

Tube Sealer CR6

User's Manual
and
Technical Reference

Distributed by:

OriGen Biomedical, Inc.

Important Safety Information

This user's manual is written for the Tube Sealer CR6 user with specific instructions for sealing OriGen CryoStore cryopreservation bags. The operational methods and routines were developed and tested to ensure a reliable, safe and effective operation of CR6. It is important that the operator read and understand the contents of this manual before using the CR6. Please refer technical questions to OriGen Biomedical (contact information on last page).



- **RF Interference:** This equipment uses radio frequency (RF) energy for tube sealing and may potentially emit low level radio emissions in the 40.68 MHz frequency range. Make sure that any sensitive equipment near the sealing unit is shielded from RF interference at this frequency.
- Never touch the jaws with your fingers during the sealing process! This may cause burns and injuries!
- Ensure that the tubing is clean and dry on the surface before sealing.

Electrical safety

Use only the battery charger approved for CR6 AA and make sure it is connected to the proper input voltage (110-240V, 50-60Hz).

Batteries

The NiMh batteries used in CR6 model AA are not considered to be dangerous for the environment but should be sent to a recycling center for disposal.

Environmental effects

The Tube Sealer CR6 model AA contains no parts of forbidden or hazardous substances noted in the RoHS directive 2002/95/EG but should be sent to a recycling center for disposal.

Table of contents:

Important.....	i
Electrical safety.....	i
Batteries.....	i
Environmental effects.....	i
Quick Start.....	2
Design Properties.....	2
Function	3
Operation.....	3
Sealing Tubing.....	4
Temperature-alarm.....	4
Charging battery	4
Maintenance and service.....	6
Cleaning the jaws.....	6
Change of batteries.....	6
Troubleshooting.....	7
Technical data.....	8
Warranty.....	8
Declaration of Conformity.....	9

Revision History:

Rev 04, Jan 2020: Removed OriGen EUAR address. Removed Declaration of Conformity Page.

Rev 03, Mar 2016: Added Troubleshooting notes

Rev 02, Jul 2014: Added Rev history, page numbers, correct typos, clarified model number

Rev 01, Apr 2014: Added Quick start section

Quick Start Instructions

1. Switch the Console OFF (the '0' position on the switch)
2. Connect the Battery charger to the Console and plug into main power.
3. Connect and lock the Coax cable to the Console and to the sealing head.
Test that it is locked with a slight tug on the cable.
4. Switch the unit ON (the ' | ' position on the switch). Note: The status LED shows green. The Battery LED on the console should also be green; if not switch off and charge the battery until the battery LED is green before proceeding.
5. Position the sealing head jaws on the area of the tube to be sealed. Ensure the tube is dry and free of condensation.
6. Close the jaws, sealing starts and the orange LED on the handle illuminates.
7. When the seal is complete, the LED on the handle goes off. Hold the handle closed for 2 seconds to allow the seal to cool, and then release.
8. The CR6 should be used without the power cord; charge the system overnight to fully charge the internal battery. Remove the charger from the system until the orange LED illuminates. Recharge the battery if the Console LED is orange or red. (Note the sealer may not even produce a seal if the Console LED is red)

Notes:

CUT, do not rip the seals apart. Pulling the seals apart risks tearing a hole in the sealed tube, and may create a leak. We recommend making two seals close to the bag, then cutting the one farthest away to ensure the seal closest to the bag is intact.

Design Properties

The Tube Sealer CR6 is comprised of 3 main components:

- Manual sealing handle with a 1.9 m (74.7") coax cable
- Console including a battery, a high frequency generator and a control unit
- Battery charger and cables

The Tube Sealer CR6 is a battery operated sealing unit especially suitable for sealing tubing from cryopreservation bags and tubing sets for administration of blood products.

It can seal PVC, PVC/EVA co-extrusions and most EVA tubing with a nominal diameter of 4 mm. The CR6 has a built in sensor that optimizes seal quality and battery life.

With a new and with a fully charged battery, the CR6 can make approximately 1500 seals in 4-5 mm PVC tubes on one charge. This high capacity makes the CR6 suitable for use

in a mobile or stationary capacity. However, the sealer should cool at least one minute after making multiple seals to produce consistent, reliable seals.



Function

Sealing is complete in 2-5 seconds depending on type of tube. The width of the seal is fixed at about 3 mm. Before sealing, a system microprocessor checks that the tube is not damp, to avoid sparks and leaking. After each seal a multicolored diode labeled 'Battery' on the console is lit indicating remaining capacity of the battery. See below.

