Operator´s Manual
CS546 Portable Battery Sealer

Qseal® • handy

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

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

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

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

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

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

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

Warning! Qseal-handy 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! 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.

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-handy, a Portable Battery sealer from Conroy Medical AB.

1.1 Introduction

Qseal-handy is a fully automatic system for sealing PVC or 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 inserting the tubing into the slot at the front of the Hand unit to create a series of seals.

The intended clinical benefit of Qseal-handy 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-handy is comprised of a hand unit and battery unit which is connected to the hand unit with the integrated cable. It is complete with inbuilt sealing head and ready to operate. The "Seal" electrode front 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-handy 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.

1.2 Performance and Specifications

The table below lists the physical specifications.

Parameter	Value/ Description
REF CS546:	Qseal-handy, a complete sealing system, which includes Battery unit, Hand unit, Charger 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:	1500 seals/charge with PVC tubes up to 5 mm outer diameter at 20 °C (68 °F)
Contin. seal capacity:	50
Mode of operation:	Operation: 25%, Intermittens: 75%
Sealing time:	0.4 up to 3 sec. depending on tubing.
Intended purpose:	Intended for sealing tubes and bags in blood component sets. Qseal-handy is intended to be used by trained medical professionals.
Input Power:	Charger 100-240 V ~ - 50-60 Hz Battery 28.8 VDC, 2.4 Ah, Li-Ion
Consumption:	Charger: 30 W, Sealer: 150 W max
Fuses:	Charger: T2 A 250 V (internal) Battery: 2 A (input) / 10 A (output) (internal)

RF Output:	80 W max. / 50 Ω / 40.680 MHz
Size (W x H x D) Weight kg (lb):	Battery unit: 165 x 106 x 32 mm (6.5 x 4.2 x 1.2 in) Battery unit: 0.67 kg (1.5) Hand unit: 0.35 (0.8)
Temperature:	Operating: 15 - 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)
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:	During charging Class II. ⧈ During use: Internal power supply. The Qseal-handy 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 CS546 Qseal-handy Portable Battery Sealer is intended for use in the electromagnetic environment specified below. The customer or the user of the CS546 Qseal-handy should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11	Group2	The CS546 Qseal-handy must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emission CISPR 11	Class A	The CS546 Qseal-handy is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Table 2:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS546 Qseal-handy is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-handy 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.
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.			

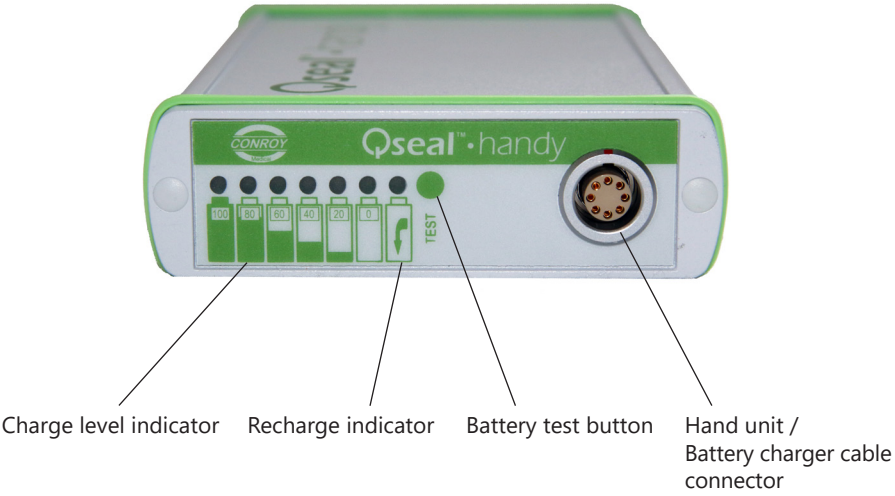
Table 4:

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CS546 Qseal-handy is intended for use in the electromagnetic environment specified below. The customer or the user of the Qseal-handy 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 CS546 Qseal-handy 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 CS546 Qseal-handy 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 CS546 Qseal-handy. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

