MostCare^{Up}
USER MANUAL

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16.1 MANUFACTURER 87

1. INTRODUCTION

MostCare^{Up} is an active portable medical hemodynamic monitoring device used to continuously survey vital parameters related to the adult patient's hemodynamic profile in real time.
MostCare^{Up} is based on the algorithm Pressure Recording Analytical Method (PRAM), described in Section 5. PRAM is a Pulse Contour Method (PCM) which analyses the arterial pressure curve without requiring any kind of calibration (patient data or calibrating systems).

1.1 Connections and interfaces

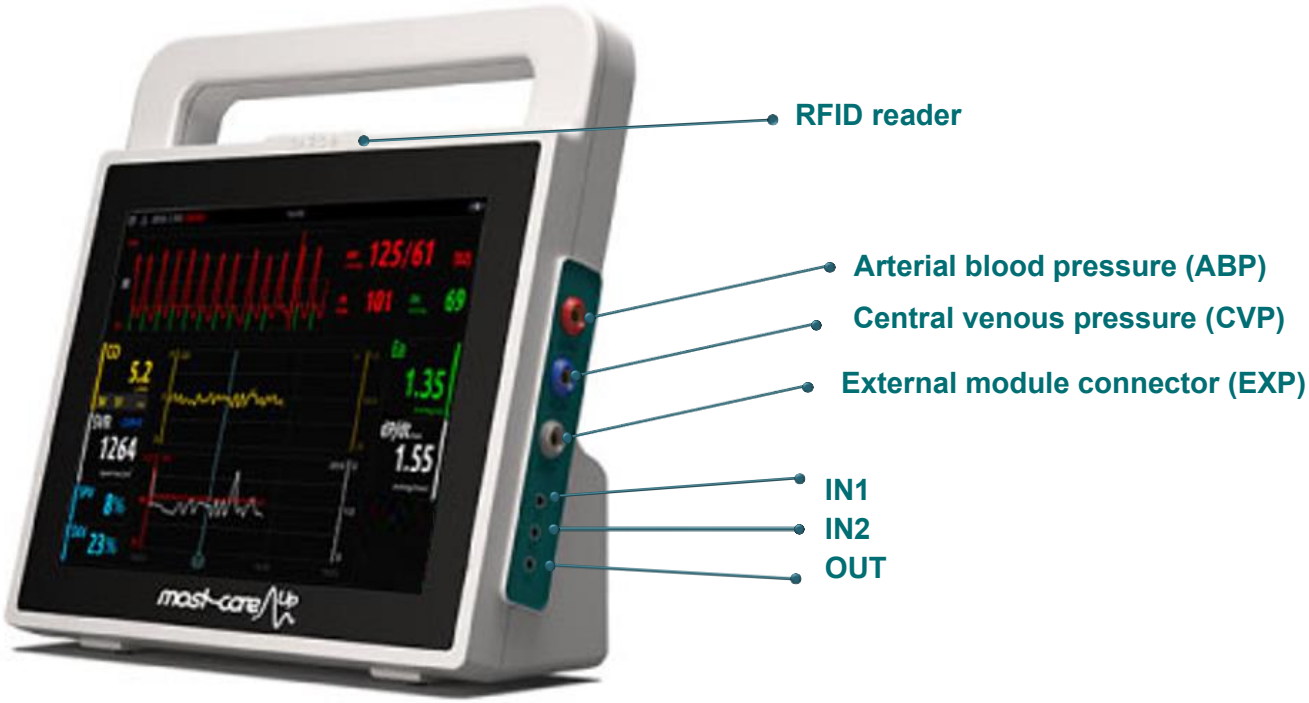


Fig.1 Device right side

Connector	Description
RFID reader	Allows the reading of RFID supports (e.g. RFID card) for credits and advanced mode activation in MostCare^{Up} model *On Demand* and for service operations.
ABP	Allows MostCare^{Up} to acquire a continuous arterial blood pressure signal from a pressure transducer connected to an arterial catheter (e.g. radial or femoral)
CVP	Allows MostCare^{Up} to acquire a continuous central venous pressure signal from a pressure transducer connected to a central venous catheter
EXP	Allows MostCare^{Up} to connect to an external expansion module
IN1	Allows MostCare^{Up} to receive and process an analog arterial blood pressure signal (e.g. from the analog output of an arterial pressure monitor)
IN2	Allows MostCare^{Up} to receive and display an analog signal (e.g. from another medical device)
OUT	Allows MostCare^{Up} to transmit the analog arterial pressure signal to an external device (e.g. another patient monitor)

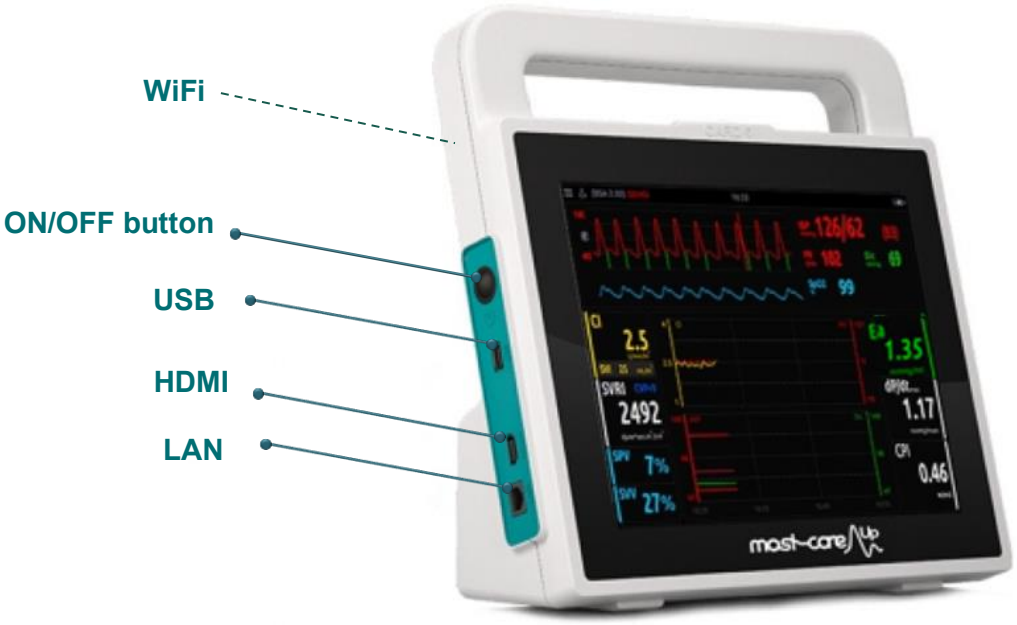


Fig.2 Device left side

Connector	Description
WiFi	Allows to enable a wireless connection between MostCareUp and the hospital information network and transmit monitored patient data (see Section 10.13).
ON/OFF button	Power ON, stand-by or shutdown switch
USB	Allows the connection of a USB flash drive that can be used for storing patient data (see Section 10.14) or service operations
HDMI	Allows to connect an external monitor to MostCare^{Up} by means of a HDMI cable and to duplicate the screen of MostCare^{Up} on the external monitor (see Section 6.2).
LAN	Allows to enable a wired connection between MostCare^{Up} and the hospital information network and transmit monitored patient data (see Section 10.12).
Handle	Handle for an easy and comfortable product transportation

Fig.3 Device backside

Connector	Description
Handle	Handle for an easy and comfortable product transportation
Power inlet	Connection to mains. When connected to mains and “O/I” switch is set to “I”, MostCare^{Up} runs on mains power and battery is in charging mode
O/I Switch	Power switch (see Section 8.1.1)
Clamp plate	Allows the connection of a specific clamp for mounting MostCare^{Up} on a patient bed vertical support (e.g. IV pole or cart)

1.2 List of symbols

Symbols featured on MostCare^{Up}

Position	Symbol	Description
MostCare^{Up} right side lateral panel	ABP	Arterial Blood Pressure
	CVP	Central Venous Pressure
	EXP	External module connector (Expansion)*
	IN1	Input1
	IN2	Input2*
	OUT	Output
		Applied CF-type part (protected from defibrillator discharge)
MostCare^{Up} left side lateral panel		On/stand-by button
	USB	USB input
	HDMI	HDMI connector
	LAN	LAN connector
MostCare^{Up} front	CARD	Contactless area
		MostCare^{Up} model
Labels		Equipotential pin
		Fuses: T1250mAH250V Model: 02151.25MXEP Littlefuse
		Follow the operating instructions
		Separate waste collection of this device will be necessary at the end of its operational life
	IP22	IP protection rate
		Indicates the presence of radio emissions connected with RFID contactless card use
	REF	Catalogue number (08MC02XXY for MostCare^{Up})
	SN	Serial number (e.g. yy/Axx-n)
	UDI	Unique Device Identification
	MD	Medical Device
	FR:	Hardware functional revision
		Manufacturer
		Manufacturing date
		Manufactured in Italy
		At the end of its useful life the product must be collected separately from other waste
		MostCare^{Up} model
		Medical prescription required

*Future implementations

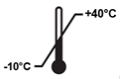
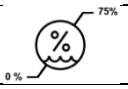
Symbols featured in the software

Position	Symbol	Description
Horizontal bar		Opens the lateral pop-up menu
		Patient icon
		ALARM DISABLED: At least one alarm (both visual and audible warnings) disabled until the end of monitoring, or until the user removes the pause

		AUDIO PAUSE: at least one alarm paused (only audio) for 2 minutes or until the user removes the pause (audible warning paused with active visual warning until the alarm status ceases)
		ALARM SILENCED (symbol): at least one alarm silenced (audible warning silenced with active visual warning until the alarm status ceases)
		Ethernet network enabled and in communication
		Ethernet network enabled but not in communication
		WiFi network enabled and in communication
		WiFi network enabled but not in communication
		Ethernet or WiFi network enabled and HL7 is active
		Ethernet or WiFi network enabled but HL7 is not active
	DEMO	A demo profile is now being displayed
		USB flash drive inserted
	REC ●	Recording under way
		Battery charge 25% The LOW BATTERY alarm switches on when this icon appears
		Battery charge 50%
		Battery charge 75%
		Battery charge >75%
		MostCare^{Up} powered (from mains voltage) + Charging battery
		Charging battery with charge complete (100%)
		MostCare^{Up} powered (from mains voltage)
	xx:xx	Current time
	BSA	Body Surface Area
Other		Active alarm condition
		Command for resetting an active alarm whose triggering is no longer occurring
		Alert icon in warning popup

Symbols featured on the packaging

Position	Symbol	Description
MostCare^{Up} packaging		Catalogue number
		Serial number
		Unique Device Identification
		Medical Device
		Operating instructions included
		Manufacturer

		MostCare^{Up} model
		Indicates the top side of the packaging
		Fragile, handle with care
		Protect from sunlight
		Separate waste collection of this device will be necessary at the end of its operational life
		Symbol and material coding for the disposal of the packaging (PAP 20 Symbol)
		Protect from rain
		Storage and transportation temperature
		Storage and transportation humidity

2. MONITOR AND ACCESSORIES

MostCare^{Up} includes:

- MostCare^{Up} monitor
- Power cable
- Accessory for floor-stand installation
- Statement of compliance
- MostCare^{Up} user manual
- 2 fuses

2.1 MostCare^{Up} transducers and transducers cables

The following transducer cables can be used with MostCare^{Up}, for the ABP and CVP applied parts:

TRANSDUCERS (Family)	
BRAUN Combitrans	
BIOSENSORS Biotrans	
EDWARDS TruWave	
ABBOTT	
DIRECT CABLES	
Cable model	**Cable code**
Compatible with BBRAUN (Combitrans) transducer	03MU-BBR
Compatible with BIOSENSORS (Biotrans)	03MU-BIO
Compatible with EDWARDS (TruWave) transducer	03MU-EDW
Compatible with ABBOTT transducer	03MU-MED
Compatible with ABBOTT transducer	03MU-MED2
Y-CABLES	
Cable model	**Cable code**
Y Cable Compatible with BBRAUN transducer	03MUY-BBR
Y Cable Compatible with BBRAUN transducer	03MUY-BBR1
Y Cable Compatible with BIOSENSORS (Biotrans)	03MUY-BIO
Y Cable Compatible with EDWARDS transducer	03MUY-EDW

NOTE: Transducer cables and transducers are all produced by external manufacturers. For more information about compatible models, please refer to your local MostCare^{Up} distributor.

NOTE: For the reusable models, please refer to the relative instructions for use in order to find information on the appropriate processes for cleaning, disinfection, packaging, the method of sterilization (if applicable), any restriction on the number of reuses and precautions to be taken in the event of changes in performance.

⚠ **WARNING: DO NOT** reuse single-use transducers and cables.

Reuse of single-use transducers or cables may result in cross-contamination, infection, and serious patient injury or death.

2.2 MostCare^{Up} MonitorIN cables

The following transducer cables can be used with MostCare^{Up}, for the monitorIN applied part:

Cable description	Cable code
INPUT/OUTPUT ANALOGIC CABLE JACK 3.5MM	MUHEMO018
INPUT/OUTPUT ANALOGIC CABLE D-S	MUHEMO024
INPUT/OUTPUT ANALOGIC CABLE 7PIN	MUHEMO031
INPUT/OUTPUT ANALOGIC CABLE GEC	MUHEMO033
INPUT/OUTPUT ANALOG CABLE NK	MUHEMO034
INPUT/OUTPUT ANALOGIC CABLE JACK 6MM	MUHEMO035

NOTE: All cables are produced by external manufacturers.

⚠**WARNING: DO NOT** reuse single-use cables.

Reuse of single-use cables may result in cross-contamination, infection, and serious patient injury or death.

2.3 Optional accessories

It is possible to use the following components with MostCare^{Up}:

Product code	Component description
10MC02-CLAMP	Pole support for MostCare^{Up}

For the updated catalogue of optional accessories that can be used with MostCare^{Up}, please refer to your local distributor.

3. SAFETY WARNINGS

MostCare^{Up} has been manufactured according to current international safety standards. The manufacturer is referred to IEC 60601-1 standard for the requirements applicable to Medical Equipment systems.

Please read the following warnings, instructions and safety information carefully before using the devices.

Carry out inspections and maintenance as specified in this manual (see Section 11).

⚠**WARNING:** The user must check the device safety and condition before use, making sure it is undamaged. The use of a damaged device during monitoring can lead to unreliable variables and therefore to an incorrect clinical decision.

3.1 Electrical safety

See also Section 12.3.
MostCare^{Up} must be powered by connecting it to a 100-240 VAC 50-60 Hz power source.
Use the device only if the power network corresponds to the requirements printed on device labels.

⚠**WARNING: DO NOT** connect the power cable using extension cables or multi-socket devices. **DO NOT** use detachable power cables other than the supplied power cable. **DO NOT** use 2-pole cables or a 3-pole to 2-pole adapters to power the device.
An unappropriated use of cables may cause fire or explosion that can result in serious injury or death to the patient/operator or in device damaging.

Before every use of the devices, perform a visual inspection, checking the condition of each cable.

⚠**WARNING: DO NOT** step on, bend or twist the cables.
Using damaged cables can result in electrical or mechanical damage, which may prevent monitoring and cause damage to the device.

The mains socket must be near the monitor and easy to reach in the event of emergency disconnections.
Disconnect the devices from the mains before performing any maintenance operation or installation.
Do not overload the mains sockets, any extension cables or the adapter, since this may cause fire or electric shock. Disconnect the devices if they are not expected to be used for long periods of time.
Disconnect the cables by pulling the plugs from their sockets. Do not pull the cables.

⚠**WARNING: DO NOT** pull the cables.
Unplug the cables from the device by pulling on the connector, not the cable, as this could cause the device to fall and become damaged.

⚠**WARNING: DO NOT** connect MostCare^{Up} to external devices that do not comply with IEC 60601-1 requirements for medical electrical systems.
When MostCare^{Up} is connected to an external device, the system must meet the requirements of Standard 60601-1 clause 16 “General requirements for the medical electrical system”.
Connection of MostCare^{Up} to non-compliant external electrical devices may result in excessive leakage currents and electrical shock, which may cause serious patient injury or death

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The USB connection must be exclusively used to connect with a USB flash drive not connected to an external power supply unit.

The means to electrically isolate the power supply circuits are:

- Cable disconnection
- Switch in the OFF position

3.2 Contact with liquid or gaseous substances

MostCare^{Up} have been designed with an IP22 protection rating (protecting against foreign objects of 2,5 mm Ø and greater and vertically falling water drops when enclosure is tilted up to 15°).

⚠**CAUTION: DO NOT** place containers or equipment containing liquids on top of MostCare^{Up}.

If liquids are spilled onto the MostCare^{Up}, this may cause electrical damage and short circuits, resulting in the device being unable to start monitoring.

Pay attention when using MostCare^{Up} in the presence of flammable materials. As it is an electronic device, it might trigger electric discharges that may lead to explosion in rooms saturated with inflammable gas or other flammable substances).

MostCare^{Up} have been designed to minimize the risk of liquid penetration. In any case take care that no liquid penetrates the devices. Should this happen, do not connect MostCare^{Up} to the mains and stop using the device.

3.3 Cleaning

Clean the device with a wet cloth and Liquinox and disinfect with isopropanol 70% disinfectant, following the instructions provided in Section 12.1.

⚠ **WARNING: DO NOT** use substances other than those specified in Section 12.1.

The use of substances other than those specified may result in incomplete cleaning and disinfection or damage to the exterior of the device.

3.4 Positioning, transport and operational conditions

Handle the devices carefully and do not expose them to temperatures higher than +40°C [+104° F] or lower than +10°C [+50° F] during operation.

⚠ **WARNING: DO NOT** place the devices near a radiator or other heat sources.

Using the device in an environment where the temperature is out of the established range may cause mechanical instability that may result in incorrect measurement during monitoring, leading to an incorrect diagnosis.

MostCare^{Up} is designed to be used:

- On a horizontal plane;
- With its specific clamp accessory for connection to vertical pole or floor-stand;
- With its specific accessory for horizontal coupling to a bed headboard.

⚠ **WARNING**: **DO NOT** use clamp accessories for connection to vertical pole or floor-stand coupling during transport.

The clamp accessories for connection to vertical pole or floor-stand coupling cannot be used as support during transport, using them during transport may result in the device falling and becoming damaged.

⚠ **WARNING**: Any accidental fall may cause serious injuries to people and damage to property and the device itself.

⚠ **WARNING**: **DO NOT** use the device in presence of devices that generate radiofrequency and microwave emissions.

The system cannot be used in rooms where magnetic resonance equipment is operating and, in general, it may give incorrect readings in the presence of other devices that generate radiofrequency and microwave emissions.

⚠ **WARNING: DO NOT** use the device during transport.
When transporting MostCare^{Up} artefacts may be produced, so any variable measured during transport cannot be regarded as reliable.

3.5 Disposal

Carefully and scrupulously follow the instructions given for the disposal of the device (Section 12.2).

3.6 Other warnings

⚠**WARNING: DO NOT** open the device in case of failure but have it serviced.

Make sure that any repairs or replacements, including battery replacement, are performed by qualified and authorized personnel only. Any repairs carried out by unauthorized personnel will immediately invalidate any warranty claims and could result in a hazardous situation (such as excessive temperatures, fire or explosion).

⚠**WARNING**: **DO NOT** replace the battery.

The replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazardous situation. If other accessories are used, make sure they comply with the safety and compatibility regulations in force.

⚠**WARNING**: Position the device so that it or any other equipment connected to it will not fall onto the patient or the operator, causing injury to them.

⚠**WARNING:** Check that transducers are at the same level as the patient's phlebostatic axis before zeroing transducers on the monitor and begin monitoring. Failure to calibrate the transducer correctly can lead to unreliable variables or their misinterpretation, resulting in an incorrect clinical decision.

⚠**WARNING:** The operator must be in a position from which he can see the monitor with a certain clarity (front position, suggested distance: 50 cm).

Viewing the device from an incorrect position can lead to unreliable variables or their misinterpretation, resulting in an incorrect clinical decision.

⚠**WARNING:** For the correct use of pressure transducers please refer to the manufacturer's specific instructions for use. The incorrect use of pressure transducers can lead to unreliable variables or their misinterpretation, resulting in an incorrect clinical decision.

4. INTENDED PURPOSE

4.1 Intended use

MostCare^{Up} is an active portable medical hemodynamic monitoring device used to continuously survey vital parameters related to the adult patient's hemodynamic profile in real time.

4.2 Intended users

MostCare^{Up} is intended for use by specialized and qualified healthcare personnel.

4.3 Intended patient population

MostCare^{Up} is intended to be used on adult patients (weighing less than 661lb) who require continuous or occasional hemodynamic monitoring.
MostCare^{Up} is intended to be used when there is an indication for mini-invasive hemodynamic monitoring. This applies to patients submitted to surgical interventions or recovered in intensive care unit, where an arterial catheter for invasive pressure monitoring is indicated.

4.4 Intended environment of use

MostCare^{Up} is intended for use in professional healthcare facility environments.
Suitable clinical settings include, but are not limited to:

- Medical and Surgical adults Intensive Care Units
- Operative rooms
- Step Down/High Dependency Units
- Trauma / Accident & Emergency Departments
- Cardiac Catheter Laboratories

Home care and other locations not listed above are excluded from the environmental reference conditions.

4.5 Indications for use

MostCare^{Up} hemodynamic monitor provides the clinician with supplementary information on the status and the variations of the cardiovascular function including measurements of blood pressure, cardiac output and associated hemodynamic parameter.
The device is indicated for use by specialized and qualified healthcare personnel in professional healthcare facility environments whenever an adequate invasive arterial pressure signal can be achieved and when there is an indication for mini-invasive hemodynamic monitoring. This applies to adult patients (weighing less than 661 lb) submitted to surgical interventions or recovered in intensive care unit, where an arterial catheter for invasive pressure monitoring is indicated.

4.6 Contra-indication

MostCare^{Up} have no specific contraindications.

4.7 Limitation of use

⚠**WARNING**: Inaccurate CO measurements, which may lead to an incorrect clinical decision, can be caused by factors such as:

- Improperly zeroed and/or leveled sensor/transducer
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure, including but not limited to:
    - Extreme peripheral vasoconstriction which results in a compromised radial arterial pressure waveform
    - Hyperdynamic conditions as seen in post liver transplant
- Excessive patient movement
- Electrocautery or electrosurgical unit interference

Aortic valve regurgitation may cause an over estimation of Stroke Volume / Cardiac Output, which may lead to an incorrect clinical decision, calculated depending on the amount of valvular disease and the volume lost back into the left ventricle.

⚠**WARNING**: **DO NOT** use MostCare^{Up} in adult patients weighing more than 661 lb.
Using MostCare^{Up} in patients weighing more than 661 lb could lead to incorrect calculations of derived variables and inappropriate clinical decision.

⚠**WARNING**: **DO NOT** make diagnoses or decide therapy based solely on these measurements and derived parameters.
The measurements detected by MostCare^{Up} and the derived parameters should be considered as additional assessment information, otherwise, clinical decisions may be made based on data that has not been compared with other tools, leading to an incorrect clinical decision.

⚠**WARNING: DO NOT** use MostCare^{Up} to assess haemodynamic variables when the catheter tip is placed into a vein, pulmonary artery or one of the cardiac chambers. This may result in inaccurate measurements and lead to an incorrect diagnosis.

4.8 Usage warnings

MostCare^{Up} might provide incorrect values in the event that the pressure signal is affected by detection errors such as, but not limited to, the following:

- Contact between the catheter tip and the artery wall;
- Wrong positioning, folding or excessive angle of the catheter or the line;
- Blood clots in the catheter or line;
- Poor quality of the pressure signal obtained through the transducer line (underdamping; overdamping).

The cardiac output indications provided by MostCare^{Up} must be checked by the operator. The better the detection of the pressure wave morphology, the more accurate the values provided by MostCare^{Up} will be.

The operator must make sure that the dicrotic point is identified correctly: it is necessary to check that, on the pressure curve graph, the dicrotic indicator (vertical green bar) is positioned on the actual dicrotic incisure, and that there are no artefacts due to poor signal quality. If the dicrotic indicator is not positioned correctly (or is not displayed), both before and after manually optimizing the dicrotic incisure detection point (Section 9.3.6), the values displayed will not be reliable.

Zero the pressure transducers connected to the monitor before every use and whenever the catheter, the pressure transducer line or the transducer positioning are changed as the patient's chest height changes. If this operation is not performed, the readings for pressure and its derived variables will not be reliable.
Errors may occur if MostCare^{Up} is used in a manner not described in this manual.

The device must be connected to an electrical system that complies with the IEC 60601-1 standard and the national standards applicable in a medical environment.

⚠**WARNING: DO NOT** connect the device to power networks without grounding protection.
Connection MostCare^{Up} to a power network without grounding protection could result in electrical shock.

Avoid conductive connections with the applied part. In the event of a connection to an external device, the grounding connection for MostCare^{Up} and the device connected to it must be made at the same potential equalization busbar.

To perform this connection, the pin on the back of the device can also be used ⏚ in accordance with the IEC 60601-1 Standard.
For fixed installations, a fixed grounding connection can be created by using the pin on the rear of the device (equipotential grounding symbol).

The device is protected from damage caused by a defibrillator. Defibrillation has no effect on the device safety and operation. Hemodynamic monitoring might however suffer a brief interference during this procedure.

⚠**WARNING: DO NOT** touch the device during defibrillation.
Touching the device during defibrillation could cause the operator to receive an electric shock.

