Operator´s Manual
CS529 Bench Top Sealer for Heavy-Duty Use

Qseal® • opti

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.

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CONROY Medical

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-opti must be used in compliance with all specifications and operational procedures listed in this manual.

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

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

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-opti should be used.

Warning! The device 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! If any of the components of Qseal-opti 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, 100-130 or 230 V ~.

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

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

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

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

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

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

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

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-opti, a Bench top sealer from Conroy Medical AB.

1.1 Introduction

Qseal-opti is a fully automatic system for sealing PVC 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 Head unit to create a series of seals.

The intended clinical benefit of Qseal-opti 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-opti is complete with inbuilt sealing head and is ready to operate. The “Seal” electrode front can be easily removed for cleaning or the whole Head unit can easily be exchanged. 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-opti 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 CS529:	Qseal-opti, a complete sealing system, which includes Main unit, built-in Head unit, Power cord 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 at 20 °C (68 °F)
Sealing time:	0.6 up to 3 sec. depending on tubing.
Intended purpose:	Intended for sealing tubes and bags in blood component sets. Qseal-opti is intended to be used by trained medical professionals.
Input Power:	100-240V ~- 50-60Hz
Consumption:	250W
Power cord:	Three wire (10 A), 2.5 meter long cable with female plug, (supplied with European plug as standard).
RF Output:	90 W max. / 50 Ω / 40.680 MHz
Size (W x H x D)	195 x 150 x 260 mm (7.6 x 5.9 x 10.2 in)

Weight kg (lb):	5.2 kg (11.5)
Temperature:	Operating: 5 - 35°C (60 - 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) (70-106 kPa)
In compliance with:	- EN 60601-1: 2006, General Requirements for basic safety and essential performance. - EN 60601-1-2: 2015, Collateral standards for Electromagnetic Compatibility.
Electrical safety:	Class I

The Qseal-opti 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 CS529 Qseal-opti Bench Top Sealer is intended for use in the electromagnetic environment specified below. The customer or the user of the CS529 Qseal-opti should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11	Group2	The CS529 Qseal-opti must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emission CISPR 11	Class B	The CS529 Qseal-opti 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 CS529 Qseal-opti is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-opti 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	± 8kV contact ± 15kV air	8kV 15kV	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 CS529 Qseal-opti requires continued operation during power mains interruption, it is recommended that the CS529 Qseal-opti be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	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.			

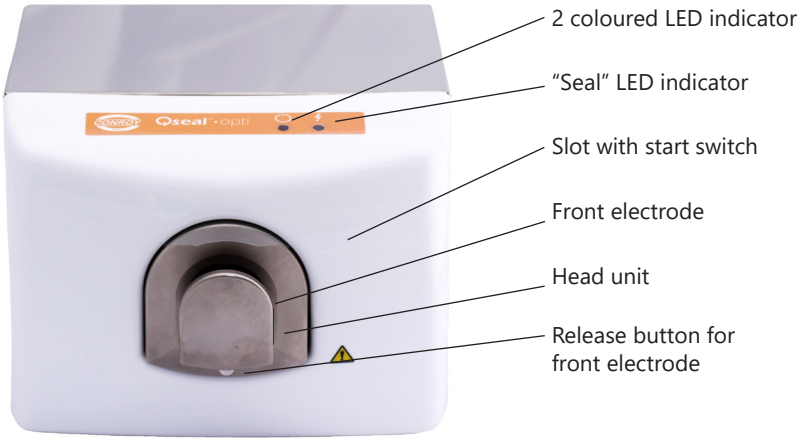
Table 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS529 Qseal-opti is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-opti should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	1 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the CS529 Qseal-opti including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 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 CS529 Qseal-opti 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 CS529 Qseal-opti. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