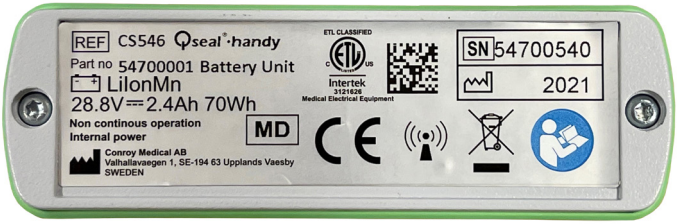
Table 6:

Recommended separation distance between portable and mobile RF communications equipment and the CS546 Qseal-handy			
The CS546 Qseal-handy is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS546 Qseal-handy can help prevent electro-magnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS546 Qseal-handy 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 $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
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.			

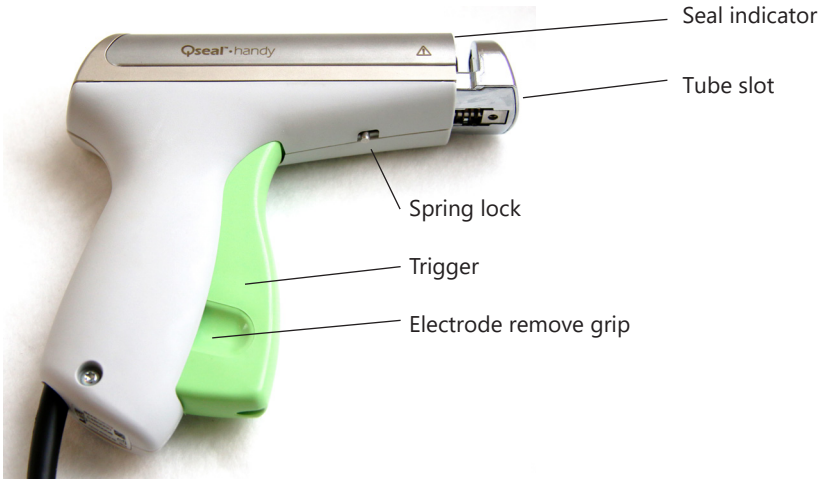
Front view of Battery unit



Rear view of Battery unit



View of Hand unit



View of Charger

1.3 Qseal-handy parts and spare parts

1.3.1 Qseal-handy, REF CS546

Qseal-handy comprises the parts listed below:

Description	Battery unit	Hand unit	Battery charger
Part No.	54700001	54600001	54400001

Description	Mains adapter kit
Part No.	64614010

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
Battery Charger	54400001	Input: 100-240 V~/50-60 Hz/700 mA Output: 18VDC/1.66A

1.3.2 **Accessories** (order separately)

Description	Holster	Extension cord, 1.2 m
REF	9547500	9547555

1.3.3 **Qseal-handy spare parts** (user interchangeable parts)

Description	Hand unit	Battery unit	Battery charger
REF	954600001	9547301	954400001

Description	Mains adapter kit
REF	964614010

1.4 Symbols/Markings Description

On instrument and labels:

Symbol for “MEDICAL DEVICE”.

This marking reflects compliance with the Council Directive 2017/745/EEC on Medical Devices.

This marking reflects compliance with EN 60601-1 and national standards for USA (ANSI/AAMI ES60601-1:2005) and Canadian (CSA C22.2 No. 60601-1) markets.

Class II Battery charger: double insulation during charging.

Battery charger UL recognised component for Canada and U.S.A.

Symbol for “CATALOGUE NUMBER”.

Symbol for “WARNING”.

Symbol for “CONSULT USER MANUAL”.

Symbol for “SERIAL NUMBER”.

Symbol for “DATE OF MANUFACTURE”.

Symbol for “MANUFACTURER”.

Symbol for “ATMOSPHERIC PRESSURE LIMITATIONS”.

Symbol for “TEMPERATURE LIMIT”.

Symbol for “RELATIVE HUMIDITY 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.