⚠**WARNING: DO NOT** use accessories, cables and transducers different from the ones specified in this user manual.
If accessories, cables and transducers other than those specified in this user manual are used during defibrillation, safety cannot be guaranteed**.**

⚠**WARNING:** When used in conjunction with high-frequency surgical equipment (electrosurgery), hemodynamic monitoring may become interfered and the shown values may not be reliable.
Please note that the applied part is isolated, so that the risk of burns during with high-frequency surgical equipment is minimized; however, always verify the good state of the cable weather an electrosurgery is due.

⚠**WARNING: DO NOT** use accessories, cables and transducers different from the ones specified in this user manual.
If accessories, cables and transducers other than those specified in this user manual are used during defibrillation, safety cannot be guaranteed, which can lead to an incorrect diagnosis or to an injury to the patient/operator.

The user must check the safety and condition of the device. Before using the device, make sure it is intact and perform a visual inspection, checking the condition of the power cable and of the cables connecting the device to the transducer or monitor.

The pressure transducer used must comply with the specifications indicated in Section 13.3.4.

It is important to check that the information entered into the initial PATIENT SETTINGS menu is correct, otherwise hemodynamic values may be subject to error.

If the CVP option from the transducer is selected and the pressure transducer is not connected to the CVP input on the right side of MostCare^{Up}, the system will estimate vascular resistance values (absolute and indexed) through a fixed, pre-set pressure value and, therefore, the results obtained might be incorrect.

If there is no heartbeat, or if a valid ABP signal is not recognized, the transducer-generated CVP value displayed must not be considered reliable.

4.9 Normal use

In normal use, the operator shall stand in front of the monitor.
Position the monitor in a location where the operator can easily see the screen, access the operating controls and can easily access the disconnection of the device.
The use of MostCare^{Up} is limited to one patient at a time.

⚠**WARNING:** In order to correctly detect the values and alarms provided by the device, and in order to correctly read MostCare^{Up} labels and indicators, the operator must be in a position from which he can see the monitor with a certain clarity (front position, suggested distance: 50 cm). Having difficulty seeing the monitor clearly can lead to an incorrect clinical decision.

4.10 Frequently used functions

MostCare^{Up} is most frequently used to perform the following functionalities:

- Patient ABP monitoring
- CO/SV evaluating, for diagnostic purposes
- Recording of the patient data

4.11 Essential performances

Essential performance		Description or standard subclause
Invasive blood pressure monitoring equipment (60601-2-34)		
1	Defibrillator protection	201.8.5.5.1
2	Accuracy of pressure measurements	201.12.1.101
3	Electro surgery interference	202.6.2.101
4	Physiological alarm conditions, alarm limits and delay time of physiological alarm signals	208.6.6.2.101
5	Detection of transducer and transducer cable fault	208.6.6.2.102
6	Detection of disconnected catheter	208.6.6.2.103

4.12 Residual risks

The risk analysis related to MostCare^{Up} was carried out in accordance with ISO 14971 by calculating the risk as the product of probability and severity. Any risk relating to the use of the product has been reduced as far as possible.

The usage indications, contra-indications, safety warnings and usage warnings are listed in Sections 3, 4.5, 4.6 and 4.8 of this user manual.

5. OPERATING PRINCIPLE AND CALCULATION METHOD

5.1 P.R.A.M. and MostCare^{Up}

The 'Pressure Recording Analytical Method' (PRAM)[1] is the method that allows for the calculation of hemodynamic variables by analyzing the shape and area of the arterial pressure wave or a specifically pre-processed plethysmographic curve (CNBP curve). The PRAM represents the application within the physiological sector of the 'Perturbation Theory', which is well known and largely applied in physics. **MostCare** (**Mo**nitor **St**oke volume and **Car**diac **E**fficiency) is the only device which integrates the full PRAM system.

As the PRAM deduces all variables (both systemic and hemodynamic) from the analysis of the arterial pressure curve only, the first MostCare^{Up} feature is to accurately acquire the analog signal and scan it at a **1000 Hz frequency.**
MostCare^{Up} works **in real time, beat by beat.** Each individual arterial pulse is detected and analyzed by the PRAM; each variation in the patient's condition and each reaction to a stimulus created by the operator are immediately detected, analyzed and displayed by the device.
The PRAM's uniqueness consists in its ability **to calculate the specific, typical cardiovascular system impedance of the subject under observation in real time.** By impedance (usually indicated in formulae as Z(t)), the resultant of different forces that mutually interact and simultaneously operate in the cardiovascular system is meant. Elements, such as cardiac contractility, vascular and arterial resistances and arterial compliance exert characteristic forces that determine different, constantly changing physio pathological profiles; the shape and area of the arterial pressure curve are affected by these elements and, therefore, they describe the instantaneous interaction of all of these elements.
Since impedance is constantly changing, MostCare^{Up} does not use constant or pre-assessed values for its calculation so as to reliably follow the physio pathological variations of the impedance. Therefore, the PRAM system **does not need any direct or indirect calibration.**

5.2 PRAM analytical expression

The *SV* volume is calculated by the ratio between the surface below the systolic component of the pressure curve *(A)* and the characteristic impedance *Z(t)*. So we can write:

[1] Romano SM, Pistolesi M. Assessment of cardiac output from systemic arterial pressure in humans. Crit Care Med. 2002 Aug;30(8):1834-41

$$SV = \frac{A}{Z(t)}$$

$$Z(t) = \frac{P(t)}{t} \times K(t)$$

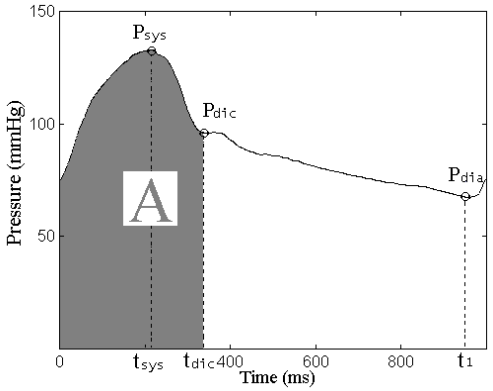

Figure 1

Where *A* is the total area below the systolic pressure curve visible in Figure 1.
The denominator *P(t)/t x K(t)* is the impedance *Z(t)* with development stopped at the first term, as described in the work by Romano SM, et al.[1] *K(t)* is a factor inversely correlated with the instantaneous acceleration of the section area, while *P(t)/t* is the instantaneous power per surface unit, analytically described by the changes to the pressure profile during the cardiac cycle.

5.3 PRAM typical hemodynamic variables

All systemic and hemodynamic variables are listed in detail in Section 8. The following paragraphs describe instead only two of the system typical variables.

5.3.1 dP/dt$_{max}$

The dP/dt$_{max}$ variable (pressure variation compared to time interval) corresponds to the maximum velocity of pressure increase during the isovolumetric contraction phase. When dP/dt$_{max}$ is detected with a catheter directly inside the ventricle, it indicates cardiac contractility.

The PRAM measures dP/dt$_{max}$ as the maximal ascending slope of the peripheral arterial pressure curve systolic component. Therefore, it has three different components:

- Cardiac contractility
- Vascular tonus
- Pressure signal quality: an inadequate and resonant pressure signal can overestimate dP/dt$_{max}$[4].

Since the pressure increase velocity is determined by the ventricle-arterial relationship, the dP/dt$_{max}$ value measured by MostCare^{Up} may be correlated both to left ventricle contractility and to the rigidity of the aorta and the main blood vessels. Vascular tonus being equal, the dP/dt$_{max}$ measured by MostCare^{Up} can be correlated with ventricular contractility. It can otherwise change as vascular tonus changes.

The dP/dt$_{max}$ measured through the PRAM is expressed in mmHg/msec with a normal range between 0.9-1.2 mmHg/msec. Thanks to the sampling of the pressure curve at 1000 Hz, the dP/dt$_{max}$ measurement is particularly accurate. The point-to-point analysis of the arterial pressure wave gives such a large amount of information that even minimal 'relative' differences of each wave-shape point are important; the propagation

velocity and reflected waves, which depend on the features of the arterial vessels (rigidity, tonus, stenosis, etc.), can affect the shape of the fundamental wave differently[2--3-4-5-6].

⚠**WARNING:** Be careful when dP/dt_{max} > 1.7 mmHg/msec because there might be an inadequate detection of the arterial pressure signal (underdamping)[4]. In the event of bad detection quality of the arterial pressure signal, the data processed by MostCare^{Up} could be wrong, leading to an incorrect clinical decision. If dP/dt_{max} is higher than 1.7, the value is highlighted and displayed in RED.

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6. OPERATING MODES AND CONFIGURATIONS

MostCare^{Up} operation is based on the analysis of the waveform of an analog arterial blood pressure signal. MostCare^{Up} can acquire the input signal in the following configurations. The data of the main monitoring variables can be transmitted to a centralized medical record system through the HL7 protocol.

6.1 PRAM mini-invasive monitoring mode

6.1.1 Use of MostCare^{Up} in Stand-alone mode

MostCare^{Up} acquires the analog arterial blood pressure signal from a pressure transducer connected to a catheter inserted into patient's peripheral artery (femoral or radial).

Step by step connection:

1. Select a TRANSDUCER CABLE compatible with the pressure transducer being used.
2. Connect the transducer cable to the ABP connector, on the right side of the MostCare^{Up}.
3. Connect the other end of the cable to the pressure transducer.
4. Zero the transducer from MostCare^{Up} user interface (See Section 10.3.1 for detailed instructions).

6.1.2 Combined use with another patient monitor

MostCare^{Up} acquires an analog arterial pressure signal from the analog output of an external patient monitor.

Step by step connection:

1. Select a MONITOR IN CABLE compatible with the patient monitor to be connected to MostCare^{Up}.
2. Connect MostCare^{Up} analog input socket (IN 1) to the analog output socket of the other patient monitor with the selected MONITOR IN CABLE.

⚠**WARNING:** When MostCare^{Up} is connected to an external device, the system must meet the requirements of the Standard 60601-1 clause 16 "General requirements for the medical electrical system", otherwise, the device could be damaged, resulting in unreliable variables that may lead to an incorrect diagnosis

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[2] Scolletta S *et al.* Assessment of left ventricular function by pulse wave analysis in critically ill patients. Intensive Care Med 2013;39: 1025-33.

[3] Giglioli C *et al.* Levosimendan produces an additional clinical and hemodynamic benefit in patients with decompensated heart failure successfully submitted to a fluid removal treatment. Congest Heart Fail 2012;18: 47-53.

[4] Romagnoli S *et al.* Dynamic response of liquid-filled catheter systems for measurement of blood pressure: precision of measurement and reliability of the Pressure Recording Analytical Method with different disposable systems. J Crit Care 2011 Aug;26(4): 415-22.

[5] Romano SM *et al.* Blood flow assessment by arterial pressure wave without external calibration. Computers in Cardiology 2006; 33: 293-6.

[6] Romano SM *et al.* "Monitoraggio emodinamico minimamente invasivo in corso di resezione epatica maggiore in pazienti cardiopatici. Minerva Anestesiologica 2006, Vol 72 (supp.2) 10; 36-37.

NOTE: If Monitor IN cable is used to acquire patient signal from an external monitor, please note that the accuracy and quality of the represented signal relies directly on the signal coming from the external monitor.

6.1.3 Combined use with another patient monitor and Y cable

MostCare^{Up} and another patient monitor acquire the same analog arterial pressure signal from a pressure transducer connected to a catheter inserted into patient's radial or femoral artery.

Step by step connection:

1. Select a TRANSDUCER Y CABLE compatible with the pressure transducer being used. Y cable features are reported in Section 13.
2. Connect one end of the Y cable to the MostCare^{Up} ABP connector, on the right side of the device.
3. Connect the second end of the cable to the pressure transducer.
4. Connect the third end of the Y cable to the appropriate connector of the other patient monitor.
5. Zero the transducer from both MostCare^{Up} and other patient monitor user interfaces (See Section 9.3.1 for detailed instructions).

⚠**WARNING**: Incorrect use of the Y-cable may result in mechanical or electrical damage to the device or in unreliable readings, which could lead to an incorrect clinical decision, please note the following:

- It is not possible to use a Y CABLE once monitoring has started: the cable will need to be configured during initial setting and connected to the device before monitoring starts. On the other hand, once monitoring using a Y CABLE has started, it will not be possible to exchange it with a standard cable during monitoring. Should such an operation be undertaken, the device will issue an error message and inhibit further use. The Y CABLE is used to detect arterial pressure only, not venous pressure, so it cannot be used with the CVP input.
- If a TRANSDUCER Y CABLE is used without connecting the patient monitor transducer cable to the Y connection, MostCare^{Up} will not be able to read any pressure value.
- To accurately read pressure values, the transducer power voltage, as supplied by the external monitor, must be stable. Otherwise, the instability condition is signalled with a technical alarm.
- When MostCare^{Up} is connected to an external device, the system must meet the requirements of Standard 60601-1, clause 16, "General requirements for the medical electrical system".
- The compatibility between MostCare^{Up}and the majority of pressure transducers and anaesthesia monitors on the market has been verified. Ask your area consultant for the TRANSDUCER CABLES, Y CABLES, MONITOR IN CABLES and monitors compatible with the devices in use (see Section 13 for details).

6.2 Combined use with an output monitor, HDMI connection

MostCare^{Up} can be used in combination with an external monitor, linked through an HDMI connection. MostCare^{Up} display will be duplicated on the screen of the external monitor.

NOTE: External monitor display is updated with a frequency of 25 Hz, hence image update may result 'staggered'.

⚠ **CAUTION:** A delay or an incorrect connection of the HDMI cable may result in a delay or inability to perform monitoring, please note the following:

- If you wish to use MostCare^{Up} via an HDMI connection with an external monitor, it will be necessary for the HDMI cable to be already connected when MostCare^{Up} is switched on. The cable must be inserted when the device is in OFF mode; stand-by mode will not be sufficient. It will not be necessary for the external monitor to be switched on.
- When MostCare^{Up} is connected to an external device, the system must meet the requirements of Standard 60601-1 clause 16 “General requirements for the medical electrical system”.

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7. VERSIONS

MostCare^{Up} is available in two versions:

- Endless (see Section 7.1)
- On demand (see Section 7.2)

In both cases, MostCare^{Up} can be used in all its operating mode and configurations (see Section 6).

7.1 MostCare^{Up} ENDLESS version

MostCare^{Up} ENDLESS is enabled for monitoring in ADVANCED mode (all the variables are calculated and displayed) forever, with no need for a CARD.
MostCare^{Up} displays the following variables.

7.1.1 Mini-invasive monitoring mode

Name	Description	Unit of measure
Dia	Diastolic pressure	mmHg
Sys	Systolic pressure	mmHg
Dic	Dicrotic pressure	mmHg
MAP	Mean Arterial Pressure	mmHg
PR	Pulse Rate	1/min
CVP (if transducer available)	Central Venous Pressure	mmHg
CO	Cardiac Output	l/min
CI	Cardiac Index	l/min/m^2
SVR	Systemic Vascular Resistances	dyn·sec/cm^5
SVRI	Indexed Resistances	dyn·sec·m^2/cm^5
SV	Stroke Volume	ml
SVI	Stroke Volume Index	ml/m^2
SVV	Stroke Volume Variation	%

SPV	Systolic Pressure Variation	%
DPV	Dicrotic Pressure Variation	%
PPV	Pulse Pressure Variation	%
dP/dt_{max}	Maximal slope of the systolic upstroke (Pressure variation velocity)	mmHg/msec
Ea	Arterial Elastance	mmHg/ml
PPV/SVV	Dinamic Elastance	[units]
SV/kg	Weighted Stroke Volume	ml/kg
Dia_{PK}	Diastolic peak	mmHg
DO_2	Oxygen Delivery derived value	ml/min
DO_2I	Oxygen Delivery Index derived value	$ml/min/m^2$
PP	Pulse Pressure	mmHg
MAP-Dic	Mean and Dicrotic pressure difference	mmHg
Z_{TOT}	Cardiovascular system impedance	mmHg·sec/ml
CPO	Cardiac Power Output	W
CPI	Cardiac Power Index	W/m^2

7.2 MostCare^{Up} ON DEMAND version

MostCare^{Up} On Demand works through the activation of credits which enable monitoring in ADVANCED mode for a limited time period/number of 'uses' (according to the card type). When used in this mode, all the variables indicated for the Endless mode are also available.

Different types of CARD are available to activate credits for ADVANCED monitoring mode:

- Mini-invasive TIME-BASED activation card
- Mini-invasive USE-BASED activation card

The CARDS may be damaged in the presence of permanent magnets or high-power electromagnetic sources.

When MostCare^{Up} On Demand is not enabled, it operates in a basic mode, supplying systemic values only, such as:

Value type	Unit of measure
Diastolic pressure (Dia)	mmHg
Systolic pressure (Sys)	mmHg
Dicrotic pressure (Dic)	mmHg
Mean Arterial Pressure (MAP)	mmHg
Pulse Rate (PR)	min^{-1}
Central Venous Pressure, if the transducer (CVP) is present	mmHg

Values for variables that are not supplied are hidden by the '- -' symbol.

Once the time period/use of a card has expired, MostCare^{Up} reverts to the basic monitoring of systemic variables only.
Data for the ADVANCED monitoring that has been completed before the expiry will however be always available and downloadable.

NOTE:

1. For time-based cards, a month corresponds to 30 days and a year to 365 days, calculated in terms of hours from the time of activation. For example, if a monthly card is activated on July 10th at 12.30 pm, activation will expire at 12.30 pm after 30 days (hence on August 9th).

7.2.1 Mini-invasive/Non-Invasive 'Time-based' activation card

With the TIME-BASED CARD, MostCare^{Up} is able to carry out an ADVANCED monitoring for the length of time indicated on the CARD (e.g.: 1 day, 30 days, 365 days)

The validity time for the ADVANCED mode is used up irrespective of whether MostCare^{Up} is in use or switched off. The residual time countdown starts from when you access the main menu after confirming the ADVANCED mode activation. Once monitoring starts, it will not be possible to modify the date and time anymore.

A time-based ACTIVATION CARD has no limits in terms of the number of patients who can be monitored during the time in which the ADVANCED mode is valid.

To verify the residual time for which MostCare^{Up} is enabled in ADVANCED mode, enter the 'Credit management' section of the main MENU, where the remaining validity time is indicated.

7.2.2 Mini-invasive 'Use-based' activation card

With the USE-BASED CARD, MostCare^{Up} is able to carry out an ADVANCED mini-invasive monitoring for the number of uses indicated on the CARD (e.g.: 1 use, 30 uses...).

One USE allows ADVANCED monitoring of one single patient for a maximum period of time of 72 hours. More than one use may be utilized for one patient, should it be necessary to continue monitoring for more than 72 hours. Once the residual time expires, it is otherwise possible to continue in ADVANCED mode without interruption via a new enabling (confirmation is requested to the user via a video message). At the end of the 72 hours monitoring period, precisely 30,10 and 5 minutes before time runs out, the following message will be displayed: “Warning: residual time is less than 30 (then 10, then 5) minutes! Get to the "Credit Management" menu to reload.” If a new 'use' is not activated, once the set time has expired MostCare^{Up} will automatically switch to basic mode.

7.2.3 Error messages connected with card usage

While the card is being read/overwritten, errors may occur; they are signaled on screen with the following messages:

Number	Error message displayed on MostCare^{Up}	Detailed manual description
ERR100	The device code stored on the card doesn't match that of the device being used	The device code stored on the card does not match that of the device being used
ERR101	It was not possible to use the credit on the card	It was not possible to use the credit on the card
ERR 102	Unrecognized card: the card used is not of the MostCare^{Up} type	Unrecognized card: the card used is not of the MostCare^{Up} type
ERR 103	Card not present	The reader could not detect a card
ERR 104	Card credit has run out	The credit on the card has run out

ERR 105	No connection with the card reader	Connection error with the application that reads the card
ERR 106	Credit type incompatible with existing credit	You are attempting to upload a type of credit that is not consistent with the residual credit available on MostCare^{Up}, i.e.: • The card is of the 'use' type while the credit available on the device is time-based, or vice versa • 'Uses' on the card are of a different duration compared to those on the device
ERR 107	Access denied: this card doesn't allow access	Access is denied because the access card does not allow it (a higher-level card is required)
ERR 108	Unsuitable card	The card offered is not suitable for the operation required, i.e.: • You are using a credit card to check access • You are using an access card to add credit

8. DIRECTIONS FOR USE

8.1 Switching on and initial settings

8.1.1 Switching on

⚠ **WARNING:** The use of damaged cables or a device with mechanical damage may result in the inability to monitor or in unreliable variables, leading to an incorrect diagnosis.
Perform a visual check of the condition of the power connector, the cable, the connection sockets, the accessories and check for any mechanical damage.

⚠ **WARNING:** Using a power cable other than the one authorized and supplied by the manufacturer may cause the machine to catch fire or explode, which could result in serious injury to the patient or operator.
Use only the power cables authorized by the manufacturer. Only the power cables authorized by the manufacturer ensure basic safety of the system.

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1. Insert the power cable into the power inlet on the back panel.
2. Power up MostCare^{Up} by flipping the switch at the rear. MostCare^{Up} is now off but powered and the battery is charging.

NOTE: The rear button is used to feed the internal battery through mains power:
- Set the rear button to the I position to charge up the internal battery (this will take place also if MostCare^{Up} is switched off). Verify that the LED on the ON/OFF button turns on.
- Set the rear button to the O position to stop internal battery charging. Verify that the LED on the ON/OFF button turns off.

---

3. Press the ON/OFF button on the left lateral side to turn on the system and switch on the device.

NOTE: MostCare^{Up} has 3 main operational modes:
a. **ON:** the device is electrically powered in all its parts and the application is active. The battery may be charging or not, depending on the rear button status, I or O.
b. **OFF:** the application is switched off and electrical power is absent. The battery may be charging or not, depending on the rear button status, I or O. If the battery is charging, the device will be electrically powered only partially, in terms of the battery's internal circuit.
c. **STAND-BY:** in this mode, the device is electrically powered in all its parts, and the application is active but the screen is switched off. It is possible to set MostCare^{Up} in stand-by mode only

if mains electrical power is available. This mode allows a quick restart of the device, with no need for an operating system reboot.
To switch the device off or set it in stand-by mode, see Section 8.1.7.

4. Verify the LED on the ON/OFF is turned on.

⚠ **CAUTION:** A delay or an incorrect connection of the HDMI cable may result in a delay or inability to perform monitoring. If you wish to use MostCare^{Up} via an HDMI connection with an external monitor, it will be necessary for the HDMI cable to be already connected when MostCare^{Up} is switched on. It will not be necessary for the external monitor to be switched on.

NOTE: The graphic display switches on showing a standard logo and a boot-up bar, and the device emits a sequence of five beeps.

Once booting is complete, the initial screen will be displayed.

8.1.2 Auto test and error messages

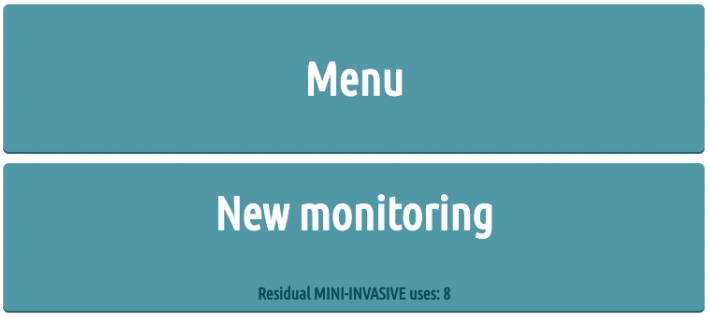
When the device is switched on, auto test is executed, including a check on the main functions (connection with SD card, battery status, internal clock) to ensure the device is operating faultlessly. In case of faults in any of the components being checked, an error message will appear, of the locking (hence the device will need to be sent in for technical assistance) or non-locking type.
Auto test is however automatically run by the device also during normal operation, and any errors can then also be displayed during normal operation.
If some part is faulty, the following error messages can appear on screen:

Code	Message on screen	Description	Type of error	Locked features
Internal error #1	Internal alarm 1. The device must be shut down.	Internal memory error	Locking alarm	All
Internal error #2	Internal alarm 2. The device must be shut down.	Internal memory error	Locking alarm	All
Internal error #3	Internal alarm 3. The device must be shut down.	Internal battery error	Locking alarm	All
Internal error #4	Internal alarm 4. The device must be shut down.	Internal serial line error	Locking alarm	All
Internal error #5	Internal alarm 5. The device must be shut down.	Internal serial line error	Locking alarm	All
Internal error #6	Internal alarm 6. The device must be shut down.	Incompatibility of sw/hw versions	Locking alarm	All

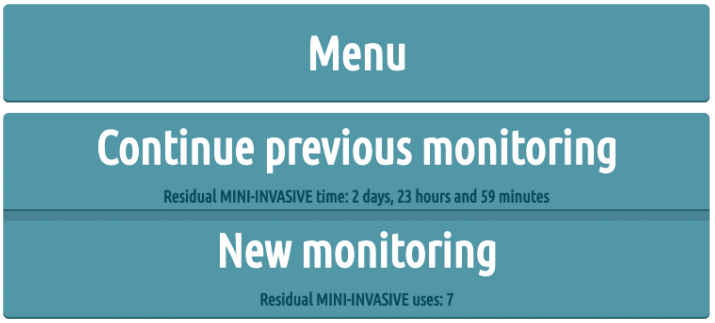
NOTE: If one of the above error messages appear on screen a few seconds after the device has been booted up, we suggest switching MostCare^{Up} off and on again. If the error appears again after a new switch-on, please contact technical assistance for further information on how to proceed.

