MESI
Simplifying Diagnostics

3 YEAR WARRANTY

MESI mTABLET VITALS Overview

Simultaneously measure key vital parameters and save them automatically on one device.

VITAL SIGNS PARAMETERS MEASURED ON ONE DEVICE

- **Automated blood pressure, SpO2 and temperature.** Contactless and contact (oral, rectal, axillary) thermometer.
- Manual entry of **respiratory rate, pain and ACVPU with a slide** for excellent time savings.
- Automated **NEWS2 S1 Early Warning Score** calculation with warnings.

CONNECTIVITY

- **Wireless** diagnostic modules with 11'' medical tablet.
- **Less administration** with immediate storing into the patient's digital file.
- **Reduced human and clerical errors** due to automated data entry.

Following are the technical information regarding MESI mTABLET, its operating system and accessories provided within the package.

MESI mTABLET

DIMENSIONS	Width	199 mm
	Depth	35 mm
	Height	278 mm
	Weight	800 g
POWER & BATTERY	AC/DC adaptor	FW8030M/05
	Input	100-240V AC / 50-60 Hz / 600 - 300 mA
	Output	5 V DC / 5.0 A
	Battery type	Rechargeable Lithium-Polymer battery
	Capacity	8800 mAh
	Battery operation	More than 8 hours
CLASSIFICATION	Protection against electric shock	Class II equipment
	Medical device classification	Class IIa
	Software safety classification	Class A
LED INDICATIONS MTABDSW	Green LED	Displays connection state (fixed light)
	Orange LED	Represents LAN activity
MTABMD SPECIFICATIONS	OS	MESI OS 1.0 (based on Android OS)
	Processor	CPU Quad ARM Cortex A53 @ up to 1.2GHz per core
	Barcode reader	1D/2D barcode imager
	Screen	1280 x 800 px IPS
	Memory	8 GB
	RAM	1 GB
	Connectivity	Wi-Fi 802.11b/g/n and 2.4 GHz single band Bluetooth 4.1
	Camera	5 MP

	Environment	IP20, 90 cm drop resistant
	Audio	Mono speaker
	Security	2 step authentication - User password or PIN, SMS verification code HTTPS transmission protocol
CONNECTIVITY	Bluetooth 2.1 + EDR	Between MTABMD and diagnostic modules
	Wi-Fi 802.11b/g/n	Between MTABMD and MTABDSW
	10/100 Mbps Ethernet connection	Between MTABDSW and LAN
OPERATING CONDITIONS	Temperature, operating	10° to 40° C
	Relative humidity	25 to 85 % (no condensation)
	Pressure during operation	700 to 1060 hPa
TRANSPORT & STORAGE CONDITIONS	Temperature	15° to 50°C (<1 month) -15° to 40°C (<3 month) -15° to 25°C (<12 month)
	Relative humidity	25 to 85 % (no condensation)
	Air pressure	700 to 1060 hPa

WARRANTY INFORMATION - SYS

A warranty period applies to the device, starting from the date of purchase (delivery date shown on the invoice). Warranty claims will only be valid if accompanied by the purchase receipt.

More details about the warranty can be found in the warranty booklet attached to the instructions for use provided.

EXTENDED WARRANTY AND OTHER MESIcare SERVICES

MESIcare is a service which ensures the flawless operation of the device and all of its accessories (patient cables, AC/DC power supply, stand) for the duration of the warranty period. In addition to flawless operation, the service also includes annual calibrations, the immediate replacement of damaged or destroyed components and software upgrades.

MESIcare services	Extension of the basic warranty for an agreed period.
	immediate replacement of damaged or destroyed components which are not included in the basic warranty.
	Annual calibrations for an agreed period.
	Software upgrades.

Contact your dealer or the manufacturer for more information.

STANDARD COMPLIANCE - SYS

The provisions of the Council Directive 93/42/EEC concerning medical devices were complied with. The standards in the table below were complied with.

Reference number	Description
EN 60601-1:2006/ A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010/ A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006/ A1:2015	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
EN 303 446-1:2017	Electromagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Specific conditions for equipment in residential locations.
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 13485:2012/ AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes

Following are the technical information regarding the MESI BP MODULE, its measurement and tubeless cuff provided within the package.