Symbol to indicate information about the battery.

Symbol for “KEEP DRY”.

Symbol for “Handle with care / FRAGILE”.

LED indications

Battery unit
- “Coloured Led´s bar indicating battery status.”
- “TEST”: button to check the battery.
  When pressed, the battery charge level indicator lights up.
  Refer to section 3.3.

Hand unit
- Indicator lights orange when RF-energy is being applied to the sealing electrode and turn off when sealing is completed.
- Indicator flashes red at overheating, sealing function is blocked.
- Indicator lights red one second in case of short circuit, sealing function is blocked.
- Indicator lights red in case of battery low level, sealing function is blocked.

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 Hand unit
   1 Battery unit
   1 Battery charger
   1 Adapter Kit
   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 15 - 35°C (60 - 95°F), and relative humidity 10% - 90%.
• Handle the components with care in a clean environment.

2.3 Installation Procedure

Preparing the sealer for use

1. Fit correct mains input plug to the battery charger.
   The changeable mains connector is available for European continent, UK, USA/Canada and Australia/New Zealand and as IEC standard 320 C8 (see 1.3.1).
2. Connect the charger (green on connector) to the combined hand unit/battery charger cable connector.
3. Plug the charger into the mains. The charger can be connected to mains voltages between 100 and 240 V AC.
4. It takes about five hours to charge the battery unit completely. When the charging level indication on the unit indicates 100% and the recharge indication flashes, the battery is fully charged.
   Charge the battery to 100% before first use.
5. Connect the hand unit cable (green at end of the cable) into the battery unit connector. Make sure the connector snaps in secured position.
6. Perform a test seal on an empty or water filled tube to ensure proper operation.

Caution! Only use the enclosed battery charger for charging the battery unit.

Note! Ensure that cable to handle is connected before use.

3. Functional Description

This chapter describes how Qseal-handy 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-handy 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-handy 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 Hand unit, between the electrodes. When the user presses the trigger on the hand unit, the tube is pressed together and 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 Hand unit is lit. When this light goes out, the sealing is complete and the trigger may be released. The intelligent sense control in the Hand unit detects, controls, and adjusts the necessary sealing activity to give the best sealing quality for the type of tubes that are being used. See section 1.4 for a description of the different LED indications on the hand unit in case of problems.

3.2 Description of Equipment

Qseal-handy consists of a battery unit and a hand unit. Below is a short description of each component. **The Hand unit** consists of an RF-generator with intelligent sense control, ergonomic handgrip with trigger, the mobile electrode (which can be removed for cleaning) and the cable with connector. The hand unit takes no power between sealing. **The Battery unit** consists of the environmental friendly LiIonMn battery pack, built-in optic charge level indicator and the combined charger/handle connector. The charge in the battery unit is sufficient for up to 1500 seals.

3.3 Checking the battery unit

To check the battery, just press the "TEST" button ❸ and the battery charge level indicator ❶ lights up. The capacity indication is in steps of twenty percent. The battery can be recharged at any time or at least when zero (red) remains. The zero level is also indicated on the handle with the red light and when seal is attempted, the seal function will be blocked.

Recharging the battery:

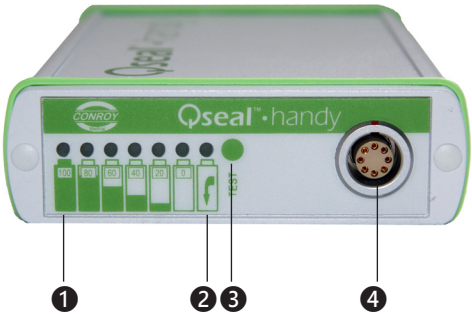
Connect the battery charger to the battery unit ❹ and the charger to the mains. The recharge indicator ❷ lights up, and the indicator LED´s start flashing. When the recharge indicator starts flashing, the battery is fully charged and the charge current is automatically turned off. The charge can be interrupted at any time without damage to the cells, but a full recharge will take less than five hours and is recommended.