8.1.3 Initial screen

1. Select 'New Monitoring' to start a new monitoring session:



2. Select “Continue previous monitoring” if the previous monitoring was not completed and wish to continue it. The displayed screen is the following:



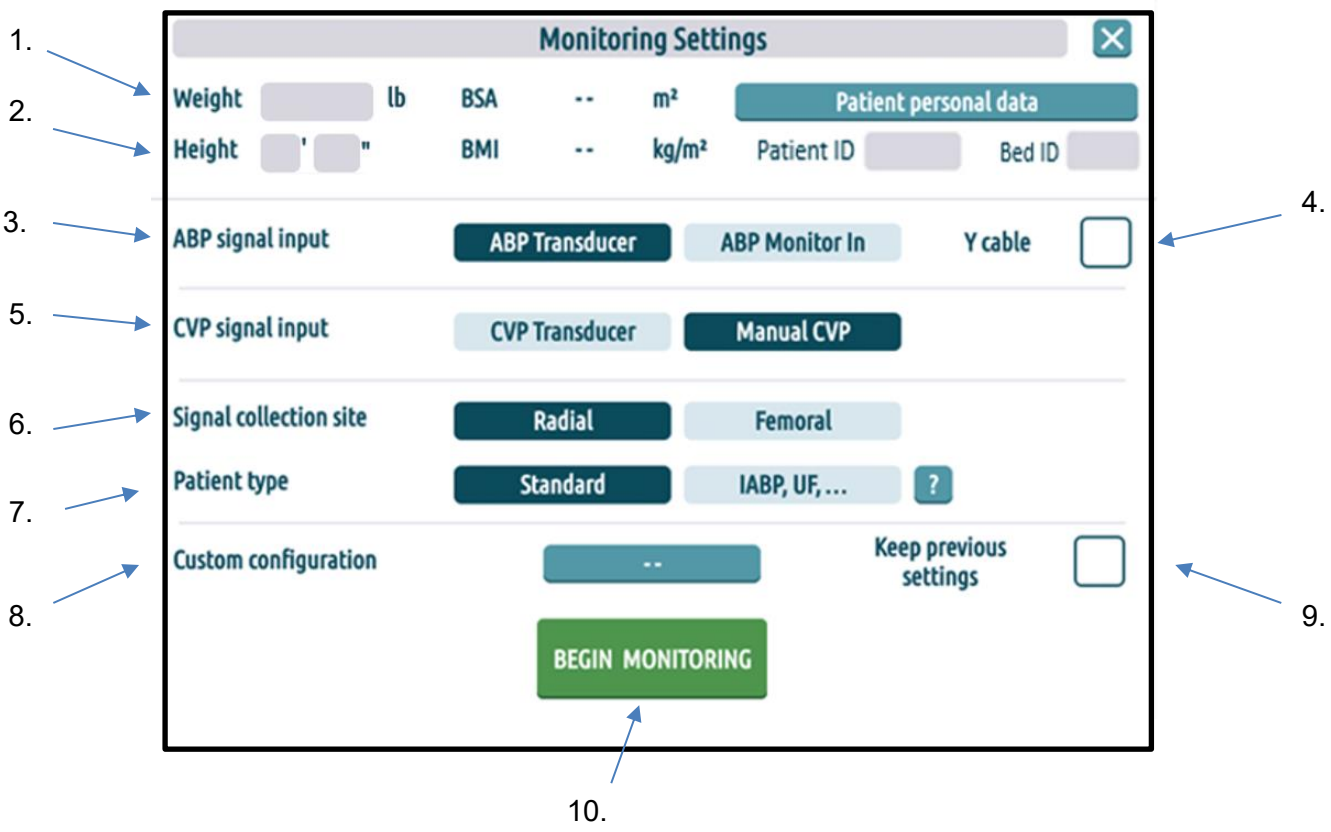
Confirmation is always asked for when using a new credit.
Below the buttons, as per the figure, residual time is shown, expressed in days/hours/minutes or uses, depending on the credit type.

If no residual credit is available, it will be necessary to upload new credit to start ADVANCED monitoring, otherwise MostCare^{Up} will display systemic variables only (see Section 7.2).

In the case of New Monitoring, the MONITORING SETTINGS page will be displayed.

8.1.4 Monitoring settings

The monitoring settings screen appears as follows:



The MONITORING SETTINGS screen allows the user to enter and select the following settings:

1. WEIGHT
Expressed in pounds (lb) or kilograms (kg) / grams (g). If the kg/g scale is set, the system automatically detects whether the value entered is to be regarded as kg or g based on the following criterion: • Input < 700, kg is used • Input ≥ 700, g is used • NB: To enter a weight below 700 g, use decimal notation (e.g. type 0.650 kg to indicate 650 g)

2. HEIGHT
Expressed in feet (‘) / inches (“) or metres (m) / centimetres (cm). If the m/cm scale is set, the system automatically detects whether the value entered is to be regarded as m or cm based on the following criterion: • Input < 10, m is used Input ≥ 10, cm is used

---

NOTE: Once monitoring has started, it will be possible to modify weight only, not height.

Anthropometric weight and height data will be used by MostCare^{Up} to calculate the Body Surface Area (BSA). This variable is used to convert the absolute hemodynamic values for Stroke Volume (SV), Cardiac Output (CO) and Systemic Vascular Resistances (SVR) into indexed values.

⚠ **WARNING:** If monitoring is carried out using incorrect weight and height measurements, this may result in the incorrect calculation of derived parameters and lead to an incorrect diagnosis.

- To begin monitoring, it is essential to enter the WEIGHT and HEIGHT information requested in the menu item.

- If the weight and height data entered is not correct, BSA and all the indexed variables processed by MostCare^{Up} may be wrong.
- It is not possible to insert a weight exceeding 699 kg. If a value greater than or equal to 700 is entered, it will automatically be converted to g.

---

3. ABP signal INPUT	
TRANSDUCER	MostCare^{Up} reads the ABP signal directly from the pressure transducer (right side ABP connector).
MONITOR IN	MostCare^{Up} reads the ABP signal from another patient monitor (right side IN 1 connector)

4. Y CABLE box
Select this box if a Y CABLE configuration is used. Do not select this box if a standard cable configuration is used.

⚠ **WARNING:** Incorrect use of the Y-cable may result in mechanical or electrical damage to the device or in unreliable readings, which could lead to an incorrect clinical decision, please note the following:

- If a Y CABLE configuration is used, it will be necessary to insert the cable into the ABP input in MostCare^{Up}, and also for the other ends of the cable to be correctly connected to the other elements (the transducer and the other device); it will also be necessary for the other device used to be switched on. Otherwise, once the “BEGIN MONITORING” button is pressed, an error notification will appear.
- This box must be selected if a Y CABLE for the ABP signal is used. If the user forgets to select this box and a Y CABLE in the ABP input is detected, an error notification will appear once the “BEGIN MONITORING” button is pressed.
- Do not select this box if a standard cable is being used. If the user selects this box and a standard cable is detected, an error notification will appear once the “BEGIN MONITORING” button is pressed.
- If the user has inserted a Y CABLE, has selected the appropriate box and once the “BEGIN MONITORING” button is pressed an error notification appears, this means that the Y CABLE in use is either damaged or faulty. It will then be necessary to change the cable.

---

5. CVP signal INPUT	
MANUAL INPUT	A constant value for CVP is chosen for the SVR/SVRI calculation. On the monitoring screen, in the SVR/SVRI button, the wording 'CVP=', followed by the selected value for constant CVP (expressed in mmHg) will then appear on the upper right side. If not modified, the default value for CVP is 9 mmHg. The mean Central Venous Pressure is used to calculate Systemic Vascular Resistances (both absolute and indexed).

TRANSDUCER	Allows actual monitoring of central venous pressure using a Central Venous Catheter (CVC). Requires a CVC connected to a pressure transducer by means of a Transducer Cable in the CVP input on the right side of MostCare^{Up}. The monitoring screenshot shows the temporal trend of the pressure curve and its related mean pressure value in mmHg in dark blue. The mean Central Venous Pressure is used to calculate Systemic Vascular Resistances (both absolute and indexed).

⚠ **WARNING**: If the CVP is incorrect, the resistances may not be calculated correctly, which could have a negative impact on the diagnosis.

- Peripheral vascular resistances (absolute and indexed) are actually calculated only when CVP is selected from TRANSDUCER. Only in this case does MostCare^{Up} directly measure the central venous pressure (CVP). The CVP mean value derived from the measured values is used by the software to calculate resistances (SVR/SVRI).
- If you select CVP from TRANSDUCER without connecting the transducer cable to the CVP pressure channel, MostCare^{Up} might provide incorrect SVR and SVRI data. If the detected CVP value is lower than 0 mmHg, the system will consider 9 mmHg as the constant CVP value.
- If an incorrect value of CONSTANT CVP is entered, the resistance calculation will be wrong. Observe and correct the CVP value set in MostCare^{Up} should the patient CVP change.

---

6. SIGNAL COLLECTION SITE	
RADIAL	By means of a catheter positioned inside the Radial Artery
FEMORAL	By means of a catheter positioned inside the Femoral Artery

---

NOTE: The signal collection site has no effect on the calculation of variables; it only affects the patient data saved in the .csv file, where a signal collection site will be recorded that does not correspond to the one actually used.

---

7. PATIENT TYPE	
STANDARD	This is the setting for patients without mechanical support
MECHANICAL SUPPORT	When the patient being monitored is supported by an Intra-Aortic Balloon Pump, another mechanical cardiac assistance system, or any other type of mechanical support.

⚠ **WARNING:** Select the “**PATIENT TYPE**” correctly, otherwise all hemodynamic values may be wrong and lead to an incorrect diagnosis.

---

8. ‘CUSTOM CONFIGURATION' button

Select this box if you want to start a monitoring that allows you to customize the monitoring screen by choosing which variables and trends to be visualized and which one to be hidden.

Do not select this box if you want to begin monitoring using default settings or those from a previous monitoring.

See Section 8.1.6 for further details.

NOTE: "**MAINTAIN PREVIOUS SETTINGS**" and "**CUSTOM MONITORING**" boxes are mutually exclusive and cannot be selected simultaneously.

NOTE: If none of the "**MAINTAIN PREVIOUS SETTINGS**" and "**CUSTOM MONITORING**" boxes is selected, the default monitoring screen will be displayed.

The following data is always maintained until a factory reset is executed:

- Custom marker
- Language
- Monitoring archive.

9. 'KEEP PREVIOUS SETTINGS' box

Select this box if you want to keep the settings of the previous monitoring.

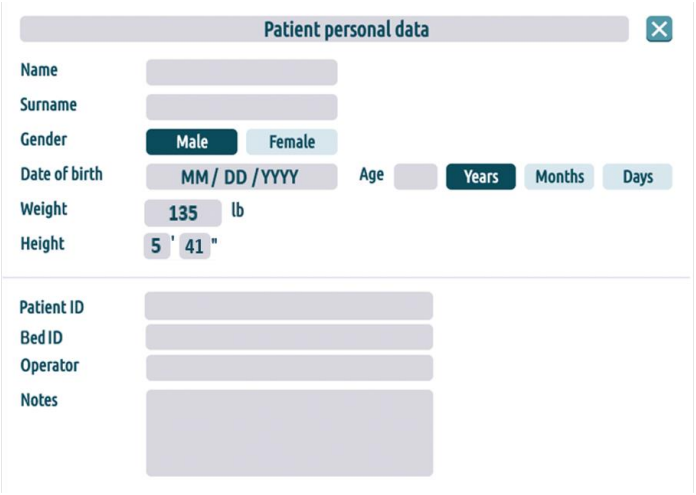
Do not select this box if you want to begin monitoring using default or new customized settings.

If the box is selected, the settings that will be kept as per the previous monitoring are listed in the table that follows. Default values are also listed.
All other settings that are not featured on the table are set to default for every new monitoring.

Variable	Default
ABP SIGNAL INPUT	ABP Transducer
TREND VARIABLES	1) Pressures group 2) CO + PR 3) Ea + dP/dt_{max} 4) PPV + SVV
TREND LAY-OUT	2 graphs (A+B)
DO&CHECK VARIABLES	**Mini-invasive**: PR, CO / PPV These variables can change according to Custom monitoring configuration choice (see Section 8.1.6).
4 CUSTOMISABLE VARIABLES	**Mini-invasive**: PPV, Ea / ---, --- These variables can change according to Custom monitoring configuration choice (see Section 8.1.6).
BRIGHTNESS	Maximum if powered via mains, minimum if via battery
PULSE VOLUME	Inactive

10. 'BEGIN MONITORING' button
By confirming and pressing the "**BEGIN MONITORING**" button, based on the settings chosen above, the following screen will appear: **"KEEP PREVIOUS SETTINGS"** box checked: Monitoring screen (Section 8.1.5), configured with the settings of the last monitoring. **"CUSTOM MONITORING"** selected: Monitoring screen (Section 8.1.5), configured with the settings of the selected custom monitoring configuration. Both options unselected: Monitoring screen (Section 8.1.5), configured with default settings.

8.1.4.1 Patient personal data



Through the "**PATIENT PERSONAL DATA**" button it is possible to enter the following information regarding both patient and monitoring:

- First name
- Surname
- Gender
- Date of birth/age (they are mutually exclusive)
- Weight
- Height
- Patient ID
- Bed ID
- Operator
- Notes

NOTE: Patient data are protected against unauthorized access. In order to view or edit patient data, user authentication is required.

All fields can be filled manually. Patient ID can also be filled by means of a barcode reader, by automatically reading the barcode from a patient identification wristband.

NOTE: None of these fields are mandatory for general purposes but could be required to activate special features. **Patient ID is a mandatory field for sending HL7 messages to the medical records** (see Section 10.12.1). Before activating HL7 communication, it is required to fill the Patient ID field.

If the user enters a date of birth, the age in years is then displayed and is not editable.
If the user enters an age, the date of birth field remains empty and is not editable.
If the user deletes age, it is once again possible to enter the date of birth (and vice versa).

If information about weight and height has already been entered in the MONITORING SETTINGS screenshot, these fields appear here as already filled-in and are editable.

To confirm the information entered, close the PATIENT PERSONAL DATA menu; each detail is accepted as soon as it is entered into the text box.

8.1.5 Monitoring screen

During monitoring, the values of all variables displayed in the monitoring screen are averaged out on 'n' heartbeats, according to user's choice (see Section 9.3.4).

The screen of mini-invasive monitoring appears as follow:

Monitoring screen includes three zones:

Curves zone

This zone includes:

- Curves
  - ABP and CVP
- Variables punctual values
  - Systolic, diastolic and mean arterial blood pressure
  - Dicrotic notch (Dic)
  - Pulse rate (PR)

- CVP

The scrolling time for the ABP and CVP curves is set by default at 6-second time windows. The time windows can be modified by the user (see Section 9.3.7).

An automatic rescaling is carried out upon every first signal acquisition. The user will however be able to rescale the signal at will (see Section 9.3.2).

Should dicrotic pressure not be properly identified, the user will be able to make adjustments via the 'dicrotic adjustment' function in the side menu (see Section 9.3.6).

Variables zone

This zone displays the chief hemodynamic variables deriving from pressure values:

- The following variables are fixed: CO, SV, SVR, and dP/dt_{max}
- The first three can be exchanged with the related indexed values depending on user choice
- The 4 variables at the bottom are configurable

The CVP value can be set from the Variables menu (see Section 9.5).
Dynamic variables (PPV% SVV%, SPV%, DPV%) are calculated over a temporal range of 15 seconds. This value can be set by the user (see Section 9.5.5).
The values of all the other variables are calculated as a mean value over a settable number of heartbeats (default setting: 10 beats). This value can be set by the user (see Section 9.3.4).

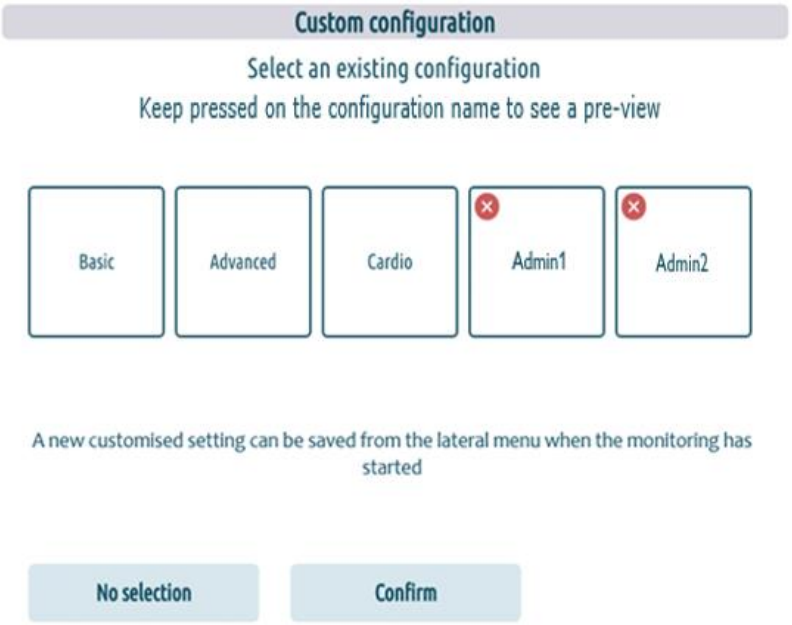
⚠ **WARNING:** If the signal is resonant, it may cause incorrect calculations of derived variables, which could lead to an inappropriate clinical decision

- The dP/dt_{max} value will be displayed in red when above 1.7, to indicate the risk of inadequate arterial signal.
- When dP/dt_{max} > 1.7 there might be an inaccurate detection of the arterial pressure signal (underdamping). In the event of bad detection quality of the arterial pressure signal, the data processed by MostCare^{Up} could be wrong.

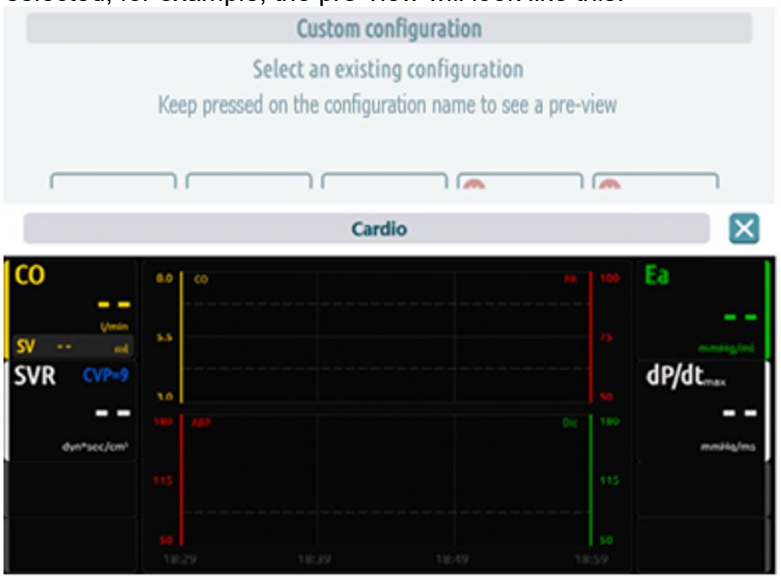
Trend zone

This zone displays the temporal trend of 4 or more variables, according to user choice. When starting monitoring, the time fraction displayed is always 30 minutes, and can be configured via the Trend menu.
The number of trends and their configuration can be customized via the Trend menu (see Section 9.4).
Markers entered by the user are displayed in blue on the graphs.

8.1.6 Custom monitoring configuration selection screen



If the cardio setting is selected, for example, the pre-view will look like this:



The custom monitoring configuration selection screen allows user to create a new custom monitoring configuration (if an empty slot is available) or to select or delete an existing one. MostCare^{Up} allows to create up to 10 custom monitoring configurations.

Monitoring configuration customization consists in selecting which variables and trends to be displayed in the variables and trends zones of the monitoring screen and which ones to be hidden.

After completing the customization of the screen according to your preferences, you can save your custom configuration by pressing the "**SAVE CONFIGURATION**" button from the lateral pop-up menu (see Section 9.1.8).

NOTE: When saving a new configuration or editing or deleting an existing one, user authentication is required.

NOTE: A user can access all the available custom configurations but only the user who created the custom configuration can edit it. System admin can delete a custom configuration but cannot edit it unless it was the one who created it.

NOTE: When saving a new configuration, you will be also asked assign a name to the new configuration. It is recommended to assign a name that will allow you to easily remember its custom settings.

8.1.7 Stand-by/Switch-off

To set MostCare^{Up} in stand-by mode, either of these methods can be followed:

1. **Stand-by in mains mode**
   - Make sure that the power cable is inserted in the system and the battery is charging (the I/O button is in the I position)
   - Open the lateral pop-up menu from the three-line button located on the upper left side of the screen (see Section 9.1)
   - Press the red "**STAND-BY**" button at the bottom
   - When asked for confirmation, accept
   - MostCare^{Up} is now in stand-by mode
2. **Stand-by in battery mode**
   - Make sure that the battery is powered by the electrical mains (the rear button is in the ON position)
   - Briefly press the ON/OFF button on the lateral side panel in MostCare^{Up}
   - When asked for confirmation, accept
   - MostCare^{Up} is now in stand-by mode

To switch MostCare^{Up} off, follow one of these three methods:

1. **Switch off in battery mode**
   - Switch the mains power off (rear button in the OFF position)
   - Open the lateral pop-up menu from the three-line button located on the upper left side of the screen (see Section 9.1)
   - Press the red OFF button at the bottom
   - When asked for confirmation, accept
   - MostCare^{Up} is now switched off.

2. **Switch off in mains mode**
   - Follow method no. 1 for setting in Stand-by mode
   - Switch the mains power off (rear button in the OFF position)
   - MostCare^{Up} is now switched off

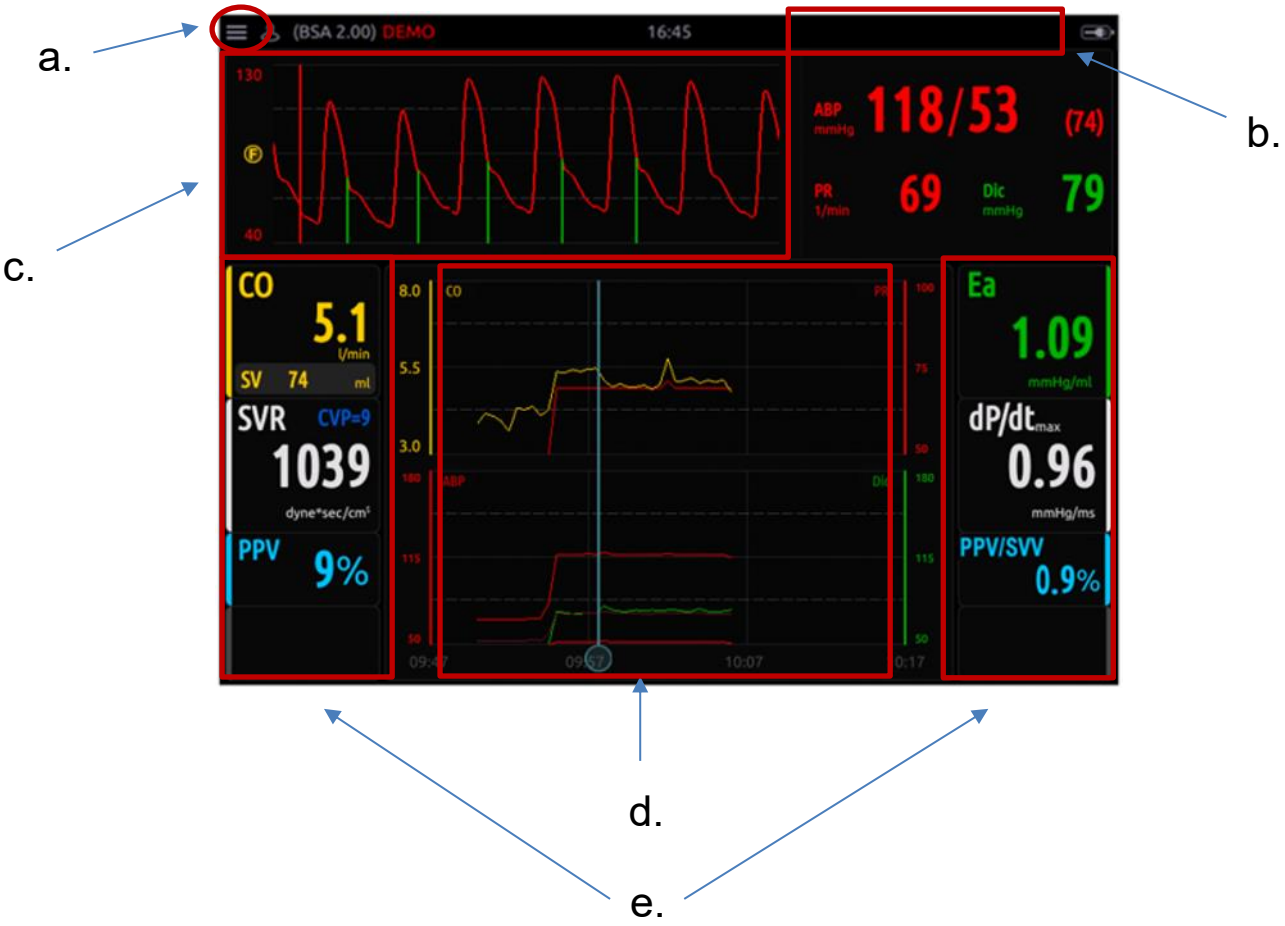
3. **Switch off in battery/mains mode**
   - Press MostCare^{Up} side button for at least 5 seconds
   - Verify that the device is starting the switch-off procedure
   - MostCare^{Up} is now switched off

8.2 LED Button and battery status

MostCare^{Up} battery has 3 operational modes.
To understand in which state the battery is, it is necessary to observe the LED on the ON/OFF left lateral side button:

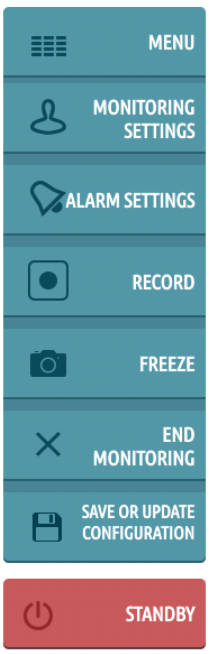
LED status		Battery status
	LED is OFF	battery not charging
	LED is continuously flashing at 1 Hz	battery charging
	LED is steady ON	battery fully charged

9. QUICK MENUS

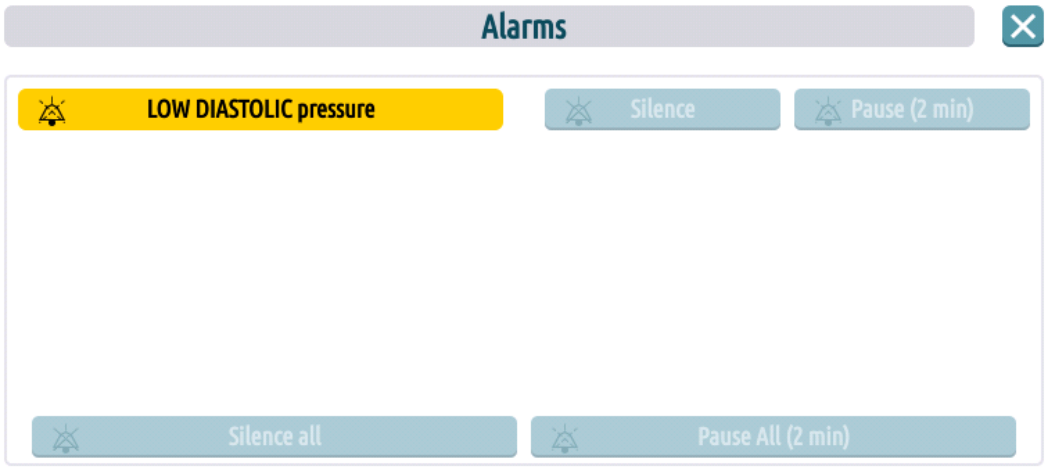


These menus allow easy, quick access to settings and functionalities.

