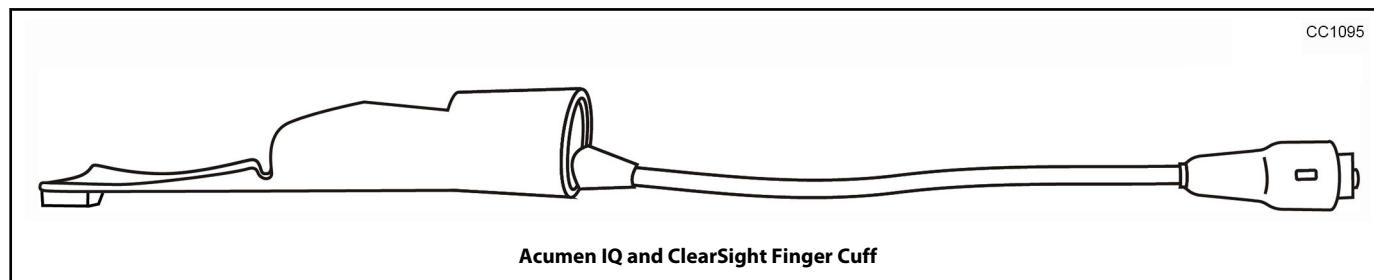




Edwards

Acumen IQ Finger Cuff ClearSight Finger Cuff

AIQCS, AIQCM, AIQCL, CSC2S, CSC2M, CSC2L



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

1.0 Description

The Acumen IQ and ClearSight finger cuffs, when used with an appropriate Edwards monitoring system, provide continuous, noninvasive hemodynamic monitoring. The Acumen IQ and ClearSight finger cuffs utilize the volume-clamp method to measure blood pressure with an inflatable bladder wrapped around the middle phalanx of the finger.

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 ClearSight system provides continuous blood pressure measurement in a non-invasive manner.

2.0 Indications

The Acumen IQ and ClearSight finger cuffs are indicated for patients over 18 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with EV1000 clinical platform NI HemoSphere advanced monitoring platform or HemoSphere Alta Advanced Monitoring Platform.

3.0 Contraindications

In some patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be

present in patients with Raynaud's disease, blood pressure measurement can become impossible.

4.0 Single Patient Use

The Acumen IQ and ClearSight finger cuffs are designed for single patient use. Upon starting measurement, the finger cuff can be used and re-applied for up to 72 hours on one patient. After 8 hours of continuous monitoring on a single finger, the finger cuff should be re-applied to another finger.

Do not attempt to clean and reuse the finger cuff on more than a single patient.

5.0 Warnings

- **Improper placement, sizing, or alignment of the finger cuff can lead to inaccurate monitoring.**
- **Do not apply the finger cuff on injured skin as this may cause further injury.**
- **To reduce the risk of skin irritation and tissue damage, do not monitor longer than 8 hours continuously on a single finger. To continue to monitor beyond 8 hours, use an additional finger cuff on another finger or move the cuff in use to another finger.**
- **Do not use two finger cuffs simultaneously on the same finger.**
- **Measurement on one finger in contradiction with the instructions for use may affect patient comfort and/or lead to minor injuries.**
- **Do not apply finger cuff(s) on a hand or finger when external constriction (that may prevent circulation to the hand or finger) is present.**
- **Do not apply finger cuff(s) on a hand or finger when a second blood pressure measurement device is actively monitoring on the same arm (or hand or finger).**
- **Do not use the finger cuff with magnetic resonance imaging.**

6.0 Cautions

- Do not use a damaged finger cuff. This may result in inaccurate measurements or may damage the Edwards monitoring system.
- Never bend a finger cuff to a flat shape as it will damage the finger cuff and affect measurement accuracy.
- Excessive ambient lighting may interfere with the finger cuff measurement. Avoid using the finger cuff under close, direct lighting.
- Always disconnect the finger cuff when it is not applied to a finger, to prevent damage by accidental overinflation.
- The effectiveness of the finger cuffs have not been established in pre-eclamptic patients.

7.0 Instructions for Use

Refer to Figure 1 on page 3 through Figure 5 on page 3 for figures corresponding to the steps below.

7.1 Size the Finger

Step	Procedure
1	Use the finger cuff sizing aid by wrapping it around the middle phalanx of the index, middle, or ring finger of the patient and pull the smaller end of the color-coded aid through the slot until snug (Figure 1 and Figure 2).
2	Based on the size indicated on the sizing aid, select the appropriate size finger cuff.

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7.2 Apply the Finger Cuff

Step	Procedure
1	Gently open the finger cuff and place the finger cuff on the middle phalanx of the sized finger. Ensure the finger cuff is centered between the second and third knuckles, and the two green lines on the inside of the finger cuff (Figure 3). Note: Do not apply the finger cuff on the thumb, small finger, or previously fractured fingers.
2	Align the distal end of the finger with the center line of the alignment tab on the finger cuff (Figure 3).
3	Allow the finger cuff to close around the finger (Figure 4). Ensure that the finger cuff remains aligned and does not rotate.
4	Remove the adhesive backing from the finger cuff and secure around the finger (Figure 4-A). Remove the adhesive backing from the distal end of the alignment tab and secure to the top of the finger cuff (Figure 4-B).
5	Lead the finger cuff cable between two fingers to the back side of the hand (Figure 5).

