Edwards

Acumen IQ Fluid Meter

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device. Refer to the HemoSphere advanced monitor operator's manual, available at eifu.edwards.com, for comprehensive monitoring procedures.

For Single Use Only

1.0 Description

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.

The Acumen IQ fluid meter (reference Figure 1) is a sterile, single use device that measures the flow of fluid delivered to a patient through the intravenous line to which it is connected. When connected to a compatible monitor via the reusable Acumen AFM cable (reference Figure 2), the Acumen IQ fluid meter automatically tracks the fluid being administered to the patient and provides that data to the Assisted Fluid Management (AFM) software feature.

The Acumen IQ fluid meter only operates when used with an Acumen IQ sensor and is part of the AFM software feature. The AFM software feature is intended to work with a single Acumen IQ fluid meter at a time. Refer to the Acumen IQ sensor instructions for use (IFU) for more details on the sensor; refer to the HemoSphere advanced monitor for details on the AFM software feature.

2.0 Intended Use/Purpose

The Acumen IQ fluid meter is a sterile single use device that is intended to be used with the Acumen AFM cable and AFM software feature to inform the user of the rate of flow. The device is intended to be used by qualified personnel or clinicians in a clinical setting for up to 24 hours.

3.0 Indications

The Acumen IQ fluid meter is indicated for surgical patients over 18 years of age to track the fluid being administered to the patient, when used with a compatible hemodynamic monitoring platform.

4.0 Contraindications

There are no contraindications for using the Acumen IQ fluid meter.

5.0 Warnings

- The Acumen IQ fluid meter, when used with Acumen AFM cable and Acumen AFM software feature, should not be used exclusively to treat the patient. A review of the patient's hemodynamics is recommended prior to initiating treatment.
- The Acumen IQ fluid meter is MR Conditional. For a patient undergoing an MRI examination, please refer to the MRI Safety Information section for specific conditions to ensure patient safety.
- Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance.
- 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.
- If all air is not removed from the intravenous flush solution bag, air may be forced into the patient's vascular system when the solution is exhausted.
- If there are air bubbles in the intravenous line, there might be an impact to the fluid meter accuracy.
- Do not allow air bubbles to enter the setup as air bubbles may lead to air emboli.
- The Acumen IQ fluid meter should not be used for more than 24 hours. Use of the Acumen IQ fluid meter for more than 24 hours may compromise accuracy of the fluid meter measurement.
- This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.
- The Acumen IQ fluid meter accuracy is affected by the fluid type and the rate of fluid delivery. The use of the Acumen IQ fluid meter could result in delivery of more than the intended amount per the performance specification provided in Table 1.

6.0 Precautions

The Acumen IQ fluid meter is not compatible with blood products. The Acumen IQ fluid meter is only compatible with the following IV solutions:

- Sodium Chloride Injection 0.9% (NaCl 0.9%)
- Ringer's lactate solution (RL), also known as sodium lactate solution and Hartmann's solution
- PlasmaLyte
- Dextran 40
- Albumin 5%
- Hetastarch 6%

Use of the Acumen IQ fluid meter with blood products or any other solution or medication may compromise accuracy of the fluid meter measurement.

7.0 Complications

There are some risks related to fluid management, which include, but are not limited to, the following:

- Pulmonary edema
- Pleural effusion
- Bladder rupture
- Myocardial Injury after Noncardiac Surgery (MINS)
- Renal-replacement therapy
- Acute kidney injury
- Anastomic leakage (for bowel surgery)
- Stoma necrosis
- Surgical site infection

Additional risks associated with the use of the device when used with a connected compatible monitor:

- Hypervolemia
- Hypovolemia
- Sepsis/Infection
- Air emboli
- Patient or clinician burns or electrical shock
- Tissue damage

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.

8.0 Compatible Devices

The Acumen IQ fluid meter is intended to be used in conjunction with a compatible Edwards HemoSphere advanced monitor, the Acumen AFM cable, and Edwards approved sensors/ closed blood sampling system as part of the Assisted Fluid Management (AFM) solution.

Note: Refer to the HemoSphere advanced monitor operator's manual, available at eifu.edwards.com, for comprehensive monitoring procedures and information on use of the Acumen AFM cable and Acumen AFM software feature.

9.0 Equipment

The Edwards Acumen IQ fluid meter can be provided as part of a kit.

9.1 Kit Components

The kits may be comprised of the following components or accessories:

- Tubing
- Stopcocks
- Caps
- Acumen IQ sensor
- TruWave disposable pressure transducer
- VAMP closed blood sampling system

Note: Refer to the Acumen IQ sensor, TruWave disposable pressure transducer and VAMP closed blood sampling system Instructions for Use for instructions on how to use these devices.