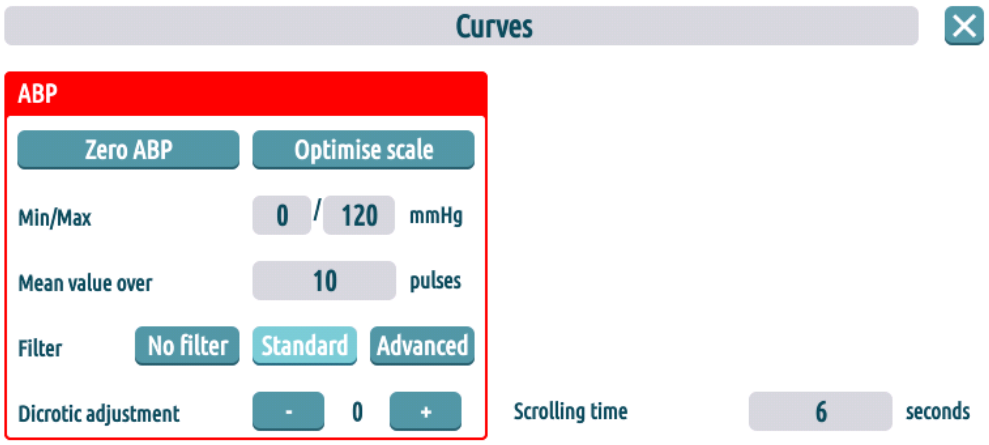
a. **Lateral pop-up menu**, which can be activated by clicking on the ☰ icon located on the upper left side on the fixed horizontal bar (see Section 9.1). If the menu is selected, the following window opens:



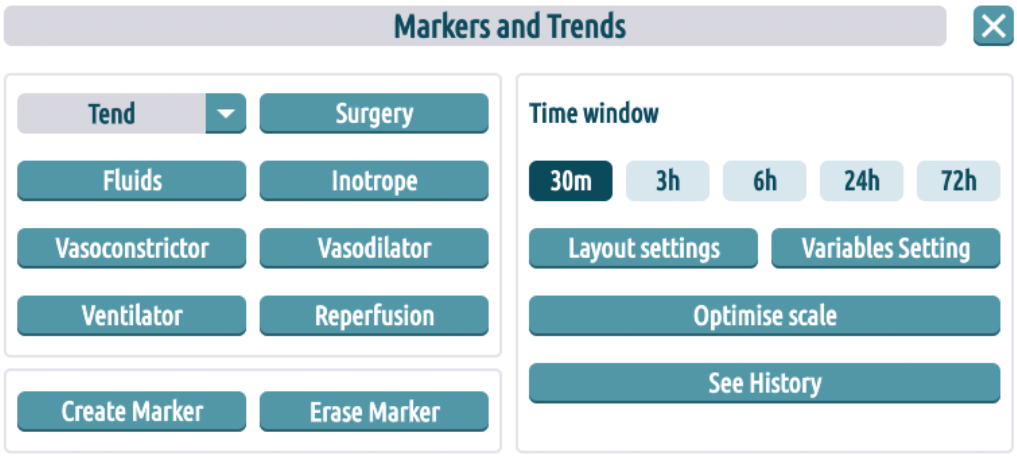
b. **Active alarms menu**, which can be activated by clicking on an alarm related string (displayed in the upper horizontal bar when an alarm condition is ongoing) (see Section 9.2). If the menu is selected, the following window opens:



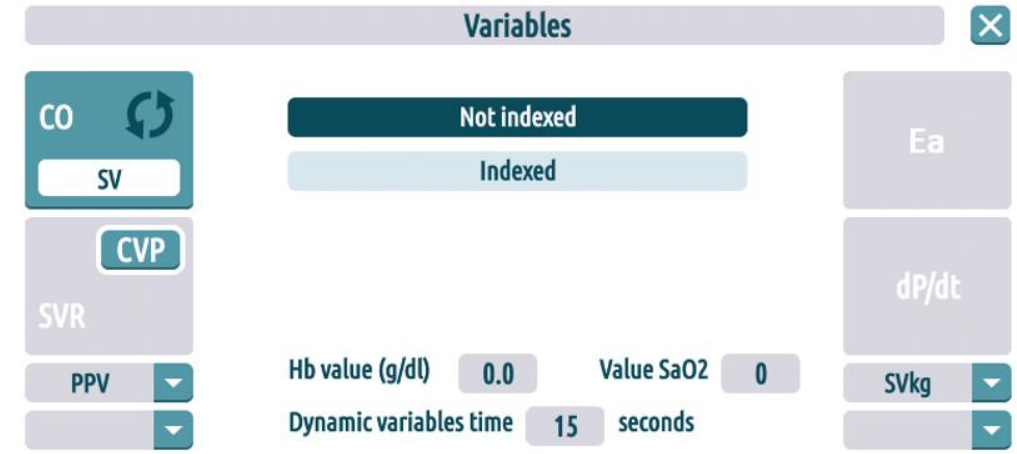
c. **Curves**, which can be activated by clicking on the display area featuring the pressure curves (see Section 9.3). If the menu is selected, the following window opens:



d. **Markers and trends**, which can be activated by clicking on the central display area featuring the trends (see Section 9.4). If the menu is selected, the following window opens:

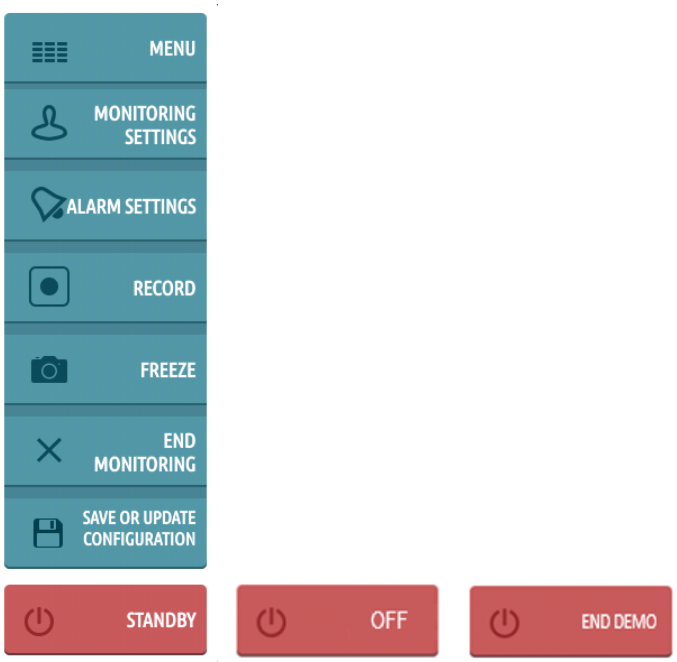


e. **Variables**, which can be activated by clicking on the two side columns of the display, featuring the parameters (see Section 9.5). If the menu is selected, the following window opens:



9.1 Lateral pop-up menu

The vertical bar is not always visible. It appears when you click on the three-line button located on the upper left side of the horizontal bar (see Section 1.2 for the three-line symbol).



If the device is in mains-powered mode, the word "**STANDBY**" will appear on the red button in the lateral pop-up menu

If the device is in battery mode, the word "**OFF**" will appear on the red button in the lateral pop-up menu

If the device is running a demo, the words "**END DEMO**" will appear on the red button in the lateral pop-up menu

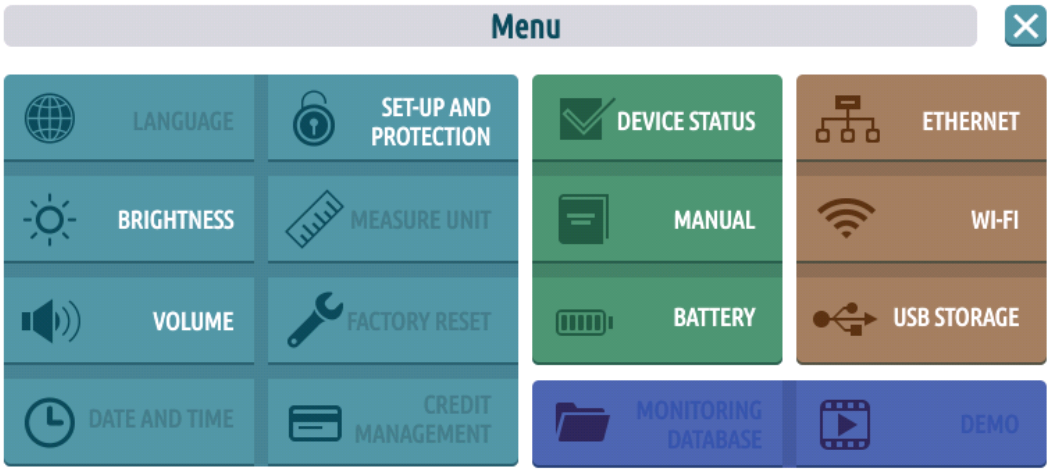
All the functions of the lateral pop-up menu are specified in the following sections:

- "MENU" Section 9.1.1
- "MONITORING SETTINGS" Section 9.1.2
- "ALARM SETTINGS" Section 9.1.3
- "RECORD" Section 9.1.4

- “FREEZE” Section 9.1.5
- “END MONITORING” Section 9.1.6
- “SAVE OR UPDATE CONFIGURATION” Section 9.1.8
- “STANDBY”/”OFF”/”END DEMO” Section 9.1.7

9.1.1 Menu

The “**Menu**” function refers back to the Main menu (see Section 10) and displays as follow:

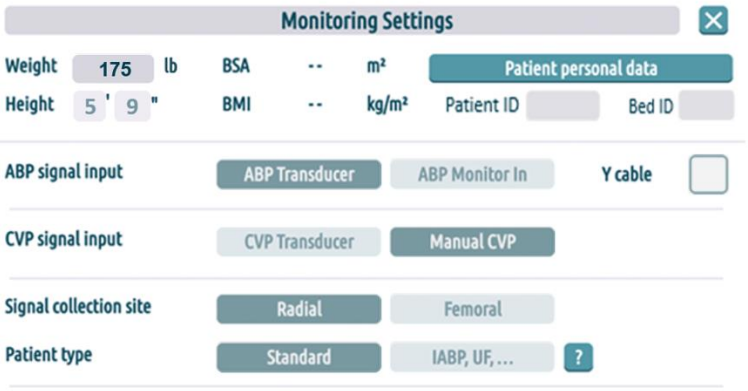


NOTE: All the buttons of functions not available during monitoring session are disabled.

9.1.2 Monitoring Settings

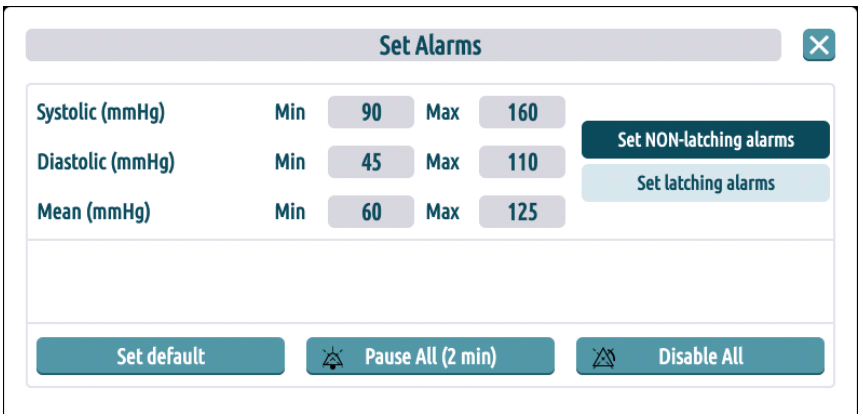
The “Monitoring Settings” function refers to the initial patient settings screen (see Section 8.1.4). This page can also be recalled while monitoring, and data on the patient being monitored can be changed from here (see Section 9.1.2).

NOTE: During monitoring, only the weight can be changed; the height will appear as uneditable.



9.1.3 Alarms settings

The “Alarms settings” function allows the user to enable or disable the alarms, and to manage their activation thresholds.



For every new monitoring, alarm values are set to default (see Section 9.2.2).
This set of default values ranges is used in case of unattended monitoring, as it is pre-configured by the manufacturer.

The following actions are possible:

Edit alarm limits: The user can set the maximum and minimum limits by entering the desired values in the corresponding boxes, which are editable.

‘**DISABLE ALL**’ button: Recalls the “Alarm paused” function for all physiological alarms. This function allows the user to disable audible and visual alarms throughout the monitoring period. The user can re-enable the function at any time, thus re-enabling all alarms.

‘**PAUSE ALL FOR 2 MINUTES**’ button: Recalls the “audio paused” function for all physiological alarms and for the technical alarms ‘DISCONNECTED CATHETER’, “Y CABLE UNSTABLE”

“**Y CABLE OUT OF RANGE**”. This function allows the user to disable the visual alarm for 2 minutes; a countdown is displayed from the time when it is activated. The user can disable this function at any time.
The alarm ‘DISCONNECTED CATHETER’ can be silenced for 2 minutes, so that the operator can make blood samples and so on.

‘SET LATCHING/NON-LATCHING ALARMS’: Set the physiological alarms as latching or non-latching:

1) A **latching alarm** continues to be generated after its triggering event no longer exists until stopped by a deliberate operator action.
2) A **non-latching alarm** automatically stops being generated when its associated triggering event no longer exists.

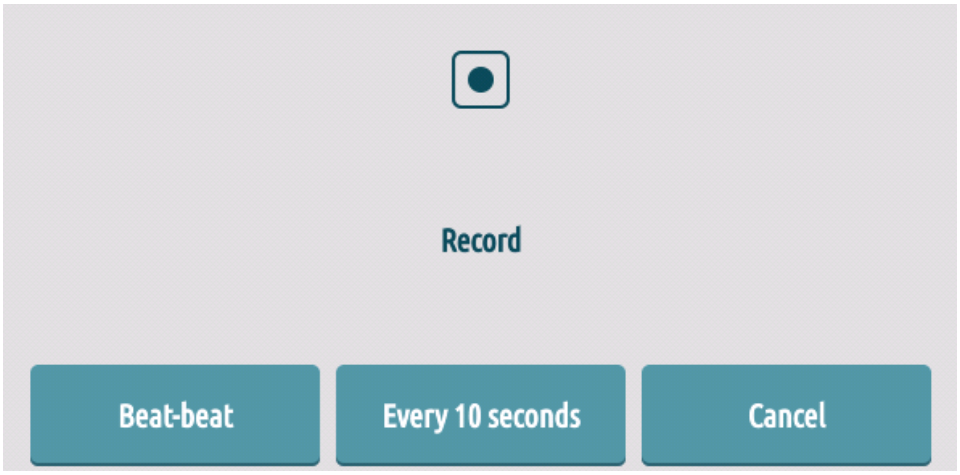
NOTE: All the technical alarms are managed as non-latching alarms and cannot be switched to latching mode.

Only system admin can set physiological alarms as latching or non-latching.

NOTE: If patient is not continuously attended by a clinical operator, all alarms should be enabled with audio ON and set as latching.

9.1.4 Record

The “**RECORD**” function allows the user to save monitoring data, with features that are different from standard recording (which MostCare^{Up} executes automatically for every monitoring).
By pressing the “**RECORD**” button, the following screen appears:



The following types of recording are available:

“**Beat-beat**” button: A sample is recorded with every heartbeat

“**Every 10 Seconds**” button: A sample is recorded every 10 seconds

To start recording, select the type of recording required. The recording activity is displayed on screen by a flashing indicator on the upper right side: REC ●.

To cease recording, open the lateral menu again and press “**STOP**” (this button is displayed when recording, in place of the “**RECORD**” button).

Both types of recording have a time limit:

- For “**Beat-Beat**” recording, if the user does not cease recording within 3 hours, the system issues a warning and stops.
- For “**Every 10 Seconds**” recording, if the user does not cease recording within 24 hours, the system issues a warning and stops.

⚠**CAUTION:** If there are issues with the internal memory and the user is unaware of them, this could lead to data loss. Please note the following:

1. You can not start the two consecutive records within the same minute. In this case, the first recording will be lost.
2. If the MEM.ERR warning is on, records will not be saved in the internal memory. A USB flash drive is needed, on which to save the recordings.

Once finished, the recording is stored into MostCare^{Up} internal memory, in the current monitoring folder, with the following format: *MostCareUp-date-time.csv*.

If the user wishes to save the recording also on a USB flash drive, the latter must be inserted into the appropriate slot before the end of the recording, so that storage can be executed automatically at the end of the recording.
If for any reason storage on the USB flash drive fails (no USB flash drive, insufficient USB memory), the following message is displayed on screen: 'USB STORAGE FAILED', with a choice between “**Retry**” and “**Cancel**”.

To access the internal memory monitoring archive on MostCare^{Up}, go to the Main menu and open the "**MONITORING DATABASE**" submenu.

9.1.5 Freeze

This function makes a screen snapshot, which is saved in the monitoring folder at the end of the monitoring and may be reviewed by PC once saved the monitoring on USB flash drive.
The function is only active during monitoring (not in demo mode). The snapshot is made when the "**FREEZE**" button is pressed. The side menu closes automatically so you can make a screenshot of the screen.
The file is saved in the monitoring folder and is named *Date_time.jpg*.
If you want to save the freeze in real time, just plug the USB flash drive and press the "**FREEZE**" button: in that case, the image will be saved on USB flash drive not in folders (the same as beat-beat recording and every 10 seconds recording).
The maximum number of freezes for monitoring is 20.

NOTE: To perform this action, it is necessary to log in using username and password.

⚠ **CAUTION:** If the operator does not save the screenshot, or if windows remain open while taking it, blocking the view of information, this will result in data loss.

- The function automatically closes only the lateral pop-up menu, but not any other windows that can be opened at the time of shooting. In that case the freeze includes also the possible screens.
- If the MEM.ERR warning is on, freezes will not be saved in the internal memory. A USB flash drive is needed, on which to save the freezes.

9.1.6 End of monitoring

This function stops active monitoring following the user's confirmation and zeroes the active monitoring residual time counter (if the device is functioning on a use-based and not time-based basis). The user should utilize this function every time monitoring needs be interrupted.

Should the user fail to utilize this function before switching off the device, when switching on again, the device will ask whether to continue with the ongoing monitoring (if there are still some minutes left) or to start a new monitoring.

⚠ **CAUTION:** If the MEM.ERR warning is on, monitorings will not be saved in the internal memory causing a loss of data. A USB flash drive is needed, on which to save the monitorings.

9.1.7 Standby / off / end demo

This function is needed to switch the software off (when functioning with battery), for software stand-by (when operating under electrical mains power) or to end a demo if you're running one. Switching off the device or putting it in stand-by mode automatically saves all data.

Before switching off the device or putting it in stand-by mode, user confirmation is required.
See images at Section 9.1.

Alternatively, it is possible to switch off/set in stand-by mode the system by pressing the ON/OFF left lateral side button and releasing it after a few seconds. In this instance too, user confirmation is required via a specific menu.

In case of a functional system block, it is possible to force a shut-down by keeping the button pressed for 20 seconds.

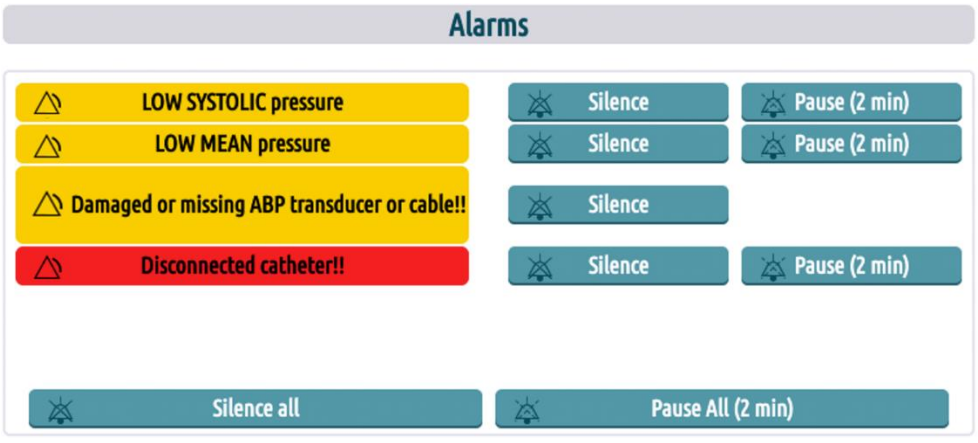
9.1.8 Save configuration

This function allows to save the actual configuration. The settings that are going to be saved inside each custom configuration are reported in the table below:

Menu item	Parameter
CURVES SETTINGS	TIME SCROLLING CURVES
	NUMBER OF BEATS ON WHICH TO AVERAGE
	CALIBRATION INTERVAL (NIV)
SETTING MARKER and TREND	TREND VARIABLES
	CHOOSE LAYOUT
	ENABLE OPTIMIZE SCALE
	TIME WINDOW
	TREND HISTORY: TEMP. WINDOW
	DO&CHECK: VARIABLES
	DO&CHECK: WINDOW TEMP.
VARIABLE SETTING	INDICATION
	VALUE CVP
	4 CUSTOMIZABLE LOWER VARIABLES
	TIME OF DYNAMIC VARIABLES
	CO → SV
MENU	VOLUME ON/OFF
	MAP CALCULATION

9.2 Alarms menu

When the physiological variable value falls outside the pre-defined range (see Section 9.2.2) or a technical alarm condition exists (see Section 9.2.3), a visual and audible alarm is triggered and the ‘’ALARMS’ is automatically displayed. An alarm related string (see Section 9.2.4) is also displayed in the upper horizontal bar. User can manually open ‘ALARMS’ by pressing on the alarm related string.



The activities connected with an ongoing alarm are the following:

"**Silence/Silence All**" button: This function allows the user to disable the sound of an active alarm. The sound disabling will not persist if the same alarm condition will be triggered again at a later time. The related visual string is permanently displayed (on the upper bar, see Section 9.2.4) as long as the alarm condition is ongoing.

"**Pause/Pause All**" button: This function allows the user to disable the sound of an active alarm for a set length of time (2 minutes). The sound disabling will persist for 2 minutes. For 2 minutes, no sound will be produced even if the alarm condition will be triggered again within. The related visual string is permanently displayed (on the upper bar, see Section 9.2.4) as long as the alarm condition is ongoing.

"**Reset/Reset All**" button: This function allows the user to reset an active alarm whose triggering is no longer occurring (Latching alarm).

"**Electrosurgery**" (Visible only when "**Y CABLE UNSTABLE**" alarm is present): Press this button if you are using an electric scalpel along with MostCare^{Up}. The 'ALARM PAUSE' symbol will be shown to indicate that the unstable voltage alarm is deactivated until the end of monitoring.

Alarms priority and visual/auditory features:
Depending on the different priorities, the alarms have the following characteristics:

Alarm priority	Audio Signal	Color on screen
LOW PRIORITY	1 single pulse repeated over time at regular intervals (10 s)	**Cyan** Constant
MEDIUM PRIORITY	Medium priority audio signal: audible alarm consisting of 3 impulses repeated over time at regular intervals	**Yellow** Slow flashing
HIGH PRIORITY	High priority audio signal: 3 impulses followed by 2 additional impulses after a slightly longer time interval.	**Red** Fast flashing

The alarm condition is indicated by the symbol accompanied by an explanation of the alarm.
The volume emitted by the auditory alarm signal is about 55 dB.

