

Bladder Box

Instructions for Use

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I. Quick Start

1. **Principle of operation:** The Bladder Box contains a pair of micro switches which are actuated by the filling and deflation of the silicone bladder it supports. One of these switches actuates an alarm and red lamp, the other can be connected via cable to an external device, such as a motor controller. For purposes of this manual, we will assume it is connected to a pump system.
2. **Rechargeable Battery:** The Bladder Box is supplied with a rechargeable 9 volt NiMH battery, and will operate from either battery power or the charger supplied. Charge the battery for a few hours before each use. The Charger is specifically designed for NiMH batteries, and falls back to a trickle charge mode as the battery is charged.
3. **Power not needed for control:** Battery power runs only the lamps and the alarms; it is not needed to send stop commands to a connected pump. Stop commands will still occur even if the battery is dead, as long as the Bladder Box is switched ON and the bladder deflates.
4. **Switch the Bladder Box OFF to release stop commands:** In the OFF position, connected equipment is not controlled by the Bladder Box. This is useful for setup and to release a pump in emergencies.
5. **Slight differences in alarm and pump stop:** Due to minute differences between individual switches, no two switches can be made to operate exactly alike. Because of this, there will be very small differences between the bladder diameter when the alarm actuates and external equipment stops. The unit is factory set so that the alarm comes on just before the pump stops.
6. **Check the operation before each use:** Switch the Toggle Switch ON, and check that the pump stops and alarm sounds. Depress the plunger and the alarm should stop and the pump be released.

II. General

Indications

The OriGen Bladder Box is intended to support a silicone bladder and provide an alarm signal when the bladder deflates, in procedures lasting less than six hours.

Contraindications

The OriGen Bladder Box is contraindicated for operation in explosive atmospheres or around Magnetic Resonance Imaging (MRI) equipment or other very strong magnetic fields.

Clinical Uses

Each Institution is responsible for the development and implementation of clinical processes and techniques for the use of this device. Each user is responsible to ensure that this device is used, tested and maintained as described in this Manual and with later revisions that may be published. Use of this device for any purpose other than those indicated places responsibility for performance and results solely with the user.

Manual Conventions

The following text conventions are used throughout this manual:

WARNING:
**AN INSTRUCTION OR PROCEDURE, WHICH IF NOT CARRIED
OUT CORRECTLY, MAY RESULT IN INJURY TO THE TECHNICIAN,
THE PATIENT OR OTHER PERSONNEL.**

CAUTION:
*An instruction or procedure, which if not carried out correctly,
may damage the equipment.*

Non-Sterile: This device is sold NON-STERILE. See the Maintenance section for cleaning procedures.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

III. Device Setup

Overview

The OriGen Bladder Box (Model BB) is designed to support a silicone bladder (the Avecor R-38 or the Avecor R-14 bladder) used in extracorporeal circuits. The Bladder Box can sense the thickness of the bladder by direct contact, and provide an alarm at a user selectable operating point.

