# **Argos** Cardiac Output Monitor



# **Operator's Manual**

60-001 Rev C 2020-09-18



#### The Retia Medical Argos Cardiac Output Monitor Operator's Manual

# WARNING

Do not use the Argos monitor if the quality control labels on either side are missing, torn, or show evidence of having been removed. If your monitor's quality control labels are missing or show signs of tampering, the monitor should be immediately returned to Retia for inspection. Please call Retia Medical customer support for assistance.

Prices and specifications are subject to change without notice. If this manual is changed, it will be re-issued. If, during your use of this manual, you discover errors, omissions or incorrect information, please contact Retia Medical.



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#### Manufacturer's Declaration of Conformity Electronic Emissions and Immunity

#### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Argos monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Argos should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment
RF emissions. CISPR 11	Conducted Emissions Class B	The Argos uses RF energy only for internal function therefore RF emissions are low and are not likely to cause any interference with nearby electrical equipment.
RF emissions. CISPR 11	Radiated Emissions Class B	The Argos is suitable for use in all establishments, including domestic
Harmonic Emissions IEC 6100-3-2	Class D	establishments and those directly
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
0	The Argos is intended for use in the electromagnetic environment specified below. The customer or the user of the Argos should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD). IEC 61000-4-2 Ed. 2.0 2008-12	±15kV Air ±8kV Contact	Complies	Floors should be wood concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF interference. IEC 61000-4-3 Radiated Immunity	80-1000 MHz,	20V/M	RF generating equipment should be used no closer to the Argos or connected cables than the
RF Interference. IEC 61000-4-3 Radiated Immunity	1.0 to 2.7GH	20V/M	recommended separation distance, according to the following formulas:

Guidance and Manufa	Guidance and Manufacturer's Declaration – Electromagnetic Immunity (cont'd)		
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			$d = \sqrt{p} * 1.17$ for 150kHz to 80MHz
			$d = \sqrt{p} * .175$ for 80MHz to 800MHz
			$d = \sqrt{p} * 0.35$ for 800MHz to 2.5GHz
			Devices marked with this symbol are known to be sources of RF energy.
			(((_)))
Voltage Dips, short interruptions and voltage variations on power supply lines. IEC-61000- 4-4 Ed 3.0 2012-04 Electrical Fast Transient Burst, Power Ports	.5kV, 1KV, 2kV, +/-, 100Khz, 5ns risetime, 50ns pulse duration, 300ms burst period, 0.75ms burst duration	Complies	Mains power quality should be that of a typical commercial or hospital environment. If user of the monitor requires continued operation during power mains interruptions, the
Power Surge IEC 6100-4- 5	.5kV, 1KV Differential, .5kV, 1kV, 2kV Common Mode	Complies	monitor uses a built in UPS for environments where power is intermittent.
Conducted Immunity – IEC61000-4-6 ed. 4.0:2013-10.	.15 to 80MHz coupling to power port, external monitor cable, BP transducer cable	Complies	Where <i>d</i> is distance measured in meters, and
Power Frequency Magnetic Immunity IEC61000-4-8 Ed 2, 2009-09.	30A/m RMS 50 and 60 Hz	Complies	p is the power in watts of the device generating RF energy.
Voltage Dips and Interrupts IEC61000-4- 11.	10, 20, 500, 5000 msec @ 230VAC, 8.3, 16.67, 500, 5000 msec @ 120VAC	Complies	

As use of electrocautery equipment can interfere with patient monitors and therefore blood pressure waveforms, and can also interfere with the RF susceptibility of the Argos monitor, it is not recommended to rely on cardiac output calculations until 5 minutes after the electrocautery tools have stopped being used.

# Recommended separation distance between portable and mobile RF communication equipment and the Argos Monitor:

The Argos is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Argos can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Argos as recommended below, according to the maximum output power.

Rated power output of the transmitter in Watts	150kHz to 80MHz $d = \sqrt{p} * 1.17$ in Meters	80MHz to 800MHz $d = \sqrt{p} * .175$ in Meters	800MHz to 2.5GHz $d = \sqrt{p} * 0.35$ in Meters
0.01W	0.117M	0.018M	0.035M
0.1W	0.37M	0.06M	0.11M
1W	1.17M	0.175M	0.35M
10W	3.7M	.55M	1.1M
100W	11.7M	1.75M	3.5M

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



# **Compatible Monitors**

The Argos monitor is compatible with the analog output of the following patient monitors:

- 1. Intellivue Models MP40 and above (MP90, MX700, MX800) which accept the M1006B module with option #C01 Pressure Module
- 2. GE Carescape Models with Patient Data Module (PDM) Solar 8000, Carescape B650, Carescape B850
- 3. Spacelabs Xprezzon
- 4. Draeger Infinity

Please consult the Retia Medical website (www.retiamedical.com) for updates to this list.

# Compatible Femoral/Radial Transducers

The Argos monitor is compatible with the following blood pressure transducer components:

# Utah Medical BP Transducer Kit (pack of 25 – 902-649) Utah Medical Transducer Interface Cable (650-299-117)

Note: These components are manufactured and distributed by Utah Medical.

# 1 How to use this manual

The Argos Cardiac Output Monitor Operator's Manual is intended for trained clinical care clinicians for use with the Argos monitor.

Do not operate the Argos monitor before reading this operator's manual and familiarizing yourself with the device's functions and capabilities for appropriate clinical use.

This Operator's Manual offers instruction and guidance on setting up and operating the Argos monitor on critically ill patients. It covers:

- Making necessary connections to other devices
- Changing which parameters are displayed and in what form
- Navigating through informational screens
- Recalling and downloading patient monitoring information
- Care and maintenance of the Argos monitor
- Contacting the manufacturer
- Approved accessories
- Parameters and limits, and physical descriptions of the Argos monitor

This manual is organized into sections which, consulted sequentially, show a new user how to operate the device, and also serve as reference for the experienced operator.

Pay particular attention to highlighted and offset text, marked as cautions or warnings ( $\bigwedge$ ) or notes ( $\bigcirc$ ).





#### CAUTION

Illustrations, including device images and screenshots, are solely intended as reference and may not precisely represent the hardware or software version of the Argos monitor you are using.

### If you are using the electronic version of this file with a viewer such as Adobe Reader, references to sections or page numbers marked with a § will take you directly to the referenced place in the text.

**§1 How to use this** *manual* (p. 5) presents the structure and contents of provided documentation.

**§2 Introduction (p. 17)** describes the function and usage of the Argos.

**§3 Intended use (p. 18)** specifies the clinical purpose(s) for which the Argos is designed.

**§4 Parameters and Performance (p. 20)** lists the parameters the Argos can monitor, and ranges for each.

**§5** Warnings, Cautions, and Labels **(p. 22)** essential for safe operation of the device are illustrated and explained.

**§6 Initial** Setup **(p. 42)** shows how to mount and connect the Argos before a monitoring session.

**§7 Basic** Navigation (p. 54) is a simple step-by-step guide to operating the Argos, with simple typical scenarios. This section is *not* intended for a user to follow during monitoring.

**§8 Using the Argos (p. 75)** is a comprehensive guide to operating the Argos, showing how to navigate the user interface.

§9 Help

**§Appendix A** Specifications

**§Appendix B** Equations

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#### Retia Argos Cardiac Output Monitor Operator's Manual

# **2** Introduction

The Argos Cardiac Output Monitor is a medical device incorporating a pulse contour analysis algorithm to accurately measure cardiac output (CO) in high-risk patients in critical care facilities, using a radial or femoral arterial blood pressure signal.

Portability and ease of connection with bedside patient monitors, combined with a user interface that can be operated quickly and intuitively, makes it a valuable tool for clinicians to verify the hemodynamic status of the patient.



# **3 Intended Use**

# 3.1 Indications for Use

The Argos Cardiac Output monitoring device is intended for use on patients above the age of 18. It is intended to be used as a hemodynamic monitor for continuously monitoring cardiac output and its derived parameters on patients in the intensive care unit or the operating room.

# 3.2 Intended Use

The Argos Cardiac Output monitor is used for the continuous measurement of cardiac output from an intravascular radial or femoral arterial blood pressure signal. This signal is derived from a blood pressure transducer or from the analog output of a vital signs monitor. The device is intended to be used by clinicians on critically ill patients in an operating room or in an intensive care unit.



### WARNING

Read this manual carefully before attempting to use the Argos monitor.



### WARNING

The Argos monitor is intended solely for use by qualified clinicians who have been trained in its use.

# 3.3 Contraindications

Use of the Argos monitor is contraindicated given:

- 1) Any type of mechanical cardiac support e.g., intra-aortic balloon pumps, left ventricular assist devices (LVADs); or
- 2) Moderate to severe aortic valve regurgitation.



#### WARNING

The Argos monitor is not indicated for use with pediatric patients (age < 18).

# 3.4 Not Intended as a Blood Pressure Monitor



### WARNING

The Argos monitor should *not* be used to monitor arterial blood pressure. The arterial blood pressure transducer input on the Argos monitor is to be used *only* when another arterial blood pressure transducer is connected in parallel to a bedside patient monitor with the appropriate blood pressure alarms.

The Argos monitor is not intended to be used as a blood pressure monitor. The Argos monitor should be used only in conjunction with a bedside patient monitor connected to a radial or femoral artery. If the blood pressure transducer input is used to capture the arterial blood pressure signal, the transducer must be a second transducer connected in parallel with the bedside patient monitor arterial blood pressure transducer.



# **4** Parameters

#### Table 4-1: Parameters, Definitions, and Units

Parameter	Abbr.	Defined	Units
Cardiac Output	СО	The amount of blood the heart pumps through the circulatory system in a minute.	L/min
Cardiac Index	CI	The ratio of cardiac output to body surface area.	L/min/m <sup>2</sup>
Mean Arterial Pressure	MAP	Average pressure in the arteries during a cardiac cycle.	mmHg
Heart rate	HR	Number of heartbeats per minute.	bpm
Blood pressure	BP	The arterial pressure of blood (systolic/diastolic)	mmHg
Stroke Volume	SV	The volume of blood pumped from the left ventricle per beat.	mL
Stroke Volume Index	SVI	The volume of blood pumped by the heart with each beat, divided by the body surface area.	mL/m²
Systemic Vascular Resistance	SVR	The resistance to blood flow offered by all of the systemic vasculature, excluding the pulmonary vasculature.	dyne-s/cm⁵
Systemic Vascular Resistance Index	SVRI	Systemic Vascular Resistance proportional to body size	dyne-s-m²/ cm²
Pulse Pressure Variation*	PPV	The difference between maximum and minimum pulse pressure over a respiratory cycle, per mean pulse pressure	%

\*PPV may not be calculated if the timing or morphology of the BP waveform does not conform to an expected morphology or timing used for pattern recognition. In this case PPV may not be calculated or displayed even though cardiac output numbers are still being calculated.

#### **Pulse Pressure Variation**

The monitor displays pulse pressure variation (PPV) calculated using the formula

$$PPV = \frac{(PP_{max} - PP_{min})}{(PP_{max} + PP_{min})/2} \times 100$$

where  $PP_{max}$  and  $PP_{min}$  are the maximum and minimum pulse pressures over a respiratory cycle. The respiratory period is based on the maximum amplitude of the power spectrum of the BP waveform within the frequency range corresponding to a periodicity of between 2 to 10 seconds. The PPV is displayed in 1% increments.



#### WARNING

Pulse Pressure Variation (PPV) is only valid in patients with closed chests on full mode control ventilation.



### WARNING

Pulse Pressure Variation (PPV) is unreliable in patients with significant arrhythmia.



# 5 Warnings, Cautions, Notes, Symbols, and Standards

This chapter describes the symbols that appear in the manual or on product labels, including those used to identify warnings, cautions, and notes. A list of all warnings and cautions used in this manual is provided here.

This chapter also includes a list of relevant standards to which the Argos monitor complies.

# 5.1 Warnings, Cautions, and Notes

Warnings, Cautions, and Notes have particular meanings in this manual. Warnings and Cautions are placed inside a text box containing a caution triangle. Note the difference between a Warning and a Caution:



### **WARNING**

Calls attention to situations or actions that could result in personal injury or death.



#### CAUTION

Calls attention to situations or actions that could damage equipment, produce inaccurate data, or invalidate a procedure.

Notes are offset from the left-hand margin and marked with an arrow:

# 0

#### Notes relevant to the procedure being described are presented primarily in the clinical how-to section of the manual.



#### WARNING

Misuse may be a hazard to the patient. Read all warnings and cautions in this section of the manual before using the Argos monitor.

At all times, the following warnings and cautions should be observed when using the Argos monitor:



#### WARNING

Do not use the Argos monitor if the quality control labels on either side are missing, torn, or show evidence of having been removed. If your monitor's quality control labels are missing or show signs of tampering, the monitor should be immediately returned to Retia for inspection. Please call Retia Medical customer support for assistance.



#### WARNING

Read this manual carefully before attempting to use the Argos monitor.



#### WARNING

The Argos monitor is intended solely for use by qualified clinicians who have been trained in its use.



#### WARNING

The Argos monitor is not indicated for use with pediatric patients (age < 18).



#### WARNING

Severe, persistent arrhythmias may affect accuracy.





Do not use the Argos monitor as a pulse rate or blood pressure monitor.



#### WARNING

The Argos monitor should *not* be used to monitor arterial blood pressure. The arterial blood pressure transducer input on the Argos monitor is to be used *only* when another arterial blood pressure transducer is connected in parallel to a bedside patient monitor with the appropriate blood pressure alarms.



#### WARNING

Pulse Pressure Variation (PPV) is only valid in patients with closed chests on full mode control ventilation.



#### WARNING

Pulse Pressure Variation (PPV) is unreliable in patients with significant arrhythmia.



#### WARNING

Do not use the Argos monitor if the Quality Control label is damaged or missing. Instead, please contact your Retia Medical representative.



#### WARNING

Do not use damaged system components.



#### WARNING

Do not attempt to use the Argos monitor if it is not fastened to a stand.



#### WARNING

The Argos monitor should *never* be placed flat on a surface or balanced on a tabletop or other surface during use.



The Argos monitor and power adapters must be positioned in an upright position to ensure IPX1 ingress protection.



### WARNING

Do not position the external power supply in such a fashion that it is difficult to unplug the mains cord in case an emergency requires the monitor to be unplugged.



# WARNING

The Argos monitor must be securely mounted. Ensure all cords and cables are placed so they pose no risk of injury to patients, users, or equipment.



### WARNING

Ensure there is sufficient room for cables and transducer or monitor lines.



# WARNING

To avoid potential fire hazard, if using a pole mount, make sure the power supply is placed on the pole so that the arrow on the label is pointing upward.



# WARNING

Do not operate the Argos monitor outside operating specifications for temperature, humidity, and air pressure (see Appendix A, Table A-3). Ensure the device is within operating specifications before use.



# WARNING

Ensure there is adequate space around the unit to allow for proper ventilation.



# WARNING

Explosion hazard! Do not use the Argos monitor in the presence of any flammable anesthetic mixture with air or with oxygen or nitrous oxide.





The Argos monitor is intended solely for use with a radial or femoral arterial catheter. *Do not* attempt to use it with any other kind of patient connection.



#### WARNING

Do not place any foreign items (unapproved 60601-1 items) in any of the Argos monitor ports.



### WARNING

Equipment that generates high energy, high frequency electromagnetic radiation should not be used in close proximity to this monitor or any other patient monitoring equipment.



#### WARNING

Do not position IEC/EN 60950 equipment, including printers, any closer than 1.5 meters to the patient's bed.



# WARNING

Do NOT use the Argos monitor if the sticker seal is absent or has been damaged. Contact your Retia Medical representative.



### WARNING

Do not attempt to connect a power supply to the monitor that has not been approved for use by Retia Medical.



### WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



#### WARNING

Do not use extension cords or multiple socket devices to connect the power adapter.



Do not connect the Argos monitor to a patient monitor using an AC or pulsed DC pressure transducer excitation voltages.



# WARNING

The Argos *must* be used in conjunction with an approved bedside patient monitor.



# WARNING

When using a transducer connected directly to the Argos monitor, make sure the transducer is leveled to the phlebostatic axis.