Caution! Always check the seals when the battery capacity is low (20% or less). See section 4.2 for sealing pattern.

Caution! Only use the enclosed battery charger for charging battery in the battery unit.

Note! To guarantee a long lifetime for the rechargeable battery, please observe the following requirements:
Charge the battery at temperature between 5 and 35°C (40-95°F).

Note! If the indicator ❷ does not light up, check the connection to the charger and mains.



4. Operating Instructions

This chapter describes the use of the instrument.

Caution! Inspect all parts of the instrument for defects before use. Check sealing pattern if hand unit is dropped.

Caution! Always check the seals when the battery capacity is low (20% or less).

Warning! Qseal-handy 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! Do not allow the hand unit to come in contact with the donor.

Warning! Do not perform a seal within 8 cm (3 in) of needle to preclude an RF burn at the needle entry point.

4.1 Preparation before Use

1. Place the instrument on a flat surface near the working place or in the holster.
2. Check that there is sufficient battery capacity by pushing the "TEST" button.
3. Connect the hand unit cable into the combined hand unit/battery charger cable connector.

Note! Use the correct hand unit, green tension relief on the cable.

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 in the Hand unit.
2. Check that the tube is placed between the electrodes in the slot.
3. Press the trigger to bring the two electrodes closer together until the light on top of the hand unit comes on. The sealing time is normally 0.4 to 0.9 seconds; after a maximum of 3 seconds the RF is turned off.

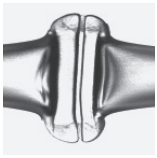
Note! Do not pull the tube and keep the trigger fully pressed down until the light goes out. If the trigger is released the sealing process stops.

4. When the light goes out, sealing is finished. Release the trigger and remove the tubing.
5. The center of the sealed pattern is very thin and pulling both sides will divide the tube into two pieces.
6. Check the tube for leakage.

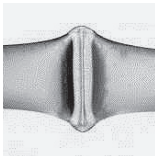
Caution! If you should make two or more seals, they should not be within 1 cm (½ in) of each other, otherwise the resulting pressure in the tube may cause microscopic cracks and holes in the seals.

Caution! In case of sealer malfunction (intermittent operation, poor seal quality, the sealing time seems too long or too short) contact your local Conroy Medical 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
Wet or dirty electrodes	Clean and dry the electrodes
Low/no capacity in battery	Check/charge battery
Over heated (red blink)	Let the Hand unit cool down.
No seals	Check battery unit and connection.

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 Battery and Hand units.
The Sealer requires minimal maintenance for efficient operation.
Follow the cleaning procedure below.

Warning! For you own safety always disconnect the hand unit or charger from the battery unit.

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 Battery Unit

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

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 Battery unit.

Caution! Do not, under any circumstances, submerge the battery unit in any kind of liquid. This will damage the battery and void the warranty.

5.2 Hand Unit

Clean once per week or more frequently, as required, if spillage of blood occurs.
For cleaning the electrodes remove the mobile electrode.

1. Pull the green trigger to "click" to release the front electrode. Push spring lock forward.

2. First push inward, then pull out the electrode.

Removal of mobile electrode:
Clean the handle and both electrodes with a soft lintfree cloth moistened with mild detergent. Dry carefully and ensure that the electrodes are completely dry to prevent sparks. To clean the electrode shaft, use a dry cotton swab.

Note! For proper funcion, add a drip of light machine oil on electrode shaft after each cleaning!

After cleaning, inspect the electrodes for any mechanical damage or wear out. Do not use damaged part.

Assemble the parts in reverse order. Make sure the trigger and spring lock is in full forward position before electrode insertion.

Insert the mobile electrode ensuring that it is positioned so as to be parallel with the fixed electrode. Press the trigger twice and ensure that the mobile electrode moves smoothly, is in position and not loose.

Note! Some sealing tests are recommended before resuming use. Compare the pattern against picture in Section 4.2.