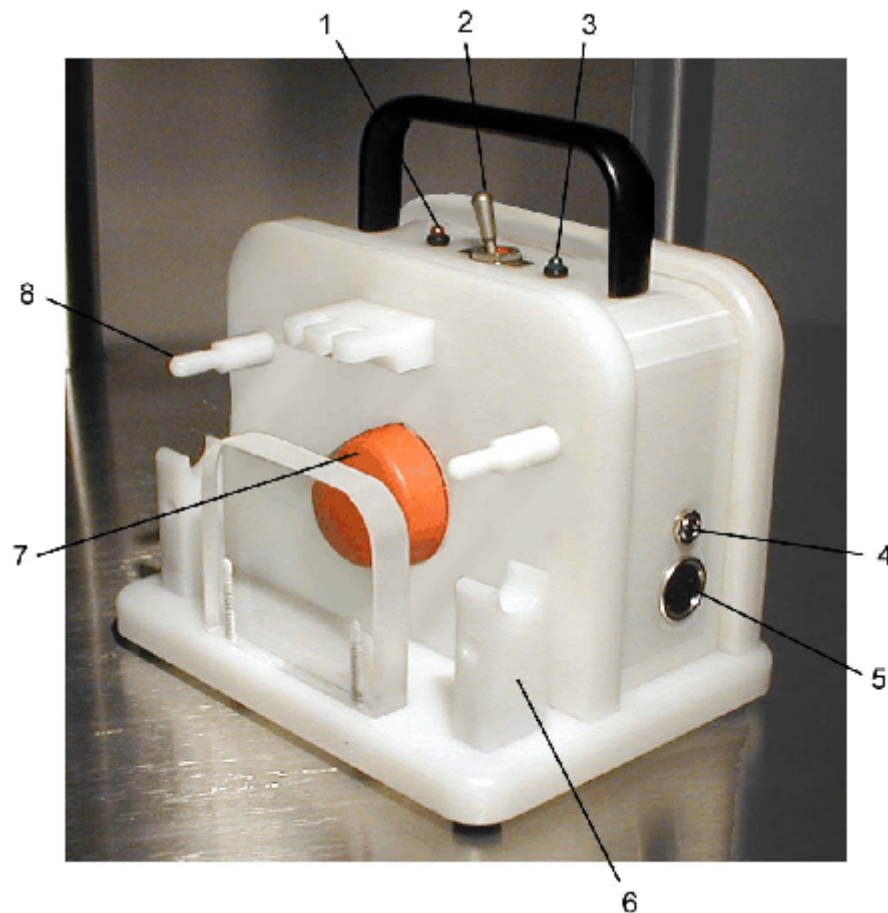


Figure 1

1	Red LED (Alarm)	5	Pump Socket
2	ON-OFF Switch	6	Clamp Saddles
3	Green LED (OK)	7	Diaphragm
4	Charger Socket	8	Mount Pins

Not Shown: Trigger Point Adjustment (Phillips head screw in rear of base)

Operating principle

The silicone bladder fitted in the Bladder Box swells in response to increasing pressure. This bladder is suspended between a fixed clear acrylic plate and a moveable plunger which is behind a flexible diaphragm. As the bladder swells, it moves the plunger which in turn presses against a pair of sealed switches, causing their contacts to open.

Bladder volume is sensed by direct contact with a sliding plunger behind the diaphragm. The plunger has a mushroom head to spread out force over the bladder, and is held against the bladder with light spring pressure. Changes in bladder volume move the sliding plunger back and forth. The end of the sliding rod activates a pair of switches when the bladder diameter is at the trigger point.

The user can set the trigger point (position of switch activation) by adjusting a captive Phillips-head screw in the base at the rear of the Bladder Box. This is the only Phillips head screw on the system.

The Bladder Box contains two internal switches: one which sounds an internal alarm, the other switch is connected to a DIN socket on the Bladder Box. A cable can be attached to this socket for signaling a remote device, such as a pump controller. It is the responsibility of the user to connect this cable to an alarm system of their choice, within the rated electrical capability of the trigger switch.

Connection

If desired, the user can connect the Bladder Box to an external alarm circuit or pump controller. Contact the pump manufacturer or OriGen for pump-specific cables.

CAUTION:

Do not connect the Bladder Box to an electrical circuit with a voltage or current draw exceeding the switch capacity as listed in 'Technical Specifications', below. The switch could be damaged.

Setting the Trigger Point

Set the trigger (alarm) point as follows:

N.B. the Bladder Box has two separate trigger switches which are actuated by a single plunger. As it is practically impossible to adjust these to go off perfectly simultaneously, they are factory set so that **the alarm circuit triggers first**. This is followed by the pump stop command. This may help give the user some notification that the bladder volume is getting low before the pump actually stops.

1. Connect the Bladder Box to the external circuit. Alternately, a battery operated lamp or Ohmmeter can be used to check the operation of the switch connected to the external cable.
2. Install a test bladder to be monitored in the Bladder Box. Connect a length of tubing to each end to form a closed loop.
3. Fill the bladder with water through one of the vent tubes. A stopcock placed on the fill tube will make adjusting the volume easier later on. Vent all air out of the other vent tube, and fill the bladder to the minimum allowed volume or pressure i.e., where you want the alarm to occur. Close the stopcock on the vent tube and evaluate the bladder; it should appear about the same size as it does in normal operation.
4. Adjust the switch to trigger point at this point as follows:
 - A. Switch the internal alarm circuit ON.
 - B. Insert a #2 Phillips screwdriver in the screw head in the middle of the base at the back. Turn the screw **clockwise** until the alarm is ON.
 - C. Slowly turn the screw **counter-clockwise** until the alarm just goes OFF.
5. Check the alarm operation by adding a small volume of liquid back to the bladder and draining the same amount off slowly, ensuring that the alarm comes on.

