Operator's Manual

Masimo LiDCO®
Hemodynamic Monitoring

For Sale in USA

These operating instructions provide the necessary information for proper operation of all models of Masimo LiDCO®. There may be information provided in this manual that is not relevant for your system. General knowledge of blood pressure and hemodynamic measurements and an understanding of the features and functions of Masimo LiDCO are prerequisites for its proper use. Do not operate Masimo LiDCO without completely reading and understanding these instructions. If you encounter any serious incident with this product, please notify the competent authority in your country and the manufacturer.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Note: Cleared Use Only: The device and related accessories are cleared by the US Food and Drug Administration (FDA) and are CE Marked for hemodynamic patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

CAUTION: Federal (USA) law restricts this device for sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Masimo Corporation
52 Discovery
Irvine, CA 92618, USA
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

CE
2862

EU authorized representative for Masimo Corporation:
EC REP
MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

Switzerland Authorized Representative
CH REP
Masimo International Sàrl
Route de Pierre-à-Bot 97
2000 Neuchâtel Switzerland

3149433

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1, and applicable Particular (IEC 60601-2-34, Standards for which the product has been found to comply by Intertek.

Patents: ***www.masimo.com/patents***

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Contents

About This Manual

This manual explains how to set up and use the Masimo LiDCO®. Important safety information relating to general use of Masimo LiDCO appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Indications, and Contraindications

Product Description

Masimo LiDCO® is a module that supports minimally invasive hemodynamic measurements that are used to derive stroke volume and heart rate from a patient's existing arterial pressure waveform using the LiDCO® algorithm.

The LiDCO algorithm calculates a number of derived parameters from the blood pressure waveform, including the following:

- Systolic Blood Pressure (Sys)
- Mean Arterial Blood Pressure (MAP)
- Diastolic Blood Pressure (Dia)
- Oxygen Delivery (DO_2)
- Oxygen Delivery Index (DO_2i)
- Oxygen Consumption (VO_2)
- Oxygen Consumption Index (VO_2i)
- Cardiac Output (CO)
- Cardiac Index (Ci)
- Stroke Volume (SV)
- Stroke Volume Index (SVi)
- Heart Rate (HR)
- Heart Rate Variation (HRV)
- Systemic Vascular Resistance (SVR)
- Systemic Vascular Resistance Index (SVRi)
- Stroke Volume Variation % (SVV)
- Pulse Pressure Variation % (PPV)
- Body Surface Area (BSA)

Masimo LiDCO gets arterial blood pressure data from the analog output of a 3rd party patient monitor (using the Analog Cable), or an interconnect between a 3rd party patient monitor and pressure transducer (using the BP Module Cable). Masimo LiDCO is intended for adult patients requiring cardiovascular monitoring who have peripheral arterial pressure monitoring in hospital and hospital-type settings.

The operator controls the unit using menus and dedicated buttons on the monitor to select various display options.

Masimo LiDCO should not be used as the sole basis for diagnosis or therapy.

Indications for Use

Masimo LiDCO is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use for the measurement of blood pressure, cardiac output and associated hemodynamic parameters in adult patients.

In addition to arterial blood pressure parameters and cardiac output, Masimo LiDCO calculates a number of derived parameters:

> Oxygen Delivery and Oxygen Delivery Index, Cardiac Index, Stroke Volume and Stroke Volume Index, Systemic Vascular Resistance and Systemic Vascular Resistance Index, Stroke Volume Variation %, Pulse Pressure Variation % and Body Surface Area.

Contraindications

The following patients are contraindicated for use with the Masimo LiDCO:

- Patients with aortic valve regurgitation
- Patients being treated with an intra-aortic balloon pump (IABP)
- Patients with highly damped peripheral arterial lines
- Patients with peripheral arterial vasoconstriction

Safety Information, Warnings and Cautions

CAUTION: Masimo LiDCO is to be operated by, or under the supervision of, qualified personnel only. Read the manual, accessories, directions for use, all precautionary information, and specifications before use. Refer to the Operator's Manual for the Root monitor for additional safety information, warnings and cautions.

Note: For any serious incident that directly or indirectly led, might have led, or might lead to any of the following, users and /or patients should notify the device manufacturer and their competent authority where the serious incident took place.

a. The death of a patient, user or other person

b. The temporary or permanent serious deterioration of a patient's, user's or other person's state of health

c. A serious public health threat

Note: Masimo LiDCO is for use in conjunction with a 3rd party patient monitor.

Note: Always use the correct cable for connecting the module to the 3rd party patient monitor.

Note: Additional information specific to the Masimo cables compatible with the module may be found in the cable's directions for use (DFU).

Safety Warnings and Cautions

WARNING: Do not use Masimo LiDCO if it appears or is suspected to be damaged. Damage to the module enclosure can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify Masimo LiDCO. Damage to the module may result in degraded performance and/or patient injury.

WARNING: Do not start or operate Masimo LiDCO unless the setup was verified to be correct. Improper set-up of the device may result in degraded performance and/or patient injury.

WARNING: Do not place Masimo LiDCO or accessories in any position that might cause it to fall on the patient.

WARNING: Only use authorized devices with Masimo LiDCO. Using unauthorized devices with the module may result in damage to the device and/or patient injury.

WARNING: Do not use Masimo LiDCO in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide to avoid risk of explosion.

WARNING: Do not use Masimo LiDCO during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Masimo LiDCO may be used during defibrillation. However, to reduce the risk of electric shock, the operator should not touch Masimo LiDCO during defibrillation.

WARNING: To protect against Electrical Shock Hazard, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Use cleaning solutions only as instructed in this Operator's Manual.
- Do not attempt to clean the module while monitoring patient.

- Do not use device if it has been exposed to more than just vertical dripping fluids.

WARNING: To ensure safety, avoid placing anything on the device during operation.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: All cables are designed for use with specific devices. Verify the compatibility of the device and cable before use; otherwise, degraded performance and/or patient injury can result.

WARNING: Do not place Masimo LiDCO where the controls can be changed by the patient.

WARNING: To ensure patient electrical isolation, all external device connections to the output interface connector must be done using only authorized data cables.

WARNING: Make sure Masimo LiDCO is securely mounted, and that all accessories and cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment.

WARNING: Before use, check the patient notes for the presence of aortic valve regurgitation. Masimo LiDCO may be inaccurate in such patients.

Performance Warnings and Cautions

WARNING: Masimo LiDCO is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Masimo LiDCO may be used during electrocautery, however this may temporarily affect the accuracy or availability of the parameters and measurements.

WARNING: The scaling factor estimate cannot be as precise as an independent calibration of the LiDCO algorithm with a well-performed indicator dilution measurement.

WARNING: Before use, check the patient notes for the presence of aortic valve regurgitation. The Masimo LiDCO may be inaccurate in such patients.

CAUTION: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Masimo LiDCO for proper functioning.

CAUTION: Do not place Masimo LiDCO on electrical equipment that may affect the device, preventing it from working properly.

Note: The Calibration Factor estimate used has boundary conditions similar to any device using a nomogram-based approach to estimate physical characteristics. Individual patient history may include a variety of potentially confounding conditions such as chronic hypertension, arteriosclerosis and/or diabetes, which may alter aortic capacitance.

Note: Care should be taken when using Masimo LiDCO in patients with severe peripheral vasoconstriction due to pre-existing disease or because of vasoactive drug treatment. In these cases, the radial artery pressure may be substantially different to the central aortic pressure.

Note: Dynamic preload response variables (e.g. SVV or PPV) are only valid in patients with closed chests on full mode control ventilation.

Note: Dynamic preload response variables (e.g. SVV or PPV) are unreliable in patients with significant arrhythmia.

Note: Use and store Masimo LiDCO in accordance with specifications. See the Specifications section in this manual.

Cleaning and Service Warnings and Cautions

WARNING: Do not attempt to remanufacture, recondition, or recycle Masimo LiDCO as these processes may damage the electrical components, potentially leading to patient harm.

WARNING: Service of the module should be done by qualified personnel only.

CAUTION: Only perform maintenance procedures specifically described in the manual. Otherwise, return the module for servicing.

CAUTION: Do not allow liquids to enter the interior of the device.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the module. These substances affect the device's materials and instrument failure can result.

CAUTION: Do not submerge the module in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the module may occur.

CAUTION: To prevent damage, do not soak or immerse the module in any liquid solution.

CAUTION: Do not attempt to sterilize irradiation, steam, autoclave, or ethylene oxide.

CAUTION: Do not attempt to clean the Module while monitoring patient.

CAUTION: To ensure safety, avoid placing anything on the device during operation.

Compliance Information Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the instrument and/or its accessories.

Note: Use Masimo LiDCO in accordance with the Environmental Specifications section in this manual.

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: For EMC compliance information, see ***Specifications*** on page 55.

Chapter 1: Technology Overview

Theory of Operation

Masimo LiDCO is a multiparameter hemodynamic monitoring device specifically designed for use in operating room and intensive care units. The beat-to-beat parameters provided by Masimo LiDCO allow clinicians to get immediate feedback on a patient's fluid and hemodynamic status. The LiDCO algorithm derives stroke volume and heart rate from the patient's existing arterial pressure waveform.