### WARNING

Do not place any foreign items (unapproved 60601-1 items) in any of the Argos monitor ports.



### WARNING

Carefully inspect the radial or femoral arterial line before use.



# WARNING

Do not use a transducer or catheter that is damaged or that has exposed electrical contacts.



# WARNING

Do not resterilize or reuse any catheter or transducer.



# WARNING

Before operating in conjunction with a bedside patient monitor, consult with your Retia Medical representative to ensure the monitor has compatible specifications.



### WARNING

Do NOT use the Argos monitor in proximity to an MRI scanner.





A hazard can exist if different alarm/alert presets are used for the same or similar equipment in any single area.



#### WARNING

Do not attempt to attach or connect a transducer, transducer line, monitor, or monitor line to the Argos monitor which has not been certified for use by Retia Medical.



# WARNING

If the Argos monitor is connected directly to a transducer, the patient must also be simultaneously connected to the bedside patient monitor with another transducer via a 4-way stopcock.



#### WARNING

Shock or fire hazard! Do not immerse the Argos monitor or cables in any liquid solution. Do not allow any fluids to enter the instrument.



# WARNING

Use of a damaged cable may result in inaccurate cardiac output measurements or may damage the Argos monitor.



# WARNING

Use of accessories, sensors, lines, and cables other than those specified in this User Guide may result in increased emission and/or decreased immunity of the Argos monitor.



# WARNING

Only an experienced practitioner should insert the arterial line.



#### WARNING

The transducer, 4-way stopcock, and connecting pressure tubing are single-use only and should never be reused.



Observe institutional guidelines for disposal of biohazard waste after use of transducer, 4-way stopcock, and connected pressure tubing.



# WARNING

The Navigation section of this manual is intended solely to familiarize users with the Argos monitor. Do not operate the Argos monitor until you have read Chapter 8 and pertinent warnings and cautions.



# WARNING

The Argos monitor is intended solely for use by qualified clinicians who have been trained in its use.



# WARNING

The Argos monitor is intended only to supplement patient assessment, and must *only* be used in conjunction with a bedside patient monitor.



# WARNING

The Argos monitor is intended solely for use with a radial or femoral arterial catheter. *Do not* attempt to use it with any other kind of patient connection.



# CAUTION

Do not expose the Argos monitor to extreme temperatures.



### WARNING

Use of the Argos monitor is restricted to one patient at a time.



### WARNING

Once patient data has been entered, it *cannot* be edited or changed. Therefore, if the patient demographic information is incorrect or needs to be changed for any reason, it is necessary to start a new session.





Failing to zero the transducer correctly may lead to incorrect monitoring results.



#### WARNING

The Argos monitor *does not* alarm upon detection of low MAP. Such notifications are a function of the bedside patient monitor.



### WARNING

Always power off the Argos Monitor using the Shut Down function from the User Menu.



#### WARNING

The BP Transducer Kit (P/N 902-649) and Transducer Interface Cable (P/N 650-299-117) are indicated for use with the Argos Monitor. No other parts should be substituted for these approved accessories.



#### WARNING

All fields must be completed accurately in order to ensure calculations of monitored values and indices are correct.



### WARNING

Each patient must be given a unique ID number. ID numbers may be up to 9 (nine) numerals in length. Consult facility policy for distributing and tracking ID numbers for instrument use.



### WARNING

Never start monitoring from "Use previous patient" unless you have verified the patient is the same patient as monitored immediately beforehand. Always carefully check that each value of the patient's demographic information is correct before proceeding with monitoring.



#### WARNING

If the patient's demographic information as entered needs to be changed, it is necessary to start a new patient session.



Once a user ends a monitoring session for a patient and another patient has been monitored, data for the first patient's session can only be exported via data export port, and can no longer be viewed on the Argos monitor.



### WARNING

Start a New Patient Session whenever a new patient is connected to the Argos monitor. Failure to do so may result in previous patient data in the historical displays.



#### WARNING

The Argos monitor presents visual alerts when parameter limits are exceeded, but does NOT provide audible alarms. Audible alarms are the function of the bedside patient monitor.



### WARNING

If the Argos monitor is connected directly to a transducer, the transducer must also be connected simultaneously to a bedside patient monitor.



# WARNING

Do not unplug the device when the battery is depleted.



# WARNING

Never start monitoring from the "Use previous patient" unless you have verified the previous patient monitored has been discharged. If monitoring a new patient, use the menu to call up the *New patient* screen.



#### WARNING

Before connecting a bedside patient monitor to the Argos monitor, consult with your Retia Medical representative to ensure your bedside patient monitor has the correct specifications.





Only connect accessories that have been qualified as part of the Argos monitor.



#### WARNING

The Argos monitor contains no user serviceable parts. Removing the cover or otherwise disassembling the monitor may expose you to hazardous voltages.



### WARNING

Shock or fire hazard! Do not immerse the Argos monitor or cables in any liquid solution. Do not allow any fluids to enter the device.



### WARNING

Ensure that after alert verification, the alert limits are adjusted to physiologically appropriate values for patient monitoring.



#### CAUTION

Illustrations, including device images and screenshots, are solely intended as reference and may not precisely represent the hardware or software version of the Argos monitor you are using.



# CAUTION

Do not expose the Argos monitor to extreme temperatures.



### CAUTION

Grasp the connector – not the cable – when connecting or disconnecting a cable or line.



#### CAUTION

Do not twist or bend connectors.



### CAUTION

Since BP waveforms may be affected by the use of electrosurgical units, distance electrocautery equipment and cables from the Argos monitor and plug the power cords into separate AC circuits. Should signal quality problems persist, call Retia Medical for assistance.



### CAUTION

Periodically inspect all cables for defects. Never coil cables tightly while using, or for the purpose of storing.



# CAUTION

If any electrolytic solution such as NaCl, Lactated Ringers, is allowed to contact the cable connectors while connected to the Argos monitor, and the monitor is turned on, the excitation voltage may cause electrolytic corrosion and rapid degradation of the electrical contacts. Therefore, do not allow electrolytic solutions to contact the cable connectors.



# CAUTION

Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the Argos monitor. Guidance on maintaining appropriate separation between communications equipment and the Argos monitor is provided in the Manufacturer's Declaration of Conformity Electronic Emissions and Immunity on page 1.



# CAUTION

The sole function of the Argos monitor's data export ports is to export data. Do not attempt to use the data export ports for any other purpose.





#### CAUTION

The Argos Cardiac Output Monitor is intended for operation while plugged into an AC wall outlet. Although it will continue to function at full capacity on battery power alone, such as when an emergency power outage occurs, it is not designed for cordless use. In case of a power outage, use of the Argos Cardiac Output Monitor should be terminated as soon as feasible.



# CAUTION

Following exposure to defibrillation voltage, the Argos monitor recovers within 10 seconds.



# CAUTION

Time and Date cannot be changed while a patient is being monitored.



#### CAUTION

Do not use AC excitation voltages from a bedside monitor for the External CVP connection. The Argos monitor is designed for use with bedside monitors which use DC excitation voltages only.



#### CAUTION

Do not pour or spray liquid onto the monitor or accessories.



#### CAUTION

Do not immerse cable connectors in detergent, isopropyl alcohol or glutaraldehyde.



### CAUTION

NEVER:

- Allow any liquid to come in contact with the power cable.
- Allow any liquid to penetrate connectors or openings in the case

Should liquid contact the power cable or penetrate the case, do not attempt to operate the monitor. Instead, shut down the monitor, disconnect power immediately, and call your Biomedical Department or Retia Medical representative.



# CAUTION

Do not use any heating device to dry cable connectors.



# CAUTION

Regularly inspect all cables for defects. Never coil cables tightly when storing.



# 5.2 Device Labels

Image	Label	Description
	Company logo label	Company logo
Argos	Product ID label	Product ID
<b>U</b> DC 18 V <b>O</b> <b>C</b>	Power input label	Power input
ს ს		Power switch
DC 18 V		Power specification
⊝-€-⊕		Power cable port

Image	Label	Description
DATA EXP	Data I/O label	Data I/O
		Bedside patient monitor line-in
MM		Transducer line- in
DATA EXP		Data export ports



Image	Label	Description
Argos Monitor         Model FG-001         SN 000-01-00         Image: SN 000-01-00	Caution and Company Contact label	Caution and Company Contact
SN		Serial Number
		Date of Manufacture
Ĩ		Read Operators Manual
IPX1		IP rating

Image	Label	Description
-25 °C		Temperature limits
10 % 95 % % non- condensing		Humidity limits
$\triangle$	Caution and Company Contact label (cont'd)	Caution
		Manufacturer
		WEEE
Do Not Use If Seal is Broken	Quality Control label	Quality Control label
TO POWER ON: PRESS BLUE BUTTON FOR 5 SECONDS	Power switch label	Power switch instructions
CONFORMS TO AAMI STD ES60601-1 IEC STD 60601-1 IEC STD 60601-1-6 IEC STD 60601-2-34 CERTIFIED TO CSA STD C22.2 # 60601-1	ETL label	Lists standards to which Argos monitor complies



#### Retia Argos Cardiac Output Monitor Operator's Manual

Image	Label	Description
WARNING! To prevent fire hazard, This end up when mounted on pole stand!		Arrow indicates correct placement of power supply on pole mount

Table 5-1: Device Labels



#### WARNING

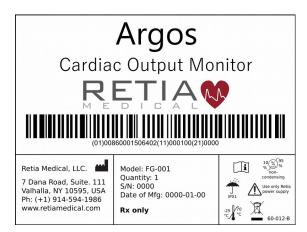
Do not use the Argos monitor if the Quality Control label is damaged or missing. Instead, please contact your Retia Medical representative.



#### WARNING

Do not use damaged system components.

# 5.3 Shipping Label



# **5.4 Standards Compliance**

Applied Part Type	1x Type CF defibrillation-proof
Equipment class	Class II
Electrical Protection Class	IEC Class I
Ingress Protection Class	IPX1
IEC Standards	IEC 60601-1:2005+AMD1:2012
	IEC 60601-1-2:2014
	IEC 60601-2-34:2011*
	IEC 60601-1-8: 2011
	IEC 62366-1:2015
Packaging standard	ISTA 2A

Table 5-2: Standards compliance

\*Not including the section (208.6) on alarms. All alarms are governed by IEC 60601-1-8.



# 6 Initial Setup

# 6.1 Mounting the Argos



#### WARNING

Do not attempt to use the Argos monitor if it is not fastened to a stand.



#### WARNING

The Argos monitor should *never* be placed flat on a surface or balanced on a tabletop or other surface during use.

The Argos Cardiac Output Monitor is designed to be operated while fastened to a stand – for example, a standard pole mount or table stand. It complies with 75mm square screw patterns and 100mm square screw patterns with screws set in four corners. (For particular mounting solutions, please contact Retia Medical at 914-594-1986, or at info@retiamedical.com.)

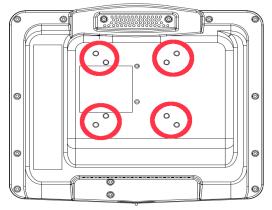


Fig. 6-1: Rear view, showing mount holes

When using the Argos monitor with a pole mount, the AC supply *must* be positioned so that the arrow on the label on the power supply is pointing upward, as shown below.



Fig. 6-2: Power supply shown mounted correctly, with arrow pointing upward





#### WARNING

The Argos monitor and power adapters must be positioned in an upright position to ensure IPX1 ingress protection.



## WARNING

Do not position the external power supply in such a fashion that it is difficult to unplug the mains cord in case an emergency requires the monitor to be unplugged.



# WARNING

The Argos monitor must be securely mounted. Ensure all cords and cables are placed so they pose no risk of injury to patients, users, or equipment.



# WARNING

Ensure there is sufficient room for cables and transducer or monitor lines.



# WARNING

To avoid potential fire hazard, if using a pole mount, make sure the power supply is placed on the pole so that the arrow on the label is pointing upward.



# WARNING

Do not operate the Argos monitor outside operating specifications for temperature, humidity, and air pressure (see Appendix A, Table A-3). Ensure the device is within operating specifications before use.



# WARNING

Ensure there is adequate space around the unit to allow for proper ventilation.



## WARNING

Explosion hazard! Do not use the Argos monitor in the presence of any flammable anesthetic mixture with air or with oxygen or nitrous oxide.



# WARNING

The Argos monitor is intended solely for use with a radial or femoral arterial catheter. *Do not* attempt to use it with any other kind of patient connection.



# CAUTION

Do not expose the Argos monitor to extreme temperatures.



# CAUTION

Grasp the connector – not the cable – when connecting or disconnecting a cable or line.



# CAUTION

Do not twist or bend the connectors.



# WARNING

Do not place any foreign items (unapproved 60601-1 items) in any of the Argos monitor ports.



# WARNING

Equipment that generates high energy, high frequency electromagnetic radiation should not be used in close proximity to this monitor or any other patient monitoring equipment.



# WARNING

Do not position IEC/EN 60950 equipment, including printers, any closer than 1.5 meters to the patient's bed.



## CAUTION

Since BP waveforms may be affected by the use of electrosurgical units, distance electrocautery equipment and cables from the Argos monitor and plug the power cords into separate AC circuits. Should signal quality problems persist, call Retia Medical for assistance.





#### CAUTION

Periodically inspect cables for defects. Never coil cables tightly while using or for the purpose of storing.



# CAUTION

If any electrolytic solution such as NaCl, Lactated Ringers, is allowed to contact the cable connectors while connected to the Argos monitor, and the monitor is turned on, the excitation voltage may cause electrolytic corrosion and rapid degradation of the electrical contacts. Therefore, do not allow electrolytic solutions to contact the cable connectors.



# CAUTION

Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the Argos monitor. Guidance on maintaining appropriate separation between communications equipment and the Argos monitor is provided in the Manufacturer's Declaration of Conformity Electronic Emissions and Immunity on page 1.



# CAUTION

The sole function of the Argos monitor's data export ports is to export data. Do not attempt to use the data export ports for any other purpose.

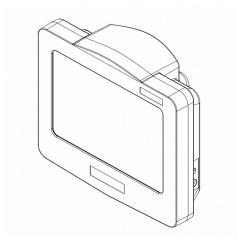
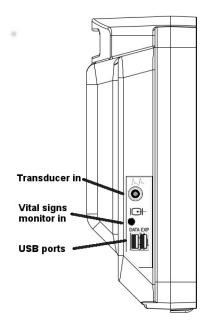


Fig. 6-3: View from top right, showing power input and power switch



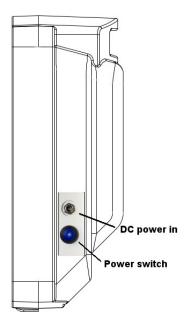


Fig. 6-4: Left and right side views



Before use, ensure sticker seals have not been tampered with.



#### WARNING

Do NOT use the Argos monitor if the sticker seal is absent or has been damaged. Contact your Retia Medical representative.



#### WARNING

Do not attempt to connect a power supply to the monitor that has not been approved for use by Retia Medical.



# WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

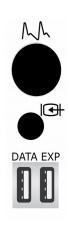


Fig. 6-5: Left side port panel, showing inputs for transducer (top) and monitor line-in (middle)

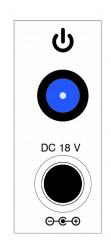


Fig. 6-6: Right side power panel, showing power cable input and power switch



Fig. 6-7: AC adapter label indicating proper orientation on pole stand



# WARNING

Do not use extension cords or multiple socket devices to connect the power adapter.



#### WARNING

Do not connect the Argos monitor to a patient monitor using an AC or pulsed DC pressure transducer excitation voltages.





## CAUTION

The Argos monitor is intended for operation while plugged into an AC wall outlet. Although it will continue to function at full capacity on battery power alone, such as when an emergency power outage occurs, it is **not** designed for cordless use. In case of a power outage, use of the Argos monitor should be terminated as soon as feasible.

Plug the power cable into to a working AC power outlet. Connect the cable to the DC power in socket of the monitor.



## WARNING

The Argos *must* be used in conjunction with an approved bedside patient monitor.



## WARNING

When using a transducer connected directly to the Argos monitor, make sure the transducer is leveled to the phlebostatic axis.