Operation



Always turn the power off before you connect or disconnect the coax cable!

Turn on the power switch, the lights for status and battery will illuminate.

- A green battery light means the battery is 50-100% charged
- An orange battery light means the battery is 25-50% charged
- A red battery light means the battery is <25% charged

If the BATTERY light is orange or red, the battery must be recharged or plugged in before operation.

Sealing PVC tubes, EVA and PVC/EVA tubes

1. Dry the tubing if it is wet. (Wet tubing will cause the system to flash the Status LED and abort the sealing operation)
2. Place the tubing between the jaws and squeeze the handle fully.
3. The sealing automatically starts and two indications are given: the “status” LED on the Console is lit and blinking, indicating high frequency power and the orange diode on the handle is also lit.
4. When the seal is complete, the Status LED on the power unit will turn green; the orange light on the handle will turn off. Wait 2 seconds to allow the seal to cool before releasing the handle.
5. A new seal can be made immediately after the green Status LED is back on.

Note:

- For the best possible seal, hold the handle closed for at least two seconds after the handle LED turns OFF, to allow the seal to cool.
- Seal in sequence moving towards the open end of the tube. Making aliquots in a closed tube will result in a pressure build up that may cause the aliquot to leak or burst.
- Never stretch the tube during sealing, as this may cause leakage.
- **Continuous sealing:** making more than 20 seals per minute over several minutes can cause overheating of the system or jaws with a declining quality of the seals or cause the “**temp alarm**” LED on the power unit to illuminate.
- Always use the 1.9m coax cable that came with the system.

Temperature-alarm

If the temperature of the RF generator exceeds a pre-set temperature, the “**temp alarm**” LED illuminates. Sealing cannot be done until the RF- generator has cooled down and the LED has turned off.

Charging batteries

The CR6 model AA battery charger is specially designed for charging the NiMH battery in the CR6. It’s approved for medical use according to EN 60601-1 and is UL recognized for US and Canada, and can use any 50 to 60 Hz AC input voltage between 100 and 240 Volts.

It has a controlled charging procedure, which is specific to NiMH batteries. The charge controller uses both voltage change sensing and timeout limits.



Use only the battery charger supplied with the CR6!

The charging LED on the Console should be either orange or red when the charging is started. If it turns green immediately after the power cable is connected to a power supply, the power cable must be unplugged and the unit allowed to cool before proceeding.

1. Connect the power supply cord to the charger socket on the Console and then to the wall socket.
2. A battery with a capacity of 25% (red LED) requires 6-8 hours to fully charge
3. For the longest battery life before battery replacement, use the sealer operating on battery until the lamp turns orange, and then recharge the battery.
4. If the charger is always plugged in, the battery life will be shorter.
5. The CR6 system can be turned ON or OFF during charging.
6. Avoid completely discharging the battery since this will shorten the life of the battery. Immediately connect the charger if the Red LED illuminates.
7. The working life of NiMH batteries depends on the number of recharge cycles, the surrounding temperature, and the temperature rise that occurs when batteries are charging. Typical expected working life is 3 years with a charging frequency of 200 cycles per year at 25°C. Deep discharging (allow the battery to be at 0-5% capacity or overcharging (leaving the system plugged in continuously) shortens battery life.
8. If the sealer is not used often, the battery needs charging every 3 months to prevent deep discharge.
9. If the battery has been completely discharged it may need to be repeatedly charged and discharged to obtain full capacity.

N.B. The battery charger does not have enough output current to run the CR6 if the batteries are completely dead or removed.

Maintenance and service

The maintenance that can be done by the operator is limited to cleaning. Electrical repairs must be done by an approved service personnel.

The power unit and the handle can be cleaned with a damp sponge and a mild soap solution or 70% Isopropyl alcohol (IPA).



For the best seal performance it is important that the jaws are always parallel, clean and dry. If the jaws are wet, it is very important to clean and dry the jaws carefully. Always turn off the Power Unit before cleaning the equipment.

Cleaning the jaws

Switch unit off. Unscrew the 2 screws holding the clear plastic cover and pivot it back or remove it. Clean the jaws with a damp sponge and water and dry with a soft cloth.

Replacement of batteries



When the battery capacity is insufficient to seal approximately one hundred seals when fully charged and the charger is disconnected, the battery should be replaced.

Battery replacement must be done by qualified service personnel. The battery charger and the sealing handle must be disconnected and the unit powered off when the battery is replaced. Always use battery packs from OriGen.

