

FCC ID: PVJ-410000409

General Description

The MobiMed system measures, monitors and stores patients' physiological data such as ECG, Pulse oximetry (SpO₂), Non-invasive blood pressure (NIBP), Respiration and patient information.

A MobiMed system consists of units exchanging information with each other via radio-communication, telecommunications and computer networks.

MobiMed 300c is connected to the patient via the necessary cables and acquires clinical data from patient, such as ECG, SpO₂, NIBP and respiration. The clinical information gathered by MobiMed 300c is transmitted via a Bluetooth link. When MobiMed 300c is used outside, it is normally run off a battery. On one-side of MobiMed 300c are connectors for ECG, SpO₂ and NIBP. All connectors are clearly marked and differ from each other to prevent confusion and facilitate ease of use. The circular contact for a fibre-optic cable is not used.

ECG cables connected to MobiMed 300c are used for collection of ECG and respiration data. The unit automatically detects when cables are connected and the type of ECG cable used (i.e. 10 lead cable, 8 lead cable, 5 lead cable or 3 lead cable). The ECG electrodes are consumable items and are not supplied with the system.

An SpO₂ measuring probe is used with a cable for registering oxygen saturation and pulse rate. NIBP data can be collected as single or periodic measurements by connecting the NIBP cuff to MobiMed 300c. The cuff is attached to the side of MobiMed 300c with a snap-on coupling.

The Bluetooth antenna and power supply connectors are located on the opposite side of MobiMed 300c. The power supply connector also charges the batteries. The connector is specific to MobiMed 300c and prevents connection to non-approved power supplies.

On top of the unit there are three buttons: On/Off, ID, and NIBP start/stop. There are also three light-emitting diodes (LEDs) indicating power on/off, battery status, and external power supply connection.

Technical specification

Classification of medical device

MobiMed 300 is classified as:

- Class IIb according to the Medical Device Directive (MDD).
- Class II according to the Food and Drug Administration (FDA).
- Class III according to Health Canada.

Connections on MobiMed 300c

Connections front:

- ECG: 12-pole, electrically isolated circular contact.
- SpO₂: 5-pole, electrically isolated circular contact.
- NIBP: Circular air nipple.
- Not used: Circular contact for fibre-optic cable.

Connections back:

- Power: 2-pole, circular connector for +12 V DC.

Power supply for MobiMed 300c

Internal battery (Lilon +7.4 V DC; 1.2 Ah) or from an Ortivus-approved external power unit. The internal battery is charged when power is supplied from the external power unit.

Bluetooth radio

Signal strength 1 mW

Frequency range 2.4 GHz ISM band, frequency hopping, 79 channels, 1 MHz spacing

Environmental

Temperature range 0 – 40 °C (32 – 104 °F), operation

-20 – 60 °C (-4 – 140 °F), storage

Air humidity 30 – 95% non-condensing, operation; 30 – 95% condensing, storage

Degree of enclosure protection: MobiMed 300c IP X4 (according to standard IEC 60529,

Degrees of protection provided enclosures.)

Vibration/Shock/Bump MobiMed 300 meets requirements in accordance with EN 1789 (Medical vehicles and their equipment – Ambulances.)

Drop/Free fall Fall test in accordance with EN 1789
(MobiMed 300c only.)

EMC/ESD

MobiMed 300 meets requirements in accordance with:

IEC 60601-1-2 (Medical electrical equipment - Part 1: General requirements for safety - 2.

Collateral Standard: Electromagnetic compatibility – Requirements and tests.)

ISO 7637-1 (Road vehicles – Electrical disturbance by conduction and coupling – Part 1: Passenger cars and light commercial vehicles with nominal 12 V supply voltage - Electrical transient conduction along supply lines only.)