# WARNING

Do not place any foreign items (unapproved 60601-1 items) in any of the Argos monitor ports.

The Argos must be connected either directly to a transducer from a radial or femoral artery catheter, or to a bedside patient monitor.



## WARNING

Carefully inspect the radial or femoral arterial line before use.



#### WARNING

Do not use a transducer or catheter that is damaged or that has exposed electrical contacts.



#### WARNING

Do not resterilize or reuse any catheter or transducer.

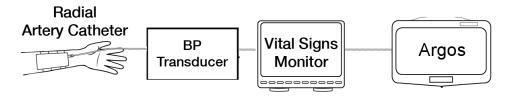


Fig. 6-8: Standard patient line, from transducer to monitor to Argos

The patient should be fitted with a radial or femoral arterial catheter.

If, as in Fig. 6-8 above, the transducer is connected to a bedside patient monitor, the Argos connects to a line from the monitor.

The Argos monitor is designed for use with a bedside patient monitor analog output with a range of 0-3V and a scale 1V=100mmHg.



## WARNING

Before operating in conjunction with a bedside patient monitor, consult with your Retia Medical representative to ensure the monitor has compatible specifications.



## WARNING

Do NOT use the Argos monitor in proximity to an MRI scanner.



## CAUTION

Following exposure to defibrillation voltage, the Argos monitor recovers within 10 seconds.



#### WARNING

A hazard can exist if different alarm/alert presets are used for the same or similar equipment in any single area.





#### WARNING

Do not attempt to attach or connect a transducer, transducer line, monitor, or monitor line to the Argos monitor which has not been certified for use by Retia Medical.

If a transducer is connected directly to Argos, as in Fig. 6-9, another transducer must be connected to the bedside patient monitor, for example with a 4-way stopcock.



## WARNING

If the Argos monitor is connected directly to a transducer, the patient must also be simultaneously connected to the bedside patient monitor with another transducer via a 4-way stopcock.

Detailed setup instructions are at §8.3.1, page 81.

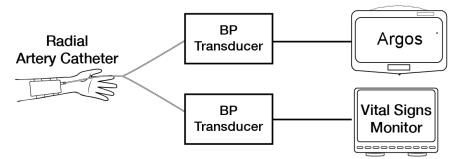


Fig. 6-9: Transducer connected directly to Argos, another to bedside patient monitor



#### WARNING

Shock or fire hazard! Do not immerse the Argos monitor or cables in any liquid solution. Do not allow any fluids to enter the instrument.



#### WARNING

Use of a damaged cable may result in inaccurate cardiac output measurements or may damage the Argos monitor.



# WARNING

Use of accessories, sensors, lines, and cables other than those specified in this User Guide may result in increased emission and/or decreased immunity of the Argos monitor.



# WARNING

Only an experienced practitioner should insert the arterial line.



# WARNING

The transducer, 4-way stopcock, and connected pressure tubing are single-use only and should never be reused.



# WARNING

Observe institutional guidelines for disposal of biohazard waste after use of transducer, 4-way stopcock, and connected pressure tubing.

If you are connecting a transducer directly to the Argos monitor, use only the transducer specified by Retia Medical.

To power on, press and hold the power button for 5 seconds. The indicator on the power button will light up blue, signaling that the device has been switched on.



# 7 Basic Navigation



#### WARNING

The Navigation section of this manual is intended solely to familiarize users with the Argos monitor. Do not operate the Argos monitor until you have read Chapter 8 and pertinent warnings and cautions.

# 7.1 Overview

The Argos Cardiac Output Monitor is lightweight, portable, and simple to operate, with a touchscreen interface providing quickness, ease of use, and maximum user accuracy.

12			CO 12.	
0 10:56:19 am	1 11:11:19 am	11:26:19 am		
60 0 10:56:19 am	11:11:19 am	11:26:19 am	57 PP\/ <sup>2</sup>	7 mL 9 T
25 - 0	11:11:19 am	11:26:19 am	Ę	。」 5 %
0ct 12 11:26	, 2017 M. 53yrs AM 5 ft 11 in, 172 lbs		5 mir	awa

Fig. 7-1: Front view of Argos monitor



#### WARNING

The Argos monitor is intended solely for use by qualified clinicians who have been trained in its use.



# WARNING

The Argos monitor is intended only to supplement patient assessment, and must *only* be used in conjunction with a bedside patient monitor.

# 7.2 The Touchscreen Interface

Operate the Argos monitor just as you would a smartphone or tablet: with a fingertip, simply tap the screen to make a selection, choose from a list, enter numeric or textual data, or verify before proceeding to the next step.

# 7.3 Entering Patient Data



## WARNING

Use of the Argos monitor is restricted to one patient at a time.



# WARNING

Once patient data has been entered, it *cannot* be edited or changed. Therefore, if the patient demographic information is incorrect or needs to be changed for any reason, it is necessary to start a new session.

Press the power button for 5 seconds to switch on the Argos monitor.

After bootup, the user is presented with the Add Patient Data screen, where patient information must be entered:



Retia Argos Cardiac Output Monitor Operator's Manual

	Add Patient Data				
[	Init System Metric Imperial				
Р	Patient ID:	En	ter		
G	Sender:	En	ter		
Δ	Age:	En	ter		
V	Veight (kg):	En	ter		
F	leight (cm):	En	ter		
	Feb 28, 2018 1:07:43 PM		Use Previous Patient	Save	

Fig. 7-2: On powerup, the Add patient data screen appears

Choose metric or imperial units by tapping the corresponding box. Here, bright white letters against a black background indicate metric units are selected:

Ad	dd Patient Data	
Metric gerial		
Patient ID:	Enter	
Gender:	Enter	
Age:	Enter	
Weight (kg):	Enter	
Height (cm):	Enter	
Feb 28, 2018 12:59:45 PM	Use Previous Patient	Save

Fig. 7-3: Metric units selected

Now you may enter the patient's demographic information. Begin by pressing *Enter* next to the field labeled Patient ID. This will bring up a number pad to enter the patient's ID number.

	Adc	l Pa	tient Data			
	it System Metric Imperial					
Pa	tient ID:	En	ter	1	2	3
Ge	ender:	En	ter	4	5	6
Ag		En	ter	7	8	9
W	eight (kg):	En	ter	С	0	×
He	eight (cm):	En	ter		OK	
	Feb 28, 2018 1:08:33 PM		Use Previous Pat	ient	S	ave

Fig. 7-4: Setup screen ready for Patient ID entry

Ensure the patient demographic data is correct as these values will be used to estimate body surface area and will affect the indexed values. After confirming the data is correct, tap the green *OK* to save.

	Add Patient Data			
Unit System Metric Imperial				
Patient ID:	22145	1	2	3
Gender:	Enter	4	5	6
Age:	Enter	7	8	9
Weight (kg):	Enter	C	-	×
Height (cm):	Enter		ОК	
Feb 28, 2018 1:10:16 PM	Use Previous Pa	tient	S	ave

Fig. 7-5: Press OK to save the patient demographic value

When you have finished completing patient data, press *Save* at the bottom right of the touchscreen.



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	Add Patient Data	
Unit System Metric Imperial		
Patient ID:	22145	
Gender:	Female	
Age:	32 years	
Weight (kg):	58 kg	
Height (cm):	167 cm	
Feb 28, 2018 1:10:44 PM	Use Previous Patie t	Save

Fig. 7-6: Press Save to continue to BP Source selection

You are ready to select the blood pressure source.

# 7.4 Select Blood Pressure Source

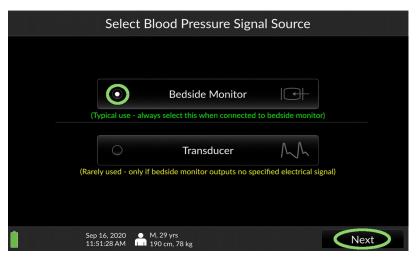


Fig. 7-7: Choose whether patient is connected via a transducer or bedside monitor

Select *Transducer* if the Argos monitor is connected directly to a transducer. Select *Bedside Monitor* if the Argos monitor is connected to a bedside patient monitor. Note that when the source is highlighted, the *Next* box the bottom right of the screen is ungreyed. Touch *Next* to proceed.

Note the patient demographic information beside the small figure in white on the bottom menu bar of the screen. Be sure to use it to check the information is correct before proceeding with monitoring.



Fig. 7-8: Verify patient demographic information is correct before proceeding

Select Blood Pressure Signal Source					
	0	Bedside Monitor			
(Typical use - always select this when connected to bedside monitor)					
		Transducer	MM		
(Rarely used - only if bedside monitor outputs no specified electrical signal)					
		29 yrs ) cm, 78 kg		Next	

Fig. 7-9: Transducer shown selected; press Next to continue

If *Bedside monitor* is selected, pressing *Next* will initiate monitoring.



If you have selected *Transducer* as BP source, you must zero the transducer before proceeding.

# 7.4.1 Zero Transducer



#### WARNING

Failing to zero the transducer correctly may lead to incorrect monitoring results.

The Zero Transducer screen appears.

1) Open the transducer to atmosphere by turning the stopcock to the *Off* position.

2) Press Zero transducer.

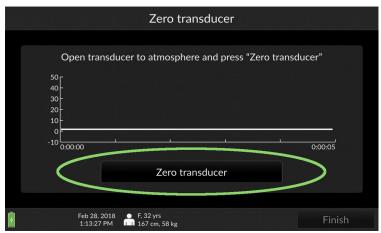


Fig. 7-10: Ready to zero transducer

3) The screen returns "Transducer zeroed."

4) Return the stopcock to *Patient*. Press *Finish* to initiate monitoring.

Please verify the alert functionality whenever the device is turned on, immediately after beginning a new monitoring session. The procedure to verify alert functionality is described in Appendix F, p. 149.

	Zero transducer	
	Transducer zeroed	
50 - 40 - 30 - 20 -		
10 0 -10 0:00:00	,	0:00:05
	Re-zero transducer	
Feb 28, 2 1:13:56	1018 ● F, 32 yrs PM	Finish

Fig. 7-11: Press finish to begin patient monitoring

# 7.5 The Trend Screen

At startup, the Argos monitor displays the previous session's selected parameters.



#### Retia Argos Cardiac Output Monitor Operator's Manual

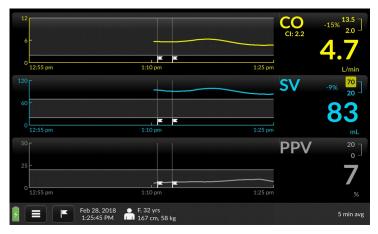


Fig. 7-12: The default trends

## To the right of each trend is the Parameter Label Field:

12 6 - 0 10:57:45 am	11:12:45 am	11:27:45	CO	12.0 2.0 <b>3.6</b> L/min
120 60 0 10:57:45 am	 11:12:45 am	11:27:45 am	57	20 J 57 mL
50	1 11:12:45 am	11:27:45 am	PPV	° 0 5 %
Oct 12, 2017 11:27 AM	● M, 53yrs ■ 5 ft 11 in, 172 lbs			5 min avg

Fig. 7-13: Parameter label field shown highlighted

showing the parameter name at the top left corner, current numeric value prominently in the bottom right.



# WARNING

The Argos monitor *does not* alarm upon detection of low MAP. Such notifications are a function of the bedside patient monitor.

In the upper right, maximum and minimum limit values are displayed.



If the measured value exceeds either of these, a yellow box indicates an alert.



# 7.5.1 Selecting a different parameter

To change monitored parameters, for instance from MAP to Cardiac Output, start by pressing and quickly releasing the Parameter Label to call up Parameter Settings.



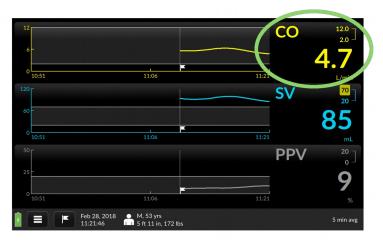


Fig. 7-14: To switch parameters, tap the parameter label

The Parameter Settings overlay appears. The Parameter Selection box is marked with a downturned triangle.

Trend settings	Parameter settings	CO <sup>12.0</sup> 2.0
CO V	<b>Color</b>	11.6
Show CI	Show % change	L/min SV 70 20
Low limit	High limit	116
▲ 2.0 ▼ L/min	▲ 12.0 ▼ 12.0	
× Cancel	✓ Save	
Feb 28, 2018 11:03:15	F, 32 yrs 167 cm, 58 kg	20 sec avg

Fig. 7-15: Tap the label to choose a different trend

Press the selection box to open a dropdown list of parameters; scroll down to see more.

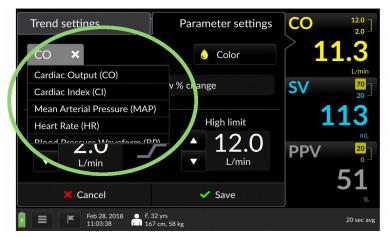


Fig. 7-16: The dropdown list of parameters

Press on the desired choice – in this case, Mean Arterial Pressure (MAP).



Fig. 7-17: MAP shown selected

Press the green checkmark Save to save your selection and return to the Trend screen.



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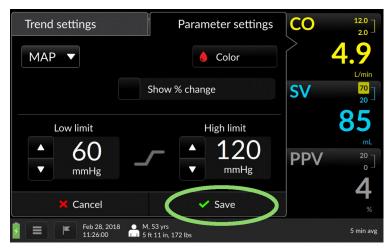
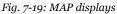


Fig. 7-18: Press Save to continue

The Trend screen returns with MAP displayed.





When initiating monitoring for a new patient, the operator is strongly encouraged to select the BP waveform parameter, in order to ensure the BP waveform is being received by the Argos monitor.

# 7.5.2 Changing Trend Settings on the Trend Screen

The Trend Settings overlay offers choices for time scales, alert limits, colors, and additional values for selected parameters. (See §8.5.1, page 107 for more detailed information.)

# Changing the scale of the trend coordinates:

The touchscreen allows for adjustment of position and scale of trends along both X- and Y- axes, and coordinate minimum and maximum values.

**To move backward or forward in the time axis**, touch the gray arrow pointing leftward (earlier) or to the right (later): slide your finger right to view earlier or left to view later until the desired timeframe comes into view.

**To compress the scale of the time axis**, place two fingers apart horizontally on a trend displayed on the touchscreen and move them toward one another in a pinching motion.

**To expand the scale of the time axis,** touch two fingertips together on a trend and spread them apart.

You can also change the time scale from the Trend settings screen. Here you may change the default time scale value from the default of 30 minutes to 10 minute, 30, minute or 1 hour intervals.

Suppose you want a more detailed view of the trends – the default value is 30 minutes.



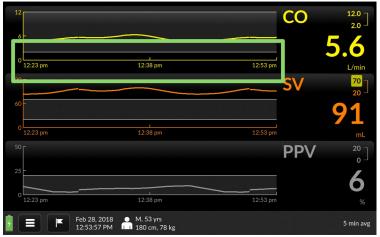


Fig. 7-20: The default interval is 30 minutes

Instead, you want to view trends in 10-minute intervals. Begin by tapping any of the waveforms to bring up Trend settings:

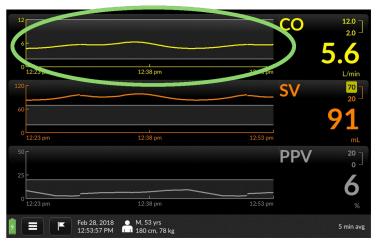


Fig. 7-21: Tap inside a trend to access Trend settings

The Time Scale selection box is labeled with the current value, along with a downturned triangle.

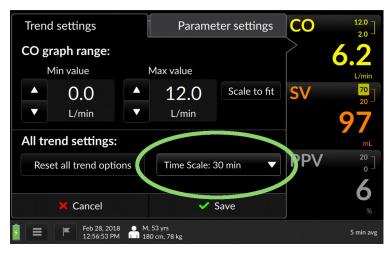
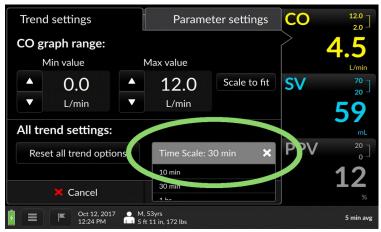


Fig. 7-22: The Time Scale selector

Touch anywhere inside it to access a range of values.