Body Surface Area (BSA) is obtained from manual input of the patient's height and weight. In addition to Stroke Volume (SV) and Heart Rate (HR), the LiDCO algorithm derives Mean Arterial Pressure (MAP), Systolic (Sys) and Diastolic (Dia) arterial pressure. Utilizing the previous values, Masimo LiDCO calculates Heart Rate Variation(HRV), Cardiac Output (CO) and Cardiac Index (Ci), Systemic Vascular Resistance (SVR) and Systemic Vascular Resistance Index (SVRi), Stroke Volume Variation (SVV) and Stroke Volume Index (SVi), Pulse Pressure Variation (PPV), Oxygen Delivery (DO_2) Oxygen Delivery Index (DO_2i), Oxygen Consumption (VO_2) and Oxygen Consumption Index (VO_2i).

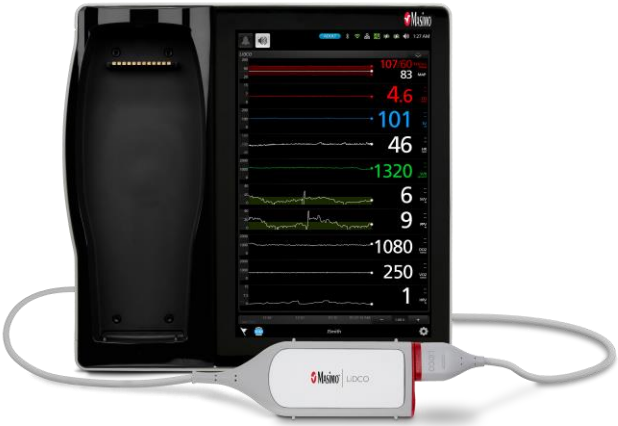
Chapter 2: Description

Masimo LiDCO is comprised of the following components:

- Monitor (Root®)
- LiDCO Module
- LiDCO Cable
- Additional 3rd party components are also required:
  - Patient Monitor that supports continuous pressure measurements
  - Pressure Transducer

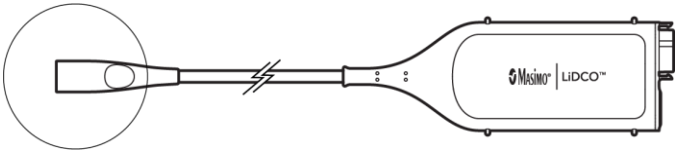
Masimo LiDCO

The following image illustrates the parameters being displayed on the monitor when using Masimo LiDCO.



LiDCO Module

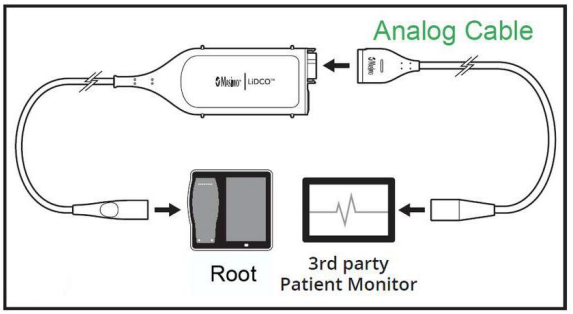
The LiDCO Module is the component with the LiDCO algorithm. The LiDCO algorithm derives stroke volume and heart rate from the patient's existing arterial pressure waveform.



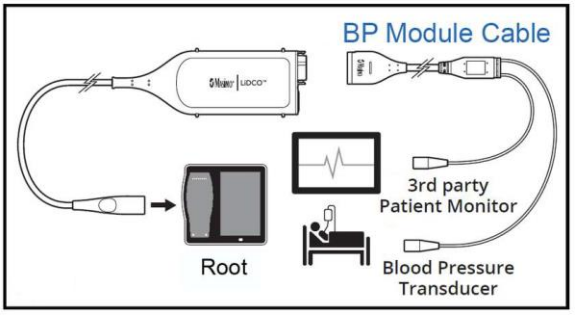
LiDCO Cable

The LiDCO cable connects to a compatible 3rd party patient monitor. The LiDCO cable comes in two types, Analog or BP Module Cable.

The Analog Cable receives blood pressure signals through the analog output of the 3rd party patient monitor. The Analog Cables are provided with different versions with connectors compatible with each of the supported 3rd party patient monitors.



The BP Module Cable receives blood pressure signals from directly from a 3rd party blood pressure transducer without interrupting the blood pressure signals to a 3rd Party Patient Monitor.



Refer to https://www.masimo.com for compatible cables and transducers.

Chapter 3: Setting Up

Unpacking and Inspecting the System

To unpack and inspect the system

1. Remove the components from the shipping carton and examine them for signs of shipping damage.
2. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
3. If anything is missing or damaged, contact Masimo Technical Service.

Preparation for Use

Prior to using Masimo LiDCO for monitoring

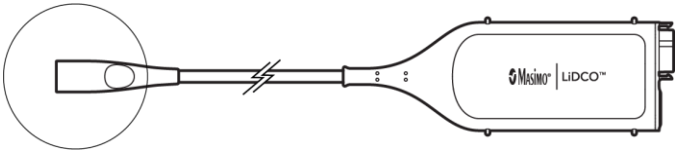
Confirm that you have all system components:

- Monitor (Root)
- LiDCO Module
- LiDCO Cable (Analog Cable or BP Module Cable)

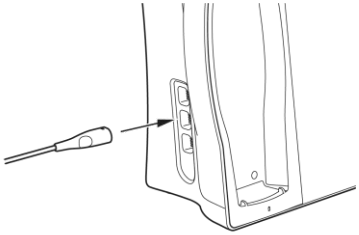
Connecting the LiDCO Module

To connect the module to the Monitor:

1. Identify the Masimo Open Connect (MOC-9) connector of the module.



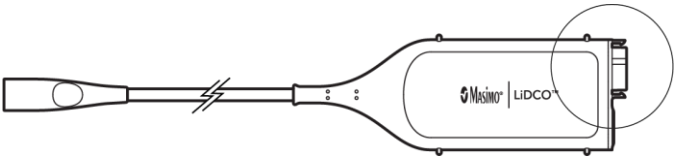
2. Insert the MOC-9 connector into a MOC-9 port on the monitor.



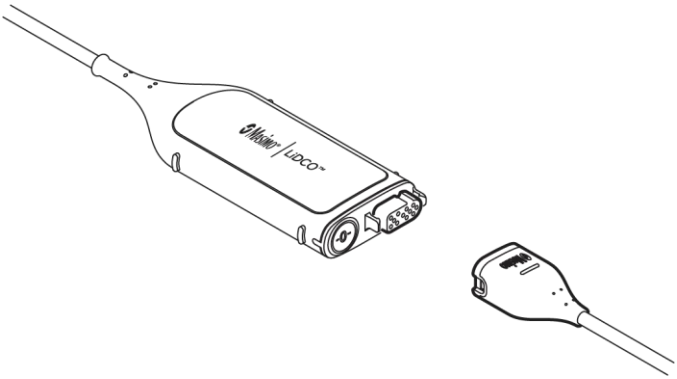
To connect the LiDCO Module to a LiDCO Cable :

For additional details, see the Directions for Use (DFU) for the cable.

1. Align the LiDCO Cable connector with the cable connector on the LiDCO Module.



2. Insert the LiDCO Cable connector securely into the LiDCO Module cable connector.



Connecting the LiDCO Cable to a Pressure Source

Note: The way to connect the LiDCO Cable to a 3rd party patient monitor varies based on the cable type. For additional details, see the Directions for Use (DFU) for the cable or reach out to your local sales representative.

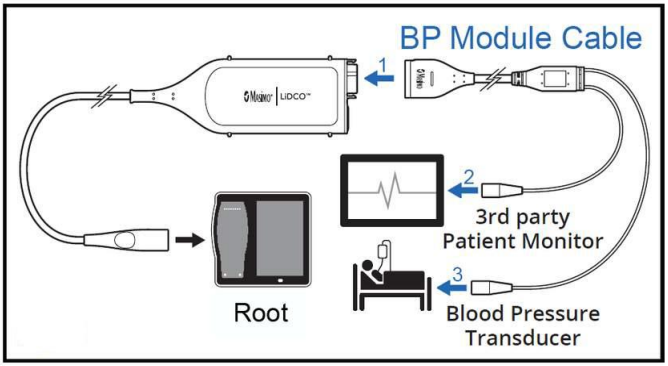
1. Using a Direct Connection to a Blood Pressure Transducer

a. Select a BP Module Cable with connectors that are compatible with your Pressure Transducer based on the connector type and manufacturer information.

b. Connect the BP Module Cable to the LiDCO Module cable connector (1).

c. Connect the BP Module Cable to the 3rd Party Patient Monitor cable connection (2).

d. Connect the BP Module Cable to the Blood Pressure Transducer (3).

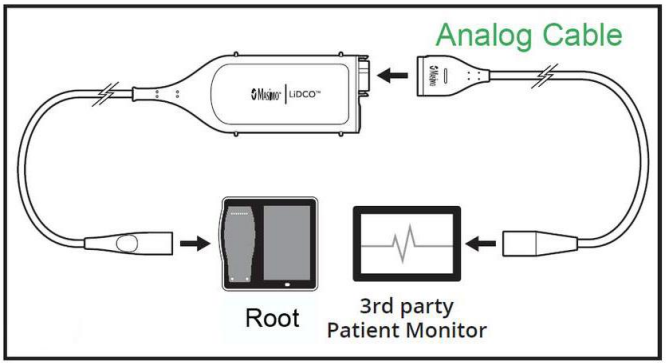


2. Using the Direct Connection to 3rd Party Patient Monitor Only

a. Select an Analog Cable with a connector that is compatible with your 3rd Party Patient Monitor.

b. Connect the Analog Cable to the LiDCO Module cable connector.

c. Connect the Analog Cable to the 3rd Party Patient Monitor.



