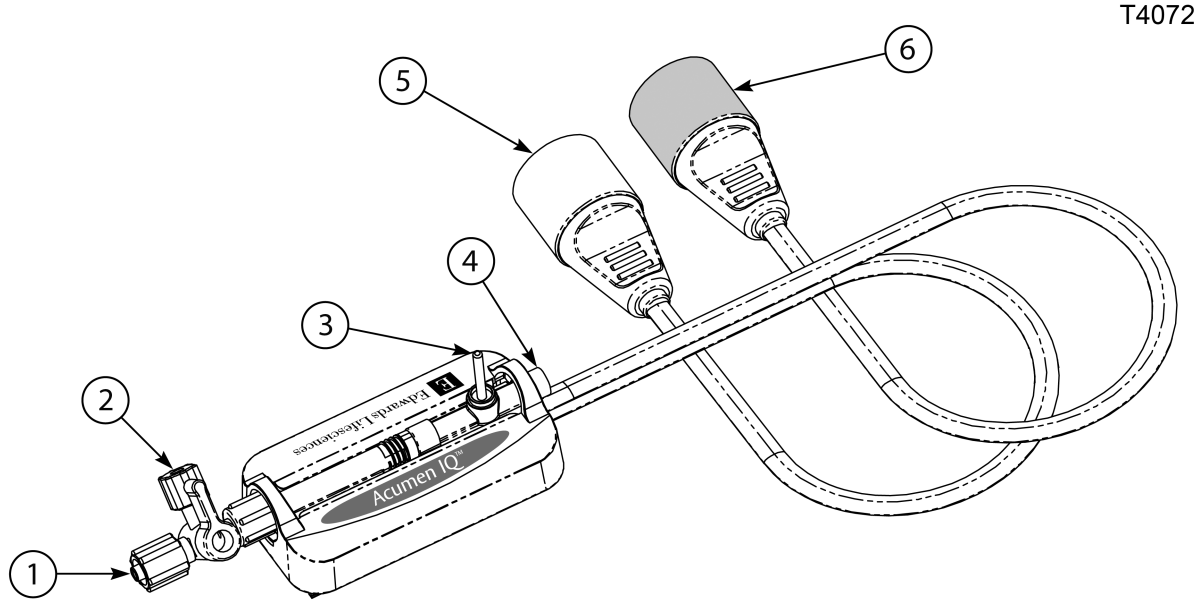
Edwards

Acumen IQ sensor
Model AIQS8S102

The devices described herein may not all be licensed in accordance with Canadian law or approved for sale in your specific region.



Acumen IQ sensor

1. To Patient
2. Sensor Vent Port
3. Snap-Tab Device
4. To IV Set
5. To Pressure monitor (red)
6. To Acumen IQ sensor compatible monitor (green)

For Single Use Only

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

These are general instructions for setting up a pressure monitoring system and/or Edwards compatible hardware with the Acumen IQ sensor. Since kit configurations and procedures vary according to hospital preferences, it is the responsibility of the hospital to determine exact policies and procedures.

CAUTION: The use of lipids with the Acumen IQ sensor may compromise product integrity.

1.0 Concept/Description

The Acumen IQ sensor is a sterile, single use kit that monitors pressures when attached to pressure monitoring catheters. When connected to a compatible monitor, the Acumen IQ sensor minimally-invasively measures cardiac output and key hemodynamic parameters, which assist the clinician in assessing the patient's physiologic status and support clinical decisions related to hemodynamic optimization. They are intended to be used in the surgical and critical care environments by medical professionals who have been trained in the safe use of hemodynamic technologies and clinical usage of arterial line pressure monitoring. The disposable sterile cable with a red connector interfaces exclusively with an Edwards cable that is specifically wired for the pressure monitor being used. The disposable sterile cable with a green connector interfaces exclusively with the Edwards cables for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware.

The Acumen IQ sensor has a straight, flow-through design across the pressure sensors with an integral flush device.

Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

When used with a compatible monitoring platform, the Acumen IQ sensor provides information regarding the hemodynamic status of the patient, which may lead to improved data driven clinical decision making for medically necessary intervention and/or clinical re-evaluation. When used in conjunction with HPI software, the Acumen IQ sensor assists in providing information regarding the likelihood of a patient trending toward a hypotensive event.

2.0 Intended Use/Purpose

The sensors measure an electrical resistance to provide blood pressure and arterial pressure based cardiac output.

3.0 Indications

The Acumen IQ sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output. They are intended to be used in adult patients.

4.0 Contraindications

There are no absolute contraindications for using the Acumen IQ sensor in patients requiring invasive pressure monitoring.

5.0 Warnings

- **Do not allow air bubbles to enter the setup. See complications section of this IFU regarding air emboli and abnormal pressure readings.**
- **Do not use the flush device during intracranial pressure monitoring.**
- **High pressures, which may be generated by an infusion pump at certain flow rates, may override the flush device restriction, resulting in fast flushing at the rate set by the pump.**
- **Avoid contact with any topical cream or ointment that attacks polymeric materials. May affect product integrity.**
- **Do not expose electrical connections to fluid contact. May result in electrical shock to user or patient, and/or arrhythmia.**
- **Do not autoclave the reusable cable as it may affect product integrity.**

- **This device is designed, intended, and distributed for single use only. Do not re-sterilize or reuse this device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.**
- **Compliance to IEC 60601-1 is only maintained when the Acumen IQ sensor is connected to a patient monitor or equipment that has a Type CF defibrillation proof rated input connector. If attempting to use a third party monitor or equipment, check with the monitor or equipment manufacturer to ensure IEC 60601-1 compliance and compatibility with the Acumen IQ sensor. Failure to ensure monitor or equipment compliance to IEC 60601-1 and Acumen IQ sensor compatibility may increase the risk of electrical shock to the patient/operator.**
- **Do not modify or alter the product in any way. Alteration or modification may affect patient/operator safety or product performance.**
- **For a patient undergoing an MRI examination, please refer to the MRI Safety Information section for specific conditions to ensure patient safety.**
- **This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: DBMC; CAS No. 119-47-1; EC No. 204-327-1. Current scientific evidence supports that medical devices manufactured from Isoprene rubber do not cause an increased risk of cancer or adverse reproductive effects.**

6.0 Procedure

1. Ensure that the cables are compatible with the monitors being used. Connect the reusable cables to the monitors, and turn the monitors on to allow the electronics to warm up.
2. Using aseptic technique, remove the sensor and kit from the sterile packaging.

   CAUTION: Modifying any Acumen IQ kit may reduce dynamic response resulting in compromised hemodynamic monitoring performance.
3. Ensure that all connections are secure but are not overtightened.
4. Connect the sensor cable with the red shield to the reusable cable appropriate for the pressure monitor.
5. Connect the sensor cable with the green shield to the Edwards' Acumen IQ connecting cable.
6. Remove all air from the IV flush solution bag.

   CAUTION: If all air is not removed from the bag, air may be forced into the patient's vascular system when the solution is exhausted. See complications section of this IFU regarding air emboli.
7. Heparin anticoagulation therapy to be administered per hospital protocol.
8. Close the roller clamp on the IV set and connect the IV set to the IV flush bag. Hang the bag approximately 2 feet (60 cm) above the patient. This height will provide approximately 45 mmHg of pressure to prime the setup.
9. Fill the drip chamber halfway with flush solution by squeezing the drip chamber. Open the roller clamp.
10. Flow is provided by pulling on the Snap-Tab device and discontinued by releasing the Snap-Tab device.
11. Prime system using gravity only (do not pressurize bag) to decrease fluid turbulence and mitigation of bubbles.
12. For kits with IV sets attached, open the sensor vent port by turning the stopcock handle. Deliver flush solution first through the sensor and out through the vent port, then through the remaining kit by turning the appropriate stopcocks. Remove all air bubbles.

