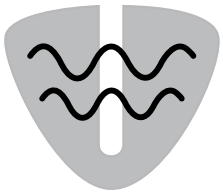

ortivus

MobiMed™ 300

User Manual

SUBSIDIARY/DISTRIBUTOR:

DECLARATION OF CONFORMITY - UNITED STATES ONLY

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

CAUTION:

U.S. Federal law restricts this device to sale by or on the order of a physician.

CE 0413

This manual describes MobiMed 300m, software version 1.01, and MobiMed 300c.

MobiMed 300 User Manual. English edition. Part number 441235481, revision 00. December 2001.

Printed in Sweden.

Production: Merk Produktinformation AB.

Contents

1 System overview

This chapter includes important information that should be read before using MobiMed 300.

1.1 Important

Ortivus only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorised by Ortivus, and
- the electrical installation complies with national standards, and
- installation and configuration of software is carried out by persons authorised by Ortivus, and
- no other software is installed on the system, and
- the equipment is used in accordance with the product documentation.

Any changes or modifications not expressly approved by Ortivus AB could void the user's authority to operate the equipment.

To ensure optimum usage only parts and accessories approved by Ortivus must be used in conjunction with the equipment.

1.2 Intended use

The MobiMed system from Ortivus AB is a cardiac and physiological monitoring system consisting of a portable unit which can communicate with a stationary unit via telecommunications networks.The physiological data includes ECG, SpO_2, NIBP and respiration. The system is intended for use by trained personnel in emergency care and pre-hospital care.

Important: *MobiMed monitoring functions are designed for use on adults and are not intended for use on infants. However, the communication functions and forms can be used to send and receive information about patients of all ages.*

The MobiMed system is not intended for use as life support equipment.

1.3 Using the manual

This manual describes how to operate MobiMed 300 in everyday use. The manual also contains instructions for maintenance and trouble-shooting. Information on technical details and service can be found in a separate technical manual.

All functions described in this manual are not available on all markets.

1.4 Safety requirements

Patient connections are type CF (cardiac floating) defibrillation-protected and are thus marked with the appropriate symbols.

Ortivus approved monitors and keyboards connected to MobiMed 300 meet the relevant IEC standard (e.g. IEC60950 for computer equipment). The person installing external units should ensure that the entire system meets IEC60601-1-1, “Safety requirements for medical electrical systems”.

MobiMed 300c is ETL listed according to UL 2601-1.

MobiMed 300c and MobiMed 300m are designed to run from internal batteries or 12 V DC. They can also be connected to earthed mains via Ortivus-approved power supplies.
N.B. The mains must be earthed.

Limitations on use of *Bluetooth* wireless technology:

- France: The use of *Bluetooth* equipment is not permitted due to restrictions on the use of the frequency band range 2.4000 to 2.4835 GHz.
- Italy: The use of *Bluetooth* equipment outdoors is not permitted.

Important: *Only Ortivus-approved electrodes, cables, hoses and cuffs may be used with MobiMed 300. See “Technical specification” on page 76.*

This symbol means that this manual should be read before anything is connected! The symbol is found on MobiMed 300c.

The equipment should not be used in the presence of explosive gasses.

1.5 Defibrillation

MobiMed 300c can remain connected to the patient during defibrillation. Check whether the patient is connected or in contact to any other equipment that is not defibrillation-protected. If this is the case, disconnect the unprotected equipment before defibrillation.

1.6 Mechanical attachments

Ortivus-approved docking stations or fixing plates should be used to install MobiMed 300m and 300c in vehicles. These should be mounted to avoid any personal injuries, and in accordance with the Ortivus instructions, see Installation Manual. When docking MobiMed 300m in the docking station, ensure that MobiMed 300m is securely locked into the dock.

Important: *MobiMed 300m shall always be placed in the docking station when in the vehicle to ensure that batteries are charged.*

1.7 Other interference and EMC

MobiMed 300 complies with the EMC requirements according to IEC 60601-1-2.

Important: *Precaution must be used when using strong emission sources so that high frequency (HF) cables are not routed on or near the device. If in doubt, contact a qualified technician or your local representative.*

MobiMed 300 is not to be used during HF surgery.

When MobiMed 300m is equipped with a radio modem that sends radio signals similar to those from a mobile telephone keep informed of any local restrictions that apply to the use of this type of equipment.

1.8 Continuous operation - built-in batteries

MobiMed 300m and MobiMed 300c run from built-in batteries. Power recharging units are available as accessories.

MobiMed 300c

Important: *When MobiMed 300c has low battery power, the battery status LED flashes on MobiMed 300c and a warning is displayed on MobiMed 300m. Connect to an external power supply to provide power continuity otherwise the NIBP will stop working and MobiMed 300c will subsequently shut down.*

The charging time for the battery is up to 4 hours. During the time the battery is charging, MobiMed 300c can be used as normal. Battery charging is indicated when the battery status LED is yellow and does not flash.

MobiMed 300m

Low power status for MobiMed 300m is indicated on the screen and by LED indicators on the unit. For information about the battery status indicators on MobiMed 300m, see the accompanying computer manual.

1.9 The MobiMed concept

This section describes the MobiMed concept and the different components in a MobiMed system.

In cases of acute illness, such as myocardial infarction and stroke, a prompt and correct diagnosis, and rapid initiation of correct and individually adapted therapy is essential. The MobiMed system makes it possible to reduce the time for diagnosis and initiation of treatment in many such situations.

The system also provides the opportunity of distributing expert knowledge far out into the care organisation without geographical limitations. In addition, patients can be transported to the best care establishment based on individual need, availability of specialist care and hospital beds. The result is better care for the patient and reductions in overall care costs.

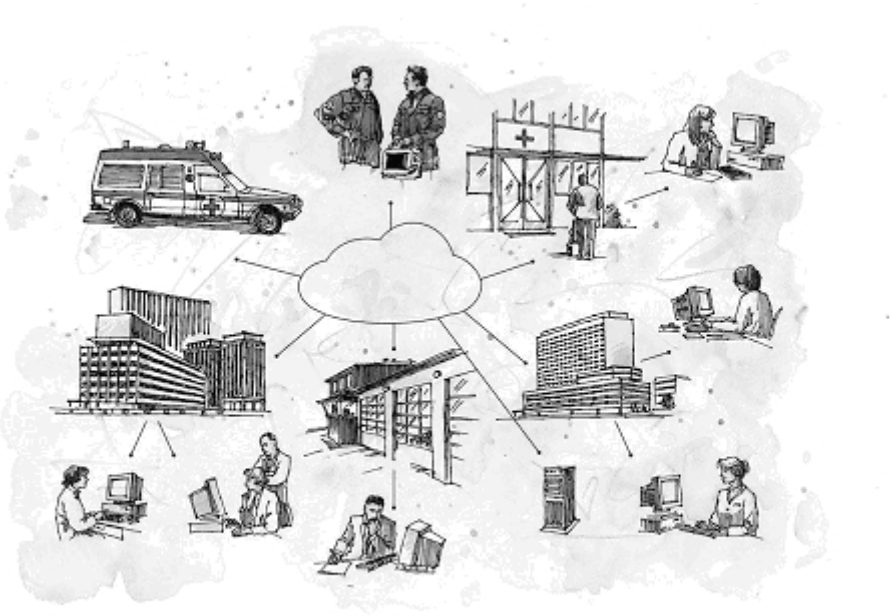

Figure 1. The MobiMed concept

The MobiMed system measures, monitors and stores patients' physiological data such as ECG, Pulse oximetry (SpO_2), Non-invasive blood pressure (NIBP), Respiration and patient information.