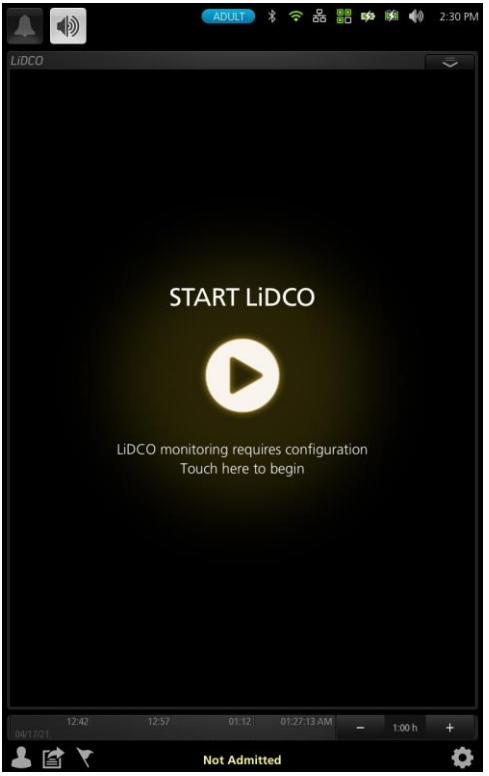
Disconnecting the LiDCO Cable from the LiDCO Module

To disconnect the module after monitoring is complete:

- Disconnect the 3rd Party Patient Monitor and Pressure Transducer, if applicable, by holding the LiDCO Cable connector and pulling.

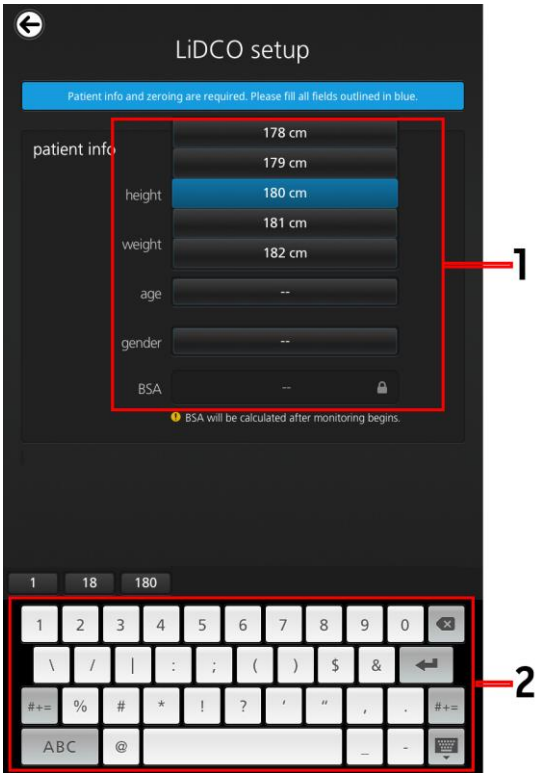
Setting Up Masimo LiDCO

1. When the module is connected, the Masimo LiDCO screen will indicate "Start LiDCO". Touch the screen to access LiDCO Setup page.



2. LiDCO menu opens. Manually enter patient info in the fields of the LiDCO setup menu (1). The smart keyboard (2) displays when height, age or weight spinner is touched. User has the option to use the keyboard or spinner to select or enter a value. Gender is not required.

   Note: BSA is a calculated value and will remain blank at the beginning of monitoring.



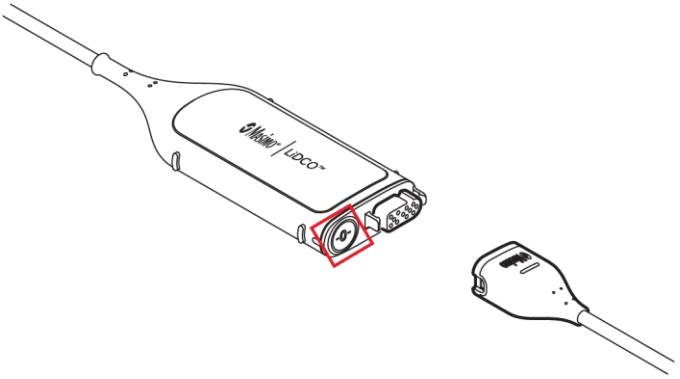
3. Once patient info is entered, Blue banner is updated. Touch Start button (3) to return to the main display with LiDCO channel in a monitoring state.

Zeroing

When using a BP Module Cable, zeroing is required to sync measurements on the 3rd party patient monitor and the LiDCO Module. Masimo LiDCO should be "zeroed" at the same time the blood pressure transducer is "zeroed" on the 3rd party patient monitor.

To zero Masimo LiDCO:

Option 1: Press the button next to the mating connector of the module.



Option 2: Or select the "Zero P" button in the LiDCO channel Action menu.

Zeroing is successful when:

- The zero status should display "Success, time of zeroing success"
- Verify the zeroing button is set to black.
- Ensure that the following parameters on the monitor have values matching those on the 3rd party patient monitor:
  - Blood Pressure (BP) waveform
  - Systolic Blood Pressure (SYS)
  - Mean Arterial Pressure (MAP)
  - Diastolic (DIA)
  - Heart Rate (HR)

Additional Settings

Allows user to choose the display as absolute value or the index value for the following parameters:

Cardiac Output (CO), Stroke Volume (SV), Systemic Vascular Resistance (SVR), Oxygen Delivery (DO_2), Oxygen Consumption (VO_2). Only CO has the option to display both the absolute value and Index value.

Parameter	Default Setting	Selectable Settings
CO	Absolute	Absolute, Index or both
SV	Absolute	Absolute or Index
SVR	Absolute	Absolute or Index
DO_2	Absolute	Absolute or Index
VO_2	Absolute	Absolute or Index

Manual Entry

Allows user to choose whether the following parameters are measured via pulse oximetry or manually entered . If manual entry is selected, enter value for selected parameter and touch OK. The date and time of last update will display.

Parameter	Default Setting	Selectable Settings
Hb	Manual	Pulse Ox or Manual
Hb unit of measure	g/dL	g/dL, mmol/L, g/L
SpO_2	Manual	Pulse Ox or Manual
SvO_2	Disable	Disable or Manual
CVP	Default	Default or Manual
Reminder interval	30 min	Off, or 30 min, 1, 2, and 3 hour

Manual Entry Reminder displays when remainder time is 0. "Use current" uses the existing values and does not update the timestamp. “Configure” takes user to the manual entry menu where new values can be entered. Any saved change in value would update the timestamp.

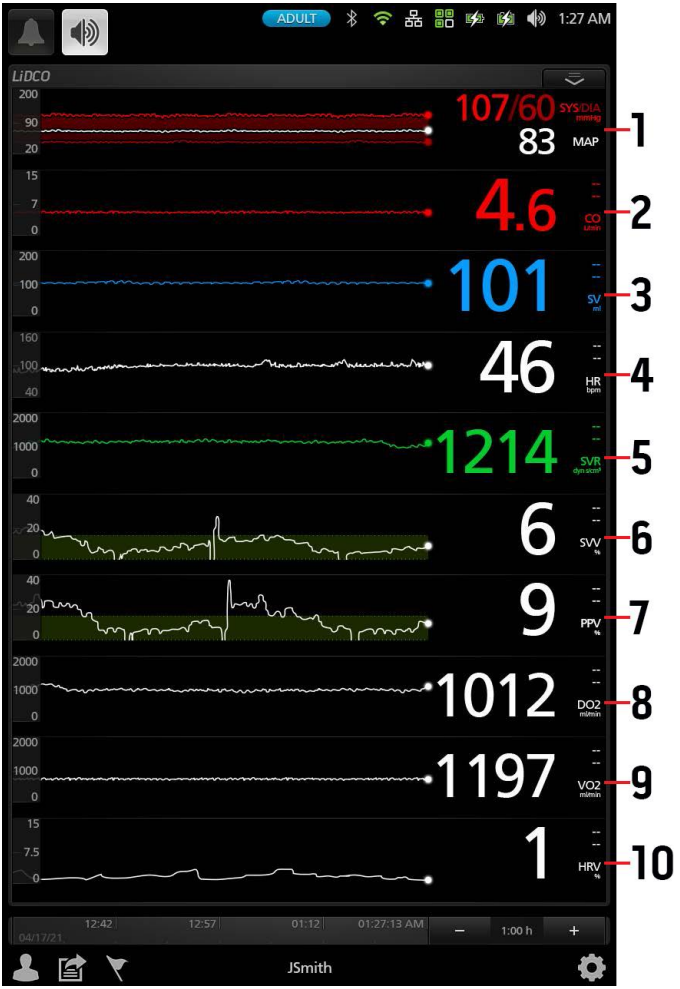
When the source for both Hb and SpO2 is Pulse Ox DO_2 and DO_2i are calculated and are noted as cDO_2/cDO_2i.