    CAUTION: Significant distortion of the pressure waveform or air emboli can result from air bubbles in the setup. See complications section of this IFU regarding air emboli.
13. Replace all vented caps on sideports of the stopcocks with nonvented caps.
14. Mount the sensor on an IV pole using the appropriate clamp and holder. Snap sensor into place in holder.
15. Pressurize IV flush solution bag after initial gravity prime. Flow rate will vary with pressure across the flush device. The flow rate with the IV bag pressurized to 300 mmHg: 3 ± 1 ml/hr.
16. Connect pressure tubing to the catheter per manufacturer's instructions.
17. Flush system per hospital policy.

    CAUTION: After each fast-flush operation, observe the drip chamber to verify that the continuous flush rate is as desired. See complications section of this IFU regarding clotted catheter and bleed-back, and overinfusion.

7.0 Zeroing and Calibration

1. Adjust the level of the sensor vent port (the fluid-air interface) to correspond to the chamber where pressure is being measured. For example, in cardiac monitoring, zero at level of the right atrium. This is at the phlebostatic axis, determined by the intersection of the midaxillary line and the fourth intercostal space.
2. Remove the non-vented cap from the stopcock above the transducer and open the sensor vent port to the atmosphere while maintaining sterility of both the inside of the cap and port.
3. Zero both the bedside monitor and the Edwards monitoring system to the atmospheric air per monitor's instructions.
4. Close the vent port to the atmosphere and then replace the non-vented cap.
5. The system is ready to begin monitoring.

8.0 Testing Dynamic Response

The assembly may be tested for dynamic response by observing the pressure waveform on an oscilloscope or monitor. Bedside determination of the dynamic response of the catheter, monitor, kit, and sensor system is done after the system is flushed, attached to the patient, zeroed, and calibrated. A square-wave test may be performed by pulling the Snap-Tab device and releasing quickly.

Note: Poor dynamic response can be caused by air bubbles, clotting, excessive tubing length, excessively compliant pressure tubing, small bore tubing, loose connections, or leaks.

9.0 Routine Maintenance

Follow hospital policies and procedures for frequency of zeroing the sensor and pressure monitor and for replacing and maintaining pressure monitoring lines. The Acumen IQ sensor is precalibrated and has a negligible drift with time (see **Specifications**).

1. Adjust zero pressure reference each time level of the patient is changed.

   CAUTION: When rechecking zero or verifying accuracy, ensure that the non-vented cap is removed before opening the sensor vent port to the atmosphere. See complications section of this IFU regarding abnormal pressure readings.
2. Periodically check fluid path for air bubbles. Ensure that connecting lines and stopcocks remain tightly fitted.
3. Periodically observe the drip chamber to verify that the continuous flush rate is as desired.
4. The Centers for Disease Control recommends replacing disposable or reusable transducers at 96-hour intervals. Replace other components of the system, including the tubing, continuous-flush device, and flush solution, at the time the sensor is replaced.

10.0 MRI Safety Information

MR Conditional

The following device was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International Designation: F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

10.1 Acumen IQ sensors

Non-clinical testing demonstrated that the Acumen IQ sensor is MR Conditional according to the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) or less
- This device and the associated cable are not intended for use inside of the bore of the MR system and should not be in direct contact with the patient; failure to follow this guideline may result in a serious patient injury
- This device and the associated cable may be in the MR system room but not in operation or connected to a pressure monitoring system during an MRI examination
- The pressure tubing connected to the Acumen IQ sensor is MR Safe and can be placed inside of the bore of the MR system during an MRI examination

11.0 Complications

Device risks may include hypervolemia, blood loss, and/or patient burn.

11.1 Sepsis/Infection

Positive cultures can result from contamination of the pressure setup. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusing fluids, and catheter related thrombosis.

11.2 Air Emboli

Air can enter the patient through stopcocks that are inadvertently left open, from accidental disconnection of the pressure setup, or from flushing residual air bubbles into the patient.

11.3 Clotted Catheter and Bleed-Back

If the flush system is not adequately pressurized relative to the patient's blood pressure, blood bleed-back and catheter clotting may occur.

11.4 Overinfusion

Excessive flow rates may result from pressures greater than 300 mmHg. This may result in a potentially harmful increase in blood pressure and fluid overdose.