Note! Do not push the trigger in after removing the electrode since this may block the locking mechanism. If electrode cannot be inserted after cleaning, the trigger is probably pressed during cleaning. To insert the front electrode again, see chapter 6.2.

Caution! Do not dip the units in liquid, as they are not waterproof.
Intruding liquid will cause malfunction, tiny arcs and void the warranty.

6. Troubleshooting

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

6.1 Battery Unit

Problem	Probable cause	Recommended action
Charge level LED's doesn't light.	No voltage.	Charge battery unit.
	Fuse blown.	Contact your local C.M. representative.
	Battery too low voltage.	Charge battery for 48 hours.
	Other cause.	Contact your local C.M. representative.
Charge level LED's lights green but when trigger is pressed the seal lamp doesn't light.	No connection.	Check cable.
	Hand unit defective.	Change hand unit or contact your local C.M. representative.
	Fuse blown.	Contact your local C.M. representative.
	Charge level indicator wrong.	Charge battery for 5 hours.
	Battery unit defective.	Contact your local C.M. representative.
	Other cause.	Contact your local C.M. representative.

6.2 Hand Unit

Problem	Probable cause	Recommended action
The sealing doesn't start.	Wet electrodes.	Dry the electrodes, see chapter 5.2.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2
	Wet tube.	Dry the tube and electrodes, try again.
	Tiny arcs between the electrodes.	Dry the electrodes and try again.
	No "click" when trigger is pushed.	Change hand unit or contact your local C.M. representative.
	Hand unit defective.	
	Battery not charged/low charge.	Charge battery for 5 hours.
	Cable broken.	Contact your local C.M. representative.
	Other cause.	
Bad sealing.	Low battery charge.	Check battery unit.
	Mobile electrode doesn't move smoothly in handle.	Clean and oil electrode shaft, see chapter 5.2.
	Wet electrodes.	Dry the electrodes and try again.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2.
	Mobile electrode out of position.	See chapter 5.2, assembly of electrode.
	Hand unit defective.	Change hand unit or contact your local C.M. representative.
	Other cause.	Contact your local C.M. representative.

6.2 Hand Unit

Problem	Probable cause	Recommended action
Hard to divide tube after seal.	Mobile electrode doesn't move smoothly in handle.	Clean and oil electrode shaft, see chapter 5.2.
	Wet electrodes.	Dry the electrodes and try again.
	Dirty electrodes.	Clean the electrodes, see chapter 5.2.
	Rim on moving electrode damaged.	Contact your local C.M. representative.
	Other cause.	
Intermittent sealing.	Hand unit defective.	Change hand unit or contact your local C.M. representative.
	Cable broken.	Contact your local C.M. representative.
	Battery unit defective.	
Seal lamp still alight after seal trigger has been released.	Seal switch is broken.	Contact your local C.M. representative.
	Hand unit defective.	Change hand unit or contact your local C.M. representative.
Seal lamp doesn't light.	Hand unit defective.	Change hand unit or Contact your local C.M. representative.
Seal lamp flickers.	Cable broken.	Contact your local C.M. representative.
	Other cause.	
Electrode cannot be inserted after cleaning.	Trigger has been pressed during cleaning which means that internal spring can come out of position.	The spring can be reset to its correct position by pulling out the trigger to the outer locked position. Thereafter carefully insert a pin (Ø3-4 mm, 100 mm long) in the front hole where the electrode is inserted and slightly push it downwards. Be careful; do not scratch the surface with the pin.

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-handy 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-handy 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 every second year, the Qseal-handy 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 the hand unit, battery unit or charger. The information in chapter 6 (Troubleshooting) covers common problems and offers suggested solutions.

7.3 Product Disposal

Product Disposal

For disposal of Qseal-handy, or parts thereof, (including accessories) at the end of the calculated life cycle of 7 years, please ensure the following:

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

For more information on return, recovery or recycling of Qseal-handy, please contact your local Conroy Medical representative.

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:	735011599100A9
Name of the Device:	Qseal-handy
Product Code:	CS546
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
CS546 Portable Battery Sealer

conroymedical.com