9.2 Additional Components Required

- Intravenous (IV) set
- Venous catheter
- IV solution

9.3 Compatible IV Solutions

- Sodium Chloride Injection 0.9% (NaCl 0.9%)
- Ringer's lactate solution (RL), also known as sodium lactate solution and Hartmann's solution
- PlasmaLyte
- Dextran 40
- Albumin 5%
- Hetastarch 6%

10.0 Procedure

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

Step	Procedure
1	Remove the Acumen IQ fluid meter from the sterile packaging.
2	Place Acumen IQ fluid meter in line with the intravenous set ensuring connections as illustrated in Figure 3 on page 4. Ensure connections are secure but not overtightened. **Precaution: The Acumen IQ fluid meter is not compatible with blood products. The Acumen IQ fluid meter is only compatible with the following IV solutions:** • **Sodium Chloride Injection 0.9% (NaCl 0.9%)** • **Ringer's lactate solution (RL), also known as sodium lactate solution and Hartmann's solution** • **PlasmaLyte** • **Dextran 40** • **Albumin 5%** • **Hetastarch 6%** **Use of the Acumen IQ fluid meter with blood products or any other solution or medication may compromise accuracy of the fluid meter measurement.**
3	Remove all air from the intravenous flush solution bag. **WARNING: If all air is not removed from the intravenous flush solution bag, air may be forced into the patient's vascular system when the solution is exhausted.** **WARNING: If there are air bubbles in the intravenous line, there might be an impact to the fluid meter accuracy.**
4	Close the roller clamp on the intravenous set and connect the intravenous set to the intravenous 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.
5	Fill the drip chamber halfway with flush solution by squeezing the drip chamber. Open roller clamp.
6	Prime system using gravity only to decrease fluid turbulence and mitigation of bubbles.
7	Mount the Acumen IQ fluid meter on an IV pole in a vertical position using the appropriate clamp and holder. Slide into place in holder.
8	Connect the extension tubing to venous catheter per manufacturer instructions.
9	Flush system per hospital policy. **Precaution: If flushing system with a non-compatible IV solution, flush from a port that is distal to the fluid meter. Flushing with a non-compatible IV solution through the fluid meter may compromise accuracy of the fluid meter measurement.**
10	Connect the Acumen AFM cable to a compatible HemoSphere advanced monitor at the end indicated by ① in Figure 2 on page 4.
	Note: Refer to the HemoSphere advanced monitor operator's manual, available at eifu.edwards.com, for comprehensive monitoring procedures and information on use of the Acumen AFM software feature.
11	Setup and initiate the compatible HemoSphere advanced monitor.
12	Connect the Acumen IQ fluid meter to the end of the Acumen AFM cable indicated by ② in Figure 2 on page 4.
13	When unplugging the Acumen IQ fluid meter from the Acumen AFM cable, always pull at the connection site. Do not pull from cable or use tools to disconnect.

11.0 MRI Safety Information

MR Conditional

WARNING: The Acumen IQ fluid meter shall not be connected to the Acumen AFM cable and HemoSphere Advanced Monitor during an MRI examination. Failure to follow this guideline may result in a serious patient injury.

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, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

11.1 Acumen IQ fluid meter

Non-clinical testing demonstrated that the Acumen IQ fluid meter is MR Conditional under the following conditions:

- Static magnetic field of 3.0 T or less.
- Maximum spatial gradient magnetic field of 3,000 gauss/cm (30 T/m).
- The Acumen IQ fluid meter is not intended for use inside the bore of the MR system and should not be in direct contact with the patient.
- The device may be in the MR system room but not in operation or connected to a monitoring system during an MRI examination.
- All parts of the Acumen IQ fluid meter should be at least 4 cm from the imaging region.

Metal in the Acumen IQ fluid meter is non ferro-magnetic. Using ASTM F2052 and ASTM F2213, there was minimal magnetic force and torque in a 3T MR system.

Image artifact was tested using sequences in ASTM F2119. Artifact was discernible at distances of up to 4 cm from the Acumen IQ fluid meter.

Precaution: Follow the conditions for safe scanning for any accessory devices that are connected to the Acumen IQ fluid meter. If the MR safety status for the accessory devices is not known, assume they are MR Unsafe and do not allow them to enter the MR environment.

12.0 Maintenance

Periodically check fluid path for air bubbles. Ensure that connecting lines and stopcocks remain tightly fitted.

WARNING: Do not allow air bubbles to enter the setup as air bubbles may lead to air emboli.