Chapter 4: Operation

The following sections describe how Masimo LiDCO information is displayed, including display details and accessing and changing user-configurable settings.

Masimo LiDCO Window

When the LiDCO Module is connected to the monitor, parameters and measurements display in a window. Masimo LiDCO parameters can display as numeric values as either absolute or indices. Only select parameters are available in indices. The image below shows Masimo LiDCO trend screen.

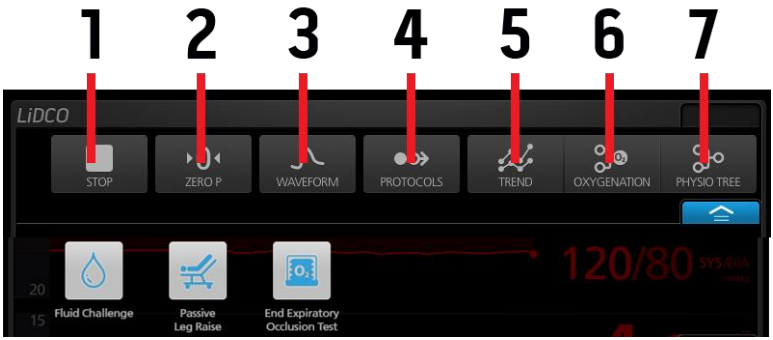


Masimo LiDCO Parameters Display

Ref.	Parameter	Description
1	Sys/Dia/MAP Display	The Systolic, Mean Arterial and Diastolic pressures are derived from the arterial blood pressure waveform. MAP is derived by integrating the BP waveform and computing the average. See ***Systolic, Mean Arterial and Diastolic Pressures*** on page 28.
2	CO Display	The product of stroke volume and heart rate. The Cardiac Output (CO) is the amount of blood pumped by the heart in a minute. See ***Cardiac Output*** on page 28.
3	SV Display	Stroke Volume is the amount of blood ejected by the heart in a given beat; updated beat-by-beat based on the LiDCO pulse power analysis algorithm. See ***Stroke Volume*** on page 29.
4	HR Display	The number of beats per minute of the heart. See ***Heart Rate*** on page 28.
5	SVR Display	The quotient of pressure and cardiac output. Systemic Vascular Resistance (SVR) reflects the resistance to flow and is calculated as the quotient of pressure and cardiac output. See ***Systemic Vascular Resistance*** on page 30.
6	SVV Display	Stroke Volume Variation (SVV) is the maximum Stroke Volume (SV) minus the minimum SV divided by the mean SV across at least one respiratory cycle (10 seconds). Values below 8% indicate the patient is unlikely to respond to fluids values above 13% indicate the patient will respond to fluids. See ***Stroke Volume Variation*** on page 29.
7	PPV Display	The maximum Pulse Pressure (PP) minus the minimum PP divided by the mean PP across at least one respiratory cycle (10 seconds). Values below 10% indicate the patient is unlikely to respond to fluids values above 15% indicate the patient will respond to fluids. See ***Pulse Pressure Variation*** on page 29.
8	DO_2 Display	Oxygen Delivery (DO_2) is the product of cardiac output and oxygen concentration. The DO_2 is the amount oxygen delivered to the tissues. See ***Oxygen Delivery*** on page 29.
9	VO_2 Display	Oxygen Consumption (VO_2) is a measure of the oxygen consumed by tissues. VO_2 is calculated from CO, Hemoglobin (Hb or SpHb) and arterial saturation (SaO_2 or SpO_2) and venous saturation (SvO_2). See ***Oxygen Consumption*** on page 29.
10	HRV Display	Heart Rate Variation (HRV) is the standard deviation in heart rate over a respiratory cycle (10 sec) divided by the mean HR. Values above 10% will not display the SVV or PPV. See ***Heart Rate Variation*** on page 28.

About the Action Menu

At the top of the Main Screen is the Action Menu with interactive icons. Each icon provides a shortcut to a menu item or an action on Masimo LiDCO. Protocols submenu displays available Guided Protocols.



Ref.	Feature	Description
1	Stop	Select the Stop button in the Action Menu and press Confirm to stop LiDCO monitoring.
2	Zero P	Initiates BP zeroing. Zero status is displayed in the channel header. Zero button in the action menu cannot be used for initial zeroing.
3	Waveform	Displays the arterial blood pressure waveform
4	Guided Protocols	Masimo LiDCO supports several methods to assist in performing fluid response assessments. Each protocol provides supporting information and guidance to complete along with a detailed display of the hemodynamic parameters. See ***Guided Protocols*** on page 42.
5	Trend	Displays each parameter or measurement alongside a graph of its values over time.
6	Oxygen Delivery Tree	When SpO_2 and Hb values are present, calculates Oxygen Delivery. If SvO_2 is entered, calculates oxygen consumption. Oxygen Delivery Tree is only displayed when there is a connected pulse oximetry channel. See ***Oxygen Delivery Tree*** on page 49.
7	Physio Tree	The Physio Tree screen displays the parameters in a manner that shows how the parameters depend physiologically on each other. The Physio Tree will always be shown and never be hidden, irrespective of the connection to a pulse oximetry channel. See ***Physio Tree*** on page 51.

Parameters Display

Each parameter display consists of a trend line and a numeric value.

- The user can swipe on any trend line to see historical information on all trend lines.
- The user can pinch in and out on any trend line to expand and contract the time frame shown on all trend lines.

For all parameters, the module sends data to the monitor every second.

Systolic, Mean Arterial and Diastolic Pressures (Sys, MAP, Dia)

Systolic (Sys) and Diastolic (Dia) blood pressure represent the peak and trough of the pressure created by the heartbeat. Mean Arterial Pressure (MAP) is the average blood pressure across the heartbeat. Systolic and Diastolic blood pressure is calculated on a beat-to-beat basis. Mean Arterial Pressure represents an estimate of the tissue perfusion pressure. It is calculated on a beat-to-beat basis.

Cardiac Output (CO)

Cardiac Output (CO) is the amount of blood the heart pumps through the circulatory system in a minute, calculated by multiplying the stroke volume by the patient's heart rate in liters/minute. Cardiac Output is calculated on a beat-to-beat basis via the arterial pressure waveform using the LiDCO algorithm. It can be expressed is an index value Cardiac Index (Ci) by dividing CO by the body surface area (BSA).

Heart Rate (HR)

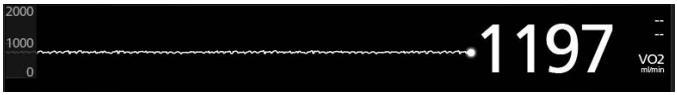
Heart Rate (HR) is the frequency of heart beats measured in beats per minute from the arterial pressure waveform. It is calculated on a beat-to-beat basis

Heart Rate Variation (HRV)

Heart Rate Variation (HRV) is a measure of the dynamic changes in HR during a respiratory cycle. Heart Rate Variation is calculated over a 10 second period which contains one or more respiratory cycles. HRV is standard deviation of HR divided by the average HR and is displayed as a percentage (0-100%).

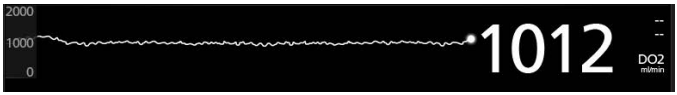
Oxygen Consumption (VO2)

Oxygen Consumption (VO_2) is a measure of the oxygen consumed by tissues in milliliters/min. Oxygen Consumption is calculated from CO, Hemoglobin (Hb or SpHb) and arterial saturation (SaO_2 or SpO_2) and venous saturation (SVO_2). It can be expressed as an index VO_2i by dividing VO_2 by the body surface area (BSA).



Oxygen Delivery (DO_2)

Oxygen Delivery (DO_2) the amount of oxygen delivered to the tissues, is calculated as the product of cardiac output and oxygen concentration in milliliters/min. DO_2 is calculated from CO, Hemoglobin (Hb or SpHb) and arterial saturation (SaO_2 or SpO_2). It can be expressed as an index (DO_2i) by dividing DO_2 by the body surface area (BSA).

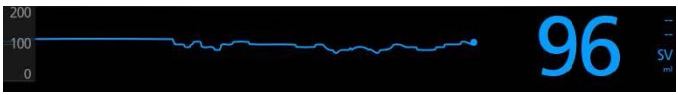


Pulse Pressure Variation (PPV)

Pulse Pressure Variation (PPV) is a dynamic variable that can predict fluid responsiveness in mechanically ventilated patients, PPV is the variation in arterial pulse pressure across at least one respiratory cycle. Pulse Pressure Variation is calculated over a 10 second period which contains one or more respiratory cycles. PPV is displayed as a percentage (0-100%).

Stroke Volume (SV)

Stroke Volume (SV) is the volume of blood ejected from the heart for each beat in milliliters (ml). The amount of blood pumped by the left ventricle of the heart in one contraction. It can be expressed is an index value (SVi) by dividing SV by the body surface area (BSA).