*Fig. 7-23: Tapping the Time Scale box opens up a selection box* 

Choose the desired interval, then press the green checkmark Save to save and return to the Trend screen.



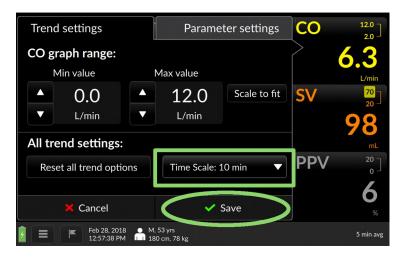


Fig. 7-24: Select the desired timescale, press Save to continue

#### All three trends are now scaled to the new value:

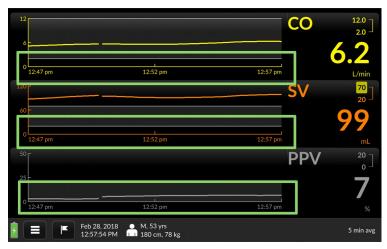


Fig. 7-25: Waveforms display in 10-minute intervals

# 7.6 Complete Session / Shut Down



#### WARNING

Always power off the Argos Monitor using the  $\operatorname{Shut}$   $\operatorname{Down}$  function from the User Menu.

To end patient monitoring, or to shut down the Argos monitor, touch the User Menu icon on the menu bar:

120		SV 70 20
		85
	2:13 pm 2:18 pm 2:23 pm	mL
		MAP <sup>120</sup> <sub>60</sub> ]
		74
	2:13 pm 2:18 pm 2:23 pm	
		<b>PPV</b> <sup>20</sup> ]
		9
	2:13 pm 2:18 pm 2:23 pm	
9(	E Feb 28, 2018 F. 32 yrs 2:23:31 PM 167 cm, 58 kg	5 min avg

Fig. 7-26: Touch the Menu Bar icon to activate the User Menu

The User Menu appears.



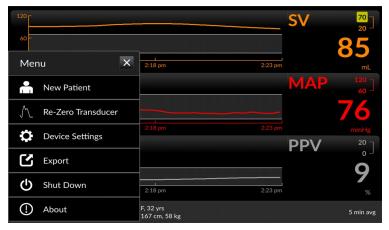


Fig. 7-27: The User Menu

## 7.6.1 Start New Patient session

To terminate the current session and start a session with a new patient, press New Patient.

120 - 60 -		SV 20 20
Menu X	2:18 pm 2:23 pi	m mL
New Patient		MAP <sup>120</sup> 60
∬_ Re-Zero Transducer		<b>76</b>
Device Settings	2:18 pm 2:23 pr	<sup>m</sup> mmHg PPV <sup>20</sup> 7
Export		- °
U Shut Down	2:18 pm 2:23 pr	. <b>7</b>
() About	F, 32 yrs 167 cm, 58 kg	5 min avg

Fig. 7-28: Press New Patient to end the current session and start a new one

A confirmation screen appears.

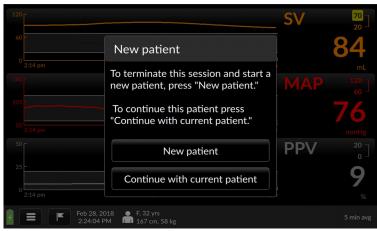


Fig. 7-29: Verify new patient

To confirm that you wish to end the current monitoring session and start with a new patient, press *New patient*. You will be taken to the Initial Patient Setup screen (see §8.3.2). If you do NOT wish to terminate the session, press *Continue to current patient* to return to the Trend Screen.

## 7.6.2 Shut down



#### WARNING

Always power off the Argos Monitor using the Shut Down function from the User Menu.

To shut down the Argos monitor, select *Shut Down* from the menu:





Fig. 7-30: Select Shut Down

#### A confirmation screen appears:

120		SV 70 20
60 -	Are you sure ?	85
2:18 pm	System is about to shutdown	mL MAP 120 60
105		83
2:18 pm	Shutdown	PPV 20 0
25 - 0 2:18 pm	Go Back	<b>4</b>
Feb 28, 2 2:28:04		

Fig. 7-31: Confirm Shutdown

To end the patient session and turn off the Argos monitor, press *Shutdown*. Otherwise, to continue the current monitoring session, press *Go Back* to return to the Trend Screen.

# 8 Using the Argos Monitor

The Argos Cardiac Output Monitor provides quick access to blood pressure monitoring and derived parameters through a rapidly configurable touchscreen interface. The next section introduces the user to the basic screens; following chapters offer step-by-step instructions for using the Argos. Please take care to observe **Cautions** and **Warnings** (boxed text marked by a △) and helpful notes (⊃).



#### WARNING

The Argos monitor *does not* alarm upon detection of low MAP. Such notifications are a function of the bedside patient monitor.



#### WARNING

The Argos monitor is intended only to supplement patient assessment, and must *only* be used in conjunction with a bedside patient monitor.

# 8.1 Guide to screens

The Argos is operated by entering information and accessing options through a touchscreen interface. Use your fingertip to select data and quickly move through screens.

The interface has two primary modes:

**Setup**, used to enter patient information at the beginning of each new session.



Add	l Patient Data	
Unit System Metric Imperial		
Patient ID:	Enter	
Gender:	Enter	
Age:	Enter	
Weight (kg):	Enter	
Height (cm):	Enter	
Feb 28, 2018 12:59:45 PM	Use Previous Patient Save	

Fig. 8-1: The Add Patient Data screen

And the **Trend Screen**, showing three trends, each identified by the parameter label field, or label, to the right.

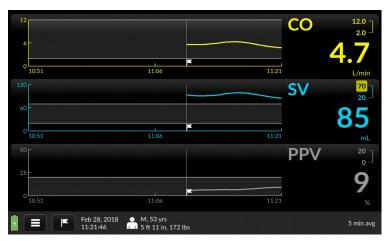


Fig. 8-2: The Trend Screen

All three trends are user-selectable. Prior monitoring session trends can be accessed via fingertip control and coordinates scaled across either axis. The parameter label field can show quantitative indices, values, or changes, and allows adjustment of alert limits. The table below gives a closer look:

Each label shows the parameter name, alert limits, and, in larger characters, current numeric value.



Optionally, a label can show a percentage change (see §8.4.2. page 97) since a specified event, or from monitoring initiation, if no event has been specified.

Some parameters can be configured to show an associated index or value.



Here, stroke volume index (SVI) displays below the Stroke Volume (SV) label.



The numbers connected by the brace in the upper right corner are high and low alert limits, which are user-configurable.

Should the value of the parameter exceed either limit, the limit will show against a yellow background for as long as the value is beyond the selected threshold.



Touching the parameter label brings up the **Parameter Settings** overlay. Here the user can select a new parameter, or add, remove, or change the way a parameter is displayed, including colors and alert thresholds.

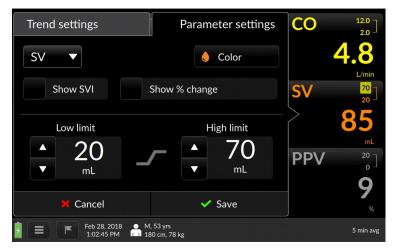


Fig. 8-3: Parameter settings

Touching the trend display summons **Trend Settings**, which allows for adjusting the trend graph, both the trend (Y-axis) value, and the time coordinate (X-axis).

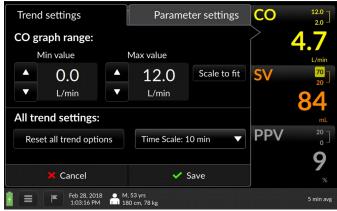


Fig. 8-4: Trend settings

## 8.1.1 Trend scrubbing

Dragging a fingertip along a waveform activates the "scrubbing" function, which pops up the numeric value of the trend at the particular moment:

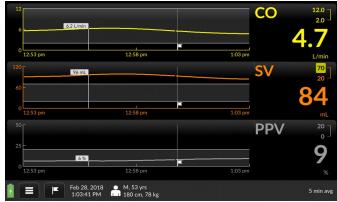


Fig. 8-5: Trend values shown on trends



# 8.2 The Menu Bar

A number of options and **settings** can be accessed via the **menu bar**, which is always visible at the bottom of the display.

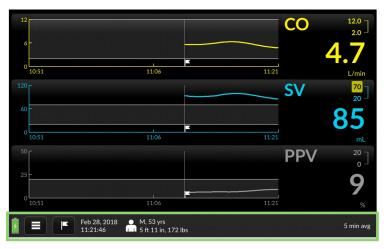


Fig. 8-6: Menu bar shown highlighted



Fig. 8-7: Menubar elements

While the Argos is monitoring, the menu bar displays numerical blood pressure and heart rate, alongside patient information, date and time, and a battery icon showing the power state. The menu bar also contains the menu icon, allowing access to critical functions. Another Menu Bar selection offers access to Event marking. Several response buttons also appear in the Menu Bar when the user is entering patient information.

# 8.3 The Setup Screens

# 8.3.1 Prepare patient

Make sure the patient has been readied for monitoring.

# If using a line from a bedside patient monitor,

connect it to the designated port. Then, proceed to §8.3.2, *Initial* setup – *Inputting patient data*.

# If using direct connection to a transducer cable:

Utilize a BP Transducer Kit (P/N 902-649) and a Transducer Interface Cable (P/N 650-299-117) to connect directly to the Argos monitor. To order these accessory parts, please contact Retia customer support or your Retia representative.

Use a 4-way stopcock to connect the patient to a bedside patient monitor and the Argos monitor simultaneously.



### WARNING

When using a transducer connected directly to the Argos monitor, make sure the transducer is leveled to the phlebostatic axis.



## WARNING

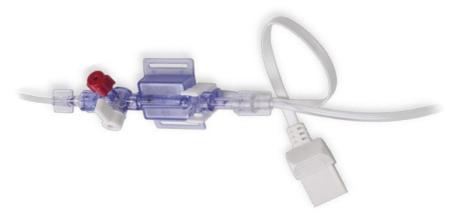
The Argos monitor must only be used with a radial or femoral arterial catheter. Do not attempt to use the device with any other type of catheter.

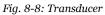


### WARNING

The BP Transducer Kit (P/N 902-649) and Transducer Interface Cable (P/N 650-299-117) are indicated for use with the Argos Monitor. No other parts should be substituted for these approved accessories.







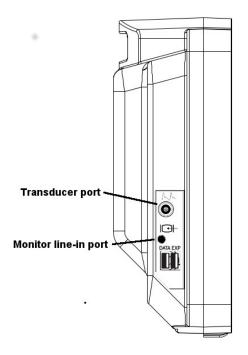


Fig. 8-9: Left side view, showing bedside patient monitor and transducer inputs

Once the patient has been fitted with a radial or femoral arterial catheter:

- 1. Connect the arterial catheter output line to the 4-way stopcock provided within the BP Transducer Kit (P/N 902-649).
- 2. Connect the transducer provided with the BP Transducer Kit (P/N 902-649) to one output from the 4-way stopcock.
- 3. Connect a transducer approved for use with the bedside patient monitor to another output from the 4-way stopcock.
- 4. Ensure that the 'off' tab on the 4-way stopcock is on the 4th, unused output. An uninterrupted fluid column should exist from the arterial catheter to the BP Transducer Kit transducer and bedside patient monitor transducer simultaneously.
- 5. Attach the bedside patient monitor transducer to the bedside patient monitor per the manufacturer's setup instructions.
- 6. Attach the BP Transducer Kit (P/N 902-649) transducer to the Argos monitor via the Transducer Interface Cable (P/N 650-299-117).
- 7. Make sure the BP Transducer Kit transducer (P/N 902-649) is level to the phlebostatic axis.
- 8. Power on the Argos monitor.
- 9. Zero the BP Transducer Kit transducer (P/N 902-649) to the Argos monitor using the procedure described below in §8.3.3.2, page 91.

You are ready to monitor the patient.



## 8.3.2 Initial setup – Inputting patient data

Whenever the Argos monitor is powered on, or a new monitoring session is started (after a previous patient session is ended – see §8.6.2.1, page 117), the Add Patient Data screen is displayed:

Add Patient Data				
Unit System Metric imperial				
Patient ID:	Enter			
Gender:	Enter			
Age:	Enter			
Weight (kg):	Enter			
Height (cm):	Enter			
Feb 28, 2018 1:07:43 PM	Use Previous Patient Save			

Fig. 8-10: Initial setup screen: Add Patient Data

The default unit for entering the patient demographic is metric. To choose imperial units, use the unit toggle at the top left of the Add Patient Data screen:

Ac	dd Patient Data				
Metric Innal					
Patient ID:	Enter				
Gender:	Enter				
Age:	Enter				
Weight (kg):	Enter				
Height (cm):	Enter				
Feb 28, 2018 12:59:45 PM	Use Previous Patient Save				

Fig. 8-11: Metric units shown selected

Note that active or selected values in the Argos display as bold white text against a

# black background. Deselected values show as light grey text against a darker grey.



#### WARNING

All fields must be completed accurately in order to ensure calculations of monitored values and indices are correct.



## WARNING

Each patient must be given a unique ID number. ID numbers may be up to 9 (nine) numerals in length. Consult facility policy for distributing and tracking ID numbers for instrument use.

## When continuing to monitor the same patient as before:



#### WARNING

Never start monitoring from "Use previous patient" unless you have verified the patient is the same patient as monitored immediately beforehand. Always carefully check that each value of the patient's demographic information is correct before proceeding with monitoring.

The Add Patient Data screen permits quick entry of the previous patient's demographic information. To restart monitoring of the patient, tap Use Previous Patient:

	Add Patient Data			
Unit System Metric Imperial				
Patient ID:	Enter	1	2	3
Gender:	Enter	4	5	6
Age:	Enter	7	8	9
Weight (kg):	Enter	С	0	×
Height (cm):	Enter		ОК	
Feb 28, 2018 1:08:33 PM	Use Previous Pat	ient	) s	ave

Fig. 8-12: Touch Use Previous Patient



The previous patient's demographic information appears, along with a user prompt.

- Trends less than one day old will display when Use Previous Patient is selected. Otherwise, trend data is archived and is only available via export (see §8.7).
- The Argos monitor has a data capacity of 1200 hours.

Continue with	previous patient?	
ID: Gender: Age: Weight: Height:	12344 Male 53 years 78 kg 180 cm	
Previous session star	ted Feb 28, 2018 11:10:27	
28, 2018 08:50 PM	Back	Next

Fig. 8-13: Verify previous patient information is correct

Use the screen to confirm demographic information is correct before proceeding.



#### WARNING

If the patient's demographic information as entered needs to be changed, it is necessary to start a new patient session.

Be sure the patient and vital information match exactly before pressing *Next* to proceed with monitoring. Should any of the information fail to match, press *Back* to return to the Add Patient Data screen and enter the patient's demographic data.

## When monitoring a new patient:



#### WARNING

Once a user ends a monitoring session for a patient and another patient has been monitored, data for the first patient's session can only be exported via data export port, and can no longer be viewed on the Argos monitor.



## WARNING

Start a New Patient Session whenever a new patient is connected to the Argos monitor. Failure to do so may result in previous patient data in the historical displays.

To fill in a value, press the box marked *Enter*. A popup entry pad appears (showing numerals in all but the *Gender* field).

- It is necessary to enter a Patient ID number for each patient before monitoring. The Patient ID number can be from 1-9 numerical characters in length.
- The Patient ID's sole purpose is to tag and identify the patient internally in the Argos monitor's database.



	Ado	d Pa	tient Data			
	Unit System Metric Imperial					
	Patient ID:	En	ter	1	2	3
	Gender:	En	ter	4	5	6
	Age:	En	ter	7	8	9
	Weight (kg):	En	ter	С	0	×
	Height (cm):	En	ter		OK	
2 =	Feb 28, 2018 1:09:44 PM		Use Previous Pati	ient	S	ave

Fig. 8-14: Tapping Enter opens a numeric pad

Enter the correct value for the patient being monitored. Press the green *OK* on the number pad to save it and proceed to the next field.