NOTE: Alarm volume is not adjustable.

⚠ **WARNING:** If the operator is unaware that an alarm is active, this may lead to the user not being alerted to a patient's health condition that requires attention, resulting in an incorrect clinical decision.
Please note:

- By selecting *"Disable All"*, both acoustic and optical alarms are disabled for the duration of the monitoring, and the symbol appears on the upper horizontal bar. User can re-enable alarms at any time.
- By selecting *"Pause"* or *"Pause All"*, alarm sound is disabled for two minutes, and the symbol appears on the upper horizontal bar. User can re-enable alarm sound at any time.
- By selecting *"Silence"* or *"Silence All"*, alarm sound is disabled for the remaining duration of the alarm condition, and the symbol appears on the upper horizontal bar.

1. MostCare^{Up} automatically detects pulse presence. During zeroing and when the transducer is connected to the patient, the alarms are disabled until the first pulse is detected.
2. Do not disable acoustic alarms if this could compromise patient safety.

A potential danger may arise in case that different alarm presets are used for the same device, or similar devices placed in the same area (e.g. in an intensive care unit or in a cardiac surgery room). Setting alarm limits to extreme values can render the alarm system useless.

9.2.1 Verification of the correct functionality of the alarm system

To verify that the alarm system is working properly:

- Start a standard demo from MENU > DEMO
- From lateral pop-up menu, enter 'ALARMS SETTINGS'
- Change the value of a limit so that the parameter (e.g. systolic pressure) is beyond the limits
- Check that the alarm is properly triggered
- Check that the alarms menu is correctly displayed
- Check that the alarm sound is heard
- Check that the alarm symbol is correctly displayed.

This operation shall be performed periodically by the clinical engineering (see Section 12 for periodicity).

9.2.2 Physiological alarms

Physiological alarms are connected to the following variables:

- High/low diastolic pressure
- High/low systolic pressure
- High/low mean arterial pressure

NOTE: MostCare^{Up} doesn't feature pulse rate related physiological alarms.

The default alarm values are the following:

Values	Minimum	Maximum	Unit of measure
Diastolic	45	110	mmHg
Systolic	90	160	mmHg
Mean	60	125	mmHg

Physiological alarms have medium priority.

Alarm delay:
All the alarm conditions are detected within a maximum time of 20 s. The alarm delay is directly proportional to the number of heartbeats on which the pressure/saturation average is done: the average can be set from 1 to 30 heartbeats, with default 10 heartbeats, and a change in value and therefore the alarm can occur for example after 10 beats.

9.2.3 Technical alarms

MostCare^{Up} alarm system includes the following technical alarms:

- Damaged/absent transducer/cable
- ABP Disconnected Catheter
- Memory error
- Battery error
- Low Battery
- Unstable Y cable voltage

- Out of range Y cable voltage

Alarm delay:
All the alarm conditions are detected within a maximum time of 10 s.

NOTE: The technical alarms are managed only during patient monitoring and are not enabled during configuration operations (from menu).

9.2.4 Alarm strings and description

The table below summarizes the alarm strings for each physiological and technical alarm condition:

String	Meaning	Description	Priority
Physiological alarms			
HIGH.DIA	High diastolic pressure	This alarm is triggered if diastolic pressure is higher that the set range limit.	**Medium**
LOW.DIA	Low diastolic pressure	This alarm is triggered if diastolic pressure is lower that the set range limit.	**Medium**
HIGH.SYS	High systolic pressure	This alarm is triggered if systolic pressure is higher that the set range limit.	**Medium**
LOW.SYS	Low systolic pressure	This alarm is triggered if systolic pressure is lower that the set range limit.	**Medium**
HIGH.MAP	High mean pressure	This alarm is triggered if mean pressure is higher that the set range limit.	**Medium**
LOW.MAP	Low mean pressure	This alarm is triggered if mean pressure is lower that the set range limit.	**Medium**
Technical alarms			
FALLING.ABP	Sudden drop in ABP pressure	Alarm is triggered in case of sudden voltage drops, from any stable pressure value to less than 10 mmHg.	**High**
ABP.ERR	Transducer error/ ABP cable damaged or absent	Alarm is triggered if the ABP pressure transducer or the related cable results damaged or absent	**Medium**
CVP.ERR	Transducer error/ CVP cable damaged or absent	Alarm is triggered if the CVP pressure transducer or the related cable results damaged or absent	**Medium**
MEM.ERR	Internal memory error	Alarm is triggered is the internal memory is corrupted or not reachable.	**Medium**
BATT.ERR	Internal battery error	Alarm is triggered if internal battery has voltage issues or is detached.	**Low**
INSUFF.BATT	Insufficient battery charge (last few minutes of autonomy remaining)	Alarm is triggered if battery charge is insufficient to safely continue monitoring and correct data storage is not guaranteed. The icon will be displayed on the upper bar of the screen. If the user does not connect the device to the mains following this alarm, the system will switch off, after issuing a warning, once the battery is fully exhausted.	**Medium**
Y.UNST	Unstable Y cable voltage	If Y cable is connected, the voltage reference is not internal but is detected from another device. This alarm signals an external voltage reference anomaly. The alarm is triggered when voltage oscillates by more than ±0.5 V within a 3 seconds interval. The maximum and minimum voltage values recorded in the last 3 seconds are shown in the alarm popup.	**Medium**

		Note: If MostCare^{Up} is used in combination with electrosurgical units, user can silence this alarm for all the duration of the monitoring using the "**ELECTROSURGERY**" button in the alarm popup.	
Y.RANGE	Y cable voltage out of range	If Y cable is connected, the voltage reference is not internal but is detected from another device. This alarm signals an external voltage reference anomaly. The alarm is triggered when voltage is above 7 V or below 2 V	**Medium**

9.2.5 Validity of measured values during alarm condition

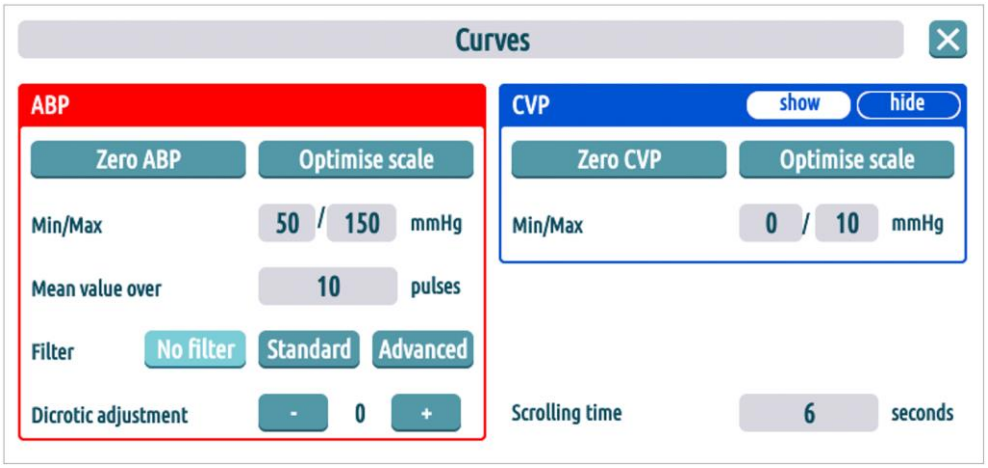
During a technical alarm condition, the displayed physiological variables and measured values could be affected. In this case, one of the following measures are taken, to permit the operator to assess the validity of the displayed value:

- The values are blanked by "---" and not visible
- The values are still shown, but in the alarm popup the indication "Values not reliable" is readable along with the alarm indication (for example in case of alarm Y.UNST and Y.RANGE).

9.3 Curves

The **Curves** menu features the following functions related to the ABP and CVP (if present).
To opern the curve menu see instructions at sections 8.1.5, 9.

The screen appears as follow:



Each function is explained in the following sections:

- "**Zero ABP**" and "**Zero CVP**" see Section 9.3.1
- "**Optimise scale**" see Section 9.3.2
- "**Min/Max**" see Section 9.3.3
- "**Mean value over**" see Section 9.3.4
- "**Filter**" see Section 9.3.5
- "**Dicrotic adjustment**" see Section 9.3.6
- "**Scrolling time**" see Section 9.3.7

9.3.1 Zero ABP and Zero CVP

The 'ZERO ABP' and 'ZERO CVP' functions allow the setting to zero of the respective detection channels for ABP and CVP pressure signals if in use. MostCare^{Up} requires zero pressure at the start of every new monitoring.

NOTE: When a patient is connected without zeroing, only pressure values will appear, together with a warning to execute zeroing.

If an ABP input from Monitor In is featured, zeroing at the start of the monitoring is not compulsory, though it will however be possible to execute it.

If MostCare^{Up} detects a sensor connected to a patient, it will not be possible to set values to zero. The user will be warned via a video message when trying to recall this function.

ZERO pressure	
ABP	Open the ABP transducer circuit putting it on 'air'. Zero by means of the specific "**ZERO PRESSURE**" button on the Curves menu. It is essential to zero this channel when it is used.
CVP	Open the transducer circuit putting it on 'air'. Zero by means of the specific "**ZERO PRESSURE"** button on the Curves menu. It is essential to zero this channel when it is being used.

⚠ **WARNING:** If the zero of the transducer is not performed, this may result in an inability to perform the monitoring. If zero calibration is performed incorrectly, this may lead to unreliable variable readings and, consequently, to an incorrect clinical decision. MostCare^{Up} will issue a warning and not zero the transducer (both ABP and CVP) if the offset relative to the 'theoretical' zero value (calculated with no voltage, i.e. the zero value for which the device has been calibrated) is higher than an absolute value of 50mmHg (lower than -50 or higher than +50).

9.3.2 Optimise scale

"**Optimise scale**" button allows the user to optimize the scale of the ABP, CVP and CNBP pressure curves. The optimize scale function allows automatically adapting the maximum and minimum limits of a curve according to the signal level.

9.3.3 Min/Max

Besides the automatic Optimise Scale function, MostCare^{Up} allows manually changing the maximum and minimum limits of the ABP, CVP and NIBP pressure curves.

The minimum settable value is 0 mmHg. The maximum settable value is 300 mmHg. The user will not be allowed to select values outside this range.

The default ranges are shown in the tables below.

Site	Minimum	Maximum	Unit of measure
ABP/CNBP	40	160	mmHg
CVP	5	25	mmHg

9.3.4 Mean value over

Mean value over allows the user to choose and manually enter the number of heartbeats used to average the values displayed.

MostCare^{Up} can in fact display beat-beat values or values averaged on a chosen number of heartbeats (up to a maximum of 30). MostCare^{Up} displays default values that are the average of 10 beats: this setting is automatically set for every new monitoring.

NOTE: This choice only relates to viewing values on the display, and has no effect on storing trends, which is controlled by other settings.

NOTE: If a number of heartbeats greater than 10 is set, it is possible that the physiological alarms will not be triggered within the times set by EN 60601-1-8.

9.3.5 Filter

This section allows the user to set the dynamic optimization of arterial pressure signal quality, when the latter is affected by resonance artefacts due to the arterial pressure transducer line (or to incorrect underdamping). MostCare^{Up} is set up for the monitoring of standard pressure signals and is usually capable of carrying out quality measurements and calculations. In some situations, patient characteristics or treatment type may require different adjustments of the filter with which MostCare^{Up} detects the pressure signal.

It is possible to select three filtering options:

- STANDARD
- ADVANCED
- NO FILTER

FILTER TYPE	
STANDARD	Default setting: a moderate filtering of the pressure signal is applied in the event of the system recognizing a case of underdamping.
ADVANCED	Utilize this setting when the pressure signal is disturbed by agents which cannot be attenuated operating on the external lines, and when the standard mode is not adequate. MostCare^{Up} re-elaborates the pressure signal, applying a more restrictive signal than in the standard case, so as to isolate and minimize the impact of the disturbing element on the pressure curve and all the variables derived from it. This selection is recommended when the patient being monitored is supported by external mechanical support devices, such as hemofiltration equipment or artificial ventricles.
NO FILTER	No filter is applied to the signal.

When a filter is active, the corresponding F symbol, to make it visible to the user, appears on the curve

	CROSSED-OUT WHITE when NO FILTER is selected
	WHITE if standard or advanced filters are selected but not active because the signal is of a good quality
	YELLOW if STANDARD filter is active
	RED if ADVANCED filter is active

9.3.6 Dicrotic adjustment

This section of the curves menu allows the user to optimize the correct detection of the dicrotic incisure, displayed as a green vertical bar.

In the majority of cases, MostCare^{Up} detects and correctly identifies the heartbeat within the ABP signal. However, under specific pathological conditions, or when the signal isn't optimally detected by the pressure sensor, it may happen that MostCare^{Up} cannot detect the dicrotic incisure point correctly for all consecutive heartbeats; for example, the green bar may tend to appear before or after the patient's actual dicrotic incisure. In such cases it is possible for the user to carry out a manual correction by means of this menu, dedicated to dicrotic optimization.
For correct dicrotic setting you need to know that:

- Zero corresponds to standard heart beats and covers the majority of cases
- If the dicrotic incisure detected ranges between systolic and 'true dicrotic', a positive adjustment of 1, 2, 3, 4 or 5 will need to be set (depending on the amount of dicrotic shift)
- If the dicrotic incisure detected lies beyond 'true dicrotic', or some pulses cannot be detected, a negative adjustment (-1, -2, -3, -4 or -5) will need to be applied.

⚠ **WARNING:** If the dicrotic notch is not positioned correctly, the derived parameters are calculated incorrectly, which can lead to an incorrect diagnosis.
Please note the following:

- Verify that MostCare^{Up} identifies the arterial pulse components correctly, by checking that, on the graphic rendering of the pressure curve, the green vertical bar coincides with the dicrotic incisure point. If this does not happen, hemodynamic data will not be reliable.
- If the green vertical bar appears before or after the dicrotic incisure, apply a more appropriate setting on MostCare^{Up}.
- The 'DICROTIC DETECTION' settings will be reset to 'NORMAL' values in the case of a new monitoring.

9.3.7 Scrolling time

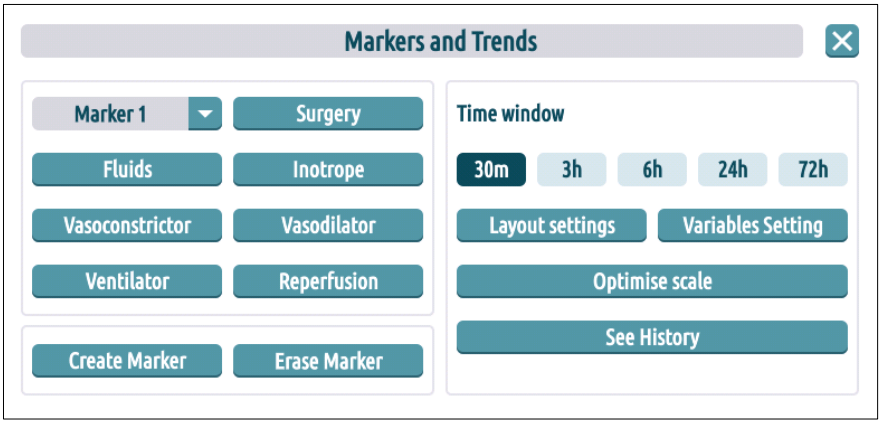
This menu setting allows the user to select how many seconds of the pressure curve will be displayed. By decreasing display time, the visibility of details in the morphology of the curve is improved, while increasing the time window generates a better overview.

The minimum settable value is 2 seconds. The maximum settable value is 12 seconds. The user will not be allowed to select values outside this range. The default value is 6 seconds.

9.4 Markers and trends

The **Markers and trends** menu features the following functions divided in two areas, markers on the left and trends on the right.
To open the markers and trends menu see instructions at sections 8.1.5, 9.

The screen appears as follow:



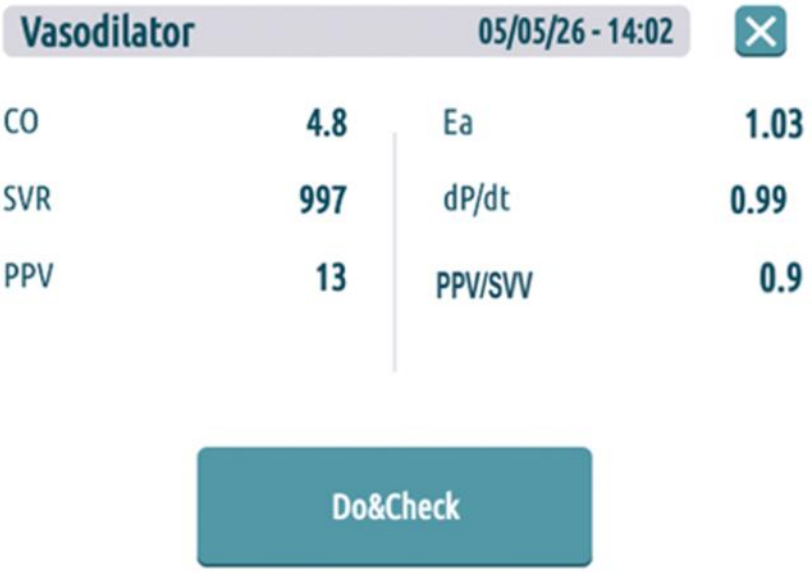
9.4.1 Marker area

This area allows the use of several marker-related functionalities.
Markers are used to show certain events which have taken place during the course of the treatment. The operator can associate a marker, identified by a sequential number, every time there is the need to highlight and remember an action or instance.
The sequential number is set back to zero every time a new monitoring is activated.

Markers are displayed on the trend graph as follow:

NOTE: The presence of a marker is stored also when saving data on a USB flash drive.

By clicking anywhere on the marker bar, a window opens displaying information about that marker, as shown below:



9.4.2 Marker choice

This function allows the user to choose which type of marker to enter.

Up to 13 different types of markers can be stored (7 are fixed by default and 6 can be entered using the "**Create Marker**" button, see below).

The default markers are:

- “**SURGERY**”
- “**FLUIDS**”
- “**INOTROPE**”
- “**VASOCONSTRICTOR**”
- “**VASODILATOR**”
- “**VENTILATOR**”
- “**REPERFUSION**”

NOTE:

- It is not possible to enter a marker in the first 30 seconds of the monitoring, and it is not possible to insert two markers less than 30 seconds apart from each other: should the user attempt such an operation, MostCare^{Up} will issue an error response, preventing the second marker from being entered.
- The MARKER is saved immediately at the time in which it is entered. The blue bar that graphically displays the event on the trend window may instead appear after a brief delay due to screen refresh. The indicator will however be positioned at the correct location.

9.4.3 Create customized marker

This function allows the user to create a new marker and add it to the list of default markers.
It is possible to create up to 6 markers. If the user attempts to create more than 6 markers, MostCare^{Up} issues an error response and asks for the deletion of one of those already stored.
Once a new marker has been created, it will be possible to select it from the drop-down menu and enter it into the trend.

The buttons involved are:
“**Create Marker**”: Allows the creation of a customized marker
“**Delete Marker**”: Allows the deletion of one or more customized markers from the memory

9.4.4 Trend area

In this area users can view and access several trend-related functionalities.

Trends show simultaneously the evolution over time of two variables (with the exception of the pressure group).

The variables keep their own colours. If however, two variables with the same colour are selected both on the right and on the left, the right-hand side one, as well as its axis, will be darker and thicker.

NOTE: The variables displayed in the trend and the layout of the trend area depend on the options selected via the "**Layout settings**" (see Section 9.4.7) and "**Variables Selection**" (see Section 9.4.6) buttons.

Each trend is subdivided in three areas so that four timings will appear on the time line: left axis, right axis and two central ones. Therefore, if the time window is 30 minutes, each area will cover 10 minutes; in the case of 6 hours, each area will cover two hours, and so on.

9.4.5 Time window

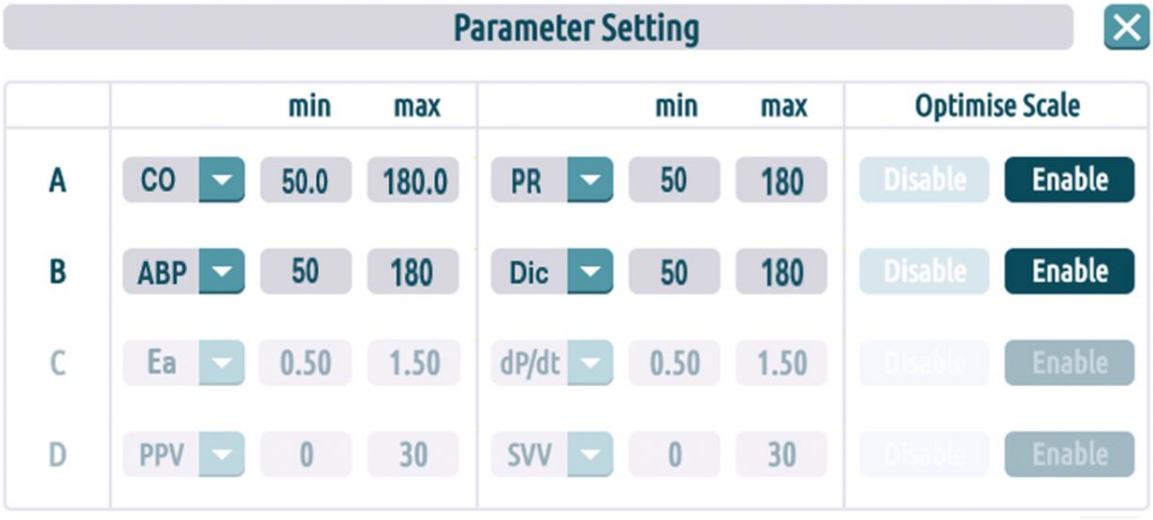
This function allows the user to adjust the real-time trend time window.

The following time windows can be selected:

- 30 minutes
- 3 hours
- 6 hours
- 24 hours
- 72 hours

9.4.6 Variable selection

By clicking on "Variables Settings" the following screen is displayed:



This function allows the user to:

- Choose the variables to be assigned to each trend
- Manually set the maximum and minimum values of the graph
- Execute an automatic rescale by pressing the "**Optimise Curve**" button

The maximum and minimum default values for each variable are indicated in the table below:

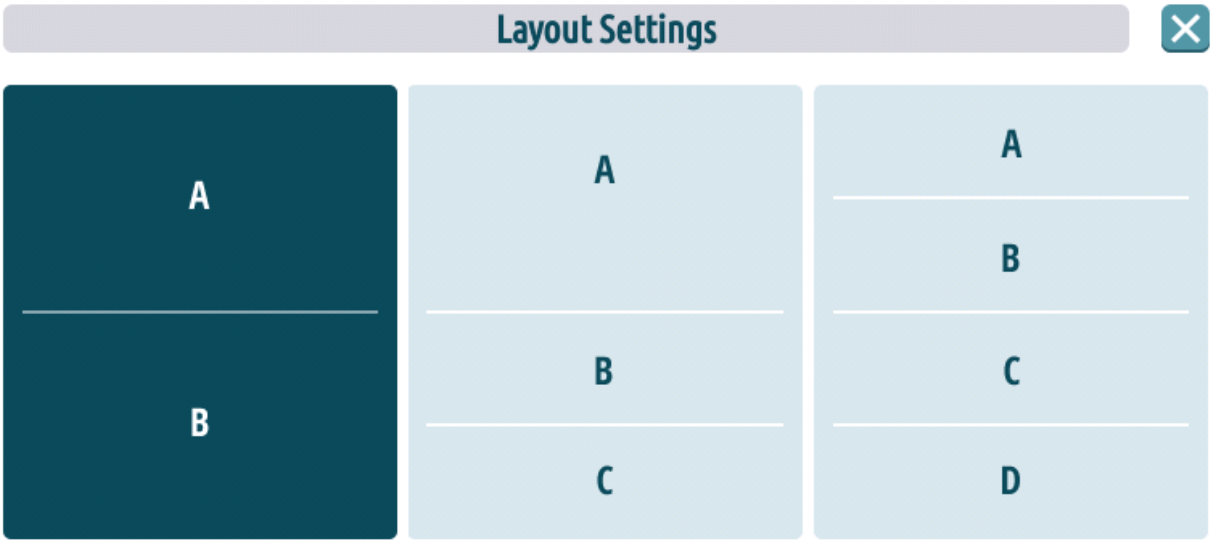
Trend	Min	Max
PR	50	100
ABP	50	180
Dic	50	180
CVP	0	10
CO	3	8
CI	2	4
SV	40	100
SVI	25	50

SVR	600	1400
SVRI	1500	2500
dP/dt_{max}	0.5	1.5
SVV	0	30
PPV	0	30
SPV	0	30
DPV	0	30
Ea	0.5	1.5
PPV/SVV	0.5	1.5
SV_{kg}	0.5	3
Dia_{pk}	0	30
DO_2	500	1200
DO_2I	250	600
PP	20	80
MAP-Dic	-20	20
Ztot	0.3	1.3
CPO	0.4	1
CPI	0.2	0.5

NOTE: If the pressure group is selected as trend variable, Dicrotic pressure will be automatically set as the other variable.

9.4.7 Layout settings

By clicking on “Layout settings” the following screen is displayed:



This function allows the user to change the trend layout on the display. It is possible to choose among the following configurations:

- 2 large trends
- 3 trends, of which one large and two small
- 4 small trends

9.4.8 Optimize scale

This function allows the user to optimize the scale for each variable simultaneously in each trend.

9.4.9 See history

This function allows the user to view a chosen part of the trend graphs (only in relation to ongoing monitoring).