MESI TUBELESS CUFF UNIT (CUFFMD)

DIMENSIONS	Width	40 mm (1.57 inches)
	Depth	40 mm (1.57 inches)
	Height	150 mm (5.91 inches)
	Weight	286 g
POWER & BATTERY	Battery type	Rechargeable lithium-polymer battery
	Capacity	1240 mAh
	Examinations per battery charge	> 200
CUFF SIZES	Medium size cuffs	Tubeless cuff - Medium - RA Tubeless cuff - Medium - LA
	Circumference	22-32 cm
	Large size cuffs	Tubeless cuff - Large - RA Tubeless cuff - Large - LA
	Circumference	32-42 cm
CLASSIFICATION	Protection against electric shock	Class II equipment
	Medical device classification	Class IIa
	Applied parts	Type BF Applied part
	Software classification	Class B
	RF emissions (CIPSR 11)	Group 1. Class B
OPERATING CONDITIONS	Temperature, operating	10° to 40° C
	Relative humidity	25 to 85% (no condensation)
	Pressure during operation	700 to 1060 hPa
		IP42 Rating

If the device is used or stored outside the specified environmental parameters, the accuracy specified within the technical specifications of the device is not guaranteed.

MEASUREMENT SPECIFICATIONS

Measurements using oscillometry and volume plethysmography:

- Systolic blood pressure
- Diastolic blood pressure
- Heart rate

Measurement range:

- Pressure: 0 to 299mmHg
- Heart rate: 30 to 199 beats per minute

Max deviation:

- Pressure: ± 3 mmHg
- Heart rate: ± 5% of value

CONNECTIVITY

Data connectivity with MTABMD (Bluetooth 2.1 + EDR)

Receiving section	
Frequency range	2401.3 MHz – 2480.7 MHz
Bandwidth	0.930 MHz

Transmitter	
Output power	0.5 – 4.5 dBm
Frequency range	2401.3 MHz – 2480.7 MHz
Modulation	GFSK

TUBELESS CUFFS

The MESI mTABLET BP package includes one Tubeless Blood Pressure Cuff Module, with two medium size tubeless cuffs (left and right arm) for measuring blood pressure, mean arterial pressure (MAP) and heart rate.

Provided tubeless cuffs:

- Right arm – red
- Left arm - yellow

NOTE

Before using the device for the first time, read the instructions for use carefully and follow the recommendations and suggestions. This chapter only includes short instructions for the use of the MESI mTABLET BP.

NOTE

When using the device for taking the blood pressure measurement the patient is sitting comfortably, has the back, elbow and forearm supported.

NOTE

The MESI mTABLET BP is intended for use in professional environment, where measurements must be carried out by adequately trained medical personnel. The MESI mTABLET BP is not intended for home use.

NOTE

This device is not intended for use on neonates, infants, or children under the age of 12 years.

NOTE

The effectiveness of this device has not been established in pregnant, including pre-eclamptic patients.

NOTE

In case of the presence of intravenous cannulas or arteriovenous (AV) fistulas, the cuffs and measurement can cause injury to the limb.

NOTE

This monitor complies with the requirements of ISO 81060-2:2013. In the clinical validation study, K5 was used on 86 subjects for the determination of diastolic blood pressure.

NOTE

This monitor has not been validated for use on pregnant patients.

Following are the technical information regarding the MESI SPO2 MODULE, its measurement and FingerClip Sensor (CS10299) provided within the package.

MESI PULSE OXIMETER UNIT

DIMENSIONS	Width	40 mm (1.57 inches)
	Depth	48 mm (1.89 inches)
	Height	135 mm (5.31 inches)
	Weight	210 g
POWER & BATTERY	Battery type	Rechargeable lithium-polymer battery
	Capacity	1240 mAh
	Examinations per battery charge	> 8000
	Continuous measurement	56h
	Charge time for depleted battery	approximately 2 hours
CLASSIFICATION	Protection against electric shock	Class II
	Medical device classification	Class IIa
	Applied parts	Type BF Applied part
	Software classification	Class B
	RF emissions (CIPSR 11)	Group 1. Class B
OPERATING CONDITIONS	Temperature, operating	10° to 40° C
	Relative humidity	25 to 85 % (no condensation)
	Pressure during operation	700 to 1060 hPa
	Ingress protection rating	IP44

NOTE
The device is protected against the ingress of a solid object greater than 1 mm in size as well as against the harmful effects of spraying water from all sides.