Ac	ld Patient Data					
Unit System Metric Imperial						
Patient ID:	22145	1	2	3		
Gender:	Enter	4	5	6		
Age:	Enter	7	8	9		
Weight (kg):	Enter	C		×		
Height (cm):	Enter		OK			
Feb 28, 2018 1:10:16 PM	Use Previous Pa	tient	S	ave		

Fig. 8-15: Press OK to save and continue entering data

Continue entering patient information until finished. Then press the Save box at the bottom right of the screen to save and proceed.

Once the patient demographic information has been saved, it cannot be changed. To change patient demographic

information, you must return to the Start New Patient screen (see §8.6.2.1, page 117).

	Add Patient Data	
Unit System Metric Imperial		
Patient ID:	22145	
Gender:	Female	
Age:	32 years	
Weight (kg):	58 kg	
Height (cm):	167 cm	
Feb 28, 2018 1:10:44 PM	Use Previous Patient	Save

Fig. 8-16: Save entered data and proceed

# 8.3.3 Steps before monitoring

Once you have entered the patient information, the Argos monitor is ready for use in conjunction with a bedside patient monitor; or if connected to a transducer, for zeroing the transducer prior to to monitoring.

When you have completed and saved patient demographic data entry, or have confirmed the previous patient information is correct, the Select Blood Pressure Signal Source screen appears.



#### WARNING

The Argos monitor presents visual alerts when parameter limits are exceeded, but does NOT provide audible alarms. Audible alarms are the function of the bedside patient monitor.



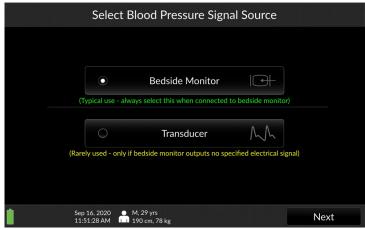


Fig. 8-17: Select BP Signal Source

#### 8.3.3.1 Connected to a bedside patient monitor:

If the Argos monitor is connected directly to the bedside patient monitor, ensure *Bedside Monitor* is selected, then press *Next* 

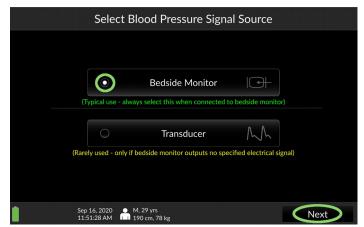


Fig. 8-18: "Bedside Monitor" selected; press Next

Monitoring commences immediately and the Trend screen appears.

# 8.3.3.2 Connected directly to a radial or femoral artery transducer:

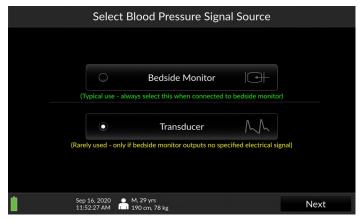


Fig. 8-19: Select Transducer and then press Next



## WARNING

Failing to zero the transducer correctly may lead to incorrect monitoring results.



#### WARNING

The Argos monitor is intended only to supplement patient assessment, and must *only* be used in conjunction with a bedside patient monitor.



#### WARNING

If the Argos monitor is connected directly to a transducer, the transducer must also be connected simultaneously to a bedside patient monitor.

If the Argos is connected directly to the patient arterial line, it is necessary to zero the transducer immediately prior to monitoring. If *Transducer* has been selected as a BP source, pressing *Next* at the bottom of the screen initiates the Zero Transducer procedure.



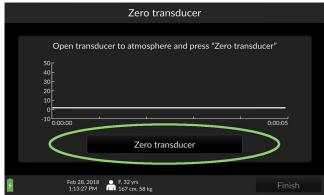


Fig. 8-20: The Zero transducer screen

Open the stopcock on the transducer line to the atmosphere. Then, press *Zero transducer*.

Zero transducer	
Open transducer to atmosphere and press "Zero transc 40 - 30 - 20 - 10 -	lucer"
-10,0000	0:00:05
Zero transducer	ノ
Feb 28, 2018 ● F, 32 yrs 1:13:27 PM ■ 167 cm, 58 kg	Finish

Fig. 8-21: Press finish to begin patient monitoring

Once you have verified that the pressure curve is flat, press *Finish*. The Argos begins monitoring.

Please verify the alert functionality whenever the device is turned on, immediately after beginning a new monitoring session. The procedure to verify alert functionality is described in Appendix F, p. 149.

# 8.4 The Trend Screen

At startup, the Argos monitor displays the previous session's selected parameters.

12	and the second	CO <sup>12.0</sup> 2.0
6 0		4.7
10:51	11:06	11:21 L/min
60 -		
0 10:51	11:06	11:21 mL
50		PPV 20 ]
25		9
0 10:51	11:06	11:21 %
	o 28, 2018 O M, 53 yrs 21:46 I 5 ft 11 in, 172 lbs	5 min avg

Fig. 8-22: The Trend screen

In addition to heart rate, the Argos can display these parameters:

- Cardiac output (CO)
- Cardiac index (CI)
- Mean Arterial Pressure (MAP)
- Pulse pressure variation (PPV)
- Stroke volume (SV)
- Stroke volume index (SVI)
- Systemic vascular resistance (SVR)
- Systemic vascular resistance index (SVRI)
- Heart rate (HR)
- Blood pressure (BP)

# 8.4.1 The Parameter Settings Screen

To change displayed parameters, access the Parameter settings screen by pressing the parameter label. The Parameter settings



overlay/tab allows the user to easily select a different parameter, change colors, adjust visual alert limits, and display additional information in the parameter label.

#### To select a different parameter:

Touch inside the label you wish to change to access the Parameter settings tab, then select the desired parameter from the dropdown.

Say you want to change the CO trend to MAP (Mean Arterial Pressure): start by pressing the CO parameter label:

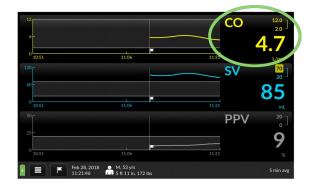


Fig. 8-23: Press any parameter label to change the displayed trend

The Parameter settings tab opens, with the currently-displayed parameter's initialism shown inside a selection box with a downward-facing triangle. Press it.



Fig. 8-24: Tap the current trend name inside the box to change it

A pulldown list of parameters appears. Scroll up or down to view the complete list.



Fig. 8-25: The dropdown list of trends

Tap on the name of a trend to select it. The selection box closes.





Fig. 8-26: MAP selected. Press Save to continue

Press the green checkmark Save to save the selection and return to the main Trend screen. The parameter you selected is now displayed.

The Argos retains the selection of parameters between sessions. If the user desires to return to the default selection of monitored parameters, navigate to User Menu/Device Settings, then tap the box labeled Reset to default configuration. Factory default settings will be reloaded.



Fig. 8-27: MAP displayed

- Should the user select a parameter that is already being displayed in a different trend window, the currently-selected parameter will display the one you select, but the previous parameter will display in the other trend window.
- The Parameter Settings page may also be used to show additional monitoring information in the label.
- When initiating monitoring for a new patient, the operator is strongly encouraged to select the BP waveform parameter, in order to ensure the BP waveform is being received by the Argos monitor.

## 8.4.2 Display change since event

You can show the net change in any parameter since an event – including monitoring initialization, or from an event that has been marked. Suppose, for example, you are monitoring a patient's cardiac output (CO) and wish to track the net change in CO over a period of time. Begin by accessing the Parameter Settings window by tapping the Parameter Label.



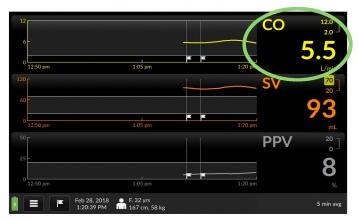


Fig. 8-28: Touch the label to access Parameter settings

The Parameter Settings page opens. Show % change is located near the center of the screen.



Fig. 8-29: "Show % change" shown highlighted

Tap the checkbox.



Fig. 8-30: "Show % change" box checked

Press the green checkmark Save to save the change you made. The percentage value of the change is now displayed.

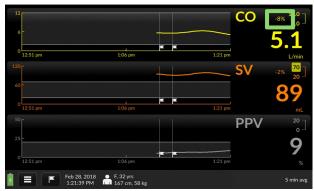


Fig. 8-31: Percentage change is measured from the flagged event

Note that when monitoring the dynamic response of the patient to an intervention, the user should take note of the selected averaging time, which is displayed in the Menu Bar at the bottom right-hand portion of the screen. In the case of the 20 second averaging time, rapid changes in the patient's hemodynamics will be reflected more quickly in the updated parameter display, whereas with the 5-



minute averaging time, hemodynamic changes will be reflected over a longer period of time. To change the averaging time, select the Device Settings option from the User Menu. Refer to Section 8.6.2 for more information.

## 8.4.3 Display an associated index or value

Certain parameters can be displayed with an associated index or pertinent value.

Trend displayed	Optional numerical trend value to show	
Cardiac Output (CO)	Cardiac Index (CI)	
Stroke Volume (SV)	Stroke Volume Index (SVI)	

Suppose you are monitoring Cardiac Output and wish to display the patient's Cardiac Index. Access the Parameter Settings page by touching the parameter label on the main screen. The *Show CI* selector is found on the left-hand side of the screen.



Fig. 8-32: "Show CI" selection box highlighted

Tick the box to display CI. Press Save 🗹 Save



Fig. 8-33: Tick the box, then tick Save

to return to the Trends screen, showing the CI value in the label.

12		CI: 2.2
6		4.8
0 12:53 pm	1:08 pm	1:23 pm L/n
	++-	SV -6% <sup>7</sup> / <sub>2</sub>
60 -		85
0 12:53 pm	1:08 pm	1:23 pm
		<b>PPV</b> <sup>2</sup>
25 -		(
	-=-=	
0 12:53 pm	1:08 pm	1:23 pm
Feb	28, 2018 O F, 32 yrs 3:03 PM III 167 cm, 58 kg	5 mir

Fig. 8-34: CI now displayed in Parameter label

# 8.4.4 Changing colors and graph limits

From the Parameter Settings page, you can also

- change the color of a trend and text
- change maximum and minimum limits of the parameter graph value (Y-axis)

To change trend display color:



Touch inside the parameter label field to call up the Parameter Settings overlay. The color selector is marked by a droplet icon bearing the currently-displayed color:



Fig. 8-35: The Color selector

Touching the color selector brings up a palette of colors:

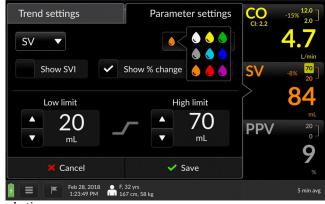


Fig. 8-36: Color selection

Choose the color you prefer.

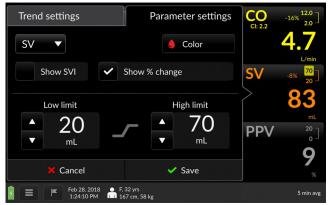


Fig. 8-37: Red selected

Press the checkmark Save label to save the value and return to the trend screen. The parameter shows in the chosen color.

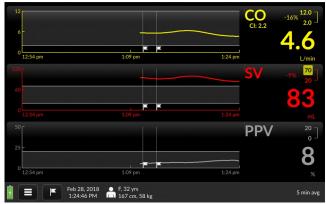


Fig. 8-38: SV trend and label displayed in red

## To change alert limits:

Bring up the Parameter Settings overlay by pressing the parameter label field. Both low limits and high limits are shown.





Fig. 8-39: High limit adjuster in Parameter settings

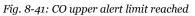
Adjust the value by tapping the up arrow or down arrow until the desired limit is reached.



Fig. 8-40: Increase the limit with the upturned triangle

When you have adjusted the values to your satisfaction, press *Save* to return to the main monitoring screen

6-		Cl: 2.2	-15 <u>k 100</u>
0 12:55 pm	1:10 pm	1:25 pm	L/m
		SV	-9% <mark>70</mark> 20
60 -			02
0 12:55 pm	1:10 pm		03
50 F		PP\	20
			۵ 
0			
12:55 pm	1:10 pm	1:25 pm	



# 8.4.5 Moving chronologically through trends

You can rapidly examine trend history by swiping a trend to the right (moving to an earlier timeframe) or to the left (to a later time). Note that only the trends recorded from the last monitored patient may be reviewed on the monitor, provided they have been recorded entirely within the previous 24 hours.

The Argos monitor can store up to 1200 patient hours of data in its memory: to access prior patients' data, use the Data Export function with a USB drive (§8.7).

Placing a fingertip on a trend brings up a light gray triangle at the left hand side:



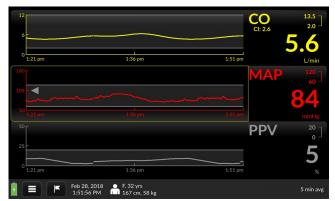


Fig. 8-42: A fingertip touching the MAP trend brings up a gray triangle

#### Note the light yellow line surrounding the trend coordinates:



Fig. 8-43: Closer view of trend and label

When the trend has been shifted to an earlier timeframe, another gray arrow appears on the right side while the timeframe is being moved.



Fig. 8-44: Arrows at both ends of the trend indicate an earlier view

To return to real-time, swipe left as far as the trend will go.

## 8.5 Trend Settings

## 8.5.1 Scaling trends

The size of the time slice shown – the scale of the X-axis – can be adjusted to any value between 10 minutes and 12 hours; by default the timescale is 30 minutes.

Fingertip control allows rapid rescaling. To compress the trends – to show a *larger* time interval – place the tips of your thumb and forefinger, or two fingers, horizontally on a trend, and draw them together in a pinching motion.

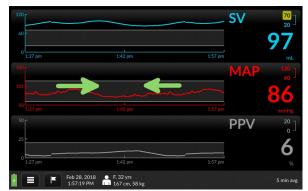


Fig. 8-45: Draw your fingertips together to compress the timescale

The trend's time axis will take in a greater duration.





Fig. 8-46: All three trends are lengthened to approximately one hour

To expand the timescale – to show a *smaller* interval in the trend windows – spread the fingertips apart

120 60			SV 70 20
0 1:27 pm	1 1:42 pm	ر 1:57 pm	97
160 -	7247 200	1.07	MAP 120 60
105			86
50 L 1:27 pm			
25 -			
			6
1:27 pm			
	Feb 28, 2018		5 min avg

Fig. 8-47: Time slice is 30 minutes before manual adjustment

The time window has now shrunk -- in this case, to ten minutes, the smallest available viewable timescale.



Fig. 8-48: The time slice is approximately 10 minutes

## 8.5.2 Trend settings: Scaling trends

You may change the time scale from the default 30 minutes to a preset numeric unit of time from the Trend settings page as well. By default, trends display over 30 minute intervals.



Fig. 8-49: Default trend timescale is 30 minutes

Tap a trend with a fingertip.

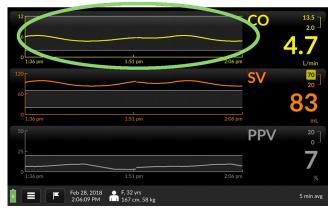


Fig. 8-50: Access Trend settings by pressing a trend

The Trend settings page opens. Current Time Scale interval is displayed in a selector box.



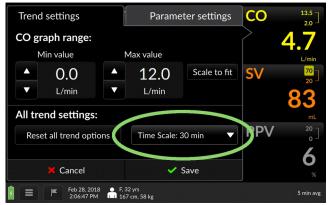


Fig. 8-51: Time scale is shown on Trend settings

Tap the box. A pulldown menu lists a choice of possible intervals:



Fig. 8-52: Timescale intervals range from 10 minutes to 12 hours

The Time Scale selection box is set to 30 minutes by default. Touch it to adjust it. Possible values are 10 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 6 hours, and 12 hours. Select the interval you prefer, then press the Save check mark **Save**.



Fig. 8-53: 10 minute interval selected, press Save 🔽 Save to continue

The Trend screen returns with the selected scale.