1.10 Units in the system

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

The MobiMed system consists of three units, MobiMed 300c, MobiMed 300m and a hospital workstation (HWS). MobiMed 300c and MobiMed 300m together are called MobiMed 300.

MobiMed 300c

MobiMed 300c is connected to the patient via the necessary cables and acquires clinical data from patient, such as ECG, SpO_2, 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. For details about MobiMed 300c hardware and accessories see “Technical specification” on page 76.

Important: *Before using MobiMed 300c check that the battery is adequately charged. If not, connect the unit to a charging source.*

On one-side of MobiMed 300c are connectors for ECG, SpO_2 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.

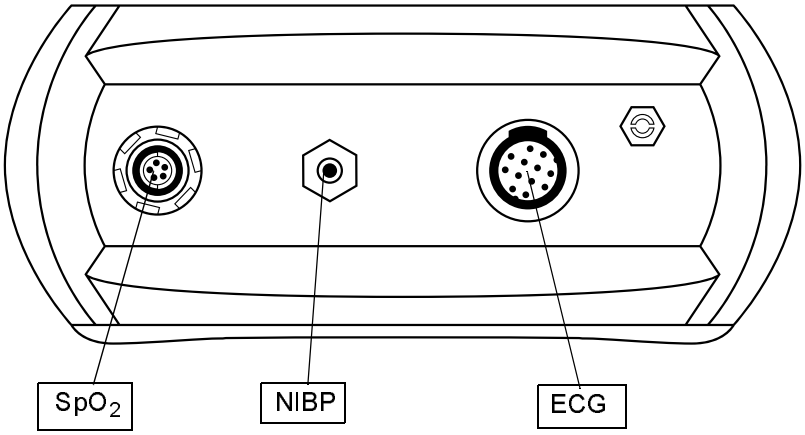

Figure 2. MobiMed 300c front view - connectors

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 SpO_2 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.

Important: *Only use Ortivus-approved cables, cuffs and probes for patient connections, See “Technical specification” on page 76. Other cables may jeopardise the safety of the patient and staff.*

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.

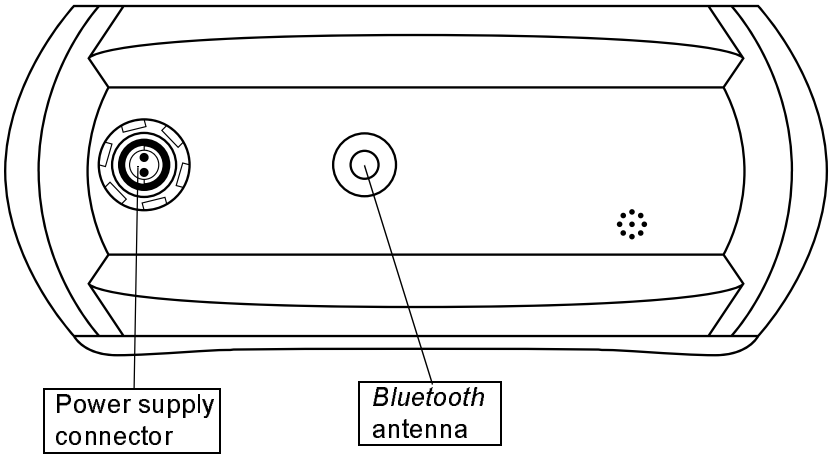

Figure 3. MobiMed 300c back view - power supply

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.

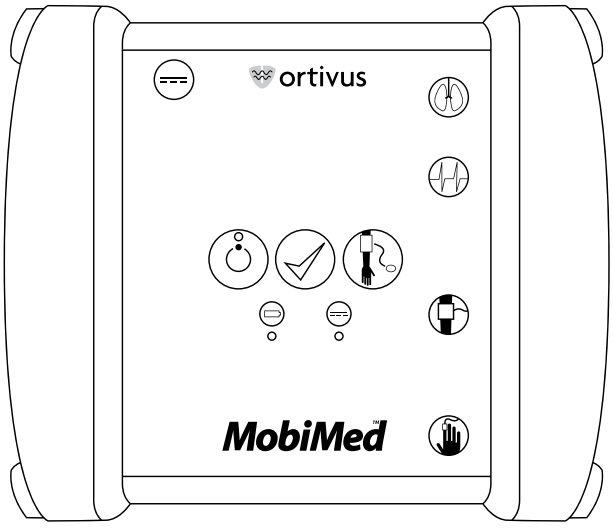

Figure 4. MobiMed 300c - buttons and indicators

Symbols

 Power supply connector

 Fibre optic connector (not used)

 ECG connector

 NIBP connector

 SpO_2 connector

Buttons

 On/Off

 ID

 NIBP start/stop

LEDs

 On/Off

 Battery status indicator. LED below indicator is illuminated if unit is running off battery. Flashes if battery is low.

 External power indicator. LED below indicator is illuminated if unit is running on external power.

Bluetooth communication

Bluetooth replaces communication cables with a short distance radio link. The maximum distance for normal communication between MobiMed 300m and MobiMed 300c is **approx. 5 metres** if no physical obstructions are present.

MobiMed 300m

MobiMed 300m consists of a portable computer and software developed by Ortivus AB. The computer is dedicated to this software and no other programs can be used on the same computer.

MobiMed 300m communicates with MobiMed 300c. Received data is analysed and stored. Real time data is presented on screen as well as averaged data and trend data. It is also possible to enter additional information such as data for patient forms. All such information is also stored. MobiMed 300m communicates with an HWS and data is transmitted. It is also possible to send and receive messages from the HWS.

There is a limit of 4 hours of data storage per patient. After these 4 hours only monitoring of real time data is possible. No new data will be stored and can therefore not be sent to the HWS (this includes Messages and changes to Forms).

For more information about MobiMed 300m (computer hardware and specifications) please refer to the separate computer information folder provided by Ortivus or the computer manual.

Please note:

- Fully charge the battery when using MobiMed 300m away from an external power source.
- To prevent damage to touch-screens, do not use sharp objects or ballpoint pens to make entries on the screen. Use only your finger or the screen stylus.

Important: *Before using MobiMed 300m, close and secure compartment doors and check that the battery pack is adequately charged. If not, connect the computer to a charging source.*

Hospital workstation

The hospital workstation (HWS) stores and presents data at the hospital. It is possible to view patient data for active sessions as well as patient data for sessions stored in HWS archives.

1.11 Using MobiMed 300

While in the vehicle, MobiMed 300m must always be placed in the docking station to ensure that the batteries are fully charged. MobiMed 300c could either be in the carrying bag or placed in the holder. It is important that MobiMed 300c is charged when it has run off batteries.

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2 Getting started

This chapter describes how to get started with MobiMed 300.

2.1 Before a patient care session

1. Check that cables connected to the patient are undamaged, replace damaged cables if necessary.
2. Check that the light emitting diode for low battery power is not blinking on MobiMed 300m or MobiMed 300c. If they are, MobiMed 300m and MobiMed 300c have limited running time and may shut down during the care session.
3. If there is other electrical equipment near the patient or patient cable, there is a risk of interference, which may cause the signal quality to deteriorate. Avoid this as much as possible; see “Other interference and EMC” on page 3.