If the device is used or stored outside the specified environmental parameters, the accuracy specified within the technical specifications of the device is not guaranteed.

MEASUREMENT SPECIFICATIONS

SpO_2 measurement range	45 – 100 %
Pulse frequency range	20 – 300 bpm
Plethysmogram	0 – 28 LSB
Raw plethysmogram	0 – 224 LSB
Signal quality	0 – 100 %

NOTE

SPO2MD is calibrated to display functional oxygen saturation.

NOTE

For compliance with ISO 80601-2-61 the temperature has been measured on each SpO_2 sensor with thermocouples (Type K ≤ 0,25 mm wire) procedure. During the measurement, a functional tester FLUKE ProSim 8 with artificial finger setting was used.

Data processing:

Data averaging	normal and 10 % VS
Update period	5 samples per second

Alerts are implemented in MESI mTABLET UNIT and are being used for monitoring oxygen saturation and pulse rate value. It is not intended to be used for monitoring vital signs of the patient.

CONNECTIVITY

Data connectivity with MTABMD (Bluetooth 2.1 + EDR)

Receiving section

Frequency range	2401.3 MHz – 2480.7 MHz
Bandwidth	0.930 MHz

Transmitter

Output power	0.5 - 4.5 dBm
Frequency range	2401.3 MHz – 2480.7 MHz
Modulation	GFSK

SpO_2 SENSORS

The SPO2MD is compatible with the following SpO_2 sensors:

- FingerClip 1.2 m (CS10299)
- FingerClip 2.5 m (CS10299-02)
- EarClip sensor (CS10109)
- SoftTip® Medium (CS10318)
- SoftTip® Large (CS10319)
- Wrap-Sensor (CS10329)
- Y-Sensor (CS10532)

The SPO2MD package includes adult FingerClip Sensor (CS10299) for SpO_2 measurement.

Provided sensor	SpO_2 FingerClip Sensor (CS10299)
Accuracy	The accuracy for the approved sensor according to this standard is given as the root-mean-square difference (Arms) between the measured SpO_2 values and reference SaO_2 values. SpO_2 FingerClip (CS10299): 2,3 % (Arms)
Length of the sensor	SpO_2 FingerClip Sensor (CS10299): 120 cm

QUICK MEASURING GUIDE

NOTE

Before using the device for the first time, read the instructions for use carefully and follow the recommendations and suggestions. This chapter only includes short instructions for the use of the MESI mTABLET SPO2.

The MESI mTABLET SPO2 is not intended for continuous monitoring.

PREPARATION FOR MEASUREMENT

MESI SPO2 MODULE is part of the MESI mTABLET SPO2 system. Before starting a measurement be sure that you are familiar with all devices and their instructions which are part of the system. MESI mTABLET SPO2 is comprised out of MESI mTABLET (MTABSYSW), MESI SPO2 MODULE (SPO2SYS) and MESI LARGE CHARGING PLATE (CS4SYS).

PAIRING WITH MESI mTABLET UNIT

Before any measurements can be performed the MESI PULSE OXIMETER UNIT module needs to be paired to the MESI mTABLET UNIT.

MESI THERMOMETER UNIT (THERMOMD)

Infra-red probe

DIMENSIONS	Width	40mm (1.57 inches)
	Depth	41,6mm (1.57 inches)
	Height	153 mm (7,05 inches)
	Weight	213 g
POWER & BATTERY	Battery type	Rechargeable Lithium-Polymer battery
	Capacity	2x620 mAh
	AC/DC adaptor	NEO030.0-I-X-05
	Input	100-240 V AC / 50-60 Hz / 600-300 mA
	Output	5V DC/5.0 A
	Number of measurements per battery charge	>2500
	Continuous use	19h
	Charge time for depleted battery	approx. 2h
	Number of discharge cycles or years after which a rechargea-ble battery needs to be replaced	500 cycles
CLASSIFICATION	Protection against electric shock	Class II
	Medical device classification	Class IIa
	Applied parts	Type BF applied part
	Software classification	Class B
	RF emissions (CIPSR 11)	Group 1. Class A

OPERATING CONDITIONS

Thermometers have a specific temperature range set by the manufacturer. Using them outside this range can cause inaccurate readings.