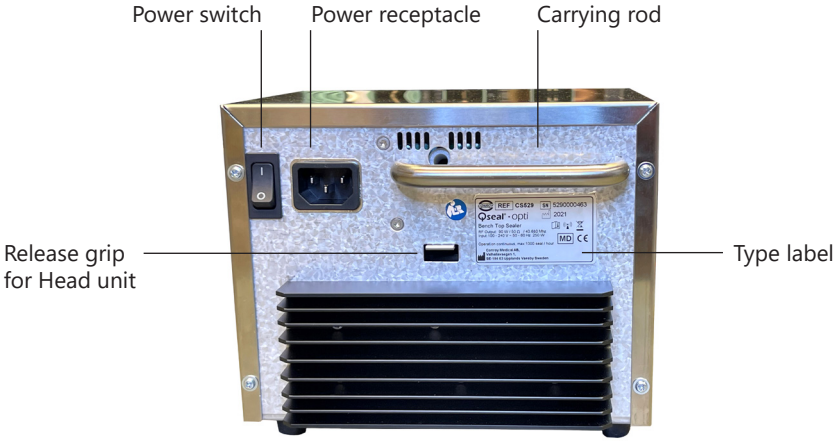
Table 6:

Recommended separation distance between portable and mobile RF communications equipment and the CS529 Qseal-opti			
The CS529 Qseal-opti is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS529 Qseal-opti can help prevent electro-magnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS529 Qseal-opti 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



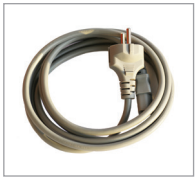
Rear view



1.3 Qseal-opti parts and spare parts

1.3.1 Qseal-opti, REF CS529

Qseal-opti comprises the parts listed below:



Description	Main unit	Head unit	Power cord, 2.5 m
Part No.	52900000	52930000	820 981 00

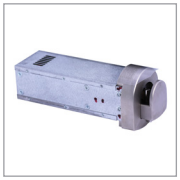
Order separate power cord for:

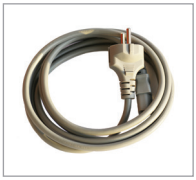
Description	USA	UK	Australia
REF	8 7901 1252	8 7901 1253	8 7901 1254

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	8 7901 1251	Three-wire (10A), 2.5 m long, female plug

1.3.2 Qseal-opti spare parts (user interchangeable parts)





Description	Head unit	Power cord, 2.5 m
REF	952930000	8 7901 1251

1.4 Symbols/Markings Description

On instrument and labels:

Symbol for “MEDICAL DEVICE”.

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

Symbol for “CATALOGUE NUMBER”.

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 “KEEP DRY”.

Symbol for “HANDLE WITH CARE / FRAGILE”.

Symbol for “ATMOSPHERIC PRESSURE LIMITATIONS”.

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.

2-coloured LED: Green when the power is on, Flashing red when an error occurs (sealing is not possible).

“Seal” LED: Yellow when RF-energy is being applied to the seal electrode.

Symbol for “CONSULT USER MANUAL”.

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 Main unit
   1 Power cord
   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 5 - 35°C (41 - 95°F), and relative humidity 10 - 90% non condensing.
• Handle the components with care in a clean environment.

2.3 Installation Procedure

Preparing the sealer for use

1. Connect the power cord to the receptacle at the rear of the Main 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.

Note! The instrument has an automatic auto range sensor, which means that it changes automatically to the correct main voltage 115 or 230 V ~.

3. Functional Description

This chapter describes how Qseal-opti 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-opti 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-opti 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 Head unit, between the electrodes. When the user presses the tube against the incorporated start switch, at the bottom of the slot, 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 sterilized welding pattern.

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

3.2 Description of Equipment

Qseal-opti consists of a Main unit with built-in Head unit. Below is a short description of each component.

The Main unit consists of the following modules:
• Power entry module, mains filter, and separate on/off switch.
• The Power supply module consists of circuit board with alternating/direct current converter and protectors.
• The RF generator module, which generates the energy for the sealing and also includes the control module, which senses the sealing activity and controls the sealing operation.

The Head unit is removable with a grip at the rear of the Main unit. Also the front electrode is removable with a release button under the front of the Head unit. At the front of the Head unit, there is a slot where the "Seal" electrode is placed. The electrode is designed to give a reliable seal with a very thin seal pattern in the middle so that is easy to separate the tube into two pieces.

Release of whole Head unit

To release, just press down on the grip at the rear of the Main unit and pull the Head unit out. To assemble head, push it in and ensure that it snaps into position.

Release of front electrode

To release, just press in the release button under the front of the Head unit and pull the front electrode out. To assemble the electrode, push it in and ensure that it snaps into position.

Front view functions of indication

2-coloured LED: Green when power is on, Flashing red when an error occurs (sealing not possible).

"Seal" LED: Yellow when RF energy is being applied.