Important: *Under no circumstances should a damaged ECG cable be used, since this would jeopardise the safety of both patient and staff.*

2.2 Starting MobiMed 300

1. Press the **On/Off** button to start MobiMed 300c. Note that the button must be held in for a moment (approx. 2 seconds). A green LED indicates Power On.
2. If MobiMed 300m is shut down, start the computer.
3. From standby mode press **New patient**.
4. If a MobiMed 300c for the *Bluetooth* connection has not been selected a dialogue to establish connection is displayed. For more information see “Unit connection settings” on page 63.
5. If the log on function is activated this is the first dialogue. It is not possible to proceed without logging on. A new user can be entered here.
6. If no default HWS receiver has been chosen or if communication has been switched off, a dialogue is displayed that enables you to choose a default receiver or turn on the communication.

7. MobiMed 300m displays the monitor view (see Figure 5). Connect the patient to the ECG cable, SpO_2 sensor or NIBP cuff. From this point, monitoring will start when signals from patient are present and communication with the receiving hospital will start automatically.
8. Press **More:Forms** and enter the relevant patient information in the forms.

Important: *If the system administrator has chosen the log on option, it is only possible to start a session after logging on.*

Monitor and workspace view

In the absence of a measuring signal, the corresponding waveform is not displayed but replaced by the one below.

The screen is divided into fields as follows:

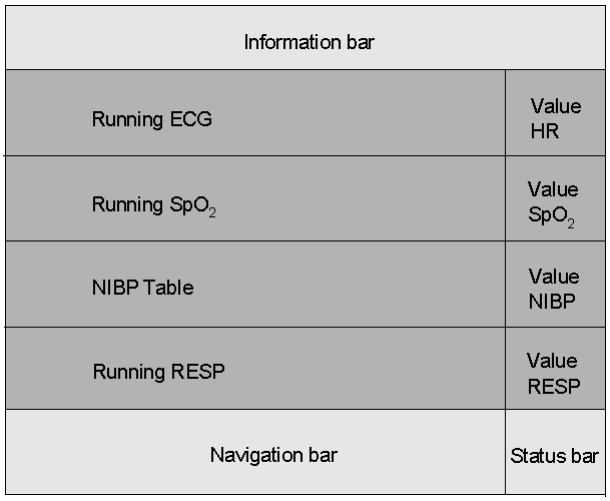

Figure 5. Division of the screen in monitor view

Information bar

The information bar displays and links up to information about the patient, communication information, communication status (available only for Mobitex 8k), system alarms and alarm-sound status.

Figure 6. Information bar

Patient name. The patient's name is displayed on the left of the information bar. By clicking on the patient name you open the forms. For more information about patient forms, see "Forms" on page 55.

Communication information. The following information is sent **automatically** (when MobiMed 300m is configured to do so) to the receiver HWS when communication is established:

- Averaged ECG complexes and rhythm strips.
- Trends.
- Any changes to Forms.

MobiMed 300m displays ***Receiver: Connecting*** when connecting to the receiver HWS. When communication is established, the receiver name is displayed with normal lettering.

As reviewers enter consultation mode (i.e. reviewers select the current session to be displayed on the HWS) their names are presented next to the receiver name.

"Receiver: Reviewer 1, Reviewer 2"

Clicking on the receiver and reviewer names opens the communication settings view, for more information, see "Communication settings" on page 59.

Important: *If the communication is switched off the text* ***Communication off*** *is displayed.*

Communication status icon. The communication status icon is available only for systems using Mobitex 8k. The quality of communication signals is indicated on the communication status icon by the number of filled bars. By clicking on the communication status icon you are connected to communication settings view, See "Communication settings" on page 59.

Short alarm texts. Display the system alarms. Click on the messages for more information in the pop-up dialogues.

Alarm sound icon. It is possible to switch on/off the alarm sound by clicking on the alarm sound icon.

On-screen keyboard icon. It is possible to open the on-screen keyboard by clicking on the icon.

Navigation bar

The menu options for MobiMed 300m can be accessed from the navigation bar. For more information about navigation and menu options see “Navigation” on page 17.

Figure 7. Navigation bar

Status bar

In the status field current time and power sources (battery or mains icons) are shown. By clicking on the icon the power status information is displayed (see Figure 8) with the following:

- Whether external or battery power supply is used.
- Battery power status (%).

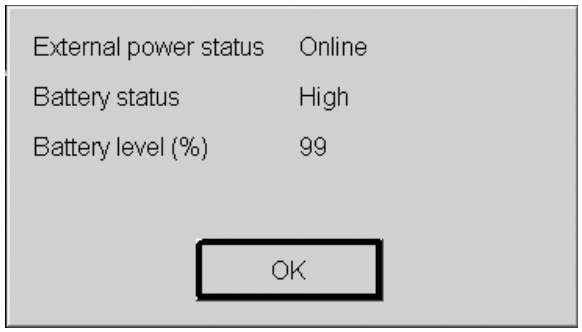

Figure 8. Power status information

Parameter data

The parameters are displayed in order of priority (ECG, SpO_2, NIBP and Resp). Clicking on a parameter data field opens the settings view for the selected parameter. ECG, SpO_2 and Resp values are updated every second and reflect the current situation. If no measurement can take place, invalid parameter values are indicated by --. The NIBP parameter value reflects the latest measurement that succeeded.

A crossed over bell in the upper right corner of a parameter data field indicates that all clinical alarms for that parameter are turned off.

Waveform area

Displays the current waveforms and a table of blood pressure measurements.

- **ECG waveform**

Displays the ECG waveform, the selected rhythm lead and a 1 mV scale bar.

- **Saturation waveform (SpO_2)**

Displays the plethysmographic pulse waveform.

- **NIBP table (Non-invasive blood pressure)**

Displays the values and times of the latest 12 measurements.

- **Respiration waveform**

Displays the respiration waveform.

Workspace

Information presented in the workspace (see Figure 9) includes Trends, ECG complexes, Messages and such that are accessed from the navigation bar menus.

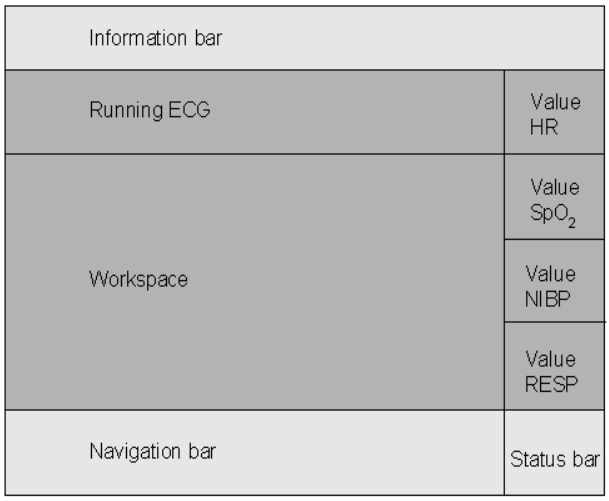

Figure 9. Screen layout with workspace view

2.3 Alarms

System Alarms

System alarms are presented as dialogues when problems arise with the system. After a dialogue is acknowledged the system alarm is visible as short text message on the information bar between the communication status icon and the alarm sound icon. For more information about the causes of system alarms and troubleshooting, See “Troubleshooting” on page 68.

