English

Monitoring Life™

Resonance OverShoot Eliminator Model R.O.S.E.™

INSTRUCTIONS FOR USE

INTENDED USE
The Resonance OverShoot Eliminator Model R.O.S.E.™ is intended to optimize pressure waveform fidelity during invasive pressure monitoring by eliminating overshoot of the pressure signal.

INDICATIONS FOR USE
The Resonance OverShoot Eliminator Model R.O.S.E.™ is indicated for use in patients who require invasive blood pressure monitoring with optimized pressure waveform fidelity.

USER / PATIENT / CLINICAL
User: Qualified nurses, clinicians and physicians
Patient: Pediatric and adult applications
Clinical: Hospitals or appropriate clinical environments

APPLICATION
In general, the R.O.S.E.™ has an application in monitoring systems with tubing lengths of 36 inches and longer. Resonance overshoot errors are most frequently produced in tubing systems within the range of 36 to 72 inches.

Figure 1 shows how the R.O.S.E.™ eliminated a 15 mmHg overshoot error in a 60-inch tubing system.

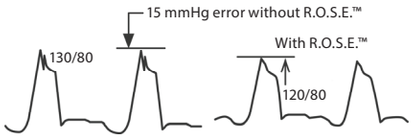

Figure 1. Typical Effect on Arterial Waveform Using the R.O.S.E.™ in a 60-inch Tubing System.

SET-UP PROCEDURE
1. Use aseptic technique and proper setup when handling the device.
2. Before set-up and filling, install R.O.S.E.™ as close to the transducer as possible in the patient line.
   NOTE: If this instruction sheet is included in a set, the R.O.S.E.™ may already be properly configured.
3. Ensure that all connections are tight and proceed with normal filling and set-up of system. The damping capillary of the R.O.S.E.™ must be fluid filled during initial set-up. To evacuate air from capillary, simply activate fast flush mode of the system's flush device three to four times after pressurizing the pressure cuff to the normal 300 mmHg setting. During this initial fast flushing procedure, small air bubbles are visibly being purged from the R.O.S.E.™. When bubbles stop appearing, the R.O.S.E.™ is fully primed and ready for use.When fluid filling monitoring lines without a continuous flush device, use a standard 10mL syringe to prime the R.O.S.E.™. To evacuate air from the R.O.S.E.™ after first filling the system, close a stopcock distal to the R.O.S.E.™ so that fluid cannot be moved through the line, then move the syringe plunger in and out about 1/4-inch three to four times. This slight positive/negative pressure will simulate the fast flushing action of a flush device to evacuate air from the R.O.S.E.™.
4. Connect catheter hub to the fluid filled monitoring line. The R.O.S.E.™ does not require any adjustment for damping.
   CAUTION : Tighten all connections before use. Do not overtighten connections as this may crack the connection resulting in cracks, leaks, air embolism, bleed backs or loss of pressure waveforms.

COMPLICATIONS
Risks associated with the use of this product include: sepsis/infection, other illness and injury, air emboli, bleed-back, and loss of pressure waveform. For further information regarding complications, contact your Merit representative.

CLINICAL BENEFIT
• Optimize pressure waveform by eliminating overshoot pressure signal.

STORAGE CONDITIONS
Store in cool dry place away from direct sunlight.

STERILE and non-pyrogenic in unopened, undamaged package. For single use only. Check integrity of the individual package before use. After use, dispose of device in a manner consistent with standard protocols for waste disposal. Do not resterilize.

Device lifetime is 72 - 96 hours base on CDC & Joint Commission Intl (JCI) recommendation.

Re-use may lead to infection or other illness/ injury.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

For reordering information or assistance please contact local representative.

	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Do not resterilize
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution
	Keep Dry
	Keep away from sunlight
	Non-pyrogenic
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
STERILE EO	Sterilized using ethylene oxide
MD	Medical Device
or	Single Sterile Barrier System or Single sterile barrier system with protective packaging inside
UDI	Unique Device Identifier
PHT DEHP DIBP DBP BBP	Does not Contain DEHP, DIBP, DBP, BBP
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within 7 calendar days, call U.S.A. or EU Customer Service.
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog number
LOT	Batch code

CE 2797

MERITMEDICAL®

www.merit.com

Manufacturer:
Merit Medical Singapore Pte. Ltd.,
198 Yishun Avenue 7,
Singapore 768926

EC REP Authorized Representative:
Merit Medical Ireland Ltd
Parkmore Business Park West, Galway, Ireland
EC Customer Service +31 43 3588222

製造販売元：メリットメディカル・ジャパン株式会社
東京都新宿区西新宿1-26-2

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