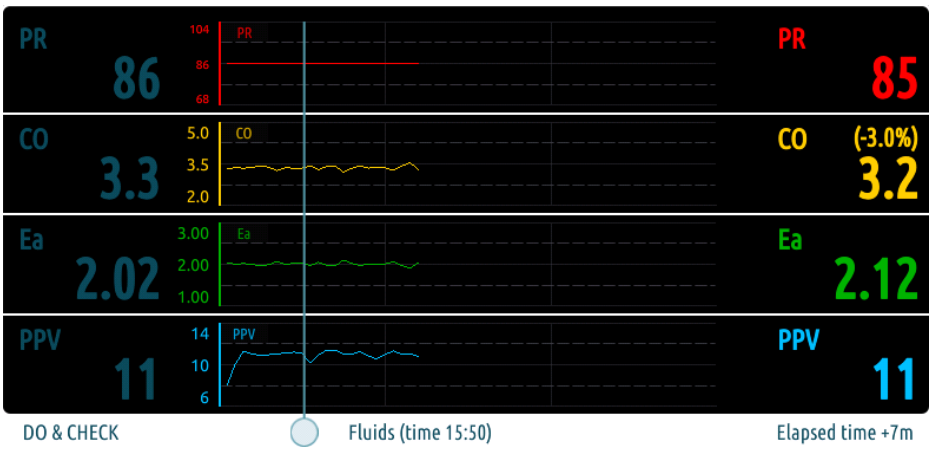
To start with, the trend history window is set for the same time period chosen for the current trend display: for example, if it is 12 noon and a 3 h period has been set, trend history will show the portion of graphs from 9 am to 12 noon.
The user can view a time interval selected from 30 minutes to 3/6/24/72 hours and choose the time and date for the start of the graph portion to be displayed.

It is possible to navigate in time using the arrows to reach the time required. Each pressure on an arrow corresponds to a 1/3 graph shift. Once the required time has been reached, the time window can be modified accordingly.

To close down the history page and return to real-time display, press on X or on the upper screen area (Curves zone).

9.4.10 Do&Check

The Do&Check function allows the user to verify the status of and view the variation in certain variables following the administration of specific treatments.



To enable the Do&Check function, please follow the procedure below:

1. Enter a marker
2. Press on the marker
3. Press the "**DO&CHECK**" button: the "**DO&CHECK**" screenshot relating to the marker is displayed
4. Touch the screen anywhere in the "**DO&CHECK**" area to execute set-up:

4.1 Choose the 4 variables to be displayed in the "**DO&CHECK**" screenshot through the 4 drop-down menus
4.2 Set the trend display time window, choosing between 30 minutes, one and 3 hours
4.3 Optimize the scale for all trends at the same time.
4.4 Close the "**DO&CHECK**" screenshot and return to graph display (using the "**END DO&CHECK**" button)

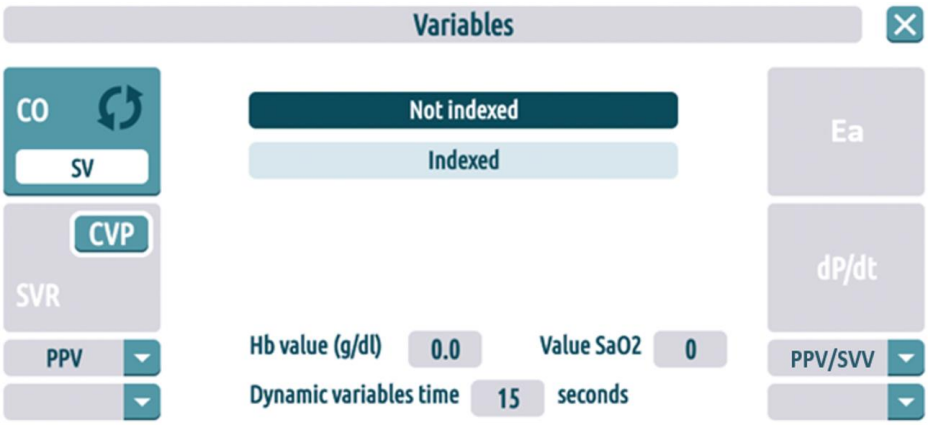
The 'DO&CHECK' screenshot features are the following:

- The left-hand values are those of 4 variables at the time the marker is set: these parameters, unlike the other on-screen values, are static and cannot be modified
- The right-hand values are the current values of those same 4 parameters, updated in real time. For these variables, the screenshot also shows the percentage variation between the initial value (the marker's value, on the left) and the current value (on the right). ABP shows the 3 values of Psis, Pdia and Pmed. At the bottom, the time elapsed from the moment the marker is set (in + hh:mm format) is updated in real time.
- The start time for the graphs is that of the marker minus 5 minutes
- The graphs are set by default on a 30 minutes time scale; after 30 minutes have elapsed, they widen to one hour and after one hour they widen to 3 hours. After three hours, they leave the fixed position on the left and begin to scroll backwards by 1/6 every time they reach the end of the scale.

The 'DO&CHECK' function can be enabled for any marker.

9.5 Variables

Variables is the menu that allows the user to customize some of the variables. It is accessed by clicking on the variables' columns.



NOTE: If the manual CVP is selected as the CVP signal input from the Monitoring Settings menu, the CVP value can be modified by pressing on CVP button (see Section 9.5.4)

9.5.1 Indexing

The "**Indexed/Not indexed**" buttons allow the user to choose whether to display absolute variables or corresponding ones, indexed by body surface area (BSA).

Absolute variables	Indexed variables
Cardiac Output (CO)	Cardiac Index (CI)
Resistances (SVR)	Indexed Resistances (SVRI)
Stroke volume (SV)	Stroke volume Index (SVI)

9.5.2 Setting of customizable variables

This section of the menu allows the user to customize the 4 areas at the bottom of the two variable columns.

It is possible to choose among the following variables:

- PPV
- SVV
- SPV
- DPV
- DO_2 or DO_2I
- PP
- MAP-Dic
- Ea
- PPV/SVV
- SV/kg
- DIApk
- Ztot
- CPI or CPO
- empty (no variable displayed in the cell)

9.5.3 Modify variable position

This function allows the user to modify the position of the two variables featured in the first block on the left side column. They are CO/SV or CI/SVI.
The change can be made by pressing the specific inversion button.

9.5.4 CVP manual entry

The CVP button is present on the screen only if the manual CVP has been selected as CVP signal input from the Monitoring Settings menu.
This function allows the user to modify the constant CVP value used during monitoring.
By pressing on the area where CVP is displayed, it is in fact possible to set it to the desired value.
If not modified, the default value for CVP is 9 mmHg.

NOTE: The mean Central Venous Pressure is used to calculate Systemic Vascular Resistances (both absolute and indexed).

9.5.5 Time window for dynamic variables

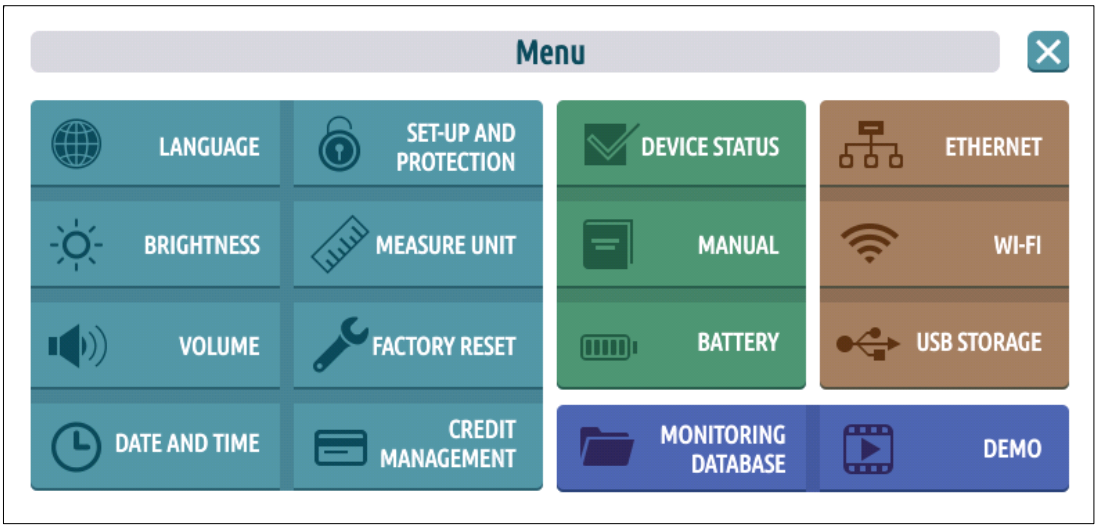
MostCare^{Up} displays the influence that intrathoracic pressure exercises on certain variables; the percentage variations recorded during the respiratory cycle are commonly used as an element to assess the patient's propensity to respond to a fluid load.
MostCare^{Up} therefore calculates the dynamic variables for this purpose, i.e.:

- PPV
- DPV
- SPV
- SVV
- PPV/SVV

MostCare^{Up} allows the user to set the number of seconds for which the percentage variation of the dynamic variable selected needs to be assessed.

The minimum settable value is 5 seconds.
The maximum settable value is 30 seconds.
The default value is 15 seconds.
For every new monitoring, this value is reset to default.

10. MAIN MENU



The main menu can be accessed in two ways:

- From the home screen, by pressing on the "**MENU**" button (see Section 8.1.3)
- From the lateral pop-up menu, by pressing on the "**MENU**" button (see Section 9.1)

The main menu is subdivided into 4 color-coded areas and includes the following items:

1. Settings:
    a. "**LANGUAGE**" see Section 10.1
    b. "**SET-UP AND PROTECTION**" see Section 10.2
    c. "**BRIGHTNESS**" see Section 10.3
    d. "**MEASURE UNIT**" see Section 10.4
    e. "**VOLUME**" see Section 10.5
    f. "**FACTORY RESET**" see Section 10.6
    g. "**DATE AND TIME**" see Section 10.7
    h. "**CREDIT MANAGEMENT**" see Section 10.8

2. Info
    a. "**DEVICE STATUS**" see Section 10.9
    b. "**MANUAL**" see Section 10.10
    c. "**BATTERY**" see Section 10.11

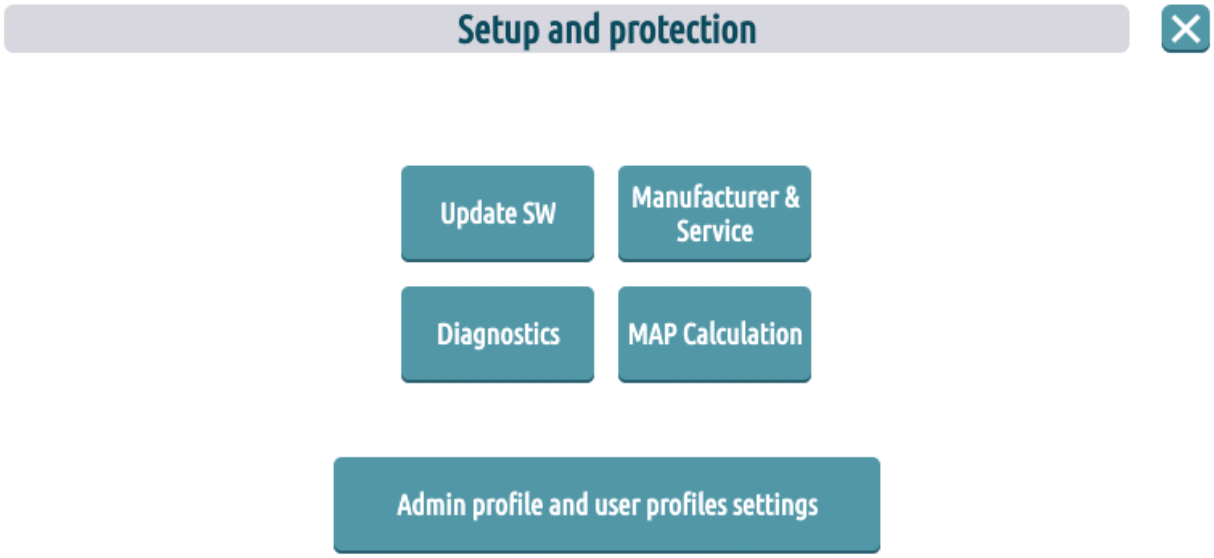
3. Connectivity
    a. "**ETHERNET**" see Section 10.12
    b. "**WIFI**" see Section 10.13
    c. "**USB STORAGE**" see Section 10.14

4. Monitoring
    a. "**MONITORING DATABASE**" see Section 10.15
    b. "**DEMO**" see Section 10.16

10.1 Language

The language available is English.

10.2 Set-up and protection



This menu features:

10.2.1 Update SW and Mnaufacturer & service

Access to reserved areas (submenus "**Update SW**" and "**Manufacturer & Service**"), with functions that are not available for the end user.

10.2.2 Diagnostics

Submenu 'DIAGNOSTICS': it is possible to read the actual voltage of the Y-cable and the last alarm occurred. It is also possible to download the LogFile, which can be helpful for diagnostics from the manufacturer.

10.2.3 MAP calculation

Submenu "**MAP Calculation**": it is possible to choose the type of calculation of the Mean Arterial Pressure:

- By formula[7-8]
- By integral – Evaluation of the average of all the points contained within a single heartbeat.

10.2.4 System admin and user profiles management

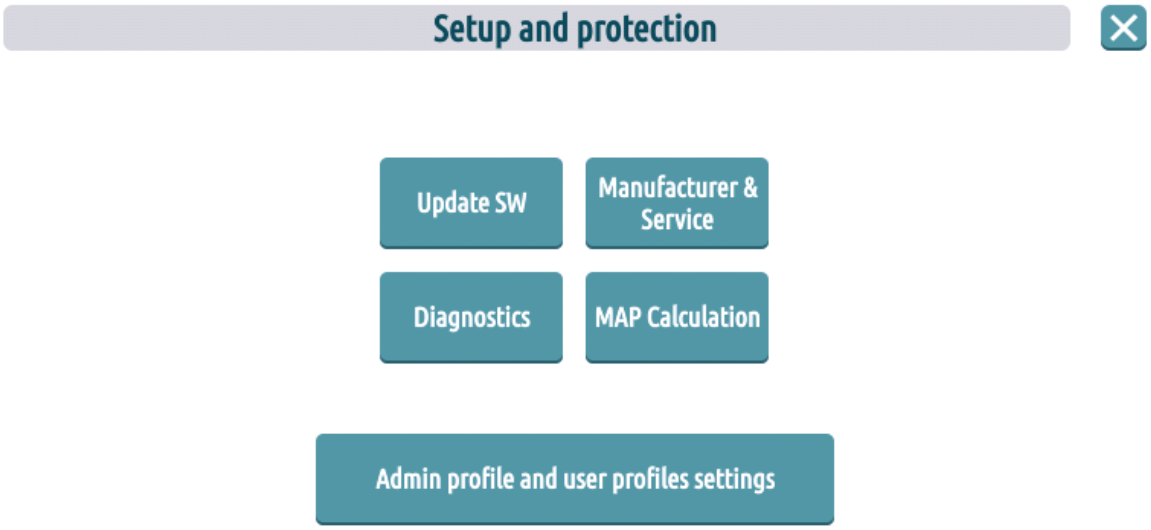
Submenu "**Admin profile and user profiles settings**": User can set the system admin profile (unique) and create or delete user profiles (up to 10 different user profiles).
System admin can be set only by authorized service personnel. User profiles can be created or deleted only by the system admin.

[7] Guyton AC. *Textbook of medical physiology*, 7th ed. Philadelphia: W.B. Saunders; 1986.

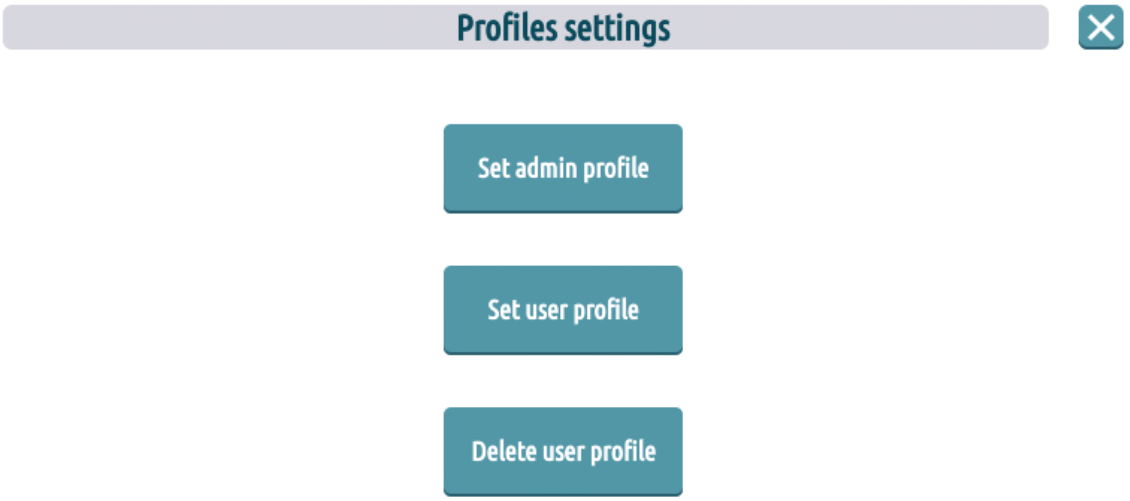
[8] Meaney E, Alva F, Moguel R, Meaney A, Alva J, Webel R. *Formula and nomogram for the sphygmomanometric calculation of the mean arterial pressure*. Heart 2000; 84:64.

To create an admin or user profile, please follow the steps below:

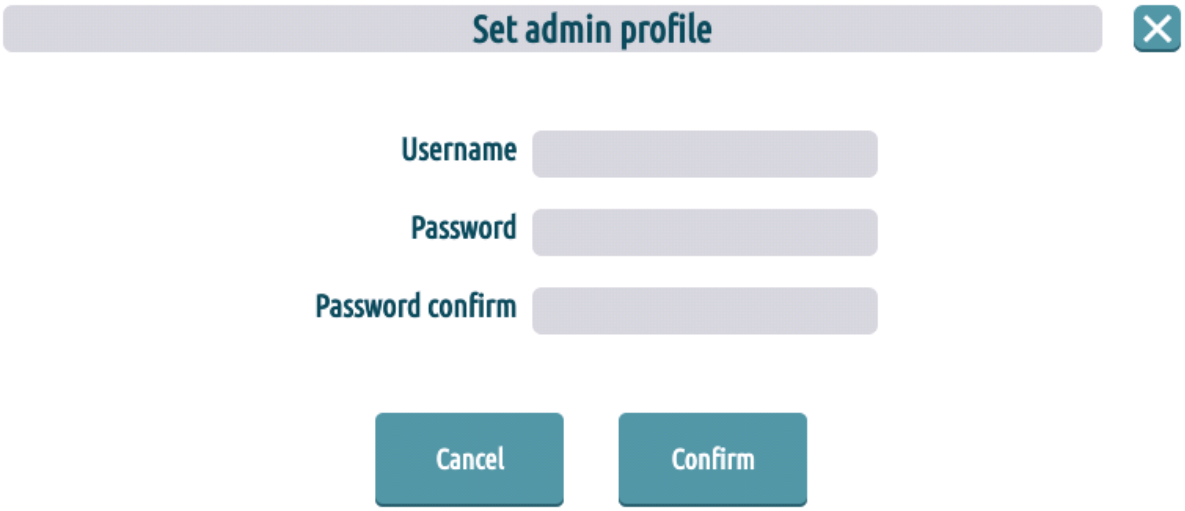
1. Open the Set Up and protection menu



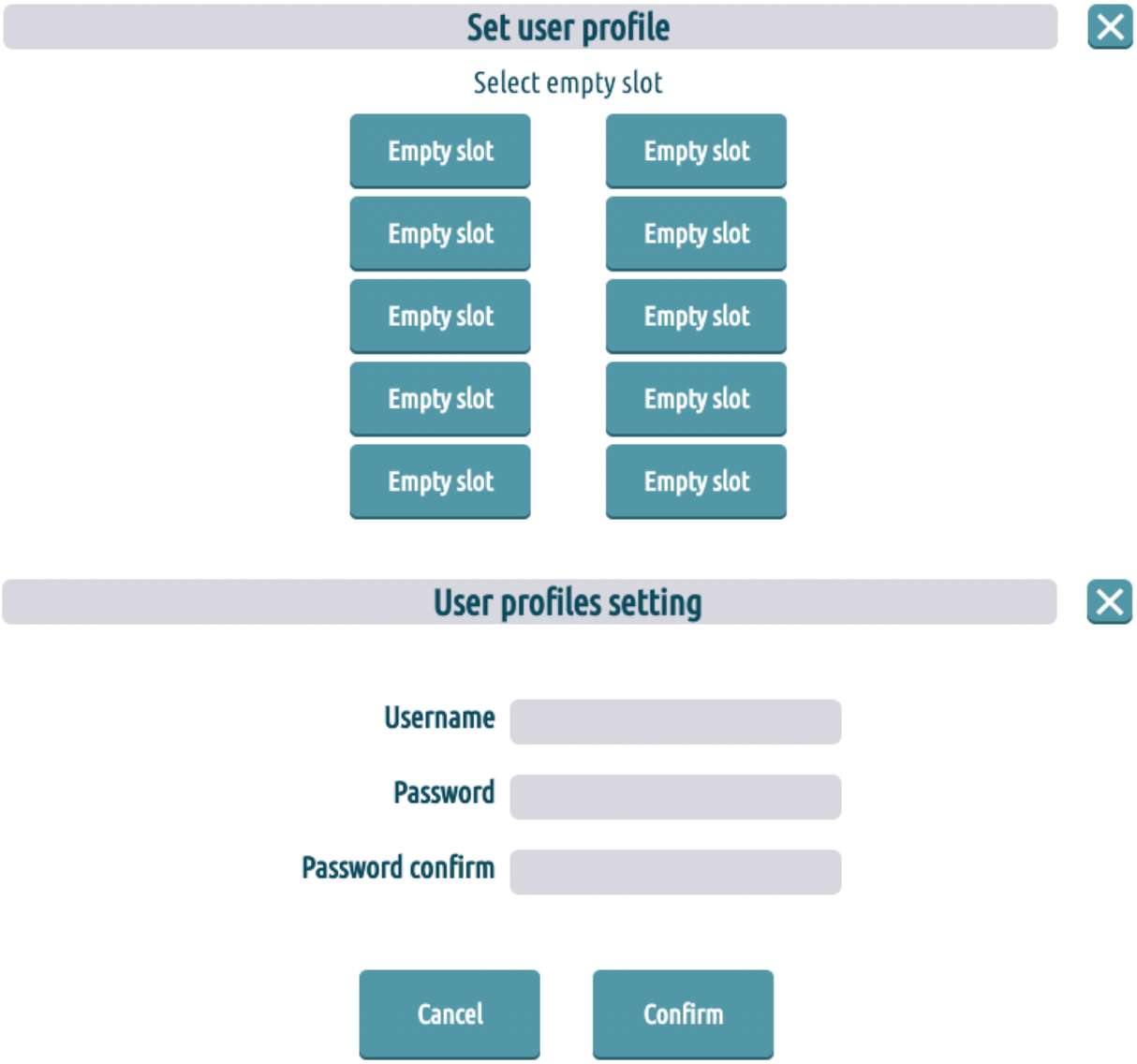
2. Tap on "**Admin profile and user profile settings**"



3. Tap on "**Set admin profile**" and insert a new username and a new password



4. Tap on “**Set user profile**” and, after logging in with admin credentials, select an empty slot and enter a new username and password for the user profile.



10.3 Brightness

The “**BRIGHTNESS**” setting allows the user to choose the display brightness at any time during monitoring. There are two brightness levels:

1. High (the default level when powered from the mains): 100% brightness
2. Low (the default level when battery-powered): 50% brightness

If brightness is reduced, the new setting will be maintained when the device is switched off. Brightness is automatically reduced during battery-powered use and automatically increased to 100% when mains-powered.

10.4 Unit of measure

The “**UNITS OF MEASURE**” setting allows the user to choose the unit of measurement to be used for patient data of height and weight:

- kilograms / grams (weight) and meters / centimetres (height)
- pounds (weight) and feet / inches (height)

10.5 Volume

The “**VOLUME**” setting allows the user to activate or deactivate the sound emitted for every pulse detected (when dicrotic pressure is detected). The default value is 'Disable'. The choice is between 'Enable' or 'Disable' sound.

10.6 Factory reset

The “**FACTORY RESET**” item allows the user to reset MostCare^{Up} to its default values as though it was brand new from the factory. All changes and customisations applied, and all monitoring data/folders stored in the archive will be deleted.
Through the factory reset the user can:

- Set MostCare^{Up} to its default values (see table below)
- Delete all customisations and all data stored in the archive.

This function can be used only if no monitoring is ongoing.