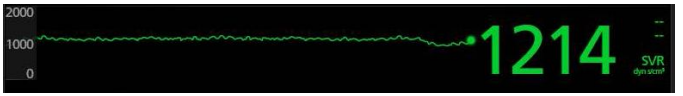
Stroke Volume Variation % (SVV)

Stroke Volume Variation (SVV) is a dynamic variable that can predict fluid responsiveness in mechanically ventilated patients. SVV is the variation in stroke volume across at least one respiratory

cycle. SVV is calculated over a 10 second period which contains one or more respiratory cycles. SVV is displayed as a percentage (0-100%).

Systemic Vascular Resistance (SVR)

Systemic Vascular Resistance (SVR) reflects the resistance to flow and is calculated as the quotient of mean arterial pressure (MAP) and cardiac output (CO) values that are calculated on a beat-to-beat basis with units of dyne - second/cm^5. It can be expressed as an index value (SVRi) by multiplying SVR by the body surface area (BSA).



Parameter Settings

Parameter configuration settings provide the user access to the parameters: Sys, MAP, Dia, HR, CO, VO2, DO_2, SV, SVV, and SVR*.

To access a specific parameter's configuration settings

- Press the parameter desired directly from the Masimo LiDCO window.

To access all parameter configuration settings

1. Press the Main Menu icon  at the bottom right corner of the screen to access menu options.
2. From the Main Menu, press the LiDCO icon.
3. Press the Parameter Settings icon.
4. Press the parameter that you want to configure.

All changes to configuration settings must be accepted by pressing **OK** when prompted. To decline changes made, press **Cancel**.

*Masimo LiDCO has the ability to control alarm priority based on the clinical use case. When Audible Alarms are set to Off, the alarm priority is Low. When Audible Alarms are set to On, the alarm priority is Medium.

Sys, MAP, Dia

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
Systolic High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 42-259 in steps of 1.
Systolic Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 41 to 258 in steps of 1.
Diastolic High Limit	The High Limit is upper threshold that triggers an alarm.	Medium	Off	32-199 in steps of 1, or Off When set to Off, alarm is disabled.
Diastolic Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	Off	31-198 in steps of 1, or Off When set to Off, alarm is disabled.
MAP High Limit	The High Limit is upper threshold that triggers an alarm.	Medium	105	37-219 in steps of 1, or Off When set to Off, alarm is disabled.
MAP Low Limit	Low Limit is the lower threshold that triggers an alarm.	Medium	70	36-218 in steps of 1, or Off When set to Off, alarm is disabled.
MAP High Caution Range	Value below High Limit to trigger caution light	NA	5	Off, or 1 to 28 in steps of 1.
MAP Low Caution Range	Value above Low Limit to trigger caution light	NA	5	Off, or 1 to 28 in steps of 1.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

* Masimo LiDCO has the ability to control alarm priority based on the clinical use case. When Audible Alarms are set to Off, the alarm priority is Low. When Audible Alarms are set to On, the alarm priority is Medium.

BP Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest value that can be displayed	180	25 to 300 in steps of 5
Y-Axis Min	Lowest value that can be displayed	30	20 to 295 in steps of 5

Heart Rate (HR)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 45-235 in steps of 5.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 40-230 in steps of 5.
High Caution Range	Value below High Limit to trigger caution light	NA	5	Off, or 5-35 in steps of 5.
Low Caution Range	Value above Low Limit to trigger caution light	NA	5	Off, or 5-35 in steps of 5.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest HR value that can be displayed	120	35-240 in steps of 5
Y-Axis Min	Lowest HR value that can be displayed	30	30-235 in steps of 5

Additional Settings

Options	Description	Factory Default	Selectable Settings
Beat Detect Threshold	Used to correct for large differences in heart rate caused by unusual blood pressure waveforms.*	30	10-90 in steps of 5
Heart Rate	Heart rate from Masimo LiDCO	NA	NA

*If the HR from pulse ox is higher than the LiDCO HR, then lower the beat detector threshold until the values are equivalent. If the HR displayed from the pulse ox is less than the LiDCO HR, then raise the beat detector threshold until the values are equivalent. Observe the heart rates and adjust using the slider until equivalent, Touch OK to accept the new value. Touch Cancel to cancel any changes since the last change.

Heart Rate Variation (HRV)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 2-19 in steps of 1.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest HRV value that can be displayed	20	5 to 100 in steps of 5
Y-Axis Min	Lowest HRV value that can be displayed	0	0 to 95 in steps of 5

Cardiac Output (CO)

CO Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	8.0	Off, or 0.3-29.9 in steps of 0.1
Low Limit	Lower limit that triggers an alarm	Low/Medium*	4	Off, or 0.2-29.8 in steps of 0.1
High Caution Range	Value below High Limit to trigger caution light	NA	.5	Off, or 0.1-2.5 in steps of 0.1
Low Caution Range	Value above Low Limit to trigger caution light	NA	.5	Off, or 0.1-2.5 in steps of 0.1
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

CO Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest CO value that can be displayed	10	0.1-30.0 in steps of 0.1
Y-Axis Min	Lowest CO value that can be displayed	1.0	0.0-29.9 in steps of 0.1

CO Additional Settings

Options	Description	Factory Default	Selectable Settings
Display parameter	how parameter is displayed on the monitor	Absolute	Absolute, Index or Both

CO Calibration

Options	Description	Factory Default	Selectable Settings
CO(L/min)	reflects the patient-specific maximum aortic capacitance and will generally remain constant over short periods of time.	NA	NA
Measure CO(L/min)*	known value for Cardiac Output (CO) taken during hemodynamically stable period with minimal variation in blood pressure or heart rate	Off	Off, or .1-30 in steps of 0.1

* Calibration can only be adjusted during an active session.

Cardiac Index (Ci)

Alarms

Cardiac Index (Ci) will display only when Index or Both is selected for Cardiac Output parameter display.

Options	Description	Alarm Priority	Faculty Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 0.3-14.9 in steps of 0.1
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 0.2-14.8 in steps of 0.1
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 0.1-1.1 in steps of 0.1
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 0.1-1.1 in steps of 0.1
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest Ci value that can be displayed	5	0.1-15 in steps of 0.1
Y-Axis Min	Lowest Ci value that can be displayed	.5	0.0-14.9 in steps of 0.1

Oxygen Consumption (VO2)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 200-900 in steps of 25.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 175-800 in steps of 25.
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 25-50 in steps of 25.
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 25-50 in steps of 25.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest VO2 value that can be displayed	500	200-3000 in steps of 100
Y-Axis Min	Lowest VO2 value that can be displayed	0	0-2900 in steps of 100

Additional Settings

Options	Description	Factory Default	Selectable Settings
Display parameter	How parameter is displayed on the monitor	Absolute	Absolute or Index

VO2 Manual Entry

Options	Factory Default	Selectable Settings
Hb	Pulse Ox	Manual or Pulse Ox
SpO_2	Pulse Ox	Manual or Pulse Ox
SvO_2	Disable	Disable or Manual
Manual Entry Reminder	30 seconds	Off, 30 seconds, 1, 2, or 5 minutes

Oxygen Consumption Index (VO2i)

Oxygen Consumption Index (VO2i) will display only when Index is selected for Oxygen Consumption parameter display.

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 180-450 in steps of 10.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 110-400 in steps of 10.
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 10-40 in steps of 10.
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 10-40 in steps of 10.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	Off, or 30 sec, 1, 2, and 5 min
Audible Alarms*	Disables audible alarm	NA	Off	On or Off.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest VO2i value that can be displayed	300	100-3000 in steps of 100
Y-Axis Min	Lowest VO2i value that can be displayed	0	0-2900 in steps of 100

Oxygen Delivery (DO_2)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	1100	Off, or 350-1500 in steps of 50.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	550	Off, or 300 to 1000 in steps of 50.
High Caution Range	Value below High Limit to trigger caution light	NA	100	Off, or 50 to 300 in steps of 50.

Options	Description	Alarm Priority	Factory Default	Selectable Settings
Low Caution Range	Value above Low Limit to trigger caution light	NA	100	Off, or 50 to 300 in steps of 50.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

* Masimo LiDCO has the ability to control alarm priority based on the clinical use case. When Audible Alarms are set to Off, the alarm priority is Low. When Audible Alarms are set to On, the alarm priority is Medium.

Trends

Options	Description	Factory Default	Selectable Settings
Trend Max	Highest DO_2 value that can be displayed	1500	100-3000 in steps of 100.
Trend Min	Lowest DO_2 value that can be displayed	500	0-2900 in steps of 100

Additional Settings

Options	Factory Default	Selectable Settings
Display parameter	Absolute	Absolute or Index
Manual Entry Reminder	30 seconds	Off, 1sec,30 sec, 1 min 2 min, and 5 min.

DO_2 Manual Entry

Options	Factory Default	Selectable Settings
Hb	Pulse Ox	Manual or Pulse Ox
SpO_2	Pulse Ox	Manual or Pulse Ox

Note: If Manual setting is selected, parameter will display as "DO_2". If Pulse Ox is selected, parameter will display as "cDO_2".

Oxygen Delivery Index (DO_2i)

Oxygen Delivery Index (DO_2i) will display only when Index is selected for Oxygen Delivery parameter display.