Parameter Alarms

Alarms connected to parameters are classified as being either clinical (*) or technical (#). For more information about the alarms, priority and messages see the Alarms sections for the individual parameters.

Clinical Alarms

A clinical alarm is activated when a patient’s data deviates from the set limit for a measured parameter. For more information see the Settings sections for the individual parameters.

- ***High priority*** **(***)**

The alarm message is displayed in the relevant parameter waveform area with a flashing **red text**. The alarm message continues to flash and alarm sound is activated until the **Silence Alarm** button is pressed (even though the cause of the alarm is over). After 1 minute, the alarm will be activated again unless the cause of the alarm is over. The system may be set-up not to require **Silence Alarm** command to silence a (***) alarm. If so, the alarm message and sound will disappear when the cause of the alarm is over.

- ***Medium priority*** **(**)**

The alarm message is displayed in the parameter waveform area with a flashing **yellow text**. The alarm message continues to flash until the cause of the alarm is over.

The alarm sounds **three** times.

- ***Low priority*** **(*)**

The alarm message is displayed in the parameter waveform area with a flashing **yellow text**. The alarm message continues to flash until the cause of the alarm is over. No alarm sound.

Technical alarms

- ***High Priority (##)***

The alarm message in **white** is displayed in the parameter waveform. The message is displayed until the cause of the alarm is over. The alarm sounds **three** times.

- ***Low Priority (#)***

The alarm message in **white** is displayed in the parameter waveform. The message is displayed until the cause of the alarm is over. **No** alarm sound.

Silence alarms

Pressing button **Silence alarms** or **Esc** or **F2** silences alarms with equal or lower priority than the alarm currently sounding for 1 minute.

2.4 Navigation

The menu options for MobiMed 300m can be accessed from the navigation bar. Figure 10 below illustrates the different views that can be accessed as a menu tree. The buttons on the left column in the diagram correspond to the navigation bar buttons.

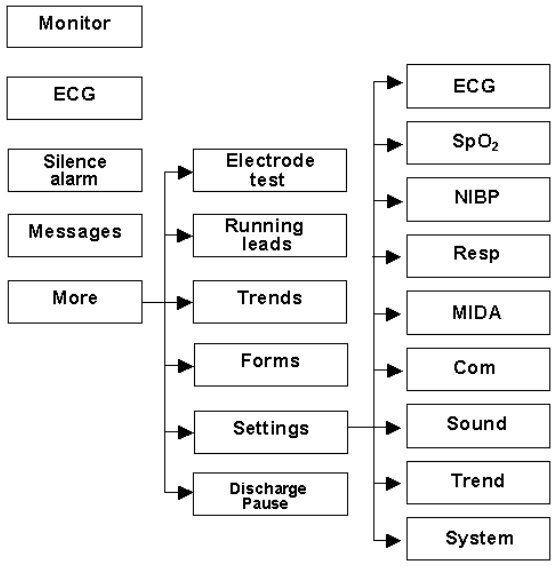

Figure 10. Menu tree

System navigation

It is possible to navigate the system with a keyboard or with the touch-screen display.

If a keyboard is attached to MobiMed 300m, it is possible to navigate the system and make menu selections by using the ARROW and TAB keys. Press ENTER or the SPACE BAR to make choices.

The functions keys act as short-cuts to different views or commands.

- **Esc** Silence alarm.
- **F1** NIBP measurement - start / stop.
- **F2** Silence alarm.
- **F5** Monitor view.
- **F6** ECG view.
- **F7** Messages view.
- **F8** More menu.

2.5 Discharge and Pause

When a patient is delivered to hospital or monitoring ceases, the care session must be closed. It is very important that this takes place after each care session.

Important: *Care sessions must be closed correctly to prevent mixing of patient data.*

2.5.1 Discharging a patient and Standby mode

To discharge a patient press **More:Discharge/Pause**. Selecting **Discharge patient** from the pop-up menu ends the current care session. Thereafter, MobiMed 300 enters standby mode. While in standby mode, MobiMed 300m displays a pop-up dialogue (see Figure 11) with the choice **New patient, Retransmit, Setup, Communication on, Communication off, 300c connection, Service** and **Shutdown**.

Service mode is for service and education only. The other seven commands are described below.

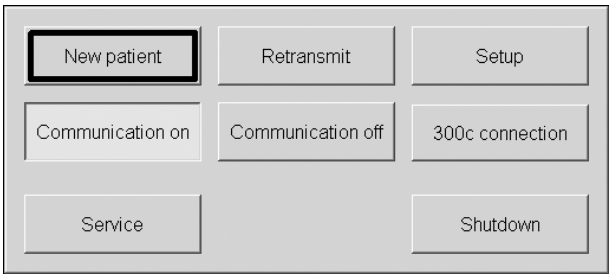

Figure 11. Standby menu when MobiMed is in standby mode

New patient
Select **New patient** to start a new session.

Retransmit
Select **Retransmit** to initiate a backup of previously recorded sessions. For more information about this function see “Retransmit” on page 61.

Setup
Select **Setup** to access the login view to the system settings.

Communication on/off
Select **Communication on** or **Communication off** to switch communication on or off.

300c connection
When **300c connection** is pressed, the unit connection view is displayed from which *Bluetooth* address can be selected and units scanned for. For more information see “Unit connection settings” on page 63.

Shutdown
When **Shutdown** is pressed, a dialogue appears and asks for confirmation to shut down the system.

Important: *Remember to switch off MobiMed 300c and recharge the batteries of both units after the care session is closed.*

Never press the Power off button on the computer to shut down MobiMed 300m. This could hazard the future functionality of the system.

2.5.2 Pause

Pressing **More:Discharge/Pause:Pause session** stops ECG, SpO_2, Respiration and NIBP measurement, it also locks the keyboard. Note that, the care session is still active. In the workspace area, a dialogue box is displayed indicating that the program has been paused. Pause mode can be cancelled by pressing **Resume**.

3 ECG

The ECG values are collected automatically as soon as a correct measurement signal is detected. ECG data is collected with following ECG cables; 10 lead, 8 lead (Frank vector), standard 5 lead and 3 lead cables. MobiMed 300c automatically detects what type of cable is connected.

MobiMed 300 uses Myocardial Ischemia Dynamic Analysis (MIDA) to create analyses of complexes in the ECG and Trend views. For more information about MIDA, see “MIDA” on page 83.

Figure 12. ECG rhythm and HR value

The ECG data field (see Figure 12) displays the ECG waveform together with the selected rhythm lead and a 1 mV scale bar. To the right, the current heart rate and the alarm limits are displayed. The alarm limits are not displayed when the HR alarm is switched off.

3.1 ECG measurement

Skin preparation

Before the electrodes are placed on the patient, the skin should be prepared for the best possible electrode contact. Clean the skin if necessary. Shave hair from the relevant electrode positions and clean the areas from dead skin by roughening with sandpaper.

Electrode placement

Figures 13, 14, 15 and 16 below show electrode placement according to **IEC** and **ANSI/AAMI** standards. Note that it is important that all electrodes are of the same type and not too old (see the “use before” date on the electrode package).