11.5 Abnormal Pressure Readings

Pressure readings can change quickly and dramatically because of loss of proper calibration, loose connection, or air in the system.

CAUTION: Abnormal pressure readings should correlate with the patient's clinical manifestations. Verify system integrity before instituting therapy.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

12.0 How Supplied

The Acumen IQ sensor is supplied sterile in preconnected monitoring kits. Contents are sterile and the fluid path is nonpyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Do not re-sterilize. Visually inspect for breaches of packaging integrity prior to use.

This device is designed, intended and distributed for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE this device. There are no data to support the sterility, non-pyrogenicity and functionality of the device after reprocessing. Such action could lead to illness or an adverse event as the device may not function as originally intended.

13.0 Storage

Store in a cool, dry place.

14.0 Shelf Life

The shelf life is as marked on each package. Storage or usage beyond the expiration date may result in product deterioration and could lead to illness or an adverse event as the device may not function as originally intended.

15.0 Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

16.0 Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 - Option 4

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

Prices, specifications, and model availability are subject to change without notice.

Refer to the latest version of the monitoring system operator's manual for more information.

Refer to the symbol legend at the end of this document.

Product bearing the symbol:

has been sterilized using Ethylene Oxide.

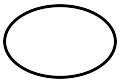
17.0 Specifications*

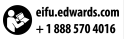
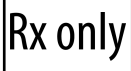
Acumen IQ sensor	
Operating Pressure Range	-50 to +300 mmHg
Operating Temperature Range	15 to 40 °C
Sensitivity	5.0µ V/V/mmHg ± 1%
Nonlinearity and Hysteresis	± 1.5% of reading or ± 1 mmHg, whichever is greater
Excitation Frequency	dc to 5,000 Hz
Excitation Impedance	350 ohms ± 10% with typical Edwards Monitor Cable attached
Phase Shift	<5°
Signal Impedance	300 ohms ± 5%
Zero Offset	≤ ± 25 mmHg
Zero Thermal Drift	≤ ± 0.3 mmHg/°C
Output Drift	± 1 mmHg per 8 hours after 20 second warm-up
Sensitivity Thermal Drift	≤ ± 0.1%/°C
Natural Frequency	40 Hz nominal for a standard kit (48"/12") (122 cm/30.5 cm); >200 Hz for sensor alone
Defibrillator Challenge	withstands 5 repeated discharges of 360 Joules within 5 minutes delivered into a 50 ohm load
Leakage Current	<2µ amps at 120V RMS 60 Hz
Overpressure Tolerance	-500 to +5000 mmHg
Shock Resistance	withstands 3 drops from 1 meter
Light Sensitivity	< 1 mmHg at 6 volts excitation when exposed to a 3400°K tungsten light source at 3000 foot candles (32,293 lumen/m^2)
Volumetric Displacement	≤0.03 mm^3/100 mmHg for transducer without flush device
Flow rate across flush device with IV bag pressurized to 300 mmHg Blue Snap-Tab device	3 ± 1 ml/hr

*at 6.00 VDC and 25 °C unless otherwise stated.

All specifications meet or exceed the AAMI BP22 Standard for performance interchangeability of resistance bridge type blood pressure transducers.

Symbol Legend

	English
	Model Number
	Caution
	Single use
	Quantity
	Lot Number
	Use-by date
	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not use if package is damaged and consult instructions for use

	English
	Manufacturer
	Date of manufacture
	Do not resterilize
	Follow Instructions for Use on the website
	Non-pyrogenic
	MR Conditional
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Contains hazardous substances
	Importer

	English
	Store in a cool, dry place
	Contents
	Medical device
	Unique device identifier
	Pressure Tubing
	VAMP needleless sample site
	VAMP 5ml blood reservoir

Note: Not all symbols may be included in the labeling of this product.

Made in Dominican Republic
CCT Critical Care Technologies S.R.L.
Parque Industrial Itabo
Km 18.5 Carr. Sanchez
Haina, San Cristobal, Dominican Republic

02/26
60061176001 A / DOC-0581618 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Edwards Lifesciences B.V.
Verlengde Poolseweg 16
4818 CL Breda, Netherlands

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU