacement at Conroy Medical´s option. Conroy Medical shall not be liable for proximate, incidental or consequential damages. Modifications, alterations, recalibrations or abuse, and service by other than a Conroy Medical authorized representative will void the warranty.

7.2 Service

Service under warranty period

While under Conroy Medical warranty, the instrument must not be opened by unauthorized personnel.

Contact your local Sales Office or approved repair vendor for service and repair information for all Qseal-multi instruments.

Shipping costs for all units returned to Conroy Medical or Conroy Medical´s authorised representative shall be paid by the original purchaser. The unit must be packed in its original box or in another box that will provide adequate protection during shipment. To ensure prompt return, a Conroy Medical representative must be notified before shipping any unit for repair.

When contacting Conroy Medical representative, please be prepared to provide part number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.

Conroy Medical will not be responsible for unauthorized returns or for units damaged in shipment due to improper packing.

Service after warranty period

After Conroy Medical warranty period, the Qseal-multi will continue to be serviced by Conroy Medical.

If servicing of the device is performed by the original purchaser´s technical department, Conroy Medical will make available on request the service manual including non-confidential information (component part lists, descriptions, calibration instructions), periodic preventive maintenance guide, and any other non-confidential information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by Conroy Medical as repairable.

Preventive Inspection and Maintenance

At least once a year, the Qseal-multi must be fully inspected:
- either by the qualified service organization of the original purchaser,
- or by Conroy Medical or Conroy Medical´s authorized representative.

7.3 Product Disposal

Product Disposal

For Qseal-multi disposal (and accessories) at the end of the calculated life cycle of 7 years, please ensure the following:

- Do not dispose Qseal-multi as unsorted municipal waste.
- Collect the Qseal-multi separately.
- Use the collection and return systems available to you.

For more information on return, recovery or recycling of Qseal-multi, please contact your local Conroy Medical Sales Office.

8. Local Sale Office

EU DECLARATION OF CONFORMITY

Legal Manufacturer:	Conroy Medical AB
Legal Manufacturer Address:	Haesthagsvaegen 14A SE-194 52 Upplands Vaesby Sweden
SRN (Single Registration Number):	SE – MF – 000027430
Basic UDI-DI:	735011599101AB
Name of the Device:	Qseal-multi
Product Code:	CS629
Intended purpose:	Intended for sealing tubes and bags in blood component sets.
Classification and Rule:	Class I, according to Rule 1 in Annex VIII of Regulation (EU) 2017/745
Main standard:	IEC 60601-1:2005 + AMD1:2012 + AMD2:2020

CE

We hereby declare that the medical device specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical device and Directive 2011/65/EU (RoHS). This declaration is supported by the quality system approval to ISO 13485 issued by Intertek IMNB. This declaration of conformity is issued under the sole responsibility of Conroy Medical AB.

Upplands Vaesby, 2024-10-07
Place and date

Nicklas Lundman, CEO

CONROY Medical

Operator´s Manual
CS629 Bench Top Sealer

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Medical

conroymedical.com