Important: *Only Ortivus-approved ECG electrodes and ECG cables may be used with MobiMed 300. See “ECG specifications” on page 76.*

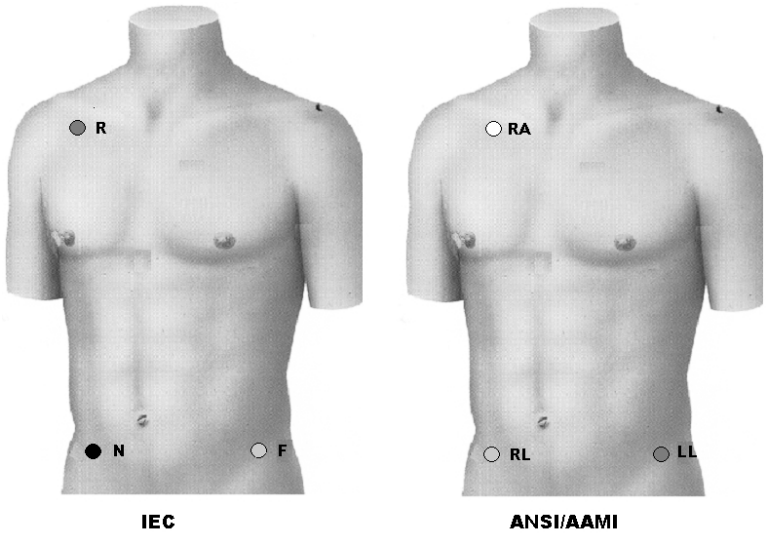

Figure 13. Electrode placement 3 lead cable

IEC		ANSI/AAMI		Placement
R	Red	RA	White	On the upper part of the right side of the chest just below the clavicle
F	Green	LL	Red	On the left hip bone
N	Black	RL	Green	On the right hip bone

Important: *Since this lead configuration is used for arrhythmia monitoring the lead placement can be changed to get a proper ECG signal. Please note that changing the positions of the R (RA) and F (LL) electrodes may affect the quality of respiration measurements.*

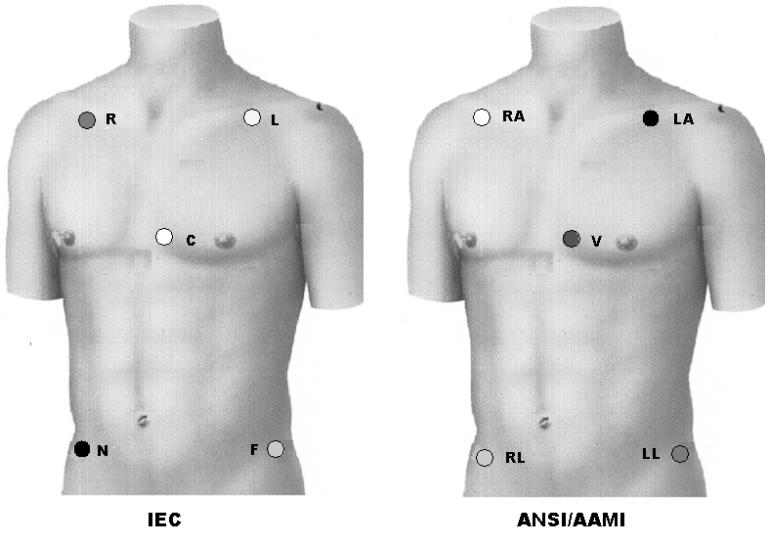

Figure 14. Electrode placement 5 lead cable

IEC		ANSI/AAMI		Placement
L	Yellow	LA	Black	On the upper part of the left side of the chest just below the clavicle
R	Red	RA	White	On the upper part of the right side of the chest just below the clavicle
F	Green	LL	Red	On the left hip bone
N	Black	RL	Green	On the right hip bone
C	White	V	Brown	Any V-lead position

Important: *For respiration measurement with 5 lead cable and 4-wire method, the C (V)-electrode should be placed close to the C4 (V4)-position.*

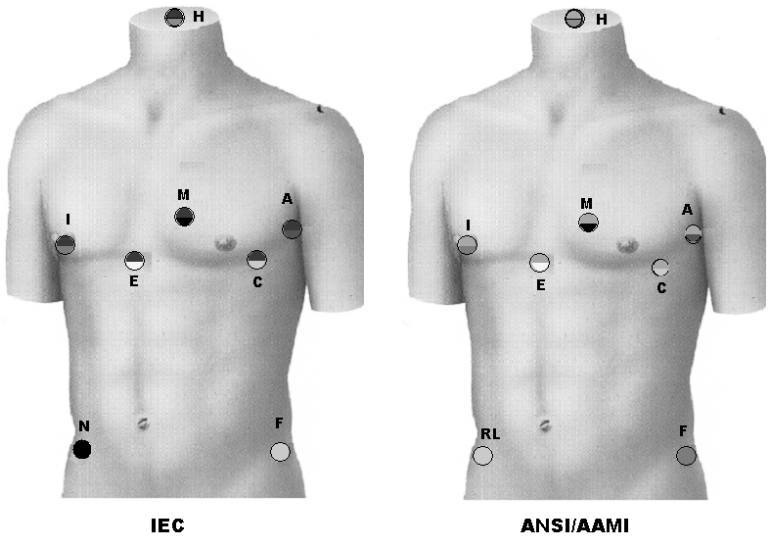

Figure 15. Electrode placement 8 lead cable (Frank)

IEC		ANSI/AAMI		Placement
H	Blue/ Purple	H	Orange/ Purple	On the neck
E	Blue/ Yellow	E	Orange/ Yellow	On the sternum at the fifth intercostal space
C	Blue/ Green	C	Orange/ Green	Midway between E and A
M	Blue/ Black	M	Orange/ Black	Opposite to E in the back next to the spine
A	Blue/ Brown	A	Orange/ Brown	In the midaxillary line on left side at the same height as E
I	Blue/ Red	I	Orange/ Red	In the midaxillary line on right side at the same height as E
F	Green	F	Red	On the left hip bone
N	Black	RL	Green	On the right hip bone

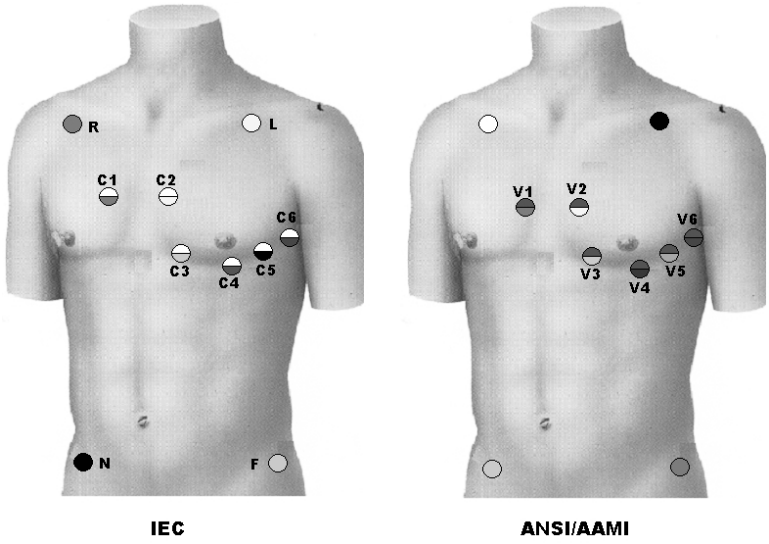

Figure 16. Electrode placement 10 lead cable (12 lead ECG)