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 200-750 in steps of 50, or
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 150-500 in steps of 50
High Caution Range	Value below High Limit to trigger caution light	NA	Offf	Off, or 50 to 300 in steps of 50
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 50 to 300 in steps of 50
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Trend Max	Highest DO_2i value that can be displayed	800	100-3000 in steps of 100.
Trend Min	Lowest DO_2i value that can be displayed	200	0-2900 in steps of 100

Pulse Pressure Variation (PPV)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low	Off	Off, or 2-99 in steps of 1
High Caution Range	Value below High Limit to trigger caution light	Low	Off	Off, or 1-29 in steps of 1
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest PPV value that can be displayed	50	5 to 100 in steps of 5
Y-Axis Min	Lowest PPV value that can be displayed	0	0 to 95 in steps of 5

Stroke Volume (SV)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 10-495 in steps of 5.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 5-490 in steps of 5.
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 5-30 in steps of 5.
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 5-30 in steps of 5.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

* Masimo LiDCO has the ability to control alarm priority based on the clinical use case. When Audible Alarms are set to Off, the alarm priority is Low. When Audible Alarms are set to On, the alarm priority is Medium.

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SV value that can be displayed	150	5-500 in steps of 5
Y-Axis Min	Lowest SV value that can be displayed	30	0-495 in steps of 5

Additional Settings

Options	Factory Default	Selectable Settings
Display parameter	Absolute	Absolute or Index

Stroke Volume Index (SVi)

Stroke Volume Index (SVi) will display only when Index is selected for Stroke Volume parameter display.

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 10-245 in steps of 5
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 5-240 in steps of 5
High Caution Range	Value below High Limit to trigger caution light	NA	5	Off, or 5-15 in steps of 5
Low Caution Range	Value above Low Limit to trigger caution light	NA	5	Off, or 5-15 in steps of 5
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SVi value that can be displayed	75	5-250 in steps of 5
Y-Axis Min	Lowest SVi value that can be displayed	15	0-245 in steps of 5

Stroke Volume Variation (SVV)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 2-29 in steps of 1.
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 1-13 in steps of 1.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SVV value that can be displayed	50	5 to 100 in steps of 5
Y-Axis Min	Lowest SVV value that can be displayed	0	0 to 95 in steps of 5

Systemic Vascular Resistance (SVR)

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 450-1500 in steps of 50.
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 400-1450 in steps of 50.
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 50-300 in steps of 50.
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 50-300 in steps of 50.
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30s, 1m, 2m, 5m.
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SVR value that can be displayed	1500	100-12000 in steps of 100
Y-Axis Min	Lowest SVR value that can be displayed	300	0-11900 in steps of 100

Additional Settings

Option	Factory Default	Selectable Settings
Display parameter	Absolute	Absolute or Index
CVP	7	1-20 in steps of 1

Systemic Vascular Resistance Index (SVRi)

Systemic Vascular Resistance Index (SVRi) will display only when Index is selected for Systemic Vascular Resistance parameter display.

Alarms

Options	Description	Alarm Priority	Factory Default	Selectable Settings
High Limit	Upper limit that triggers an alarm	Low/Medium*	Off	Off, or 850-3000 in steps of 50,
Low Limit	Lower limit that triggers an alarm	Low/Medium*	Off	Off, or 800-2950 in steps of 50
High Caution Range	Value below High Limit to trigger caution light	NA	Off	Off, or 100-600 in steps of 50
Low Caution Range	Value above Low Limit to trigger caution light	NA	Off	Off, or 100-600 in steps of 50
Silence Duration	Length of time that the audible alarm remains silenced	NA	2 min	30 sec, 1, 2, or 5 min
Audible Alarms*	Disables audible alarm	NA	Off	On or Off

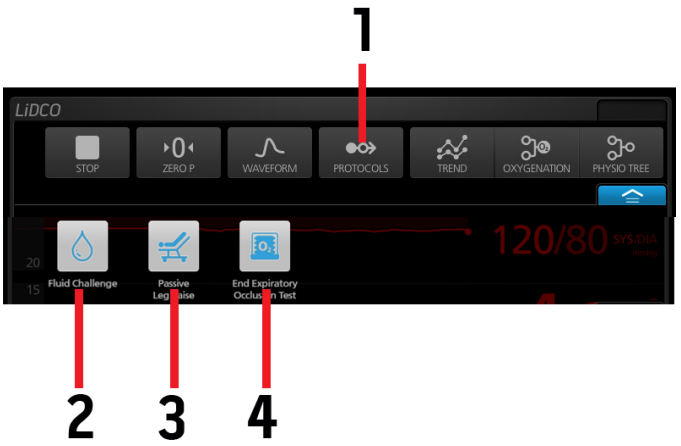
Trends

Options	Description	Factory Default	Selectable Settings
Y-Axis Max	Highest SVRi value that can be displayed	3000	1000-12000 in steps of 1000
Y-Axis Min	Lowest SVRi value that can be displayed	0	0 to 11000 in steps of 1000

Guided Protocols

Masimo LiDCO provides Guided Protocols to assist in performing fluid response assessments. They provide supporting information and guidance to complete each along with a detailed display of the

hemodynamic parameters. Touch Guided Protocols for drop-down menu. This menu option is not available when SVi is being displayed.



Guided protocols(1) are intended to aid the clinician in giving a fluid challenge and observing the effects on advanced hemodynamic parameters including Stroke Volume (SV), Mean Arterial Pressure (MAP), Heart Rate (HR) and Stroke Volume Variation (SVV) – if applicable.

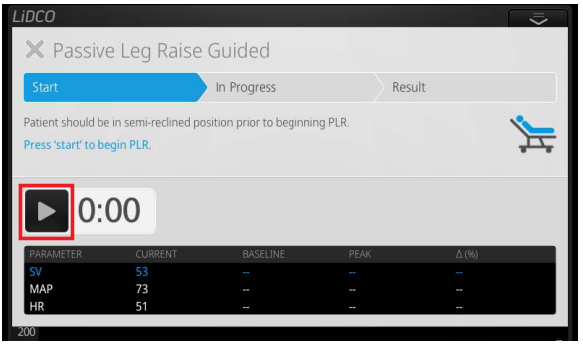
Use the *Additional Settings* screen to configure the following:

Ref	Options	Description	Purpose
2	Fluid Challenge	Giving a small amount of fluid in a short period of time to assess whether the patient has a preload response that can be used to increase the stroke volume with further fluids.	If SV increases by ≥10% then likely fluid responsive
3	Passive Leg Raise	Using the bed to position the patient's upper body at zero degrees while simultaneously raising both legs to about 45 degrees 30-90 seconds.	If SV increases by ≥10% then likely fluid responsive
4	End Expiratory Occlusion Test	Occluding the airway at the end of expiration for 10-30 seconds and observe the maximum rise in SV.	If SV increases by ≥5% then likely fluid responsive

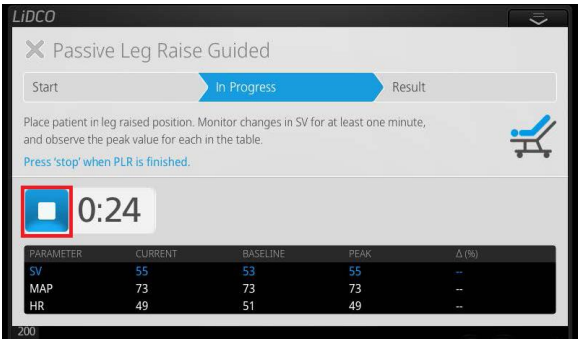
Passive Leg Raise

1. Touch/Select the protocols button to open a sub menu displaying the available guided protocols. Select a protocol from the Protocols submenu. The protocol will open behind the action menu.

2. The initializing screen is displayed only while Masimo LiDCO is getting ready to provide data. Until then, data in the table is displayed as"--". The start button is disabled until Masimo LiDCO is ready.Touch/Select Start to begin protocol. Follow instructions as displayed.

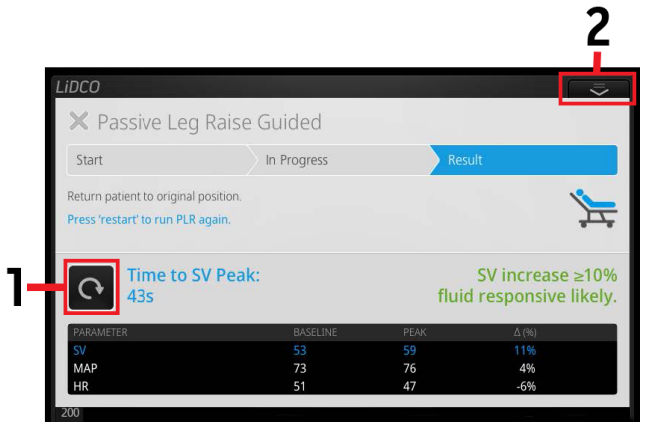


3. While the protocol is running, title will display "In Progress" and a Stop button replaces the start button with time left for the protocol to complete. Touch/Select stop to end protocol.

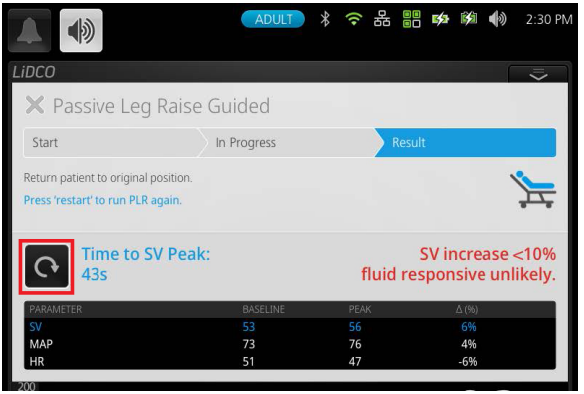


4. A positive result is indicated by green text. Once protocol is complete, a restart button (1) replaces the stop button once the protocol has completed. Results will be displayed in the space to the right of the button. The chart below displays result data. Touch restart (1) to run

the protocol again. Close (2) will remove the protocol from the display. Trends will return to standard positions.



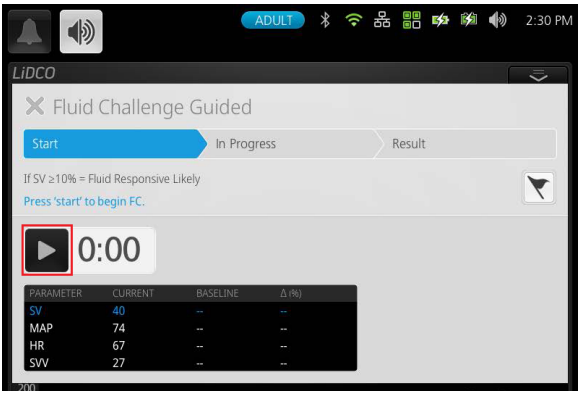
5. A negative result is indicated by red text.



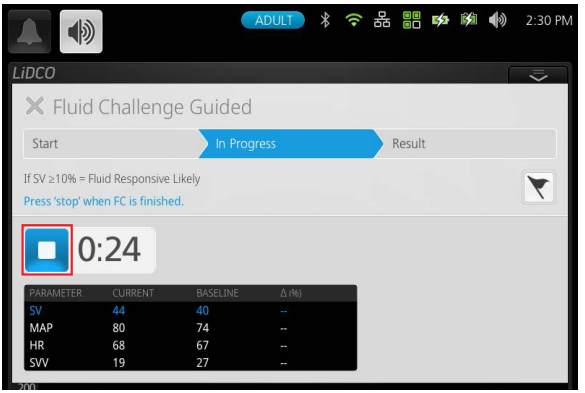
Fluid Challenge

1. Touch/Select the protocols button to open a sub menu displaying the available guided protocols. Select a protocol from the Protocols submenu. The protocol will open behind the action menu.

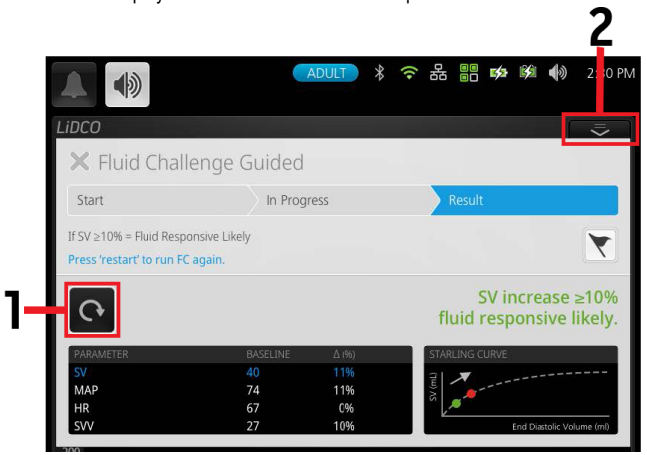
2. The initializing screen is displayed only while Masimo LiDCO is getting ready to provide data. Until then, data in the table is displayed as"--". The start button is disabled until Masimo LiDCO is ready. Touch/Select Start to begin protocol. Follow instructions as displayed.



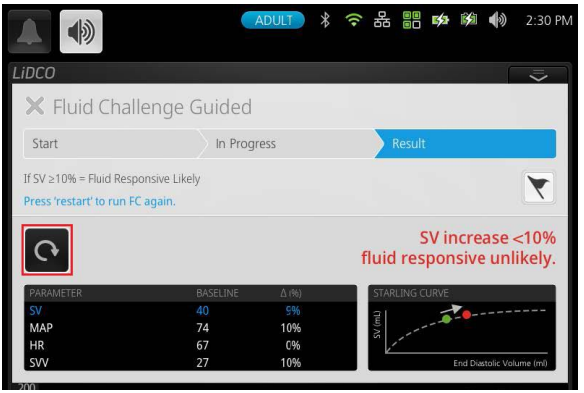
3. While the protocol is running, title will display "In Progress" and a Stop button replaces the start button with time left for the protocol to complete. Touch/Select stop to end protocol.



4. A positive result here displays a static graphic along with the results message in green text. Once protocol is complete, a restart button (1) replaces the stop button once the protocol has completed. Results will be displayed in the space to the right of the button. The chart below displays result data. Touch restart (1) to run the protocol again. Close (2) will remove the protocol from the display. Trends will return to standard positions.



5. A negative result is indicated by red text.



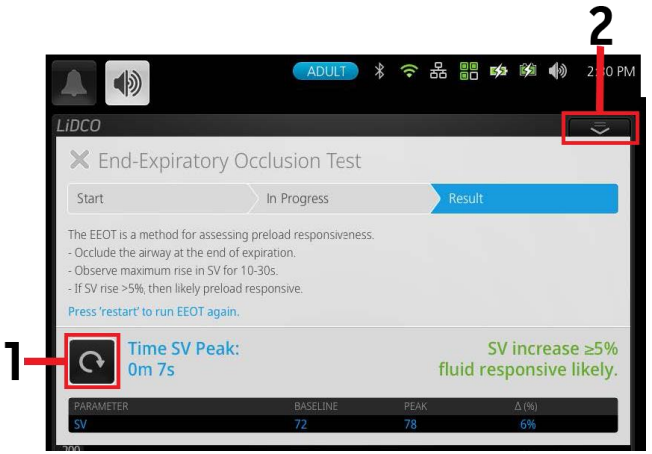
End Expiratory Occlusion Test

1. Touch/Select the protocols button to open a sub menu displaying the available guided protocols. Select a protocol from the Protocols submenu. The protocol will open behind the action menu.

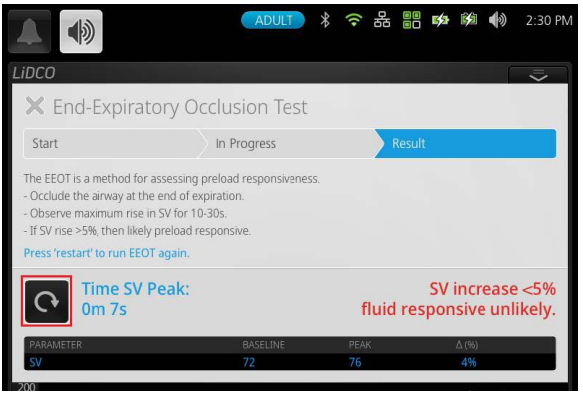
2. The initializing screen is displayed only while Masimo LiDCO is getting ready to provide data. Until then, data in the table is displayed as"--". The start button is disabled until Masimo LiDCO is ready. Touch/Select Start to begin protocol. Follow instructions as displayed.

3. While the protocol is running, title will display "In Progress" and a Stop button replaces the start button with time left for the protocol to complete. Touch/Select stop to end protocol.

4. A positive result is indicated by green text. Once protocol is complete, a restart button (1) replaces the stop button once the protocol has completed. Results will be displayed in the space to the right of the button. The chart below displays result data. Touch restart (1) to run the protocol again. Close (2) will remove the protocol from the display. Trends will return to standard positions.



5. A negative result is indicated by red text.

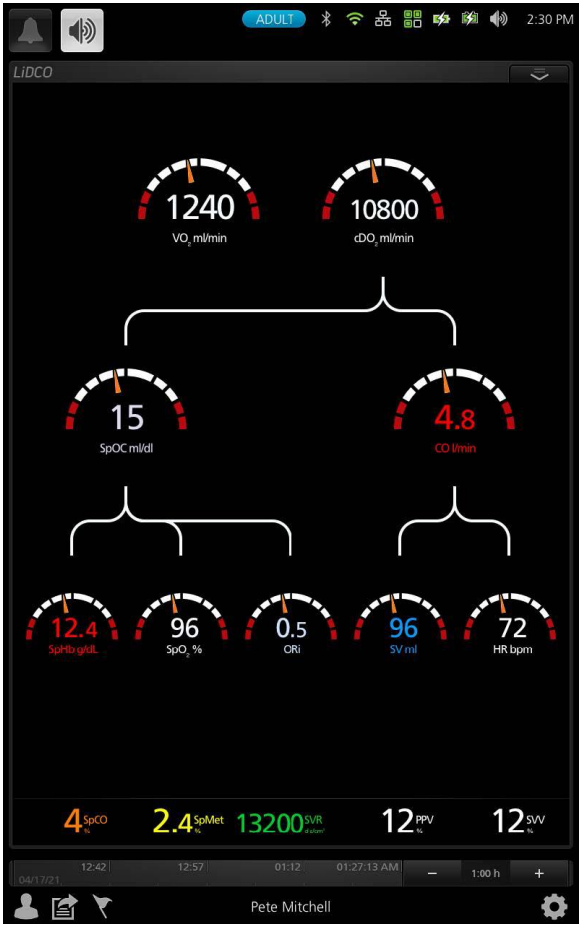


Oxygen Delivery Tree

Toggle to Oxygen Delivery Tree view in the action menu.