1. Turn off the CR6.
2. Unscrew the 4 screws holding the cover and remove it.
3. Disconnect the two electrical quick connects (red and black).
4. Unscrew the 2 screws on the battery holder, and the battery pack can be removed.
5. Exchange battery pack and reassemble in reverse order.

Warning: The battery used in CR6 contains NiMh and is not considered to be dangerous for the environment but should be left to a recycling station for recycling

Troubleshooting

Issues/Problems	Solutions
Initial seals are good, but unit makes poor or no seals on the 3 rd or 4 th try	Allow unit to cool slightly between seals. Keep handle closed for a few seconds after the handle LED goes out, try to start seals 8-10 seconds apart to allow RF generator to cool.
Sealing takes too long, error indications	Check that the cable is exactly 1.9m (74.7") long. Other length cables will cause RF errors and degrade seal performance.
At the end of sealing, the 'Status' LED blinks red rapidly and the unit beeps three times	The system cannot judge if the seal is complete. Pressure check the seal carefully, and in the case of 100% EVA tubing, consider sealing right over the same seal again.
The LED "Temp Alarm" is lit and sealing does not start.	The RF-generator is overheated. Let the system cool down until the alarm is turned off. (usually 15 to 30 minutes)
The Red or Orange 'Battery' LED is lit	Recharge the battery.
The LED "Sealing" flashes and sealing does not start.	The tube is damp, dry the tube and the jaws before sealing.
Sparks appear by the jaws during sealing.	This can happen if the jaws are bent, the tube is damp or the jaws are overheated due to too many seals too quickly. Let the system cool down, check the jaws are parallel, and/or dry the tubing. If there has been sparks and arcing has left carbon particles on the jaws, these particles must be removed completely before sealing can continue. Use 400 grit sandpaper. If this happens consistently and the tube is dry, it can indicate that the jaws are not parallel. Contact service personnel.
The seal is done poorly, and/or leakage may appear in the seals.	Check that the coax cable is correct; the length must be <u>exactly</u> 1.9m (6 feet).

Power Unit

Technical data

Batteries:	NiMh battery pack 24V/ 3,8Ah
Internal fuse:	Overload protection type PTC, self-recovery, and thermal fuse.
Power Output:	100W /50 Ohm.
Seal time:	Automatic 1-2 sec
Frequency:	40.68 MHz.
Dimensions:	266x119x88 mm (LxWxH) incl. HF contact.
Weight:	2.15 Kg (4.7 lbs) incl. battery.
Rel. Humidity incl. storage and transport:	10-95% not condensing
Working temperature:	10-40 °C
Storage- and transportation temperature:	-40 to +50 °C. (The battery life may be shortened from storage at high temperatures).
Operation:	Recommended: less than 1 seal every three seconds during continuous use or maximum 50 seals in sequence and a 15 minutes rest after that.
Protection against electrical shock:	Class II type B.



Limited Equipment Warranty

Ljungberg & Kögel AB (L&K) hereby guarantees the original buyer that Tube Sealer CR6 is manufactured in a professional and quality manner, and will be free from all faults during a period of one year from the date of delivery from OriGen. The warranty includes equipment and components that proves to have faults during the warranty period.

L&K will without cost for the customer, repair or replace the equipment that is faulty. The warranty is not valid for the battery pack since this is considered to be consumable. The warranty is not valid if the equipment has been repaired by anyone else than qualified personnel, that is approved by L&K.

The warranty is not valid if the equipment has been changed in any way that, according to L&K's opinion, affects the reliability or stability of the instrument. The warranty is not valid when the serial number has been changed, crossed over or been removed, or if the fault has been caused by misuse or abnormal use. In these cases L&K or L&K's representative will inform the customer about the decision, and if wished by the client will repair the equipment at the normal rate. An estimated price can be given on request.

Disclaimer of Warranties

OriGen Biomedical warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from OriGen. OriGen's sole obligation shall therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of this device is beyond our control, OriGen cannot warrant for a good effect or against a bad effect in the application and use of this device. The buyer therefore assumes all liability arising from any cause for damages resulting from use, misuse, use other than as intended, or resterilization of this product. OriGen therefore gives no warranty of merchantability or fitness for a particular purpose. OriGen shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of this product. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual has the authority to vary the terms of this warranty.

Distributed by:

OriGen Biomedical, Inc.
7000 Burleson Rd., Bldg. D
Austin, TX, USA 78744
Tel: +1 512 474 7278
Fax: +1 512 617 1503
Email: sales.us@origen.com

www.origen.com

LC30.R04, January 2020; © OriGen Biomedical, Inc., All Rights Reserved