IEC		ANSI/AAMI		Placement
L	Yellow	LA	Black	On the upper part of the left side of the chest just below the clavicle
R	Red	RA	White	On the upper part of the right side of the chest just below the clavicle
F	Green	LL	Red	On the left hip bone
N	Black	RL	Green	On the right hip bone
C_1	White/ Red	V_1	Brown/ Red	Over the 4th intercostal space, just to the right of the sternum
C_2	White/ Yellow	V_2	Brown/ Yellow	Over the 4th intercostal space, just to the left of the sternum
C_3	White/ Green	V_3	Brown/ Green	Midway between C_2 and C_4
C_4	White/ Brown	V_4	Brown/ Blue	Over the 5th intercostal space along the left mid-clavicular line
C_5	White/ Black	V_5	Brown/ Orange	The same height as C_4, on the left anterior axillary line
C_6	White/ Purple	V_6	Brown/ Purple	The same height as C_4, on the left midaxillary line

Important: *The extremity electrodes R (RA) and L (LA) can be placed on the wrists and N (RL) and F (LL) can be placed on the ankles, however, by doing this respiration measurements are affected.*

3.2 Pacemakers

The pacemaker mode is activated in the ECG settings view, see “ECG settings” on page 31. To select pacemaker detection press the **Pacemaker** button. Pacemaker detection is indicated in the upper left of the ECG waveform beside the indicator for the current ECG lead. When pacemaker spikes are detected they are displayed as vertical bars in the waveform, see Figure 17.

Figure 17. Pacemaker detection

Important: *Some pacemaker pulses can be difficult to find. If MobiMed 300 cannot recognise pacemaker pulses, they may be detected as QRS-complexes, which can give wrong HR-value. Therefore, pacemaker patients need to be under careful supervision.*

Respiration measurement by the impedance method should not be made on patients with pacemakers/ICDs that use impedance measurement to control rate-response function since it may affect the function of the pacemaker/ICD.

3.3 Electrode test

The Electrode test function is used for checking the signal quality from the ECG leads. Access the Electrode test function by pressing **More:Electrode test**.

The Electrode test view (Figure 18) is divided into two sections. To the right, a torso is displayed with the electrode positions. To the left, the waveforms for all the electrodes are displayed.

Figure 18. Electrode test view

Important: *The Electrode test view is not intended for diagnosis.*

The ECG amplifier in MobiMed 300c measures whether the contact between the electrodes and the patient is good enough to register ECG signals. If this is not the case, a **warning text** is displayed on the relevant waveform and the colour code on the torso display changes from **green to either yellow or red**.

If a warning text is displayed, check the electrodes and clips carefully. Noisy or poor signals may be due to poor electrode contact. Check that the skin has been prepared properly. For more information, see section “ECG measurement” on page 21. Electrodes may dry out due to being left in open packaging for too long. Check that the storage times stated by the electrode manufacturer have not been exceeded.

Important: *Movements by the patient can cause interference with the ECG.*

Electrodes

A description of how to place the electrodes with the chosen cable set is available by pressing **Electrodes**.

3.4 ECG view

The ECG view displays (see Figure 19) averaged ECG complexes together with a rhythm strip. The field to the right is for navigating the view. Updates of the averaged ECG complexes and rhythm strip are

sent to the HWS automatically or manually, according to the system configuration.

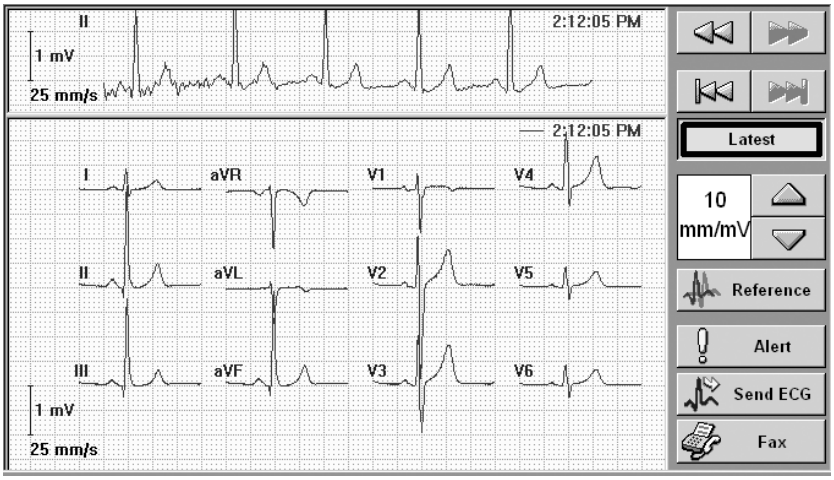

Figure 19. ECG view

Rhythm strip

The rhythm strip displays the lead active in the ECG waveform. The end time of the rhythm strip is displayed in the upper right corner. Pacemaker spikes are only presented in the rhythm strip when the pacemaker option is selected, see “Pacemakers” on page 26.

Important: *ST analysis cannot be performed on information from the rhythm strip due to filter interference.*

ECG complexes

This area presents the most typical ECG complexes recorded during the previous minute.

The complexes displayed in the ECG complex view include true 12 lead ECG (10 lead cable), derived 12 lead ECG (8 lead cable) or limb-leads and one V-lead (5 lead cable). The 3 lead cable gives no complex view. If there are no ECG complexes available, this is presented as a text string. The time at the end of the measuring period is displayed in same colour as the complex in the upper right corner of the area.

When the reference complex is activated, the reference complex time is displayed under the current complex time in upper right corner of the area.

Important: *Information presented from the derived 12 lead ECG (8 lead cable) might differ from the standard 12 lead ECG (10 lead cable).*

Pacemaker spikes are not indicated in the averaged ECG complexes. They are indicated in the rhythm strip if pacemaker mode is activated see "Pacemakers" on page 26.

Navigational area

The two uppermost buttons are for scrolling backward and forward in time in the rhythm strip. Below these buttons are buttons for navigating between complexes. Under the navigating buttons is a spin control for setting the gain (5, 10, and 20 mm/mV) on the rhythm strip and the complexes.

The **Latest** button is used to view the **most recent complex**. Note that the **Latest** button is pressed by default.

The **Reference** button displays the **first complex** as an overlay. The button is disabled when the reference complex has another source, i.e. ECG cable, than the current complex.

It is possible to send ECG data for the current time focus manually (even if the periodic transmitting choice has been selected) by pressing the **Send ECG** button. An alert is sent by pressing the **Alert** button.

Important: *Pressing the **Send ECG** button to update the ECG information is recommended only when the user has an important observation to report.*

When Mobitex 1200 is used, only the last seconds of the Rhythm strip is sent to the HWS.

The **Fax** button opens the fax function dialogue if the optional fax has been installed, see "Fax" on page 67.

3.5 Running leads

Running leads view (Figure 20) displays the true 12 lead ECG (10 lead cable), derived 12 lead ECG (8 lead cable) or limb-leads and one V-lead (5 lead cable) in real-time. If no ECG cable or 3 lead cable is applied, this menu cannot be accessed. The name of the lead is placed at the left side over each lead diagram. Press **Limb leads** or **Chest leads** to choose which leads to display. **Chest leads** is selected by default.