12		CO <sup>13.5</sup> 2.0
6 0		<b>4.9</b>
1:57 pm	2:02 pm	2:07 pm L/min
60 -		
0 1:57 pm 50 m	2:02 pm	2:07 pm mL
25		PPV °0]
0 1:57 pm	1 2:02 pm	2:07 pm %
	28, 2018	5 min avg

Fig. 8-54: All three trends are scaled at 10 minute intervals

## 8.5.3 Changing the graph range (y-axis)

Maximum and minimum values of the coordinates for each trend parameter may be raised or lowered from the Trend settings screen. You can also choose to allow the trend to determine the scale values.

Suppose we want to reduce the maximum range value for Mean Arterial Pressure. To adjust graph ranges, press the trend whose y-



axis range you wish to alter on the Trend screen to bring up Trend settings.

Note the *graph range* portion of the screen, showing Min(imum) and Max(imum) values:

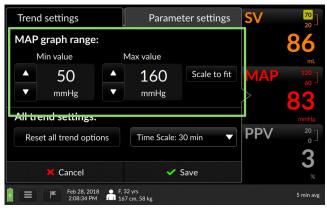


Fig. 8-55: Set MAP graph range values here

In this case, we wish to lower the maximum MAP graph value.

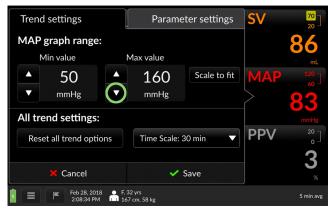


Fig. 8-56: MAP trend settings with max graph value selector highlighted

Use the triangle to incrementally decrease the numerical value.

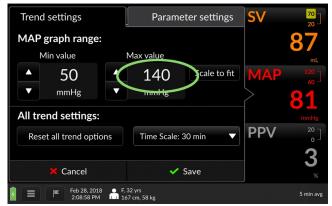


Fig. 8-57: Max graph range value is now 140 mL

Press Save to return to the Trend screen with the new value.

- Choosing Scale to Fit allows the trend to set minimum and maximum graph coordinates.
- To return all Trend settings to default values for a displayed Trend, press the Reset all trend options box. Settings will revert to bootup values.

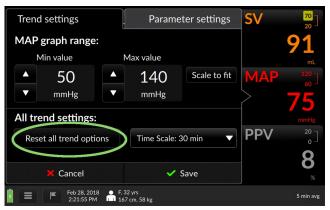


Fig. 8-58: Press Reset all trend options to return settings to defaults



## 8.6 The Menu Bar

The Menu Bar at the bottom of the screen displays

- Date and time
- Patient demographic information
- Power and battery status

battery state icon	access Events Menu patient demographic information	
	Feb 28, 2018 O F, 32 yrs 2:23:00 PM III 167 cm, 58 kg	5 min avg
\ access User Menu	date and time	averaging time

Fig. 8-59: Menu Bar elements

The Menu Bar also provides access to critical functions. From here, the user may

- Switch to a new patient
- Re-zero the transducer
- Access device settings
- Export monitoring logs
- Shut down
- Obtain information about the device
- Mark events
- Recall marked events
- Change system settings

## 8.6.1 The Battery State Indicator

At the far left of the Menu Bar, the battery indicator displays the power level and A/C outlet connection status.



## CAUTION

The Argos Cardiac Output Monitor is intended for operation while plugged into an AC wall outlet. Although it will continue to function at full capacity on battery power alone, such as when an emergency power outage occurs, it is not designed for cordless use. In case of a power outage, use of the Argos Cardiac Output Monitor should be terminated as soon as feasible.

Should the battery become disconnected from AC outlet, it will continue to supply power for approximately 30 minutes.

Battery State	Icon
When the battery is properly connected to an operational external power source, the indicator icon is colored green and shows a lightning bolt	4
When the battery is disconnected from external power, the icon is green, but without the lightning bolt	
As the battery loses power, the green shade lowers	
When battery power drops below 25%, the battery icon shows yellow	
Immediately prior to emergency shutdown, the battery shows a sliver of red	

## Table 8-1: Battery icons



Battery State	Icon
If the monitor is plugged in while the	
battery is depleted, the bolt becomes	7
visible as the battery charges	_



Do not unplug the device when the battery is depleted.

## 8.6.2 The User Menu

The User Menu enables the user to

- End a session and begin monitoring a new patient
- Power down
- Save patient monitoring data
- Change system settings for the Argos, including averaging time, date and time formats, units, and language
- export monitoring data via USB
- Restore all settings to factory default values

To access the User Menu, press the User Menu navigation icon beside the battery icon:

120		SV	<mark>70</mark> 20
60 -			85
0 2:13 pm	2:18 pm	2:23 pm	m
		MAP	
105			7/
50 2:13 pm	2:18 pm	2:23 pm	mmH;
		PPV	
25 -			Ô
			7
2:13 pm			
	b 28, 2018		5 min a

Fig. 8-60: Touch the three-lined User Menu navigation icon to access it

The User Menu appears in the bottom left-hand corner.

120 - 60 -		SV 70 20
Menu X	1 2:18 pm 2:23 pm	mL
Rew Patient		MAP <sup>120</sup> 60
∫ Re-Zero Transducer		76
Device Settings	2:18 pm 2:23 pm	mmHg
Export		
🖒 Shut Down		, 7
() About	F, 32 yrs 167 cm, 58 kg	5 min avg

Fig. 8-61: The User Menu

## 8.6.2.1 Start New Patient

If you wish to start monitoring a new patient, selecting *New Patient* from the User Menu





will bring up a confirmation screen:



Fig. 8-62: New patient confirmation screen

If you are sure you wish to end the current session and start a new patient, press *New patient* as directed by the screen.



#### WARNING

Never start monitoring from the "Use previous patient" unless you have verified the previous patient monitored has been discharged. If monitoring a new patient, use the menu to call up the *New patient* screen.

The Add Patient Data screen will appear. Follow the instructions for the Add Patient Data screen (§8.3.2, page 84).

If you wish to continue with the patient being monitored, press *Continue with current patient*, as directed.

## 8.6.2.2 Re-Zero Transducer

If you are connected directly to a transducer and need to re-zero the transducer, selecting *Re-Zero Transducer* 



Will take you to the Zero transducer screen:

	Zero transducer	
	Transducer zeroed	
50 Г		
40 - 30 -		
20 - 10 - 0 -		
-10 0:00:00	<u> </u>	0:00:05
	Re-zero transducer	
Dec 12, 2 11:39:09	017 F, 78 yrs AM 190 cm, 80 kg	Finish

Fig. 8-63: Re-zero transducer screen

Refer to the Zero transducer screen section of this manual (§7.4.1, page 60) for guidance.

## 8.6.2.3 Device Settings

Selecting Device Settings



Brings up the Settings menu:



Settings General		Reset to default configuration
Language		English $\diamond$
Date	Date Format: M/D/Y D/M/Y	Month: Day: Year: FEB 0 28 0 2018 0
Time	Time Format: 24H 12H	Hour: Minute: Second:
Signal Processing		
Averaging Time		5 Min 20 Sec
Feb 28, 2018 2:25:14 PM		Back Save

Fig. 8-64: The Settings menu

Settings *Time#C	Date setting is disabled during each	Reset to default configuration			
General					
Language		English	\$		
Date	Date Format: M/D/Y D/M/Y	Month: Day: FEB 28	Year: 2018		
Time Time Format:			ute: Second: 4 : 41		
Signal Processing					
Averaging Time		5 Min	20 Sec		
Feb 28, 2018 2:24:53 PM		Back	Save		

Fig. 8-65: The Settings menu (during patient monitoring session)

Here the user may change Language, Date and Time settings. (Languages other than English will be available in the future.)



#### CAUTION

Time and Date cannot be changed while a patient is being monitored.

## 8.6.2.3.1 Averaging Time

The Argos offers two averaging time options, 5 minutes or 20 seconds. For both options, the display of each parameter value is a

rolling average that is updated every 5 seconds. In the case of the 20 second option, rapid changes in the patient's hemodynamics will be reflected more quickly in the updated parameter display, whereas with the 5-minute option, hemodynamic changes will be reflected over a longer period of time. When monitoring the effect of an intervention, the user should take note of the selected averaging time.

After choosing the desired averaging time, press Save to return to the Trend Screen.

## 8.6.2.3.2 Reset to default configuration

To return all device settings to factory defaults, press *Reset to default configuration*:

Settings General		Reset to default configuration
Language		English $\diamond$
Date	Date Format: M/D/Y D/M/Y	Month:         Day:         Year:           FEB $\circ$ 28 $\circ$ 2018 $\circ$
Time Time Format:		Hour: Minute: Second: 2 PM $\diamond$ : 25 $\diamond$ : 12 $\diamond$
Signal Processing		
Averaging Time		5 Min 20 Sec
Feb 28, 2018 2:25:36 PM		Back Save

Fig. 8-66: Reset to default configuration selector

#### A confirmation screen appears:





Fig. 8-67: Confirm reset to defaults

Confirming will reset all settings (except for system time) to factory defaults: including Trend selections, colors, display choices, parameter limits, graph ranges, time scales, and units.

Press Reset System Settings to reset to factory defaults.

If you do not wish to reset the device, press Go back.

## 8.7 Export





#### CAUTION

The sole function of the Argos monitor's data export ports is to export data. Do not attempt to use the data export ports for any other purpose.

Patient monitoring data can be exported to a USB drive via the Export Data menu. Plug a USB drive into one of the Argos's data

export ports. Then from the User Menu, select Export to bring up a list of saved monitoring sessions.

		Export o	lata				
PID22145	Female	32yrs	Fel	o 28,	2018	1:11:00	PM
PID12344	Male	53yrs	Fel	o 28,	2018	11:10:27	AM
PID12345	Male	53yrs	Fel	o 28,	2018	11:08:10	AM
PID22145	Female	32yrs	Fel	o 28,	2018	10:59:12	AM
PID58	Female	58yrs	De	: 15,	2022	2:55:50	PM
PID58	Female	58yrs	De	: 15,	2015	2:55:36	PM
Feb 28, 2:26:04				Ba	ck	Expo	ort

Fig. 8-68: Export data

Sessions are listed chronologically, identified by Patient ID number. When you have identified the patient and session you wish to export, tap it to select it, insert a formatted USB drive into one of the Argos's data export ports, and press *Export*.

		Export	data			
PID22145	Female	32yrs	Feb 28, 2	2018	1:11:00	PM
PID12344	Male	53yrs	Feb 28, 2	2018	11:10:27	AM
PID12345	Male	53yrs	Feb 28, 2	2018	11:08:10	AM
PID22145	Female	32yrs	Feb 28, 2	2018	10:59:12	AM
PID58	Female	58yrs	Dec 15, 2	2022	2:55:50	PM
PID58	Female	58yrs	Dec 15, 2	2015	2:55:36	PM
Feb 28, 2 2:26:24			Bac	k	Expc	ort

Fig. 8-69: Tap the Export box

An Export... Please wait message pops up.



	Export	data	
PID22145	Female 32vrs	Feb 28, 2018	1:11:00 PM
PID12	Expo	ort	:10:27 AM
PID12			:08:10 AM
PID22	Please	Wait	:59:12 AM
PI			:55:50 PM
PI			:55:36 PM
Feb 28, 2 2:27:15		Back	Export

Fig. 8-70: Exporting confirmation popup

If no USB drive is inserted, an error message appears:

	Export data			
PID2214	5 Female 32vrs Feb 28	. 2018 1:11:00 PM		
PID12	Error: USB drive missin			
PID12		:08:10 AM		
PID22	Insert formatted USB driv	:59:12 AM		
PI	insert formatted 05D driv	:55:50 PM		
PI		:55:36 PM		
	Ok			
	28, 2018 :39 PM B	ack Export		

Fig. 8-71: Insert a formatted USB drive

Insert a USB drive as directed, and press Ok to continue.

Once the Export data screen returns, data has been successfully exported, and the USB drive may safely be removed. Press *Back* to return to the Trend screen.

## 8.7.1.1 Shut Down



#### WARNING

Always power off the Argos Monitor using the  $\operatorname{Shut}$   $\operatorname{Down}$  function from the User Menu.



Pressing Shut Down brings up a confirmation prompt



Fig. 8-72: Confirm shutdown

Press *Go Back* to resume monitoring, or *Shutdown* to end the session and turn the Argos off.



## 8.7.1.2 About

Select About



to view firmware and software version information.

	Add Patient Data	
Unit System: Metric Impe	About	
Patient ID:	Software Version: v1.19 Firmware Version: (Firmware Version)	
	© 2020 Retia Medical, LLC. All rights reserved.	
	Go back	

Fig. 8-73: The About screen provides software and firmware information

## 8.7.2 Events

The Argos permits user notation and recollection of events via the Events popup on the Menu Bar. To access Events, press the flag icon:



Fig. 8-74: Tap the flag icon to notate or recall events

The Events page appears with the Mark Event tab selected. A virtual keyboard allows entry into a text box, with the current time for logging the entry. Adjusters permit changing the marked time.

Ma	rk Event	Event Hist	cory ]
1		@ 12 : •	▲ 02 PM
$\begin{bmatrix} 1 \\ Q \end{bmatrix} \begin{bmatrix} 2 \\ W \end{bmatrix}$	$\begin{bmatrix} 3 \\ E \end{bmatrix} \begin{bmatrix} 4 \\ R \end{bmatrix} \begin{bmatrix} 5 \\ T \end{bmatrix}$	$ \begin{bmatrix} 6 \\ Y \end{bmatrix} \begin{bmatrix} 7 \\ U \end{bmatrix} \begin{bmatrix} 8 \\ I \end{bmatrix} \begin{bmatrix} 8 \\ I \end{bmatrix} \begin{bmatrix} 7 \\ I \end{bmatrix} \begin{bmatrix} 8 \\ I \end{bmatrix} \begin{bmatrix} 7 \\ I \end{bmatrix} I \end{bmatrix} \begin{bmatrix} 7 \\ I \end{bmatrix} I \end{bmatrix} \begin{bmatrix} 7 \\ I \end{bmatrix} I \end{bmatrix} I \\ I \end{bmatrix} I \\ I I I I I I I I I $	9 0 O P
Â		\$ % ^ & G H J K	
Caps Shift	( ) ( ) ( + ) ( ,	$\begin{bmatrix} - & - & - & - \\ - & - & - & - \\ - & - &$	Clear ]
 Back		ter > .	Save
	12, 2017 F, 48 yrs 2:13 PM 180 cm, 80 kg		5 min avg

Fig. 8-75: Event marking screen, with Mark Event selected

Use the keyboard to describe the event. If you need to notate an earlier time, adjust the time using the triangle buttons.



Fig. 8-76: Description of event



To save the event text, press *Save*. The Trend screen resumes. To recall events, press the Event History tab. All saved events appear in chronological order.

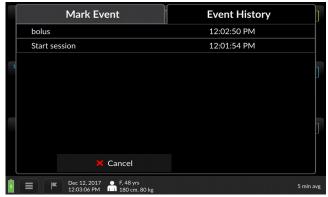


Fig. 8-77: The Event History tab

To edit an event, touch it in the chronology line. The Event: Edit Event screen appears:

	Event: Edit event	]
1	bolus @ 12 : 02 PM	
	$ \begin{bmatrix} 1 & 2 & 3 & 4 & 5 & 6 & 7 & 8 & 9 & 0 \\ Q & W & E & R & T & Y & U & I & 9 & P \\ \tilde{Q} & \tilde{Q} \\ \tilde{Q} & \tilde{Q} \\ \tilde{Q} & \tilde{Q} \\ \tilde{Q} & \tilde{Q} \\ \tilde{Q} & \tilde{Q} \\ \tilde{Q} & \tilde$	
	$ \begin{array}{c c} Caps \\ Shift \\ Z \\ \end{array} \begin{array}{c} ( \\ X \\ \end{array} \begin{array}{c} + \\ C \\ \end{array} \begin{array}{c} - \\ V \\ \end{array} \begin{array}{c} = \\ B \\ \end{array} \begin{array}{c} \overline{N} \\ M \\ \end{array} \begin{array}{c} ? \\ Clear \\ \leftarrow \end{array} \end{array} $	
	K      Enter     >     >       Back     ,     Space     .     Save	
۶	E Cec 12, 2017 A 7, 48 yrs 12:04:16 PM 180 cm, 80 kg 51	min avg

Fig. 8-78: Edit event

Here the user may alter text, adjust the Event Time as desired, or use the keyboard to make changes. Press Save to commit the changes. To return to the Trend screen from the Event History overlay, press Cancel.