Periodically observe the drip chamber to verify that the continuous flush rate is as desired.

Follow hospital policies and procedures for replacing and maintaining IV/pressure monitoring/fluid lines.

WARNING: The Acumen IQ fluid meter should not be used for more than 24 hours. Use of the Acumen IQ fluid meter for more than 24 hours may compromise accuracy of the fluid meter measurement.

Do not steam, radiate, or EtO sterilize the device. Do not immerse.

13.0 How Supplied

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

14.0 Storage

Store in a cool, dry place.

15.0 Specifications

15.1 Operating Conditions/Use Environment

Temperature Range: 10 to 37 °C

Humidity range: 20 - 80% non-condensing

Altitude (Atmospheric Pressure):
0 m/0 ft (1013 hPa) to 3048 m/10,000 ft (697 hPa)

IP Rating: IPX4

16.0 Shelf Life

The recommended shelf life for the Acumen IQ fluid meter is 24 months from the date of manufacture.

17.0 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

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.

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

18.0 Disposal

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

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

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

Product bearing the symbol:

has been sterilized using Ethylene Oxide

Table 1: Acumen IQ fluid meter Performance Specification

Liquid	Flow Rate (mL/min)		
	Low Flow (0-50)	Medium Flow (50-100)	High Flow (100-150)
Plasmalyte	-1.5 ± 1.4%	-0.6 ± 2.2%	-1.4 ± 1.5%
NaCl 0.9%	1.6 ± 1.8%	2.1 ± 1.6%	1.3 ± 2.4%
Lactated Ringers	-0.0 ± 3.1%	1.0 ± 2.7%	0.2 ± 2.8%
Dextran 40	-6.2 ± 1.8%	-5.1 ± 5.1%	-7.8 ± 2.5%
HESPAN (Hetastarch 6%)	-2.7 ± 2.1%	-3.2 ± 1.8%	-3.4 ± 2.1%
Albumin 5%	-0.9 ± 1.6%	-1.8 ± 2.0%	-2.1 ± 2.8%

**Accuracy tested under laboratory conditions*

Figures

Figure 1: Acumen IQ Fluid Meter

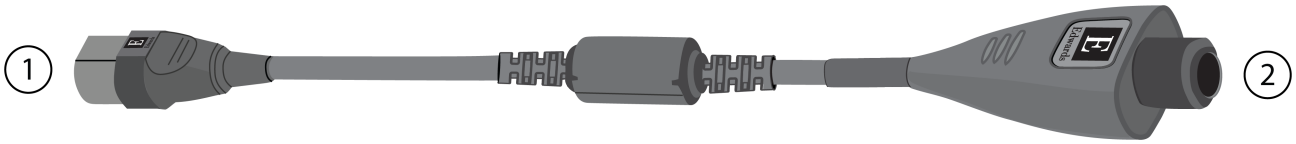
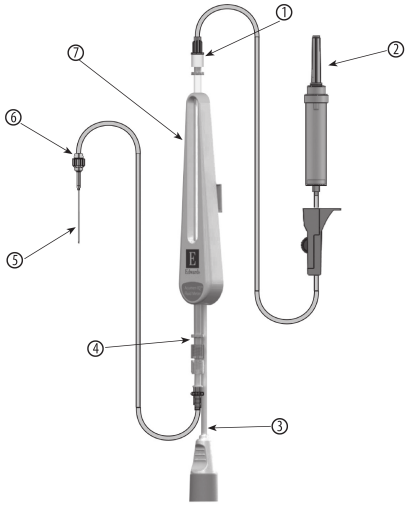


Figure 2: Acumen AFM cable



Tubing attachments proximal and distal to the fluid meter can be configured per hospital policy.

1. Connects to IV line
2. To IV bag
3. Connects to AFM cable
4. Connects to tubing
5. To patient
6. Venous catheter
7. Acumen IQ fluid meter

Figure 3: The Acumen IQ fluid meter connected to an IV line and tubing/Venous catheter

Symbol Legend

	English
#	Model Number
eifu.edwards.com + 1 888 570 4016	Follow instructions for use on the website
	Consult instructions for use
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community/European Union
LOT	Lot Number
MR	MR Conditional
IPX4	Provides protection against water splashing in any direction to IPX4 standard

	English
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not re-use
STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged and consult instructions for use
CE 0123	Conformité Européenne (CE Mark)
MD	Medical device
	Use-by date
	Caution
QTY	Quantity

	English
	Importer
	Non-pyrogenic
STERILIZE	Do not resterilize
	Single sterile barrier system
	Contains hazardous substances
UDI	Unique device identifier
	Store in a cool, dry place

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

EC REP

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