Oxygen Delivery Tree is only displayed when there is a connected pulse oximetry channel.

Touching SpHb parameter would open its manual entry menu. Touching any other parameter would bring up their respective parameter setting.

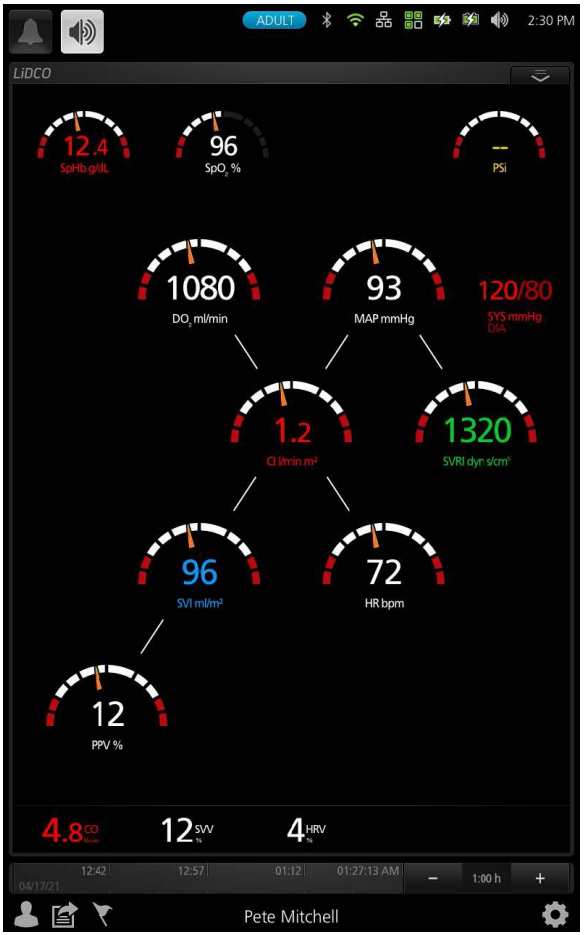


Physio Tree

Toggle to Physio Tree view in the action menu.

The Physio Tree will always be shown and never be hidden, irrespective of the connection to a pulse oximetry channel.

Touching SpHb and SpO2 parameters would open their manual entry menu. Touching any other parameter would bring up their respective parameter setting.



Chapter 5: Troubleshooting

Troubleshooting

The following table lists potential causes and corrective action when troubleshooting Masimo LiDCO.

Observation	Potential Cause	Next Steps
No values are displayed for any channel	Cable may be disconnected	Check all cable connections
	No cable for any channel	Contact Masimo representative for a cable
	LiDCO software license or per-patient disposable not active	Contact Masimo representative for license options
No BP waveform is observed on any channel	Cable may be disconnected	Check all cable connections

Chapter 6: Specifications

Display Range

Parameter	Display Range*
Oxygen Consumption (VO_2) (Index)	10-3000 ml/min (ml/min/m^2)
Oxygen Delivery (DO_2) (Index)	10-3000 ml/min (ml/min/m^2)
Cardiac Output (CO) (Index)	0.1 – 30 l/min (0.1 - 15 l/min/m^2)
Stroke Volume (SV) (Index)	1-500ml (1-250 ml/m^2)
Systolic Pressure	40-300 mmHg
Mean Arterial Pressure	35-260 mmHg (MAP Static Pressure Range -30 – 300 mmHg)
Diastolic Pressure	30-250 mmHg
Heart Rate (HR)	35-240 bpm
Systemic Vascular Resistance (SVR) (Index)	100-12,000 dyn s/cm5 (dyn s m^2 /cm5)
Stroke Volume Variation (SVV)	0-100%
Pulse Pressure Variation (PPV)	0-100%
Heart Rate Variation (HRV)	0-100%

* the accuracy of blood pressure measurement is +/-3mmHg and is in accordance with IEC 60601-2-34.

Resolution

Parameter	Resolution
Oxygen Consumption (VO_2)	1 ml/min
Oxygen Delivery (DO_2)	1 ml/min
Cardiac Output (CO)	.1 L/min
Stroke Volume (SV)	1 ml
Sys/MAP/Dia Pressure	3 mmHg
Heart Rate (HR)	1 beat/min
Systemic Vascular Resistance (SVR)	50 dyn s/cm5
Stroke Volume Variation (SVV)	1%
Pulse Pressure Variation (PPV)	1%
Heart Rate Variation (HRV)	1%

Environmental

Environmental Conditions	
Operating Temperature	+32°F to +104°F (+0°C to +40°C)
Storage Temperature	-40°F to +158°F (-40°C to +70°C)
Humidity	10% to 95%, non-condensing
Atmospheric Pressure	500 to 1060 mBar

Module Physical Characteristics

Dimension	Measurement
Overall Length	3.7m (12 ft)
Module Length	15.24cm (6 in)
Module Width	5cm (2 in)
Module Height	1.78cm (.7 in)
Weight	191g (.4 lb.)
Service Life	2 years

Safety Classifications

Equipment Classification per IEC 60601-1	
Type of Protection	Class II
Degree of Protection of Electrical Shock	Defibrillation proof CF-Applied Part
Protection against harm from liquid ingress	IP24, Protection against vertically falling water drops.
Mode of Operation	Continuous operation

Safety Compliance

Safety Compliance
EN 60601-1:2006/A12:2014
EN 60601-1-6:2010/A1:2015
IEC 62304:2006/AMD1:2015
EN 60601-2-34:2014
ANSI/AAMI ES60601-1:2005/A1:2012
CAN/CSA C22.2 No. 60601-1:2014

EMC Compliance

EMC Compliance
EN 60601-1-2:2015

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 2862	European Union Conformity Mark		ETL Intertek certification See ***Declarations on Page 1*** for certifications
IP24	Protection from ingress and particulates and water spray		Separate collection for electrical and electronic equipment (WEEE)
	Defibrillation-proof. Type CF applied part	**Rx ONLY**	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician
EC REP	Authorized representative in the European community		Biohazardous Waste
	Not made with natural rubber latex		Caution

Symbol	Description	Symbol	Description
	Manufacturer		Serial number
	Date of manufacture YYYY-MM-DD		Catalog number (model number)
	Storage temperature range		Masimo reference number
	Keep dry		Storage humidity limitation
	Atmospheric pressure limitation		Fragile, handle with care
	Less than		Do not use if package is damaged
	Greater than		China Restriction of Hazardous Substances
	Unique Device Identifier		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note:** eIFU is not available in all countries.		

Chapter 7: Service and Maintenance

Cleaning Procedures

The module for Masimo LiDCO is a reusable instrument. The instrument is supplied non-sterile.

To clean the module:

1. Disconnect the module from the monitor and ensure the cable is not connected to the module.
2. Wipe the outer surfaces using a dampened soft cloth with a mild detergent and warm water solution or one of the recommended cleaning solutions twice or until the surfaces are free of any visible residue.
3. Dry the module thoroughly prior to using on a patient.

The surfaces of the module may be cleaned with the following solvents or cleaning agents:

- 70% Isopropyl Alcohol (IPA)
- Glutaraldehyde (Cidex® Plus)
- 0.5% sodium hypochlorite water solution (10% bleach/water solution)
- Quaternary ammonium chloride
- Accelerated Hydrogen Peroxide® solutions (Oxivir® TB)

See ***Safety Information Warnings and Cautions*** on page 9

General Maintenance for Module

Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

The following is a checklist for the general maintenance of the module:

- Visually inspect equipment for functional or structural damage, including poor seals, cracks, damaged springs, etc.
- Visually inspect cables, connectors, and connector pins for signs of damage or wear.
- Visually inspect product identification labels to ensure they are clear and legible.
- Visually inspect for evidence of fluid ingress.

Service Instructions

The module has no customer serviceable parts. Attempting to service the module will void the warranty.

Safety tests and internal adjustments should be done by qualified personnel only.

See ***Sales & End-User License Agreement*** on page 61.

See ***Contacting Masimo*** on page 60.

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in ***Cleaning Procedures*** on page 59. Make sure the equipment is fully dry before packing.

To return the module for service, please follow the ***Return Procedure*** on page 60.

Return Procedure

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the equipment. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the instrument is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating that the module has been decontaminated for bloodborne pathogens.

Return the equipment to the following shipping address:

USA, Canada, and Asia Pacific:	**Europe:**	**All Other Locations:**
Masimo Corporation 52 Discovery Irvine, California 92618 Tel:+1 949 297 7000 Fax:+1 949 297 7001	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel- Switzerland Tel:+41 32 720 1111 Fax: +41 32 724 1448	Contact your local Masimo Representative

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Sales & End-User License Agreement

This document is a legal agreement between you (“purchaser”) and Masimo Corporation (“Masimo”) for the purchase of this Product (“Product”) and a license in the included or embedded Software (“Software”) except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: each new Product and the Software media as delivered are free from defects in workmanship or materials. Masimo’s sole obligation under this warranty is to replace any product that it deems to be covered under warranty with a replacement Masimo LiDCO.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo’s written authorization; b) supplies, instruments or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone other than an authorized Masimo agent; d) use of the Product with Sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products Modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

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Index

S

T

U

W

Z

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