Menu item	Parameter	Factory default
MONITORING SETTINGS	WEIGHT	Empty
	HEIGHT	Empty
	ABP SIGNAL INPUT	ABP Transducer
	CVP SIGNAL INPUT	Manual
	SIGNAL COLLECTION	Radial
	PATIENT TYPE	Standard
	PATIENT DETAILS	All fields are empty
CURVE SETTING	GRAPH MIN/MAX (APB, CVP)	Auto scale
	CURVE SCROLLING TIME	6 sec
	NUMBER OF BEATS FOR MEAN CALCULATION	15
	FILTER	Standard
	DICROTIC ADJUSTMENT	0
MARKER and TREND SETTING	CUSTOM MARKER	Data deletion
	PARAMETER SELECTION	1) Pressures group 2) CI + PR 4) PPV/SVV
	TREND MIN/MAX	See tables in Section 9.4.6
	LAY-OUT SELECTION	2 graphs (A+B)
	OPTIMISE SCALE	Enable (for all trends)
	TIME WINDOW	30 min
	TREND HISTORY: TIME WINDOW	30 min
	DO&CHECK: VARIABLES	PR CO PPV
	DO&CHECK: TIME WINDOW	30 min
VARIABLE SETTING	INDEXING	Indexed
	CVP VALUE	9 mmHg
	4 CUSTOMISABLE VARIABLES	On the left: PPV and DPV On the right: Ea and MAP-Dic
	DYNAMIC VARIABLES TIME	15 sec
	CO → SV	CO above and SV below
	HB and SaO_2	0 and 0
ALARMS	DISABLE ALARMS	Alarms enabled
	ALL ALARM LIMITS (DIA, SYS, MEAN)	See tables in Section 9.2.2
MENU	LANGUAGE	English
	BRIGHTNESS	Maximum if powered via mains, minimum if via battery
	PULSE VOLUME	0
	MONITORING ARCHIVE	Data deletion

10.7 Date and time

The “**DATE AND TIME**” item allows the user to modify the set date and time. Set time is the basis for all data representations.

The credit counter (for time-based cards) is linked to the date/time change, so that if the clock is set back/forward, residual duration does not change.
It will not be possible to adjust time during monitoring.

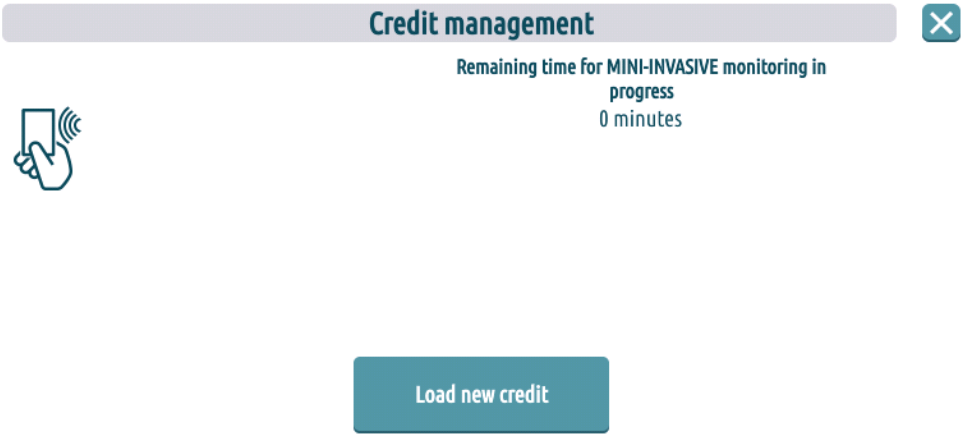
NOTE: Pay attention to correctly set the UTC according to your geographical position and taking into account Daylight-saving time (DST)

NOTE: When HL7 communication is enabled (see Section 10.12.1) and MostCare^{Up} correctly connects to NTP server, manual date and time setting is disabled but user is still required to set UTC.

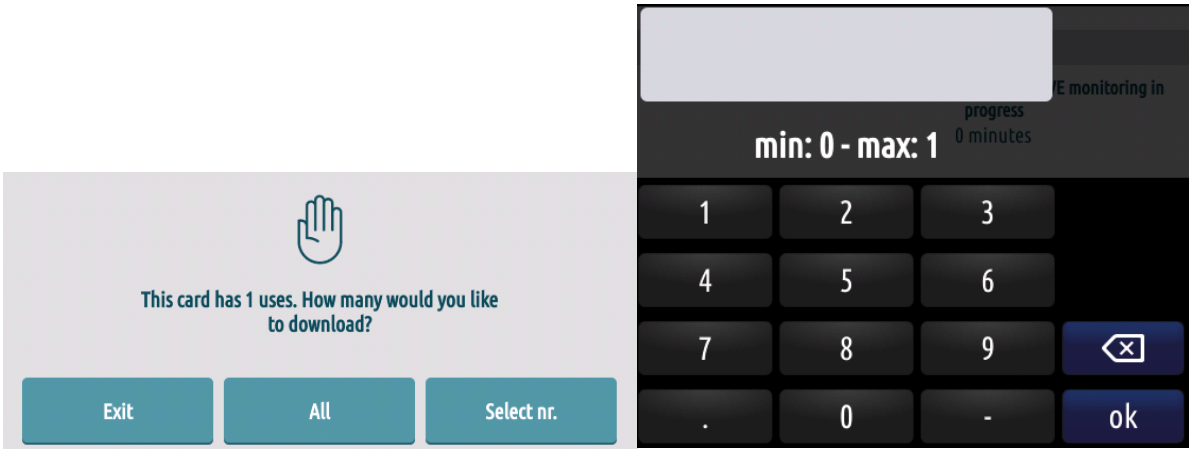
10.8 Credit management

To manage credit updates, please proceed as follows:

1) Open the Credit management menu by clicking on "**CREDIT MANAGEMENT"** button from the main menu (see Section 10)
2) Tap on "Load new credit" and place the card in the designated slot on the top of the device.

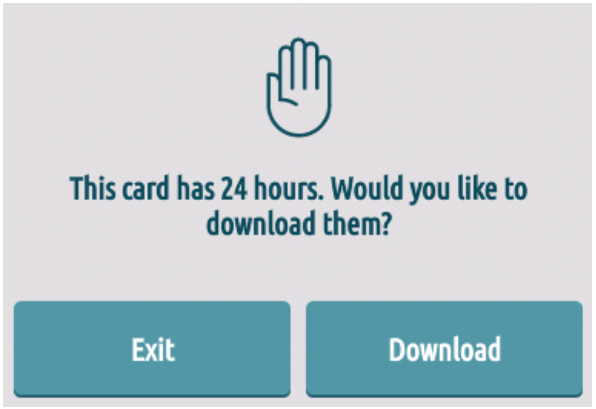


3) In the case of use-based cards, select the number of credits to download; in the case of time-based cards, it is only possible to download all the time present on the card.
In case of use-based credits the screens appear as follow:



The screen on the left shows the number of credits remaining on the card; clicking on "**Select nr.**" brings up the keypad (screen on the right), which allows you to enter the number of credits you wish to top up.

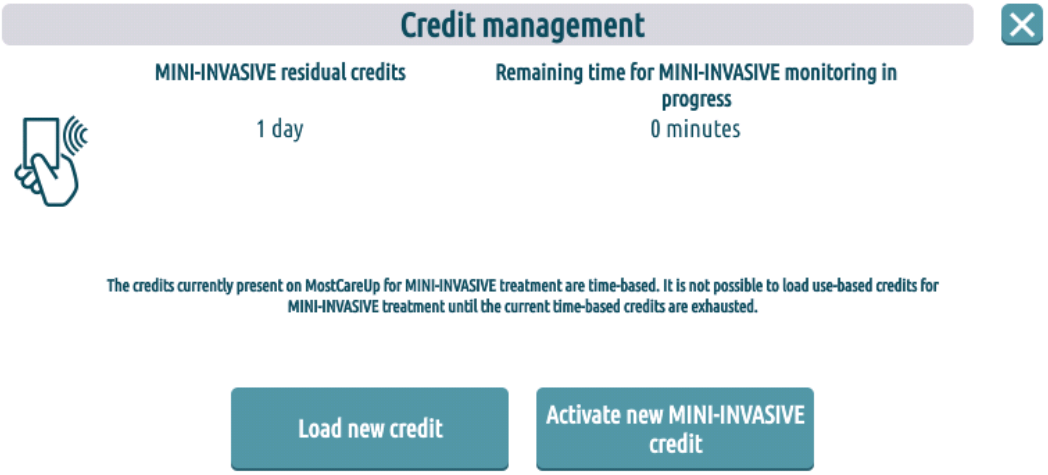
In case of time-based credits the screens appear as follow:



After clicking on “Download”, a confirmation pop-up will appear.

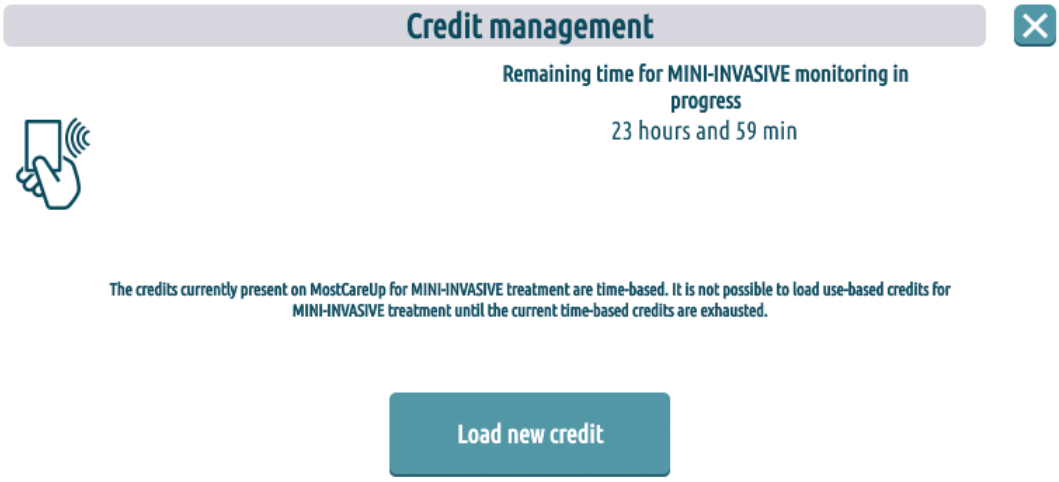
4) Once the use-based credits have been added, the screen appears as follow:

Once the time-based credit has been added, the screen appears as follow:



NOTE: In the case of time-based credit, the time must be activated to be able to use it.

5a) Only in the case of time-based use, activate the time downloaded by pressing on "**Activate new MINI-INVASIVE credit**", then the remaining time will be displayed on the screen.



5b) Start a new monitoring session. Only in the case of use-based credits, confirm the use of a credit for advanced monitoring.

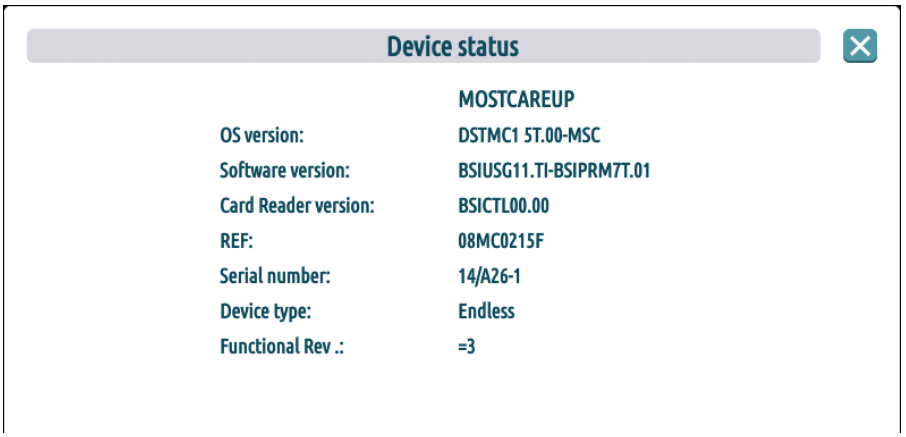
NOTE:
The "**CREDIT MANAGEMENT**" item allows the user to:

- Check the residual available credits (number of uses, or time in hours and minutes). If the device works on a credit basis the residual time in the credit being used is also shown.
- Activate the procedure to download new credits from the card (even if the residual device credits have not been exhausted).

NOTE: It is not possible to upload different types of credits (i.e. time- and use-based) simultaneously.

10.9 Device status

The “**Device status**” screen appears as follow:



The “**DEVICE STATUS**” item allows the user to display device-related information:

- MostCare^{Up} display software version
- Device release number (functional revision)
- Device serial number
- Type of MostCare^{Up} device (endless/on demand)
- MostCare^{Up} internal software versions (operative system, firmware, card reader software)

10.10 Manual

The “**MANUAL**” item displays the following information:
'The MostCare^{Up} user manual is available in .pdf format on the website www.bio-si.it'

10.11Battery

The “**BATTERY**” item allows the user to access information on the battery charge level in terms of % of battery life remaining. The percentage indication changes in 25% steps; when the battery is charging, no information on remaining capacity is available.
This screen can display the battery voltage expressed in V (with two decimal points) and the number of charge cycles executed.
The charge cycle counter is increased whenever the device detects a transition from any battery-powered to any mains-powered state, the latter remaining operational for at least 2 minutes. The charge cycles executed when the device is switched off are therefore excluded from this count.
When the device is battery-powered, the low-consumption mode is automatically activated, and brightness is minimized.

NOTE: The battery status is always visible from the right side of the top bar through the battery icon (see Section 1.2)

NOTE: Until the full battery icon appears, the battery is charging.

10.12 Ethernet

The “**ETHERNET**” menu allows the user to access the following features:

- Enable/disable the Ethernet connection. If activated, its symbol appears in the upper right (see table in Section 1.2)
- Setting network parameters:

- IP address (static)
- Netmask
- Gateway

- HL7 Configuration Protocol (see Section 10.12.1)

The settings are maintained even if power is turned off.

⚠ **CAUTION:** Data transmitted to the hospital network via Ethernet could be intercepted by unauthorized persons, which could result in the loss and/or corruption of sensitive data**.**
The hospital Ethernet network must be adequately protected from possible intrusions.

10.12.1 Network settings for sending data in medical records

MostCare^{Up} can communicate with the hospital information system (HIS) through Ethernet or WiFi using the HL7 protocol. The purpose of the connection to the IT hospital network is to send patient data in real time to the central informative system.
To enable HL7 communication, access the HL7 settings menu from the Ethernet or WiFi menu, depending on which technology you want to use.
Data that can be sent using the HL7 protocol include patient data and technical or physiological alarm status.

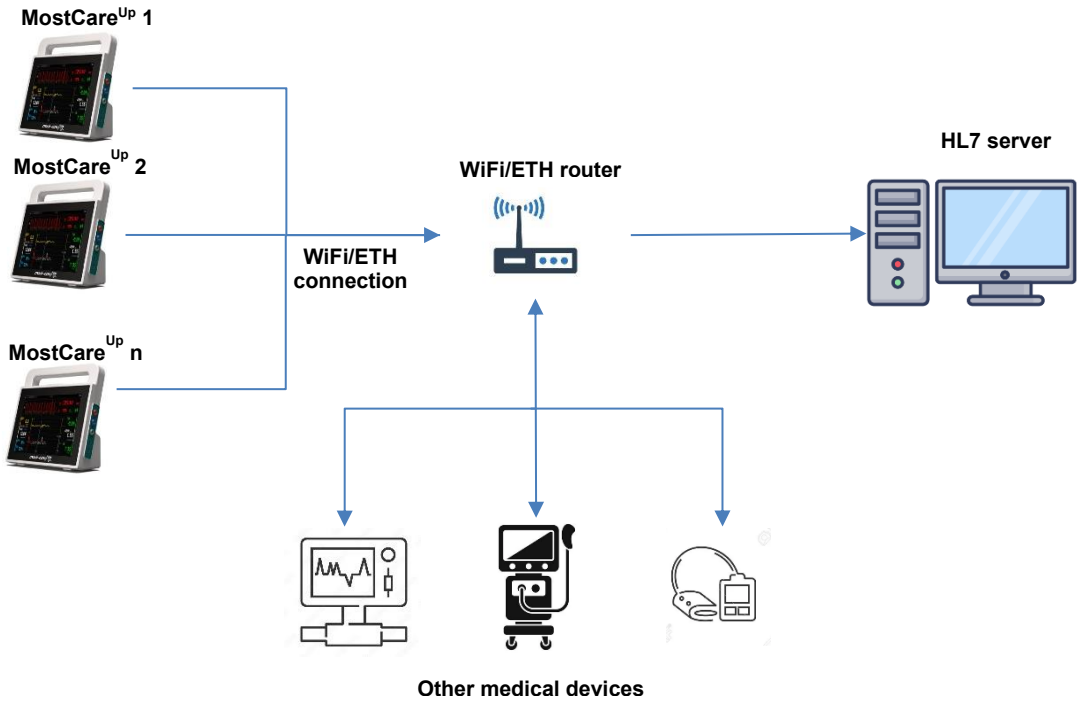
The required network characteristics and configuration are as following:

- Network should have Ethernet/WiFi access points, such as Ethernet ports supporting RJ45 connectors, routers, WiFi repeaters…
- HL7 ports should be opened in order to be accessed from MostCare^{Up}
- MostCareUp supports obtaining IP address through DHCP
- Ethernet speed should be 10/100 Mps
- Ethernet duplex mode supports half/full auto-negotiation
- WiFi wireless interface should support 802.11 B/G/N standard
- WiFi bandwidth is 2.4 GHz; 5 GHz is not supported

Other network security specifications include:

- WiFi password should be WPA2 PSK type
- Informative system should foresee an anti-virus protection

A possible intended flow between MostCare^{Up} and the network is as following:



The following possible hazardous situations could result from a failure of the network:

- Hospital server is unreachable / WiFi or Ethernet connection failure / Hospital server IP address or communication port is not set correctly / IP address is the same of another device in the network, causing the impossibility to send patient data/alarms to hospital server
- Access to Ethernet open doors from inside or outside the hospital / Virus infection / External intrusions, causing abnormal or unstable operation of the device with consequent potential harm to patient
- Unauthorized access to patient sensitive data / Data transmitted to the Hospital Network via Ethernet or WiFi is intercepted by unauthorized person, causing sensitive data loss and/or corruption

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⚠ **CAUTION:** Data transmitted to the hospital network could be intercepted by unauthorized persons, which could result in the loss and/or corruption of sensitive data.
Please note as follow:

- Any MostCare^{Up} connection to the network that includes other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks.
- Any subsequent changes to the hospital network could introduce new risks, and therefore require additional analysis. Changes may include:
  - changes in the network configuration
  - connection/disconnection of items to/from the network
  - update/upgrade of equipment connected to the network

10.12.2 HL7 protocol settings on MostCare^{Up}

Before activating HL7 communication the following settings must be configured:

- TCP connection. This setting depends on the hospital information system architecture. Two options are available: TCP Client or TCP Server.
  - If TCP Client is selected, the address of the HIS server, including IP (e.g. 192.168.1.1) and port (e.g. 8080) must be set.
  - If TCP Server is selected, only the communication port must be set (e.g. 8080).

- NTP server address. This setting is required to synchronize MostCare^{Up} and HIS time. This setting is mandatory to ensure data time consistency. The IP and port of the hospital time server must be set.

- Sampling interval. This setting defines data transmission frequency. User can set the time interval between two consecutive data transmissions from 5 to 60 seconds. Default is 15 seconds. For example, by default, MostCare^{Up} will transmit data to HIS every 15 seconds.

- Application name. This field can be set as you like. Choose a name that will help you easily identify the data source once they are stored in the HIS database. By default, application name is MostCare^{Up}.

- Facility name. As for the application name, this field can be set as you like. Choose a name that will help you easily identify the data source once they are stored in the HIS database. By default, facility name is empty.

NOTE: Patient ID is a mandatory field for HL7 messages. Before activating HL7 communication, it is required to set patient ID from patient personal data menu (see Section 8.1.4.1).

NOTE: For security reasons, all SSH ports have been shut down on MostCare^{Up}, therefore it is not possible to access MostCare^{Up} through SSH communication.

As regards the start/end message markers and the various separator characters, you have:

- Start/end message marker (in hex)
- Field separator

- Component separator
- Repetition separator
- Escape Character
- Subcomponent separator

After configuring HL7 settings, you can save them and activate HL7 communication by pressing the "**Enable HL7**" button. HL7 settings cannot be edited while HL7 communication is enabled. To edit HL7 settings you must disable HL7 communication first. Settings are maintained even when device is turned off.

When HL7 is enabled, during patient monitoring, MostCare^{Up} automatically sends HL7 packets including patient data and/or alarm status to HIS with the specified frequency.

⚠ **WARNING:** Alarm status and patient data transmissions are synchronous and are performed with the frequency set by the user (sampling interval). Therefore, an alarm status can reach remote server up to 60 seconds after its activation. Pay attention to the selected sampling interval, as a delay in identifying an alarm can lead to an incorrect diagnosis due to a lack of awareness of an alarming condition in the patient.

10.13 WiFi

The WiFi menu allows the user to access the following features:

- Enable / disable the WiFi network. If activated, its symbol appears in the upper right (see table in Section 1.2)
- List of the WiFi networks available and addition of a non-visible WiFi
- Password entry
- Setting network parameters:
  - IP address (static)
  - Netmask
  - Gateway
- HL7 Configuration Protocol (see Section 11.12.1)

The settings are maintained even if power is turned off.

⚠ **CAUTION:** Data transmitted to the hospital network via WiFi could be intercepted by unauthorized persons, which could result in the loss and/or corruption of sensitive data.
The hospital WiFi network must be adequately protected from possible intrusions.

10.14 USB storage

The USB STORAGE item allows the user to save the current monitoring on a USB flash drive.
When a USB flash drive is inserted/removed, the related icon shows up on/disappears from the top bar.
In order to save data, insert a USB flash drive into its dedicated lateral slot and press the "**Download Data**" button.
A folder will then be copied into the USB flash drive, its name in the MostCareUp-mmddyyyyThhmmAM or MostCareUp-mmddyyyyThhmmPM format, containing the following:

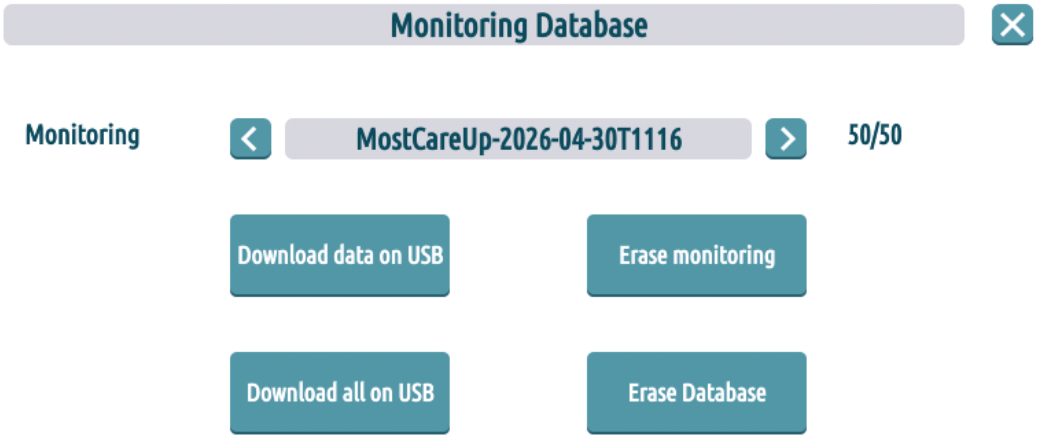
- A .csv file containing all the data acquired with a 30 seconds sampling, from the start of the monitoring period to the present time
- A .txt file with the patient details
- Any recording (e.g. beat-beat).

⚠ **CAUTION:** If the USB storage device is not performed properly, this could result in data loss.
Please note the following:

1. If the USB flash drive is removed at any time before the end of the transfer, this will be cancelled and the data lost.
2. For a correct reading of the data contained in the recording files, it is necessary for the dot to be set as system decimal separator in the operating system that will be reading the file.
3. Monitoring data is protected against unauthorized access. To access USB storage menu user must authenticate with username and password.

10.15 Monitoring Database

The “Monitoring Database” screen appears as follow:



From this menu, the user can access the monitoring archive available in the internal memory.
Monitoring data is collected in chronological order.
The user may carry out the following operations:

- Download a selected folder to a USB flash drive
- Delete the monitoring folder selected, after confirmation; this operation deletes all the information contained within the folder
- Download to a USB flash drive all the folders available in the archive
- Delete the entire monitoring archive, after confirmation.

Folders downloaded to a USB flash drive will be named using the MostCareUp-mmddyyyyThhmmAM or MostCareUp-mmddyyyyThhmmPM format, and will contain:

- A .csv file containing all the data acquired with a 30 seconds sampling, from the start to the end of the monitoring period
- A .txt file with the patient details
- Any recording (e.g. beat-beat).

⚠ **CAUTION:** The device will only save a maximum number of 50 monitorings. Thereafter, previous monitorings will be overwritten and this may cause data loss.

⚠ **CAUTION:** If there are undetected issues with the internal memory, this could result in data loss.
Please note as follow:

- If the MEM.ERR warning is on, the monitoring archive will not be accessible.
- Monitoring data is protected against unauthorized access. To access monitoring archive menu user must authenticate with username and password.

10.16 Demo

The DEMO item allows the user to display the real pressure curves stored on MostCare^{Up}, simulating a pressure signal reception. The arterial curve undergoes regular analysis by the software; the data displayed are the result of the actual application of the PRAM to the curve that was sampled and analyzed.

This demo is a simulation of what usually happens during the monitoring of a patient. Its purposes are testing and training; it is used to check that the software is functioning correctly and for user training.
Four demos are available.

To exit “DEMO” mode open the lateral pop-up menu and select “END DEMO”.

⚠ **WARNING**: When a DEMO is running an indication is displayed on the top bar indicating that the system is in “DEMO” mode. The monitoring data displayed in demo mode may be interpreted by the user as data from a real-time monitoring session. This can lead to misinterpretation of the parameters and an incorrect diagnosis.

11. MAINTENANCE, REPAIRS AND TECHNICAL ASSISTANCE

This paragraph describes the inspections and maintenance operations which must be carried out routinely. Only explicitly specified actions can be executed by the operator, while all other actions must be executed by technical assistance personnel or exclusively by the manufacturer or by technical personnel authorized by the manufacturer.
Each unauthorized operation may cause damage to the functioning of the system and engender hazardous situations.