Important: *Information presented from the derived 12 lead ECG (8 lead cable) might differ from the standard 12 lead ECG (10 lead cable).*

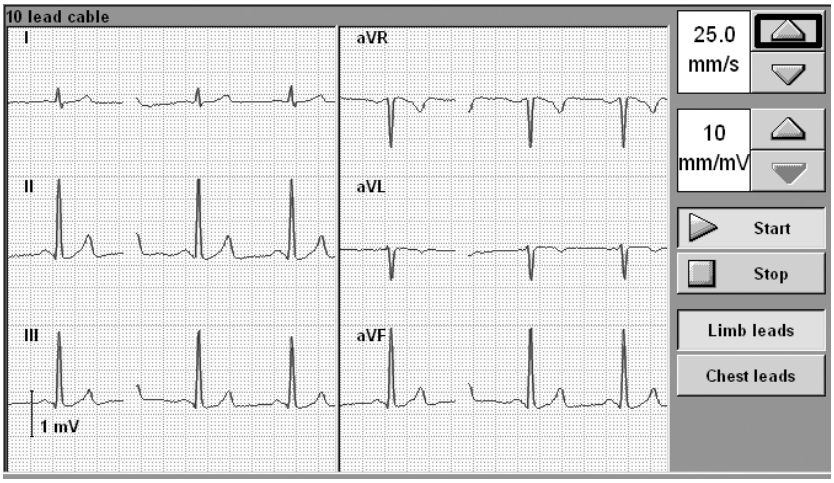

Figure 20. Running leads view

The sweep speed can be set to 12.5, 25 or 50 mm/s and the gain can be set to 10 or 20 mm/mV. The presentation can be frozen by pressing, **Stop** and restarted by pressing, **Start.**

3.6 ECG alarms

Clinical alarms

Alarms are generated from ECG when heart rate deviates from the upper and lower limits that are displayed below the parameter value. The No Heart Rate alarm is activated if no heartbeat is detected within a period of 5 seconds.

Message	Priority
No beat	***
HR low <	***
HR high >	***

Technical alarms

Message	Priority
No ECG cable	##
No HR calculation	##
Bad signal	##
ECG learning	#

The *No HR calculation* message indicates that no QRS detection can be done. If so, check signal quality in the Electrode test view.

The *ECG learning* message is displayed when the MobiMed system is learning to find the QRS-complexes in the ECG signal. A learning period lasts for 10 seconds. If a learning period fails, a new one is automatically started and the *ECG learning* message remains.

If the *ECG learning* message does not disappear within a minute after the ECG cable has been applied, check for signal quality in the Electrode test view.

3.7 ECG settings

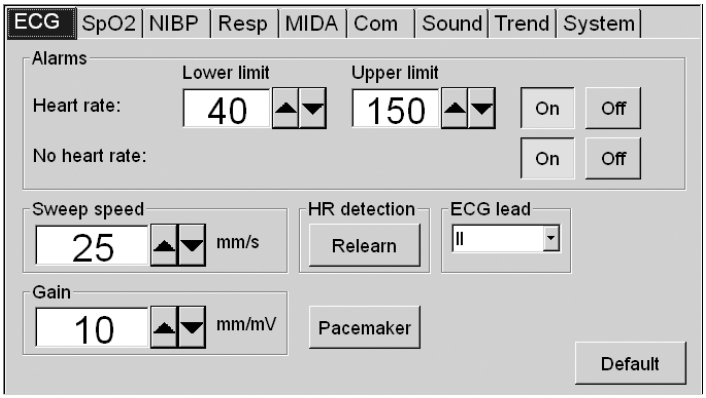

Figure 21. ECG settings

ECG settings (Figure 21) can be accessed by pressing **More:Settings:ECG** or by clicking on the ECG parameter data in the monitor view.

The upper and lower alarm limits for heart rate are set in the ECG settings view. An alarm for *No heart rate* can be activated/deactivated.

The selections for Sweep speed and Gain only affect the ECG waveform presented in monitor view. The ECG lead can be selected for the active lead set. The pacemaker option can also be selected. Selecting the **Relearn** button initiates a relearn of the HR detection.

To return to the default settings select the **Default** button.

3.8 MIDA alarms

Technical alarms

MIDA alarms are displayed in the ECG waveform area; for more information see “MIDA” on page 83. The technical alarms indicate if no MIDA analysis can take place i.e. no ECG complexes for further trend calculations are created.

Message	Priority
Selecting dominant beat	#
No ST analysis	#

The message *Selecting dominant beat* is displayed while the system identifies the normal beat of the patient. This is done when the patient is hooked up and should not take more than 30 seconds after all electrodes have been attached and the signal quality is good. Check the signal quality with the Electrode test view unless the *Selecting dominant beat* message disappears.

The *No ST analysis* message indicates that no average complex was created when expected. The reason could be bad signal quality; lead failure or that the normal beat of the patient has changed rapidly. Check signal quality in the Electrode test view. For more information about **Relearn MIDA** in the MIDA settings, see “MIDA settings” on page 32.

3.9 MIDA settings

MIDA (**M**yocardial **I**schemia **D**ynamic **A**nalysis) trends are used in MobiMed 300 to monitor the normal ECG complex of the patient. Rapid changes of the normal beat may cause MobiMed 300 to loose track of the normal beat, consequently, no ST-analysis takes place. In this situation, the “Relearn” option should be used, see Figure 22. MobiMed 300 then clears the previous template for a normal beat and creates a new one based on current ECG. MIDA alarms are displayed in the ECG waveform area. For more information see “MIDA” on page 83.

To relearn MIDA select, **Settings:MIDA:Relearn**. The status area is cleared before the command is sent and notification is given if the system fails to find a new template beat.

If MIDA status settings are changed, the status text is updated. If no cable or a 3 lead cable is connected, the “Relearn” button is disabled.

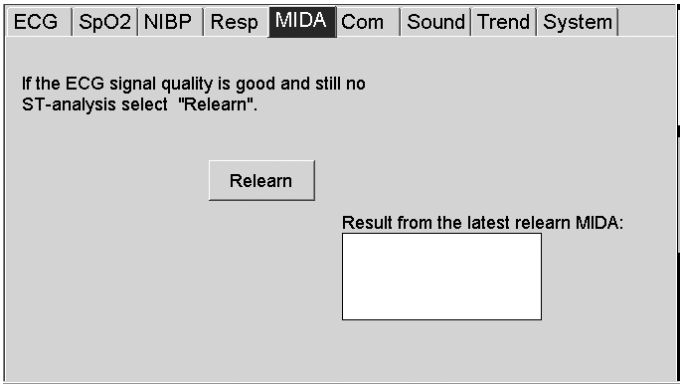

Figure 22. MIDA settings

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4 Pulse oximetry and pulse

The SpO_2 function measures the oxygen saturation of the arterial blood and pulse rate. It also presents a plethysmographic pulse waveform. The saturation value is represented as the percentage of oxygenated haemoglobin in relation to the total haemoglobin.

The running plethysmographic pulse waveform is drawn from left to right. The label “SpO2” is displayed together with current SpO_2 value and pulse value (Figure 23).