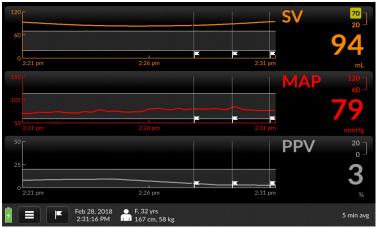


Fig. 8-79: Press cancel to recall the Trend screen

Note that flags, representing the marked events, now appear on the trends.

## 8.7.3 Complete Patient/End session

Patient data is retained for export via the data export port. (For directions on exporting data, see §8.7, page 122.)



#### WARNING

**Only** power off the Argos Monitor using the Shut Down function from the User Menu. **Never** power off the monitor by pressing the power switch or unplugging the device.

To end a monitoring session, call up the User Menu and press "Complete Patient." The screen displays a warning:





Fig. 8-80: System shutdown confirmation screen

To power down the Argos monitor, press *Shutdown*; otherwise to continue monitoring, press *Go Back*.

## 9 Help

The following is a list of error messages and recommended actions:

Message	Possible cause(s)	Suggested action
Check Arterial BP	Arterial BP waveform signal	Check the arterial BP
waveform	quality is insufficient to	waveform for sources of
	calculate CO	noise, from patient to
		the Argos monitor
	Noisy BP signal due to	
	patient/cable movement	Check the arterial waveform for
	Electromagnetic interference	physiological causes of
	from high frequency	artifact such as severe
	electrosurgical equipment or	hypotension, severe
	other sources	hypertension, or motion
		artifact.
	Very low pulse pressure,	
	Systolic Pressure too high or	
	Diastolic pressure too low	
	Non-physiological BP signal	
	due to occluded/disconnected	
	transducer tubing	
	Inspect all arterial pressure	
	lines. Ensure stopcocks are	
	properly positioned.	
	Inspect the arterial catheter.	
	Ensure it is not blocked or kinked.	
	KIIIKEU.	
	Make sure the transducer is	
	aligned with the patient's	
	phlebostatic axis.	
	-	
	Re-zero the transducer.	



Message	Possible cause(s)	Suggested action
Check cable connection	Transducer cable is	Check cable connection
	disconnected	to the transducer
		Check cable to the
	External monitor cable is	external monitor
	disconnected	
Low Battery	Argos Monitor is operating on	Plug in the Argos
	internal battery power and the	monitor to the AC
	battery level is below 25%	mains. If the battery no
		longer holds a charge
		after connecting to a
		working mains, it needs
		to be replaced. Contact
		Retia Medical Technical
		Support.
Internal Error	Internal System malfunction	Power off system and
		Restart the monitor. If
		problems persists,
		contact Retia Medical
		Technical Support.

Table 9-1: Troubleshooting error messages

#### Notes:

- 1. If the software freezes and the device becomes unresponsive, press the power button for at least 30 seconds to initiate a forced shutdown.
- 2. Because the Argos monitor is not used as a stand-alone patient monitor, all alerts, including CO and derived hemodynamic monitoring parameters, are low priority.



#### WARNING

A hazard can exist if different alarm/alert presets are used for the same or similar equipment in any single area.

3. When a monitored parameter exceeds an upper or lower alert limit, a yellow box will highlight the displayed limit. Please see section 8.1, page 78 for more details.

- 4. Alerts are fully visible to a user operating the Argos monitor facing the screen.
- 5. If the Argos monitor detects artifacts or noise in the BP signal for any reason, in addition to displaying an error message on the status section of the menu bar as listed above, the monitor will not display numeric trend values:

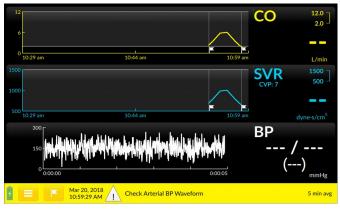


Fig. 9-1: Error message displayed, with null trend values

After correction of the condition which led to the error, while the error message may disappear, allow at least 25 seconds for the sample size to produce accurate results.

If any of the indicated solutions does not work, or you are experiencing any other problems or issues with the Argos monitor, contact Retia Medical technical support by phone at (+1) 914-594-1986 or email at info@retiamedical.com.



## **Appendix A: Specifications**

The Argos Cardiac Output Monitor measures cardiac output (CO) and derived hemodynamic parameters when used with an appropriate radial or femoral artery sensing device. Appendix A includes summaries of the following:

- Physical and Mechanical Specifications
- Electrical Specifications
- Environmental Specifications:
  - Operating Conditions
  - Transport and Storage Conditions
- Displayed Parameters
- Standards Compliance
- Monitor and Accessories part numbers

Attribute	Value		
Weight	8.3 lb. / 3.76 kg		
Dimensions	Height	10.6" / 269.5 mm	
	Width	12.36"/ 314 mm	
	Depth	3.86" / 98 mm	
Display	Туре	10.1" Color TFT LCD, touch screen	
	Viewing area	8.54" x 5.34"/ 216.96mm x 135.6mm	
	Resolution	1280 x 800	
User interface	Touch screen		
Data capacity	1200 hours		
Data Export	FAT32-formatted, USB 2.0-compatible, removable drive.		

## Table A-1: Physical and Mechanical Specifications



## Table A-2: Electrical Specifications

Attribute	Value
Mains Voltage	100 to 240 V, AC
Mains Frequency	50/60 Hz
Power Consumption	36 W
Bedside patient monitor input	1 V/100 mmHg

#### **Table A-3: Environmental Specifications**

Property	Value	
Operating conditions		
Temperature range	5 to 35 °C	
Relative Humidity	10 to 95 %	
Ambient Pressure	70 to 106 kPa	
Transport and Storage Conditions		
Temperature range	-25 to 70 °C	
Relative Humidity	10 to 100 %	
Ambient Pressure	50 to 106 kPa	

#### **Table A-4: Parameters**

Parameter	Specification	
СО	Reproducibility	0.1 l/minute
	Update Rate	5 seconds

#### **Table A-5: Standards Compliance**

Applied Part Type	1x Type CF defibrillation-proof
Equipment class	Class II
Electrical Protection Class	IEC Class I
Ingress Protection Class	IPX1
IEC Standards	IEC 60601-1:2005+AMD1:2012
	IEC 60601-1-2:2014
	IEC 60601-2-34:2011*
	IEC 60601-1-8: 2011
	IEC 62366-1:2015
Packaging standard	ISTA 2A

\*Not including the section (208.6) on alarms. All alarms are governed by IEC 60601-1-8.



#### Table A-6 Argos Cardiac Output Monitor and Accessory Part Numbers

Item/Category	Part number			
Argos hemodynamic monitor	FG-001			
Bedside patient monitor interface cable				
Philips Blood Pressure Interface cable	FG-002			
GE Solar (with TRAM RAC 4A) interface cable	FG-005			
GE PDM interface cable	FG-003			
Draeger interface cable	FG-006			
Spacelabs Xpresson	FG-007			
Parts and Accessories				
Utah Medical BP Transducer Kit (pack of 25): includes BP Transducer, Y connector, tubing	902-649			
Utah Medical Transducer interface cable	650-299-117			
AC power cord	30-012			
Power supply	30-011			
Custom pole mount roll stand	30-035			
Table/Pedestal stand	30-036			
Operator's Manual	60-001			
Quick Start Guide	60-025			
Retia Service Manual	60-026			

To order parts or accessories please contact Retia customer support or your Retia representative.



### WARNING

The Argos monitor should not be used to monitor arterial blood pressure. The arterial blood pressure transducer input on the Argos monitor is to be used only when another arterial blood pressure transducer is connected in parallel to a bedside patient monitor with the appropriate blood pressure alarms.



## WARNING

Before connecting a bedside patient monitor to the Argos monitor, consult with your Retia Medical representative to ensure your bedside patient monitor has the correct specifications.



## WARNING

Only connect accessories that have been qualified as part of the Argos monitor.



## CAUTION

Do not use AC excitation voltages from a bedside monitor for the External CVP connection. The Argos monitor is designed for use with bedside monitors which use DC excitation voltages only.



# Appendix B: Equations for Calculated Patient Parameters

Table B-1: Hemodynamic Parameters				
ParameterCardiac OutputCO		Formula	Units	
		Proprietary MBA algorithm	L/min	
Cardiac Index	CI	Cardiac Index CI = CO/BSA where: CI - Cardiac Index, CO - Cardiac Output, L/min BSA - Body Surface Area, m <sup>2</sup>	L/min/m <sup>2</sup>	
Mean Arterial Pressure	MAP	Average systemic arterial blood pressure.	mmHg	
Heart rate	HR	Number of heartbeats per minute.	Bpm (beats/min)	
Blood pressure	BP	The pressure of blood in the circulatory system.	mmHg	
Stroke Volume	SV	Stroke Volume SV = (CO/HR) x 1000 where: CO - Cardiac Output, L/min HR - Heart rate, beats/min	mL	
Stroke Volume Index	SVI	Stroke Volume Index SVI = (CI/PR) x 1000 where CI - Cardiac Index, L/min/m 2 HR - Heart rate, beats/min	mL/m <sup>2</sup>	
Systemic Vascular Resistance	SVR	Systemic Vascular Resistance SVR = {(MAP - CVP) x 80} /CO (dyne-sec/cm 5 ) where: MAP - Mean Arterial Pressure, mmHg CVP - Central Venous Pressure, mmHg CO - Cardiac Output, L/min	dyne-s/cm⁵	

Table B-1: Hemodynamic Parameters				
Parameter		Formula	Units	
Systemic Vascular Resistance Index	SVRI	Systemic Vascular Resistance Index SVRI = {(MAP - CVP) x 80} /CI where: MAP - Mean Arterial Pressure, mmHg CVP - Central Venous Pressure, mmHg CI - Cardiac Index, L/min/m <sup>2</sup>	dyne-s-m²/ cm <sup>5</sup>	
Pulse Pressure Variation	PPV	The difference between maximum and minimum pulse pressure over a respiratory cycle, per mean pulse pressure	%	

For further information please visit retiamedical.com, or contact us by email or phone.



## Appendix C: Default Settings

Parameter	Min Graph Default	Max Graph Default	Graph Setting increment	Low Alarm Default	High Alarm Default	Alarm Setting Increment	Color
CO	0	12	1	2	12	0.1	Yellow
CI	0	12	1	1	6	0.1	Yellow
SV	0	120	20	20	70	5	Orange
SVI	0	80	20	20	70	5	Orange
SVR	500	1500	100	500	1500	50	Purple
SVRI	1000	3000	200	500	3000	50	Purple
MAP	50	160	20	60	120	5	Red
HR	60	120	20	60	120	5	Green
PPV	0	50	10	0	20	1	Gray
BP	50	160	10	NA	NA	NA	White

#### **Table C-1: Argos Monitor Defaults**

- For SVR and SVRI, default CVP is 7 mmHG
- Averaging Time Default: 5 minimize
- Date Format Default: MM/DD/YY
- Time Format: 12-hour Time (HH: MM AM/PM)
- "Show CI" and other indexed parameters are unselected
- Time Scale Default: 30 minutes
- Default event flag for "Start Session"
- Default parameters on Trend Screen: Cardiac Output (CO), Stroke Volume (SV), and Pulse Pressure Variation (PPV)

### Appendix D: Unit Conversions

### lbs to/from kg

Conversion factors:  $lb \rightarrow kg: lb \div 2.2$  $kg \rightarrow lb: kg x 2.2$ 

### inches to/from cm

**Conversion factors:** 

inches  $\rightarrow$  cm: inches x 2.54 cm  $\rightarrow$  inches: cm  $\div$  2.54



### Appendix E: Care, Service, and Support

Only clean the Argos monitor as directed in this appendix.

No other scheduled maintenance or routine service is required: the Argos monitor contains no user-serviceable parts, and should only be repaired by a service representative authorized by Retia.

Information on contacting a Retia Medical representative for support, repair, or replacement may be found at the end of this appendix.

The expected service life of the Argos Monitor is 5 (five) years.



#### WARNING

The Argos monitor contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.



#### WARNING

Shock or fire hazard! Do not immerse the Argos monitor or cables in any liquid solution. Do not allow any fluids to enter the device.

# **Cleaning the Monitor**



#### CAUTION

Do not pour or spray liquid onto the monitor or accessories.

To clean the surface of the Argos Monitor, dampen a clean cloth with disinfectant, either

- 70% isopropyl alcohol solution
- diluted bleach solution (1 part bleach to 10 parts water)
- a non-abrasive liquid commercial cleaner

Lightly wipe the surface of the Argos monitor.

## **Monitor Maintenance**

Periodically inspect the monitor for signs of wear. Check to make sure the monitor body is intact and not broken or cracked, and shows no sign of abuse or tampering.

# **Cable Maintenance**



#### CAUTION

Do not immerse cable connectors in detergent, isopropyl alcohol or glutaraldehyde.





#### CAUTION

NEVER:

- Allow any liquid to come in contact with the power cable.
- Allow any liquid to penetrate connectors or openings in the case

Should liquid contact the power cable or penetrate the case, do not attempt to operate the monitor. Instead, shut down the monitor, disconnect power immediately, and call your Biomedical Department or Retia Medical representative.



### CAUTION

Do not use any heating device to dry cable connectors.



### CAUTION

Regularly inspect all cables for defects. Never coil cables tightly when storing.



#### CAUTION

If any electrolytic solution such as NaCl, Lactated Ringers, is allowed to contact the cable connectors while connected to the Argos monitor, and the monitor is turned on, the excitation voltage may cause electrolytic corrosion and rapid degradation of the electrical contacts. Therefore, do not allow electrolytic solutions to contact the cable connectors.

Periodically inspect cables and lines for signs of wear or age. Discontinue use immediately if you find fraying cable, cracked or broken insulation, or faulty (broken pins, cracking housing) connectors, or exposed electrical or mechanical contacts.

From time to time, or as needed, wipe the patient cable with a clean cloth using 10% bleach and 90% water. Allow the cable to air dry.

# Software Maintenance

The Argos monitor software cannot be updated in the field or by the end user. The unit can be returned to the manufacturer for maintenance and updates as needed.

# Data Port Maintenance

The port on the side of monitor is meant for data export only and is locked for any other purpose. The Argos monitor does not have any capability for network connection. Do not use USB drives containing any executable.

If you need further assistance, please contact Retia Medical.

# **Expected Service Life**

The expected service life of the Argos Cardiac Output Monitor is 5 (five) years. However care should be taken to ensure its continuing operability: therefore, periodically inspect the device to ensure it is fully functional. Discontinue use immediately if:

- Cables are frayed
- Screen and/or or enclosure cracked or show signs of functional wear
- Labels torn or tampered with
- Battery incapable of holding a charge for 30 minutes
- Connectors loose or broken
- Monitor shows evidence of overheating



# **Service and Support**

See **§9 Help** for diagnosis and remedies. If you still cannot solve the problem, contact Retia Medical by phone at (+1) 914-594-1986 or email at info@retiamedical.com

If you are calling, please have at hand:

- The monitor's serial number, printed on the rear panel;
- The text of the error message(s), if any, and detailed information as to the nature of the problem.

### Appendix F: Alert Functionality Verification

To confirm alert capability, follow this procedure:

- 1. Note the current value for CO.
- 2. Press the CO trend label to change the upper alert limit, as described in §8.4.4, page 103, to a value lower than the current CO value, and press Save.
- 3. Verify that in the CO numeric area, the upper alert limit is highlighted with a yellow box.
- 4. Press the CO trend label to change the lower alert limit to a value higher than the current CO value, and press Save.
- 5. Verify that in the CO numeric area, the upper alert limit is highlighted with a yellow box.
- 6. Adjust the alert limits for future patient monitoring.
- 7. Disconnect the external monitor cable.
- 8. Verify that the status bar turns yellow and displays the message "Check cable connection".
- 9. Connect the external monitor cable back into the Argos monitor.



#### WARNING

Ensure that after alert verification, the alert limits are adjusted to physiologically appropriate values for patient monitoring.