Operating temperature	15 to 40 °C
Relative humidity	15 to 90% (no condensation)
Pressure during operation	700 to 1060 hPa
Ingress protection rating	IP42

NOTE

The probe is protected against the ingress of solid objects larger than 1 mm and against vertically falling water drops when the enclosure is tilted up to 15 degrees.

MEASUREMENT SPECIFICATIONS

Distance from measuring point	3 cm
Measurement range	Surface temperature: 34 to 42 °C Body temperature: 36,4 to 43,8 °C
Extended measure-ment range	Surface temperature: 28,6 to 41,2 °C Body temperature: 32 to 43 °C
Accuracy for measurement range	+-0,3 °C
Accuracy for extended measurement range	+-0,4 °C

CONNECTIVITY

Data connectivity with MTABMD (Bluetooth 2.1 + EDR)

Receiving section

Frequency range	2402 MHz – 2480 MHz
Bandwidth	1 MHz

Transmitter

Output power	0 dBm
Frequency range	2402 MHz – 2480 MHz
Modulation	GFSK

TRANSPORT & STORAGE CONDITIONS

Temperature	-25° to 70°C
Relative humidity	15 to 90% (no condensation)
Atmospheric pressure	500 to 1060 hPa (mbar)

The device should be inspected by a qualified service engineer at least every 12 months for the following safety checks:

- Any mechanical or functional damage on the device and accessories
- Performance of device in accordance with the Instructions for Use
- Legibility of warning label
- Battery cycle count

Contact probe

DIMENSIONS

Fi	10 mm (0,39 inches) X 9 mm (0,35 inches)
Length	118 mm (4,65 inches)
Weight	7.5 g

POWER & BATTERY

Battery type	Rechargeable Lithium-Polymer battery
Capacity	15 mAh
Wireless charging from IRT	
Number of measurements per battery charge	>120
Continuous use	2h
Charge time for depleted battery	approx. 2h
Number of discharge cycles or years after which a rechargeable battery needs to be replaced	500 cycles

To prevent electric shock hazards due to current leakage, only use AC/DC power supplies that are compliant with the technical specifications of the device. The AC/DC power supply must be connected to an easily accessible socket (the AC/ DC power supply also serves as galvanic isolation).

CLASSIFICATION

Protection against electric shock	Class II
Medical device classification	Class IIa
Applied parts	Type BF applied part
Software classification	Class B
RF emissions (CIPSR 11)	Group 1. Class A

OPERATING CONDITIONS

Thermometers have a specific temperature range set by the manufacturer. Using them outside this range can cause inaccurate readings.

Operating temperature	10 to 40 °C
Relative humidity	15 to 90% (no condensation)
Pressure during operation	700 to 1060 hPa
Ingress protection rating	IP66

NOTE

The probe is dust-tight and protected against powerful water jets.

If the device is used or stored outside the specified environmental parameters, the accuracy specified within the technical specifications of the device is not guaranteed.

MEASUREMENT SPECIFICATIONS

Measurement range	Surface/body temperature: 34 to 42 °C
Extended measurement range	Surface/body temperature: 32 to 43 °C
Accuracy for measurement range	+-0,1 °C
Accuracy for extended measurement range	+-0,4 °C

CONNECTIVITY

Contact probe BT low energy

Receiving section

Frequency range	2402 MHz – 2480 MHz
Bandwidth	1 MHz

Transmitter

Output power	0 – 8 dBm
Frequency range	2402 MHz – 2480 MHz
Modulation	GFSK

TRANSPORT & STORAGE CONDITIONS

Temperature	-25° to 70°C
Relative humidity	15 to 90% (no condensation)
Atmospheric pressure	500 to 1060 hPa (mbar)

The device should be inspected by a qualified service engineer at least every 12 months for the following safety checks:

- Any mechanical or functional damage on the device and accessories
- Performance of device in accordance with the Instructions for Use
- Legibility of warning label
- Battery cycle count