Calibration is now complete.

IV. Normal Operation

Pump Override: Switch the Bladder Box to the OFF position to silence all alarms and allow a pump connected to the external cable to run. Useful for emergency override or pump setup.

1. Connect the Unit

The OriGen Bladder Box has two internal switches that are toggled ON or OFF by the position of the bladder. One sounds an internal alarm and flashes a warning lamp, the other is connected to the external cable for a user-supplied alarm circuit.

WARNING:
**THE ORIGEN BLADDER BOX IS NOT RATED FOR USE IN
 EXPLOSIVE ATMOSPHERES. DO NOT USE IN THE PRESENCE OF
 FLAMMABLE ANESTHETIC GASES.**

2. Test the system

WARNING:
TEST THE UNIT FOR PROPER OPERATION BEFORE EACH USE.



Figure 2

Switch the Internal alarm ON, using the toggle switch under the handle. Using your finger, move the diaphragm back and forth to check that the alarm circuit triggers reliably. If the alarm point needs to be tested or re-set, see “Setting the Trigger Point”, above.

3. Mount the Bladder

The OriGen Bladder Box (Bladder Box) is intended to be used with the AVecor R-38 or R-14 silicone bladder, cut to a 6" (152 mm) length.

a. R-38 Bladder: Put a tie strap over the R-38 bladder near the end of the connector, close to the wing as shown by the black arrow in Figure 2. Mount the bladder on the pins, centering the bladder between the clear plate and the sensing diaphragm. Connect the circuit tubing to the

bladder per your normal protocol.

Fit the ends of the bladder in the Clamp Saddles, so that the silicone ends are just beyond the saddle outboard edges.

Strap the bladder in place with tie wrap straps by placing the straps through the holes in the saddles, and looping them back up over the bladder tubing, as shown by the white arrow in Figure 2. Snug them down just enough to hold the bladder securely, but not so tight that they crack the connector.

Connect the external circuit to the bladder as required.

- b. **R-14 Bladder:** Start by cutting a 3/4" length of 1/2"x3/8" PVC tubing as a shim, split the tubing, and slip it over the end of the bladder, beyond the connector, as shown by the black arrow in Figure 3.

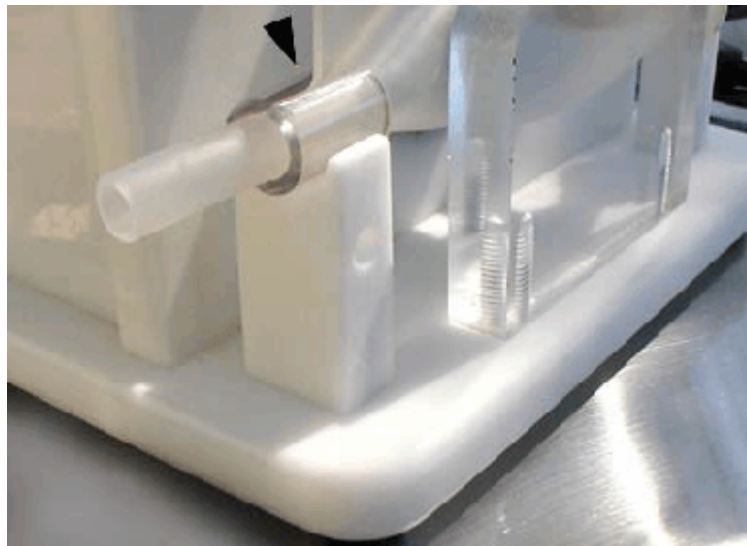


Figure 3

Mount the bladder on the pins, centering the bladder between the clear plate and the diaphragm. A tie strap is then placed through the hole in the Saddle, and over the tubing shim as shown by the black arrow in Figure 4.



Figure 4

Snug the tie straps down just enough to hold the bladder securely, but not so tight that they collapse the tubing. Connect the circuit tubing to the bladder per your normal protocol.

V. Maintenance

Cleaning

The OriGen Bladder Box is made from Acetal Copolymer, which is very resistant to impact damage and is resistant to most cleaners, acids and bases.

CAUTION:

The clear plate is made of acrylic, and may craze or be easily damaged by strong cleaners: be careful when cleaning the clear plate.