4. Operating Instructions

This chapter describes the use of the instrument.

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

Warning! Qseal-opti 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.

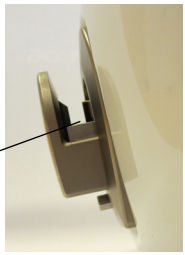
Warning! This instrument emits a low level of electromagnetic (non-ionizing) radiation while sealing. It should not be used near high frequency sensitive electronic equipment. *See table 1 for guidance.*

Warning! Mains plug is considered as disconnecting device from the mains. Make sure, that the mains socket outlet is easily reachable during use of the equipment.

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 appliance 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 ⏻ indicator 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 down to the bottom of the slot ❶ of the Head unit.
2. Gently press the tube down to hit the start switch and to start the sealing process. The sealing electrodes press the tube together and the LED "Seal" light on the Main unit lights up. The sealing time is normally 0.6 to 3 seconds. Avoid stretching the tube during the sealing process.

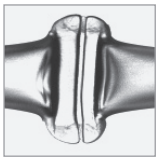
Note! Do not pull the tube and keep the tube fully pressed down until the light goes out.

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.

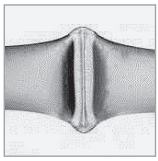
Caution! If you should make two or more seals, they should not be within 1 cm (½") of each other, otherwise the resulting pressure in the tube may cause microscopic cracks and holes in the seals.

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 Main unit

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

5. Cleaning

This chapter gives information on the cleaning (procedure, frequency) of the Main and Head units.
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. Mains plug shall be disconnected from the socket outlet before cleaning procedure.

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 Main Unit

Cleaning may be required as a result of spilled drops of blood or once per week.

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 Main unit.

5.2 Head Unit

Clean once per week or more frequently, as required, if spillage of blood occurs.

For cleaning the electrodes you should loosen the front electrode of the Head unit by pressing the release button under the head. Pull out and remove the front electrode.

Note! The loosened front electrode can be dipped in liquid, as it is waterproof. 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. To clean the solenoid shaft, use a dry cotton swab.

Note! After cleaning, inspect the electrodes for damage.
Assemble the parts in reverse order, ensuring that they snap in position.

Note! Some sealing tests are recommended 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 Head unit and power cable. The following information covers common problems and offers suggested solutions.

6.1 Main Unit

Problem	Probable cause	Recommended action
LED doesn't light up green.	No Voltage.	Check power supply.
	Other cause.	Contact your local C.M. representative.
LED lights up green, but when the tube is depressed the LED doesn't light.	No connection.	Check sealing head connection.
	Head unit defective.	Change Head unit.
	Other cause.	Contact your local C.M. representative.
LED flashes red.	The Main 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.	Main unit defective.	Contact your local C.M. representative.

6.2 Head Unit

Problem	Probable cause	Recommended action
The sealing doesn't start.	Wet electrodes	Dry the electrodes, see Section 5.2
	No "click" from start switch, when depressing the tube	Contact your local C.M. representative.
	Cable broken	
	Other cause	
Tube cut or breaks during sealing.	Stretch of tube during sealing	Do not stretch tube. See Section 4.2
	Seals to close	Min 50 mm between seals. See Section 4.2
	Moving electrode obstructed.	Clean electrode shaft. See Section 5.2
	Wrong adjustment of electrodes.	Contact your local C.M. representative.

6.3 Parts Replacement

Power cord replacement

• Turn the power switch off and disconnect the power cord.
• Replace the power cord with the same or an equivalent model (see Section 1.3).

Head unit replacement

• Turn the power switch off and disconnect the power cord.
• Press the release grip on the back. Carefully remove and replace the Head unit (see Section 1.3).

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-opti 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-opti 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-opti must be fully inspected:
- either by the qualified service organization of the original purchaser,
- or by Conroy Medical or Conroy Medical´s authorized representative.

Interchangeable Parts Replacement (Maintenance performed by user)

Maintenance is limited to changing Head unit and cable. The information in chapter 6 (Troubleshooting) covers common problems and offers suggested solutions.

7.3 Product Disposal

Product Disposal

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

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

For more information on return, recovery or recycling of Qseal-opti, 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-opti
Product Code:	CS529
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
CS529 Bench Top Sealer for Heavy-Duty Use

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