Manufacturer will provide circuit diagrams, component part lists, descriptions and calibration instructions to assist trained service personnel in parts repair.
The minimum qualifications for the service personnel concern training by the manufacturer or by specially designated technical personnel.

NOTE: The manufacturer is responsible for the safety, reliability and performance of the appliance only if the installation, maintenance and assistance of the machine is carried out by authorized personnel, the electrical system complies with all applicable regulations and the appliance is used according to the instructions given in this user manual.

NOTE: Software maintenance is not allowed to the user.

Execute the following checks before using MostCare^{Up}:

Check Description	
1	Visual check of the condition of the power connector, the cable and the connection sockets
2	Visual check for any mechanical damages
3	Visual check of the accessories
4	Visual check of the alarm system (see Section 9.2.1 for details).

The visual checks reported above are suggested on a daily basis. However, clinical engineering should follow the internal hospital guidelines for the periodicity of the operations.

We recommend periodic maintenance every 2 years to perform functional tests performed by clinical engineering, and electrical safety tests, performed by clinical engineering or a designated service center.

For MostCare^{Up}, we recommend maintenance every 8 years to replace internal batteries.
Replacing the internal rechargeable battery may be necessary after shorter periods depending on the way the device is used (number of charge/drainage cycles, or usage and storage temperatures).

⚠**WARNING:** No modification, repair, or alteration of the MostCare^{Up} monitor is permitted. Any change may cause a loss of the essential safety performance of the device and result in injury to the patient/operator.

⚠**WARNING:** Battery replacement involves opening the device and should only be performed by the manufacturer's technical assistance personnel. Any change may cause a loss of the essential safety performance of the device and result in injury to the patient/operator.

⚠**WARNING:** Fuses must be replaced only by qualified personnel.
Fuses must be replaced in any case with fuses of the same type and the same capacity (2 T1250mAH250V fuses, model 02151.25MXEP Littlefuse). Any change may cause a loss of the essential safety performance of the device and result in injury to the patient/operator.

If MostCare^{Up} does not operate according to these operating instructions, please have the device serviced and stop using it.

11.1 Cleaning and disinfection procedure for the device

⚠ **WARNING:** Incorrect cleaning and disinfection may result in cross-contamination, infection, and serious patient injury or death.

- Carefully read the instructions before processing the device.
- To clean and disinfect the device use only the manual processes described below. Device cannot withstand any automatic cleaning and disinfecting process.
- Do not spray or apply the cleaning or disinfecting agent directly on the touch screen surface as the liquid may permeate into the front bezel of the display and damage it.
- Do not immerge the device or the cables into the cleaning or disinfecting agent.
- Do not use sharp objects or objects with a cutting edge
- Do not use a cloth that could scratch the display monitor, and wipe delicately
- Do not use the brush on the touch screen surface.
- Even if the caps are inserted, take care that no liquid substance penetrates the device through the connectors. If this should happen, do not connect the device to the mains.
- The instructions are not applicable to device accessories not provided together with the device (e.g. pressure transducers and catheters). For these accessories please follow the separate instructions provided by their respective manufacturers.
- Device and cables are not sterilizable. Do not sterilize device and cables by means of any sterilization process. Do not use steam, heat or radiations.

To clean and disinfect MostCare^{Up}, proceed as follows:

1. Wear protective gloves.
2. Turn off the device and unplug it from the power supply.
3. Disconnect all connected accessories.
4. Apply protective caps to all device connectors (e.g. USB, HDMI, LAN).
5. Use only non-abrasive cloths for the touch screen.

11.1.1 Cleaning procedure

To clean MostCare^{Up}, proceed as follows:

1. Clean all surfaces of the device, including the rear support if present, and the cables along their entire length with a lint-free cloth slightly moistened with Liquinox until no visible residual soil (if present).
2. Use a soft brush for hard-to-reach areas (not on the touch screen).
3. Rinse all the surface with a lint-free cloth sightly moistened with tap water, avoiding water dripping.
4. Dry all surfaces and cables thoroughly with a soft, dry cloth, removing any detergent or liquid residue.

11.1.2 Disinfection procedure

To disinfect MostCare^{Up}, proceed as follows:

1. Disinfect all surfaces of the device, including the rear support if present, and the cables along their entire length with a lint-free cloth lightly moistened with isopropanol 70% disinfectant.
2. Wait no less than 60 seconds.
3. To remove any eventual disinfectant residue, dry all surfaces and cables thoroughly with a soft and dry cloth.

⚠ **CAUTION**: Detergent and disinfectant mentioned in the procedures below are the only ones approved for cleaning and disinfecting the monitor. If your safety procedures foresee the use of different substances, we inform you that the following substances have been tested as safe for not damaging the monitor's surfaces:

- Hydrogen Peroxide 5%
- Ethyl Alcohol 96%
- Clinell Universal Spray
- Clorexinal 2%

DO NOT use any further different substances as they may cause device damaging.

11.2 Waste disposal

Follow local regulations for the disposal of medical and electronic equipment, including batteries.

11.3 Troubleshooting

The table that follows lists the symptoms and the possible solutions for the most common problems the user may encounter while using the device.

PROBLEM	CAUSE	SOLUTION
The device does not switch on	The battery is flat	Verify if side LED is on/blinking. If not, connect MostCare^{Up} to the mains and flip the switch at the rear
	The power cable is inserted incorrectly	Disconnect and connect the power cable again
	The main electrical system is not functioning	Check that electrical power is available
	The fuse has blown	Verify if left side LED is on/blinking. If not, substitute the fuse at the rear of the device with T1250mAH250V fuses, model 02151.25MXEP Littlefuse
The battery doesn't charge up	The switch at the rear is in the OFF position	Verify if side LED is on/blinking. If not, flip the switch in the ON position
	The fuse has blown	Verify if side LED is on/blinking. If not, substitute the fuse at the rear of the device with T1250mAH250V fuses, model 02151.25MXEP Littlefuse
	The battery is faulty	Despatch the device for technical assistance.
The battery life is too short	Battery substitution needed	Despatch the device for technical assistance.
Dicrotic pressure isn't detected where expected	Error in dicrotic detection setting	See Section 9.3.6.
An alarm is triggered	Physiological/Technical alarm	See Section 9.2.4.
An error popup is triggered	Internal error	See Section 8.1.2.
Card reading gives error	Error in reading/writing card	See Section 7.2.3.

⚠ **WARNING:** The device must not be opened or modified, as this would compromise its safety and could result in damage to the device or injury to the patient or operator.

For any other kind of device malfunction, other than those listed above, please contact technical assistance.

12. TECHNICAL FEATURES

The following paragraphs show the technical features of MostCare^{Up}.

12.1 General features

Device name	**MostCare^{Up}**
Protection class	**I**
Device class	**II**

12.2 Technical specifications

12.2.1 Environmental specifications

The environmental specifications for the use of MostCare^{Up}, its accessories (CARDS included) are the following:

Operational conditions

Temperature	**(+50° F) – (+104° F) [(+10 °C) - (+ 40 °C)]**
Relative humidity	**≤ 75 % (non-condensing)**
Atmospheric pressure	**700 – 1060 hPa**
Liquid penetration protection	**IP22**

Storage and transportation

Temperature	**(+14° F) – (+104° F) [(-10 °C) - (+40 °C)]**
Relative humidity	**≤ 75 % (non-condensing)**

⚠ **CAUTION:** Damage to or malfunction of the cards may cause the inability to perform monitoring in advanced mode.
Data stored on the CARDS may be damaged in the presence of permanent magnets or high-power electromagnetic sources. Store CARDS in suitable locations.

12.2.2 Variable specifications - Blood pressure monitoring

Variable	Lower Limit	Upper Limit	Accuracy (including the transducer)	Unit of measure
ABP (with and without Y cable)	0	250	Error <4% or 4 mmHg*	mmHg
CVP	0	250	Error <4% or 4 mmHg*	mmHg
PR	30	240	±1 min^{-1}	min^{-1}

(*) the higher of the two values

Variable	Lower Limit	Upper Limit	Accuracy	Unit of measure
IN1	0	2.50	Error < 0.03V	V
OUT (ABP signal repetition)	0	2.50	Error < 0.02V	V

12.3 Electrical specifications

12.3.1 Electrical safety

MostCare^{Up}	
Degree of protection for ABP and CVP applied parts	CF (protected from defibrillator discharge)
LAN port insulation	1,500 Vrms 1min
USB, HDMI, EXP, IN1, IN2, OUT ports	Not insulated with grounded GND

⚠ **WARNING:** If the device, when used in conjunction with an external monitor, is not used in accordance with its safety specifications, it may cause injury to the patient or operator.
When MostCare^{Up} is connected to an external device, the system must meet the requirements of Standard 60601-1 clause 16, “General requirements for the medical electrical system”.

12.3.2 Power supply

MostCare^{Up}	
Voltage	100-240 Vac
Frequency	50/60 Hz
Absorbed power	60 VA
Fuses	2 x T1250mAH250V fuses, model 2151.25MXEP Littlefuse
Fuses nominal melting I^2t	>2.9 A^2Sec
Inrush current	120 Vac: 30 A max. 230 Vac: 60 A max

NOTE: If mains supply is interrupted, device automatically switches to battery power without any functionality interruption.

⚠ **WARNING:** Using a power cable other than the one authorized and supplied by the manufacturer may cause the machine to catch fire or explode, which could result in serious injury to the patient or operator.
Use only the power cables authorized by the manufacturer. Only the power cables authorized by the manufacturer ensure basic safety of the system.

12.3.3 Batteries

There are two internal batteries. Batteries can only be substituted by technical assistance personnel.

MostCare^{Up} POWER BATTERY	
Type	Rechargeable NiMH battery
Battery life	> 1h *
Maximum storage time	If the device is unused/stored away, the battery must be fully charged at least every 6 months in order to ensure nominal performance continuity. It is suggested to maintain a 50% charge in storage devices.

* performance when device is new. The battery life is likely to decrease over time due to several factors such as the utilisation mode, the number of charge/drainage cycles and the operational use and storage temperature.
The duration of a complete charge cycle is approximately 13 hours. In any case the battery is considered fully charged only when the charge icon 100% appears on screen (see Section 1.2).

CLOCK POWER BATTERY	
Type	Lithium
Compliance	IEC 60086-4

12.3.4 ABP and CVP transducer specifications

⚠ **WARNING:** The use of non-biocompatible transducers can lead to inflammation and intoxication in the patient.
The transducer biocompatibility must be tested in compliance with UNI EN ISO 10993-1. Transducers must be compatible with the electrical specifications listed below:

Minimum measuring range	From 0 to 250 mmHg
Zero offset	Between ±50 mmHg
Transducer sensitivity	5 μV/V/mmHg
Excitation voltage	5 Vdc
Maximum allowable error	<3% or 3 mmHg (the greater of the two)

12.3.5 External monitor specifications for Y cable (ABP) connection

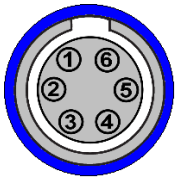
⚠ **WARNING:** Incorrect pressure values reading can lead to an incorrect diagnosis.
For an accurate reading of pressure values, the transducer power voltage, as supplied by the external monitor, must be stable. Otherwise, the instability condition is signaled by issuing a technical alarm.

Range of excitation voltage supplied by an external monitor in case of Y cable connection	3-7 Vdc

12.3.6 ABP and CVP connectors specifications

Connection cables: the device has been tested with cable length in excess of 9.8 ft. [3 m].

ABP Connector			
	1	+V exc ext	+V exc excitation voltage supplied by an external monitor in the case of a Y cable connection
	2	+V exc	+V exc transducer excitation voltage provided by MostCare^{Up} (+5 Vdc)
	3	IN+	Transducer (positive) signal input
	4	IN-	Transducer (negative) signal input
	5	-V exc	-V exc transducer excitation voltage provided by MostCare^{Up} (0 Vdc)
	6	-V exc ext	-V exc excitation voltage supplied by an external monitor in the case of a Y cable connection

CVP Connector			
	1		
	2	+V exc	+V exc transducer excitation voltage provided by MostCare^{Up} (+5 Vdc)
	3	IN+	Transducer (positive) signal input
	4	IN-	Transducer (negative) signal input
	5	-V exc	-V exc transducer excitation voltage provided by MostCare^{Up} (0 Vdc)
	6		

ABP and CVP connectors are clearly distinguishable by colors: RED for ABP and BLUE for CVP, as reported in the above images.

NOTE: Always make sure to check the color of the connector before inserting the cable.

⚠**WARNING:** The use of an unvalidated transducer may lead to the calculation of incorrect variables and, consequently, to an incorrect diagnosis.
The compatibility between MostCare^{Up} and the majority of pressure transducers and anaesthesia monitors available on the market has been validated. Ask your area consultant for the TRANSDUCER CABLE, the MONITOR IN CABLE and the monitor that are best suited for the devices in use.

12.3.7 IN 1, IN2, OUT connectors specifications (left side panel connector)

3.5 mm mono male connector jack (for external cable)		
	SIG	Signal
	GND	Ground

IN1	
Connector	3.5 mm mono female jack
Signal	DC voltage
Range	0-2.50 V (or 0-250 mmHg range, e.g. 100mmHg = 1.00 V)
Input impedance	High impedance
GND reference	GND referred to ground

OUT (external monitor output)	
Connector	3.5 mm mono female jack
Signal	DC voltage
Range	0-2.50 V (or 0-250 mmHg range, e.g. 100mmHg = 1.00 V)
Output impedance	To be connected to a high-impedance input (>10 kOhm)
GND reference	GND referred to ground

NOTE: this output does not reproduce the pressure signal if it is detected via the IN1 input

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Connection cables: The device has been tested with cable length in excess of 3 m [9.8 ft.].

⚠ **WARNING:** If the device, when used in conjunction with an external monitor, is not used in accordance with its safety specifications, it may cause injury to the patient or operator.
External devices interfacing with MostCare^{Up} (analog inputs and outputs) must meet the requirements of Standard 60601-1, clause 16, “General requirements for the medical electrical system”.

⚠ **WARNING:** If MostCare^{Up} is connected to a device that is not grounded at the same point, it may catch fire or explode, causing serious injury to the patient or operator. MostCare^{Up} and any device connected to it must be grounded at the same point.

12.3.8 USB

USB connector (MostCare^{Up})	
Connector	Female A-type
Protocol	USB 2.0
Type	Host (for USB flash drives or slave devices)
Maximum deliverable voltage	500mA

12.3.9 LAN

MostCare^{Up} LAN connector	
Connector	Female RJ45 with integrated LEDs
Protocol	10/100 Base-TX LAN
Electrical insulation	1.500Vrms 1min

Connection cables: The device has been tested with cable length in excess of 3 m [9.8 ft.].

⚠ **CAUTION:** Data transmitted to the hospital network via WiFi could be intercepted by unauthorized persons, which could result in the loss and/or corruption of sensitive data.

For security reasons, we recommend connecting to the Ethernet only if planning to use the Ethernet communication functionality. When connecting, ensure that the connection takes place with a network that is adequately protected from external intrusion.

12.3.10 WiFi

MostCare^{Up}	
Standard	WiFi IEEE 802.11
Operating frequency	2400 MHz
Bandwidth of receiving section	2412 – 2472 MHz

12.3.11 HDMI

MostCare^{Up} HDMI connector	
Connector	Female A-type

Connection cables: The device has been tested with cable length in excess of 3 m [9.8 ft.].

⚠ **WARNING:** If the device does not meet the safety requirements, this may cause electrical damage and injury to the patient or operator.
The HDMI port is not isolated. Any external device interfacing with MostCare^{Up} must meet the requirements of Standard 60601-1, clause 16, “General requirements for the medical electrical system”.

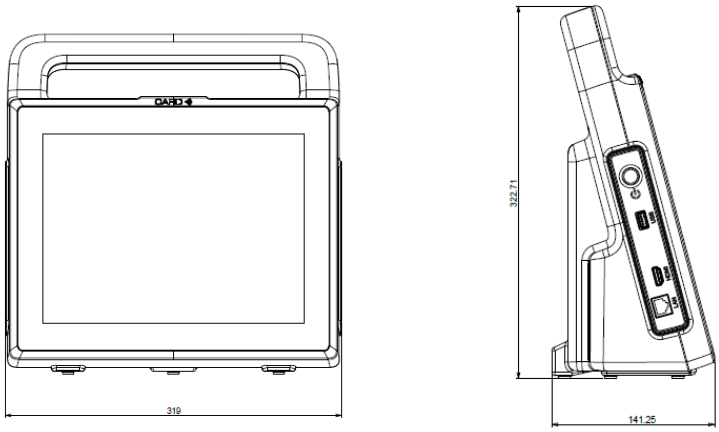
12.3.12 Contactless RFID interface

MostCare^{Up}	
Standard	RFID
Card type	Cards to be specifically used with MostCare^{Up}
Operating frequency and modulation type	13.56MHz, ISO14443A (ASK modulation)

12.4 Mechanical specifications

12.4.1 MostCare^{Up}

Display	12" colour LCD
Resolution	800x600 (SVGA)
Touch	Resistive
Weight	3.6 kg
Width	319 mm [12.5 in]
Height	322.7 mm [12.7 in]
Depth	141.2 mm [5.56 in]



12.5 Electromagnetic compatibility (EMC)

The MostCare^{Up} device requires special precautions in terms of EMC and must be installed and operated in accordance with the following information.

The device is designed to operate within an electromagnetic environment where radiofrequency-irradiated disturbances are under control. If strong electromagnetic disturbances occur, the signal received by the device may be affected by such disturbances; this, however, does not create hazardous circumstances since the device software contains specific features capable of recognising (and discarding as invalid) any data affected by artefacts. The operator using the device can contribute to preventing electromagnetic interferences by ensuring a minimum distance between any mobile and hand-held RF (transmitter) communication equipment and the device, as recommended below, in relation to the maximum output power of the radio-communication equipment.

⚠**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation, leading to an incorrect diagnosis. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MostCare^{Up}, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result, leading to a potentially incorrect diagnosis.

Manufacturer guide and statement - electromagnetic emissions (Table 1)		
MostCare^{Up} is designed for operation in the electromagnetic environment specified below. MostCare^{Up} clients or users should guarantee that the device is used in such environment.		
Emission test	***Compliance***	***Electromagnetic environment***
RF emissions CISPR 11	Group 1	The MostCare^{Up} medical device uses RF energy for its internal operation only. Its RF emissions are therefore extremely low and not likely to cause any interference in the electronic equipment located nearby.
RF emissions CISPR 11	Class A	This medical device is suitable for use in any environment, other than domestic environments and those directly connected to public, low-voltage mains power, supplying buildings used for domestic purposes.
Harmonic emission	Class A	
Voltage fluctuation/flicker emissions	Compliant	

⚠ **WARNING:** Using the device outside industrial areas and hospitals could compromise radio-frequency protection, resulting in injury to patients or operators. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Manufacturer guide and statement - electromagnetic immunity (Table 2)			
MostCare^{Up} is designed for operation in the electromagnetic environment specified below. MostCare^{Up} clients or users should guarantee that the device is used in such environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment***
Electrostatic discharge	± 8 kV contact discharge ± 15 kv air discharge	± 8 kV contact discharge ± 15 kv air discharge	Floors must be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the related humidity must be at least 30%.
Transistors/electrical impulse sequence	± 2 kV for power lines ± 1 kv for input/output lines	± 2 kV common mode ± 1 kv differential mode	The mains voltage quality ought to be that of a typical retail or hospital environment.
Over-voltage	± 2 kV phase (i)-grounded ± 1 kv phase (i)-phase(i)	± 2 kV common mode ± 1 kv differential mode	The mains voltage quality ought to be that of a typical retail or hospital environment.
Proximity magnetic fields	30 kHz (CW), 8 A/m 134.2 kHz (2.1 kHz PM 50%), 65 A/m 13.56 MHz (50 kHz PM 50%), 7.5 A/m	30 kHz (CW), 8 A/m 134.2 kHz (2.1 kHz PM 50%), 65 A/m 13.56 MHz (50 kHz PM 50%), 7.5 A/m	The mains voltage quality ought to be that of a typical retail or hospital environment.
Voltage dips, brief interruptions and voltage variations in the power supply input lines	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The mains voltage quality ought to be that of a typical retail or hospital environment. If the device user requires continued operations also during mains voltage interruptions, we recommend powering the device with uninterruptible power supply or batteries.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage Interruptions	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	

Network frequency magnetic field (50/60 Hz)	30 A/m	30 A/m	Network frequency magnetic fields must be at a level typical of a retail or hospital environment.
NB: Ut is the a.c. mains voltage before the test level application.			

MANUFACTURER guide and statement - electromagnetic IMMUNITY (Table 3)			
MostCare^{Up} is devided to function within the electromagnetic environment specified below. MostCare^{Up} clients or users should guarantee that the device is used within such an environment.			
Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment (Distance between a transmitter and the device)***
Conducted RF Irradiated RF	3 Veff (150kHz÷80MHz) 3 V/m (80MHz÷2,7GHz)	3 Veff 3 V/m (80MHz÷2,7GHz)	Hand-held and mobile RF communication equipment should not be used any closer to any part of MostCare^{Up}, cables included, than the recommended separation distance, calculated via the equation applicable to the transmitter frequency. Recommended separation distance $d = 1{,}17 \cdot \sqrt{P}$ $d = 1{,}17 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2{,}33 \cdot \sqrt{P}$ from 800 MHz to 2.7 GHz Where P is the transmitter maximum nominal output power rating, expressed in W, according to the transmitter manufacturer, and *d* is the separation distance expressed in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic survey on site [a] should be lower than the compliance level in each frequency interval [b] . Interference may occur close to equipment bearing the following label:
NB1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies. NB2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio telephones (mobile/cordless) and mobile land radios, amateur radios, AM and FM radio transmitters and TV transmitters cannot be predicted theoretically with any accuracy. To assess the electromagnetic environment caused by fixed RF transmitters, an on-site electromagnetic survey should be considered. If the field strength detected on the location where MostCare^{Up} is used exceeds the applicable compliance level indicated above, the operations of MostCare^{Up} should be monitored. If abnormal performance is detected, extra measures may be necessary, such as a different orientation or positioning of MostCare^{Up}. [b] Field strength in the frequency range between 150 kHz and 80 MHz should be lower than 3 V/m.			

Recommended separation distances between hand-held and mobile radio-communication equipment and MostCare^{Up} (Table 4)			
MostCare^{Up} is designed for operation in an electromagnetic environment where RF-irradiated disturbances are under control. Clients or users of MostCare^{Up} can contribute to preventing electromagnetic interferences by ensuring a minimum distance between any mobile and hand-held RF (transmitter) communication equipment and MostCare^{Up}, as recommended below, in relation to the maximum output power rating of the radio-communication equipment.			
Maximum rated output power of the Transmitter (W)	***Separation distance for the transmitter frequency (m)***		
	from 150 kHz to 80 MHz	**from 80 MHz to 800 MHz**	**from 800 MHz to 2.7 GHz**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the transmitter frequency, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NB1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.
NB2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection from structures, objects and people.

12.6 Federal Communications Commission (FCC) Compliance Information

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RADIO FREQUENCY (RF) RADIATION EXPOSURE STATEMENT: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This transmitter is considered as mobile device and should not be used closer than 20 cm from a human body. To allow portable use in a known host class 2 permissive change is required.

⚠ **CAUTION:** changes or modifications not expressly approved by the party responsible for compliance could avoid the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

12.7 Useful life

The regulations define "useful life" as the maximum service life period defined by the manufacturer. In order to define service life, the most critical items of the device have been taken into consideration. The useful life of MostCare^{Up} corresponds to **a maximum period of 8 years**.

13. TRADEMARKS

PRAM and MostCare are trademarks of Bio-Si International s.r.l. All other trademarks are the property of their respective owners.

14. WARRANTY

MostCare^{Up} is guaranteed against any material and manufacturing defect for a period of **two years** starting from its installation. This warranty is the only valid warranty and replaces any other expressed or implicit warranty, including any device operation warranty under usage conditions different from those specified in this manual. The suitability of MostCare^{Up} for the use with a specific patient depends on the assessment of the physician in charge only.
In the event of a defect, the distributor will repair the device free of charge or replace it, at their own discretion, keeping the replaced parts, if any. In no case will the distributor be responsible for damage of property, personal damage or any other derived damage except for whatever is strictly foreseen by the applicable law.

Batteries and parts subject to wear and tear are not covered by this warranty, and neither is damage due to natural disasters, accidents, electrical system defects, negligence, improper use or abuse by the operator and damage caused by any repairs performed by unauthorized personnel.
In no case may the customer claim reimbursements for damages due to the machine not being used.

The manufacturer is responsible for the device safety, reliability and performance, provided that:

- Assistance interventions, including battery substitution, are carried out by the manufacturer or personnel authorized by the manufacturer only;
- The electrical system to which the machine is connected complies with IEC regulations;
  The device is used in accordance with the instructions provided in this manual.

15. APPLICABILITY OF THIS MANUAL

This manual is applicable for MostCare^{Up}, and is valid for the following software versions:

- MostCare^{Up} software version: BSIUSG12.xx

The manual is based on the information available at the moment of its publication.
The distributor and the manufacturer do not undertake any obligation to inform the manual owners of any change made after delivering the device. Revisions of this document are available on request in digital format.

16. MANUFACTURER INFORMATION

16.1 Manufacturer

Bio-Si International S.r.l.
Via di Barbacane, 19
50133 Firenze (FI) – Italy
info@bio-si.it

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.