7.3 Connect the Finger Cuff to the System

Step	Procedure
1	Plug the finger cuff connector into the pressure controller (Figure 5). Refer to the pressure controller instructions for use for more details.
2	If using a heart reference sensor (HRS), attach the finger end of the HRS to the HRS tab on top of the finger cuff (Figure 5). Refer to the HRS instructions for use for more details.
3	Initiate monitoring with the connected Edwards noninvasive monitoring system. To enable advanced parameters, refer to the monitoring system operator's manual for more details.
4	If using double cuff monitoring, repeat all previous steps to apply the second finger cuff.

8.0 Recommendations

The Edwards noninvasive monitoring system will pause blood pressure measurements periodically per the monitoring system configuration settings. At this time, the fingertip should be checked for perfusion and potential tissue damage. The fingertip should also be checked periodically according to hospital protocol.

9.0 MRI Safety

This device is MR-unsafe and poses hazards in the MRI environment. This device contains metallic components, which can experience RF-induced heating in the MRI environment.

10.0 Storage Conditions

Store in a cool, dry place away from direct sunlight.

Temperature: -18 ° to 40 °C

Humidity: 10% to 90% RH

11.0 Disposal

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

12.0 Models

Model Number *	Model Description
AIQCS	Acumen IQ Finger Cuff Small
AIQCM	Acumen IQ Finger Cuff Medium
AIQCL	Acumen IQ Finger Cuff Large
CSC2S	ClearSight Finger Cuff Small
CSC2M	ClearSight Finger Cuff Medium
CSC2L	ClearSight Finger Cuff Large

* All models may not be available in all regions.

13.0 Warranty

The Acumen IQ and ClearSight finger cuffs are for single patient use only. The Acumen IQ and ClearSight finger cuffs are warrantied at time of delivery to the end user only. The Acumen IQ and ClearSight finger cuffs are a non-serviceable part.

14.0 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.

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

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.

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

Figures

CC1105

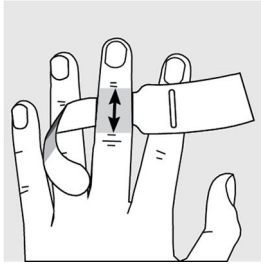


Figure 1: Size the finger.

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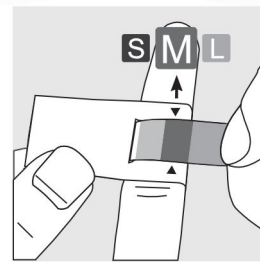


Figure 2: Select the finger cuff size.

CC1098

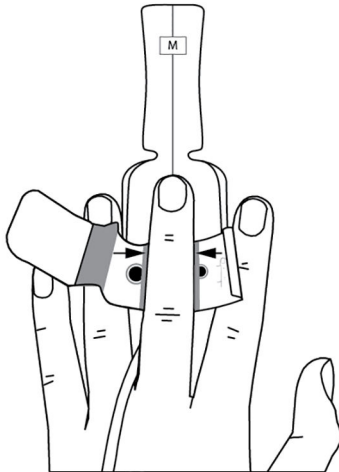


Figure 3: Apply the finger cuff.

CC1128

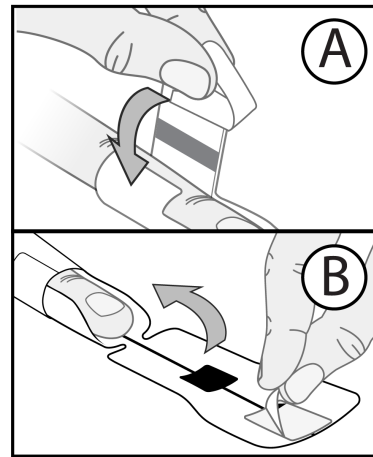


Figure 4: Secure the finger cuff.

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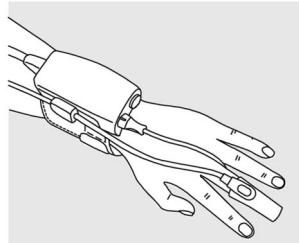



























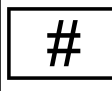



Figure 5: Connect the finger cuff to the system.

Symbol Legend

	English
	Keep away from sunlight
	Fragile, handle with care
	Keep dry
	Small
	Medium
	Large
	Manufacturer
	Use-by date
	Do not re-use
	Date of manufacture

	English
	Lot Number
	Temperature limit
	Humidity Limitation
	Non-sterile
	Authorized representative in the European Community/European Union
	Quantity
	Caution
	Follow instructions for use
	Follow instructions for use on the website
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

	English
	Medical device
	MR Unsafe
	Separate collection for electrical and electronic equipment in accordance with EC Directive 2012/19/EU
	Conformité Européenne (CE Mark)
	Importer
	Do not use if package is damaged and consult instructions for use
	Store in a cool, dry place
	Model Number
	Unique device identifier

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



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