The assembly hardware is stainless steel, the diaphragm is silicone rubber, and the Alarm switches are sealed against water splashes. While most cleaners can be safely used, water-based cleaners and disinfectants are recommended. Keep the more aggressive ones away from the diaphragm and the clear plate. If in doubt, try the cleaner on the underside of the base to judge the effect.

CAUTION:

*Do not immerse the OriGen Bladder Box in water.
The unit is resistive to splashes, but is not water tight.*

Note: Ammonia-based cleaners and lengthy exposure to strong sunlight or UV may cause a slight yellowing of the white Delrin plastic. This change in coloration does not cause a significant loss of strength in the polymer.

Trigger Point

If the alarm trigger point needs to be changed, see “Setting the Trigger Point” in Section II.

Periodic Maintenance

The internal micro (trigger) switches and alarm battery should be replaced annually or if the battery no longer holds a charge. OriGen can perform this periodic maintenance, re-calibrate the unit and loan you a replacement unit, if needed, please contact us.

Battery Replacement

To replace the alarm battery, follow these steps.

1. Remove the two 10-24 x 3/4" cap screws holding the rear plate to the base.
2. Remove the two 10-24 x 3.25" cap screws holding the Mount Pins.
3. Remove the rear plate by pushing or tapping it lightly it towards the rear of the system. You may need to cut through the silicone sealing the case joints to remove the back. Have a look at the wiring inside, and be careful not to damage it in the next step.
4. Remove the old battery, releasing it from the velcro holding it down.
5. Slide the old battery out, release it from the connector, and snap in a new 9 V NiMH Battery.
6. Place a new piece of self adhesive velcro on the battery, and press it back into place.
7. Reassembly is the reverse of removal. Use a good grade of silicone sealant to seal the case, available at any hardware store.

Switch Replacement

To replace the switches, follow these steps.

1. Remove the case back as above, steps 1 through 3.
2. Carefully pull back the cover and handle, taking care not to pull any of the wires free.
3. Note the position of the wire connections and unplug the leads. Remove the two 4-40 screws and remove the switch.
4. Adjust the switch roller levers so the switches operate near simultaneously, with the alarm circuit triggering first.
5. Reassembly is the reverse of removal.

VI. Technical Specifications

Dimensions

5.25" x 6.75" x 5.5"H (13.3 x 17.2 x 14 H cm)

Weight

4 pounds (1800 g.)

Electrical

Switch capacity: Honeywell Micro switch, 1 A @ 125 VAC, or 0.1 A @ 30 VDC

NOTE: there are no circuit breakers or fuses in this system

Alarm Battery: Standard 9 V NiMH battery

Note: NiMH batteries do not have 'memory', and can be recharged at any point.

Construction materials

Case: Acetal copolymer; the clear plate is acrylic

Fasteners: Stainless Steel

Case DIN Socket

DIN 3 for direct switch applications

DIN 4 for resistive load applications

Nominal Trigger point (bladder diameter)

0.82" (2.1 cm)

Trigger point adjustment range (bladder diameter)

Nominal Diameter ± 0.2 " ($\pm .51$ cm)

Warranties

Disclaimer of Warranties

This device is warranted to be free from defects in components or workmanship for one year from date of original delivery. Any part found defective shall be replaced or repaired at OriGen's sole discretion. Warranty repairs shall not cover equipment which has been damaged through abuse, neglect or accident. OriGen warrants that reasonable care has been used in the manufacture of this device. This exclusive warranty is in lieu of all other warranties, whether expressed or implied. OriGen makes no other warranty of any kind regarding this product, including, but not limited to, the implied warranty of merchantability and fitness for a particular purpose. As OriGen has no control over the conditions under which this device is used, OriGen shall not be liable for incidental or consequential loss or damage resulting directly or indirectly from the use of this product. OriGen will replace any device which we feel was defective at the time of shipment. No representative of OriGen is authorized to change any aspect of this policy, and further may not assume any additional responsibility or liability in connection with this product.

Responsibility of the Manufacturer

OriGen can only be responsible for the reliability and performance of this device if repairs, adjustments, modifications or retrofit are performed by authorized OriGen maintenance personnel, and the device is used according to the instructions set forth in this manual.

Suggestions

OriGen is constantly seeking to improve its products. If you have comments, suggestions, improvements or questions about the Bladder Box or this manual, we would like to hear from you. Please contact us at the address given below.

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