### Appendix G: Clinical Studies

#### **Chapter Overview**

This chapter provides information on the clinical validation study using the Argos Hemodynamic Monitor. A Reference Bibliography containing additional clinical studies is available on Retia's website (www.retiamedical.com) or by contacting your Retia Medical Customer Service representative.

An adult study was performed on critically ill patients in the operating room and intensive care unit comparing the accuracy of the cardiac output (CO) measurements from the Argos Monitor to the accuracy of CO measurements from the predicate device (Edwards Lifesciences' Vigileo Cardiac Output Monitor version 3). The accuracy of both devices was determined with respect to reference cardiac output readings obtained via the thermodilution method, from a pulmonary artery (PA) catheter. The study was performed on 40 patients under informed consent as part of a protocol approved by the IRB for Columbia University Medical Center (Predicate Comparison Study). No adverse events attributable to the Argos Monitor were reported during the study. The Predicate Comparison Study evaluated the accuracy of the CO values as reported by the Argos Monitor compared to the reference CO values obtained via a pulmonary artery catheter. For the reference CO, both bolus thermodilution and continuous PA catheter measurements were used. Accuracy of the predicate device CO measurements was evaluated similarly, with respect to the same CO reference. Finally, the absolute and trend accuracy of the Argos monitor was compared with the predicate device. Both the Argos

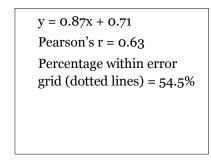
and predicate device calculated CO via analysis of the same blood pressure waveform from a radial or femoral arterial catheter.

The 40 patients included: 20 operating room (OR) patients (liver transplant and cardiac surgeries) and 20 intensive care unit (ICU) patients (post-liver transplant and post-cardiac surgery); 28 males and 12 females; age 20 to 83 years, with a mean of 62 years. Out of a total of 236 possible data points, 32 were removed due to missing signal (BP or reference CO) and 15 were removed due to signal artifact or hemodynamic instability in accordance with the data selection criteria, leaving 189 time points available for analysis.

**Methods**: Reference cardiac output measurements from the PA catheter (including the reference time points) were recorded along with Blood pressure signals, which were simultaneously fed to the Argos and the predicate monitors. For the OR patients, reference measurements were made according to pre-defined surgical landmarks. In the case of liver transplants, these were: incision, pre-clamping of the vena cava, post-clamping, post-unclamping, and closure. In the case of cardiac surgeries, these were: incision, pre-bypass, post-bypass, and closure. In the case of ICU patients, the time points were every 2 hours when reference measurements were available.



#### **Results:**



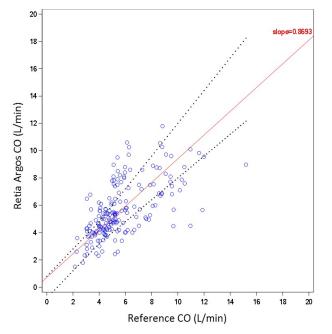


Fig. G-1: Regression (unweighted Deming) plot for Retia Argos CO versus reference CO for all patients

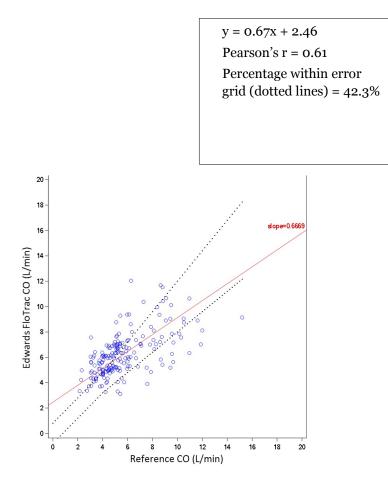


Fig. G-2: Regression (unweighted Deming) plot for predicate CO versus reference CO for all patients



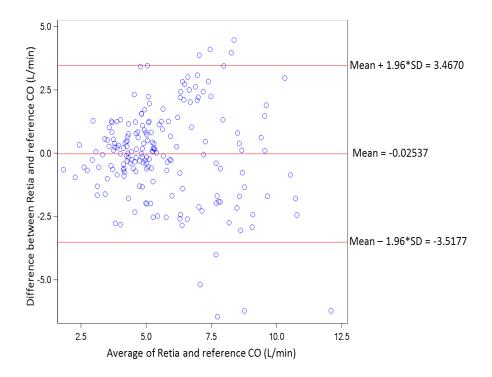


Fig. G-3: Bland-Altman plot comparing Retia Argos CO to reference CO for all patients. LOA [-3.52 to 3.47]

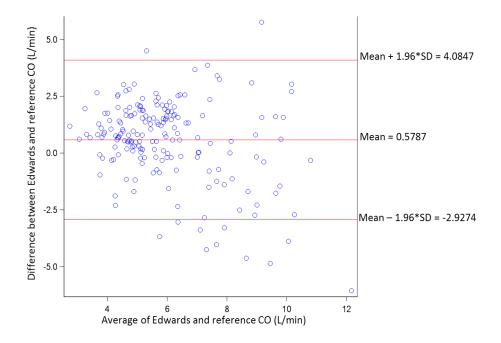


Fig. G-4: Bland-Altman plot comparing predicate CO to reference CO for all patients. LOA [-2.93 to 4.08]



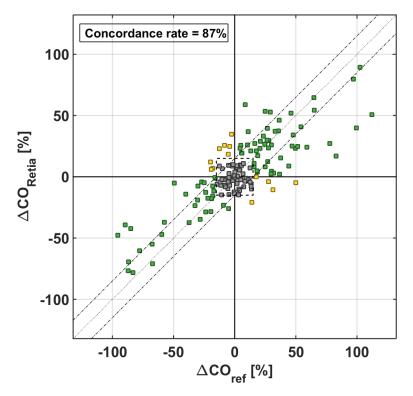


Fig. G-5: Concordance plot for percentage changes in Retia Argos CO versus percentage changes in reference CO

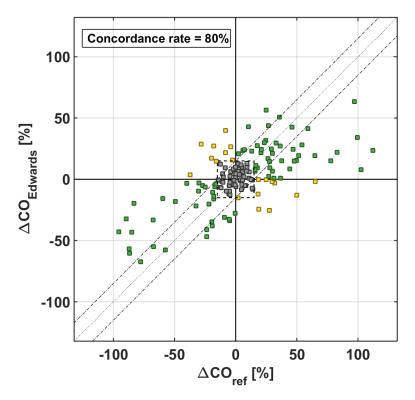


Fig. G-6: Concordance plot for percentage changes in predicate CO versus percentage changes in reference CO  $^{\rm CO}$ 



Analysis subgroup	Performance metric with respect to CO- Thermodilution	Retia-Argos [95% CI]	Predicate device [95% CI]
Overall CO	Bias	-0.03 L/min [-0.53 to 0.47]	0.58 L/min [-0.12 to 1.04]
	Precision	1.78 L/min [1.52 to 2.15]	1.79 L/min [1.56 to 2.10]
	NRMSE	31.5%	33.2%
	Concordance Rate	87% [81.3 to 91.9]	80% [74.2 to 86.2]
CO≥5 L/min	RMSE	2.09 L/min	2.05 L/min
CO < 5 L/min	RMSE	1.19 L/min	1.62 L/min

Table G-1: Summary statistics including bias, precision, normalized root mean squared error (NRMSE), concordance and root mean squared error for sub-group analyses.

The NRMSE represents the average size of error in percentage of a device. Specifically defined as follows:

$$NRMSE = 100 \cdot \frac{\sqrt{\mu^2 + \sigma^2}}{E(X)}$$

where  $\mu$  is the bias,  $\sigma$  is the precision, and E(X) is the expected value (or average) of the reference CO.

The RMSE is computed as follows:

 $RMSE = 100 \cdot \sqrt{\mu^2 + \sigma^2}$ 

Concordance was calculated using a 15% exclusion zone as recommended in Critchley, L. A., Lee, A. & Ho, A. M. H. A critical review of the ability of continuous cardiac output monitors to measure trends in cardiac output. Anesth. Analg. 111, 1180–1192 (2010).

Percentage within the error grid was calculated according to Forrest, S.W. et al. Statistical Comparison of Cardiac Output Measurement Methods: Advantages of an Error Grid Representation. Journal of Cardiac Failure, Volume 14, Issue 6, S56.

#### Validation with femoral BP

To validate the Argos monitor's performance when using femoral BP signal as the input, a study similar to the one described above was performed. The purpose of the study was to evaluate the accuracy of the Argos monitor and Edwards Lifesciences' Vigileo Cardiac Output Monitor version 3, with the reference CO measured via the continuous thermodilution method, from a pulmonary artery catheter (PAC). The study was performed with data from 22 adult patients undergoing liver transplant surgery, collected under informed consent as part of a protocol approved by the IRB for Columbia University Medical Center.

Analysis methods follow the Predicate Comparison study above. CO estimates from the Argos and the Edwards devices were obtained by simultaneously feeding the femoral BP waveforms to both devices. These estimates were then compared to the reference CO at the following surgical landmarks: incision; pre-clamping of the vena cava; post-clamp; post-unclamp; and closure.

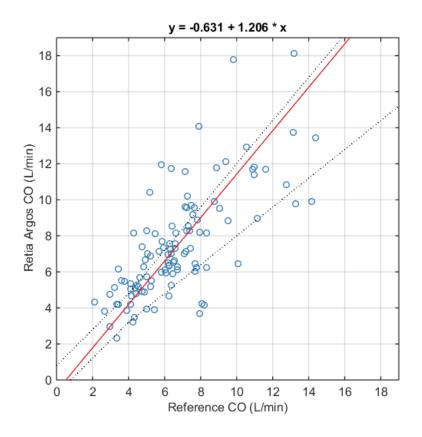
The 22 patients included 13 Males and 9 females; age 19 - 69 years (mean age 54 years). In one of the subjects, 2 measurements were excluded due to instability of the reference CO, in accordance with the data selection criteria, leaving a total of 108 measurements available for analysis. For the concordance analysis, percent change between consecutive segments was used for each method (reference, Argos and Edwards Vigileo). A total of 86 changes were available for the concordance analysis. Figures G-7 through G-12 show the Regression, Bland-Altman, and Concordance plots for the Argos and the Vigileo device, with thermodilution as the reference.

Results are shown in Table G-2 below.



Analysis subgroup	Performance metric with respect to CO- Thermodilution	Retia-Argos [95% CI]	Predicate device [95% CI]
Overall CO	Bias	0.75 L/min	0.23 L/min
		[-0.09 to 1.58]	[-0.60 to 1.06]
	Precision	2.13 L/min	2.30 L/min
		[1.73 to 2.78]	[1.89 to 2.93]
	NRMSE	33.7%	34.4%
	Concordance Rate	94%	87%
CO < 5 L/min	Bias	0.98 L/min	1.53 L/min
		[0.43 to 1.52]	[0.84 to 2.22]
	Precision	1.15 L/min	1.46 L/min
		[0.91 to 1.59]	[1.14 to 2.03]
	NRMSE	38.3%	34.4%
$CO \ge 5 L/min$	Bias	0.67 L/min	-0.25 L/min
		[-0.26 to 1.59]	[-1.11 to 0.62]
	Precision	2.31 L/min	2.29 L/min
		[1.87 to 3.03]	[1.88 to 2.92]
	NRMSE	31.1%	29.8%

Table G-2: Summary statistics including bias, precision, NRMSE and concordance for all data and subgroups. Note that concordance is not calculated for the subgroups due to restricted data.



*Fig. G-7: Regression (unweighted Deming) plots for Argos CO versus reference CO. Pearson's r = 0.73; Percentage within error grid = 50%* 



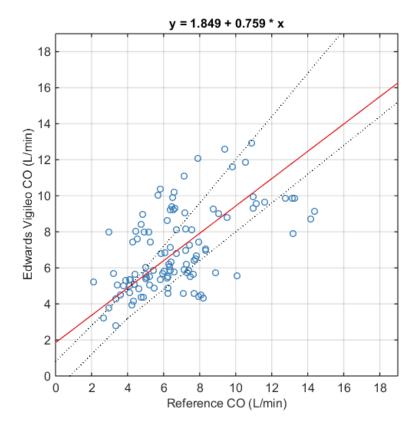


Fig. G-8: Regression (unweighted Deming) plots for Vigileo CO versus reference CO. Pearson's r = 0.57; Percentage within error grid = 49%

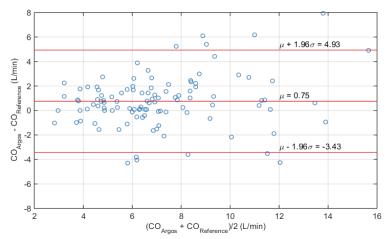


Fig. G-9: Bland-Altman plot comparing Argos CO to reference CO. LOA [-3.43 to 4.93]

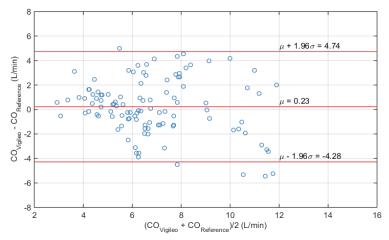


Fig. G-10: Bland-Altman plot comparing Vigileo CO to reference CO. LOA [-4.28 to 4.74]



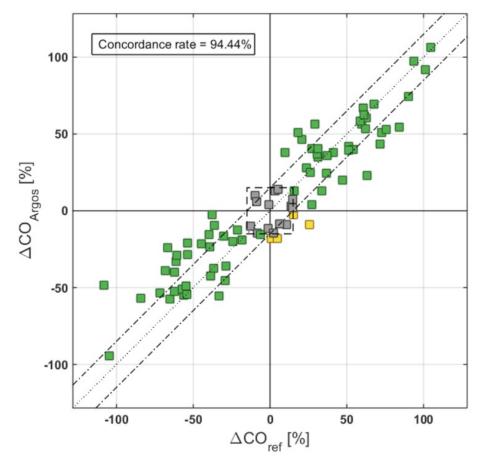


Fig. G-11: : Concordance plot for percentage changes in Argos CO versus percentage changes in reference CO  $\,$ 

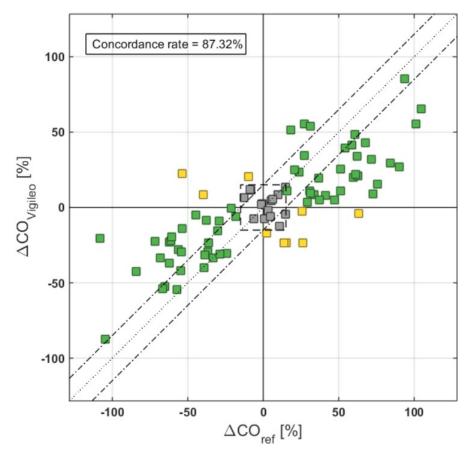


Fig. G-12: Concordance plot for percentage changes in Vigileo CO versus percentage changes in reference CO



### Appendix H: Manufacturer's Declaration

### Retia Medical LLC Headquarters

7 Dana Road Valhalla, NY 10595 (+1) 914-594-1986 info@retiamedical.com

## **Monitor Disposal**

Before disposing, to avoid contamination of individuals, the environment, or other equipment, make sure the monitor and/or cables are properly disinfected and decontaminated in accordance with local and national laws regulating the disposal of equipment containing electrical and electronic parts.

For single-use parts and accessories, where not otherwise specified, follow local and institutional regulations regarding disposal of hospital waste.

### Warranty

Retia Medical (Retia) warrants that the Argos Cardiac Output Monitor is fit for the purposes and indications described in the labeling for a period of one (1) year from the date of purchase when used in accordance with the directions for use. Unless the equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include cables and connectors used with the Argos Cardiac Output Monitor. Retia Medical's sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the Argos Cardiac Output Monitor at Retia Medical's option. Retia Medical shall not be liable for proximate, incidental, or consequential damages. Retia Medical shall not be obligated under this warranty to repair or replace a damaged or malfunctioning Argos Cardiac Output Monitor if such damage or malfunction is caused by the customer's use of accessories other than those certified by Retia Medical.



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This Cardiac Output Monitor is designed and manufactured by Retia Medical LLC.

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

Retia Medical Argos User Guide



