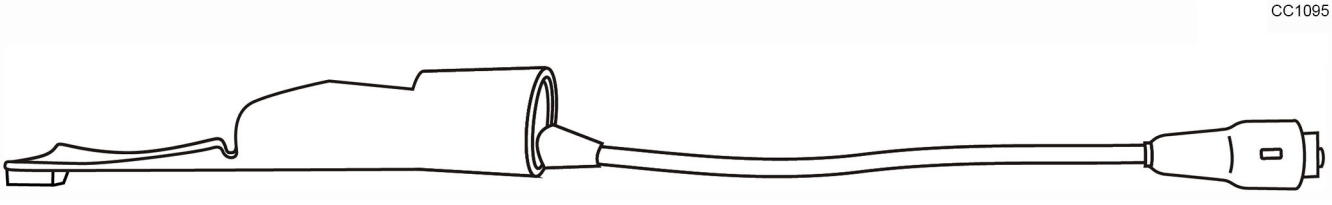
Edwards

VitaWave Finger Cuff Adult

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

VWCA



VitaWave Finger Cuff Adult

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

1.0 Description

The VitaWave finger cuff adult, when used with an appropriate Edwards monitoring system, provides continuous, noninvasive hemodynamic monitoring and the applicable derived parameters. The VitaWave finger cuff utilizes the volume-clamp method to measure blood pressure with an inflatable bladder wrapped around the middle phalanx of the index, middle or fourth/ring finger. This device is supplied non-sterile. Potential risks include inappropriate/unintended treatment, adverse reaction to device materials, patient or clinician burns or electrical shock, peripheral ischemia, and/or minor tissue damage.

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.

Device is used by clinicians who have been trained in safe use of noninvasive hemodynamic technologies in accordance with their institutional guidelines.

2.0 Intended Use/Purpose

The intended purpose is to noninvasively measure blood pressure and use the information to derive hemodynamic parameters when connected to a HemoSphere advanced monitoring platform.

3.0 Indications

The VitaWave finger cuff is indicated for patients over 18 years of age to noninvasively measure blood pressure and associated hemodynamic parameters when used with a HemoSphere advanced monitoring platform.

4.0 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.

5.0 Single Patient Use

The VitaWave finger cuff is 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, such action could lead to illness or an adverse event as the device may not function as originally intended.

6.0 Warnings

- **Improper placement 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.**

7.0 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.**

8.0 Instructions for Use

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

8.1 Apply the Finger Cuff

Step	Procedure
1	Gently open the finger cuff and place the finger cuff on the middle phalanx of the index, middle or fourth/ring 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 1). **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 1).
3	Allow the finger cuff to close around the finger (Figure 2). 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 2-A). Remove the adhesive backing from the distal end of the alignment tab and secure to the top of the finger cuff (Figure 2-B).
5	Lead the finger cuff cable between two fingers to the back side of the hand (Figure 3).

8.2 Connect the Finger Cuff to the System

Step	Procedure
1	Plug the finger cuff connector into the pressure controller (Figure 3). 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 3). 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.

9.0 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.

10.0 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.

11.0 Storage

Store in a cool, dry place.

12.0 Shelf Life

The shelf life is 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.

13.0 Disposal

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

14.0 Specification Table

Model	Size Range
VWCA	43-71 mm

15.0 Warranty

The VitaWave finger cuff is for single patient use only. The VitaWave finger cuff is warrantied at time of delivery to the end user only. The VitaWave finger cuff is a non-serviceable part.

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.

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

CC1098

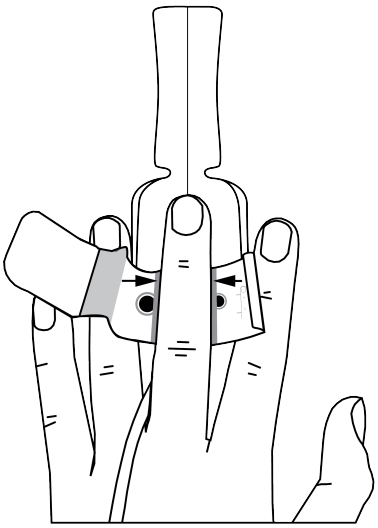


Figure 1: Apply the finger cuff.

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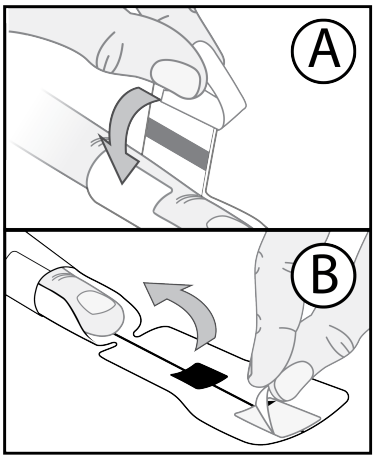


Figure 2: Secure the finger cuff.

CC1120

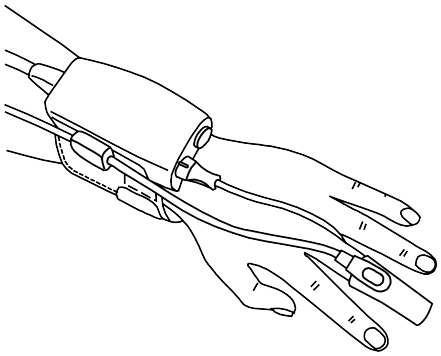
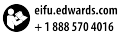
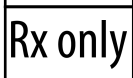


Figure 3: Connect the finger cuff to the system.

Symbol Legend

	English
	Fragile, handle with care
	Keep dry
	Manufacturer
	Use-by date
	Do not re-use
	Date of manufacture
	Lot Number
	Non-sterile
	Authorized representative in the European Community/European Union

	English
	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.
	Medical device
	MR Unsafe
	Separate collection for electrical and electronic equipment in accordance with EC Directive 2012/19/EU

	English
	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.

EC REP

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