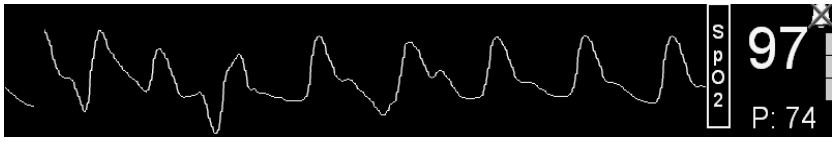

Figure 23. Plethysmographic pulse waveform and SpO_2

Important: *The waveform is displayed with automatic scaling and therefore cannot be used to determine the signal quality. Signal quality is displayed to the right of the parameter data in a bar diagram.*

The current signal quality is displayed as a vertical bar to the right of SpO_2 value. The signal quality has three different levels:

- **Three green** sections indicate **high** signal quality.
- **Two yellow** sections indicate **medium** signal quality.
- **One red** section indicates **low** signal quality.

If the saturation value cannot be measured, the symbol for invalid value is presented (- -).

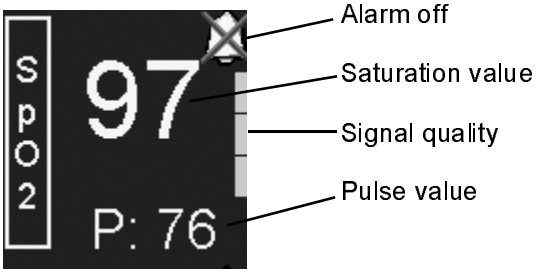

Figure 24. SpO_2 Parameter data

4.1 SpO_2 and pulse measurement

To start SpO_2 measurement, connect the Xpod and sensor to MobiMed 300c. Detection follows automatically.

Important: *Only Ortivus-approved SpO_2 sensors and extension cables for SpO_2 sensors may be used with MobiMed 300, see "SpO2 specifications" on page 77.*

Probe placement

Place the probe on the index finger with the cable on the upper side of the finger. Check the position for the sensor. If the probe cannot be positioned correctly, or an index finger is not available, a smaller finger can be used. Do not use a thumb or toe or place across a child's hand or foot.

When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intra-vascular infusion line.

Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements. The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

If the sensor does not track the pulse reliably, the skin may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occurs, reposition the sensor.

4.2 Warnings/Interference

For the SpO_2 measurement to work requires that:

- the sensor is applied to a finger with adequate peripheral circulation.
- the patient has nominal concentrations of carboxyhaemaglobin (COHb) and methemoglobin (MeTHb).
- the sensor temperature is between 28 and 42 °C (82.4 - 107.6 °F).
- no strong light sources, compared to normal lighting, are near the sensor. This may cause light interference. Protect the sensor from light sources by covering it.
- the patient must not move too much. This can cause interference.

Do not allow the sensor to stay in one place for too long. It should be moved every 4 hours to ensure precise monitoring.

Important: *Pulse oximetry can interfere with Magnetic Resonance analysis (MR).*

4.3 SpO_2 and pulse alarms

Clinical alarms

Message	Priority
Sat low <	***
Sat high >	**
Pulse low <	***
Pulse high >	***

Technical alarms

Message	Priority
No sensor	##
Sensor off	##
Bad signal	##

4.4 SpO_2 settings

The SpO_2 settings view (see Figure 25) can be accessed by selecting **More:Settings:SPO2** or by clicking on the SpO_2 parameter data in the monitor view.

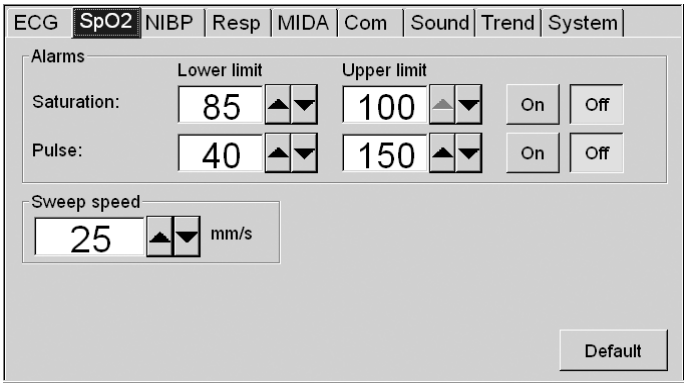

Figure 25. SpO_2 settings

In the SpO_2 settings view the upper and lower alarm limits can be set for pulse and saturation. The alarms can be activated/deactivated and the sweep speed can be set. To return to the default settings select the **Default** button.

5 Blood pressure

Non-invasive blood pressure (NIBP) measurements values are taken periodically or as single measurements with the NIBP function. Measurement is taken oscillometrically during the inflation of the cuff. The maximum time the NIBP-cuff can be inflated is 2 minutes.

The NIBP data (Figure 26) is presented as table in the waveform area of the monitor view. The table displays the time of the measurement, the systolic and diastolic pressures and the mean blood pressure in parentheses.

Figure 26. NIBP table

Information about the most recent NIBP measurement is displayed in parameter area. The time of measurement is indicated. For periodic recording, “interval” or “STAT” is indicated.

5.1 Before NIBP measurement

Please check the following before measurement

- Measurements should not be taken from patients with an increased disposition to hemorrhaging.
- Measurements should not be taken on infants or small children.
- Measurements should not be taken from the same extremity that intravenous infusions or catheters are placed.
- Prolonged repeated measurements on an extremity may be associated with purpura, neuropathy and ischaemia. Therefore, check that the extremity has sufficient blood, and normal colour, warmth and feeling.
- Patients with the risk of blood clots should not be subjected to continuous measurements.
- Measurements may be unreliable in patients who are in serious shock (or hypothermia) since blood flow in the extremities is limited.

- Measurements cannot be carried out when the patient's pulse is below 30 bpm, or above 300 bpm.
- Measurements on obese patients may be impaired or inaccurate since the fat layer muffles the signals.
- Measurements cannot be carried out if the patient is connected to a heart-lung machine.
- Rapidly changing blood pressure values or arrhythmia during the measurements may prolong or prevent measurement.
- Physical disturbance to the compressed air system (cuff, hose or MobiMed 300c), or patient movement may affect measurement accuracy or prevent measurement.
- Thrombosis and anatomical variations may affect the NIBP values.

5.2 Selection and placement of the cuff

Important: *Only Ortivus-approved NIBP-cuffs and extension hose for NIBP-cuffs may be used with MobiMed 300, see "NIBP specifications" on page 77.*

It is important that the correct cuff size is selected so that the patient is not harmed, and so that the accuracy is as great as possible.

Circumference:	Cuff:
18-26 cm	Small adult size
25-35 cm	Adult size
33-47 cm	Large adult size

The cuff is connected using a nipple on the side of MobiMed 300c.

Measurements should preferably take place on bare skin. If the cuff is applied over clothing, the measurement values may be erroneous. The hose from the cuff should sit over the artery where measurement is taking place. The position is also marked with a circle with a line through it (see 1 in Figure 27).

The cuff is marked to indicate the limits within which the circumference may vary (see 2 in Figure 27). The cuff must close within this marking when it is around the extremity.

The cuff is fastened around the extremity so that approximately two fingers can be accommodated in the intervening space.

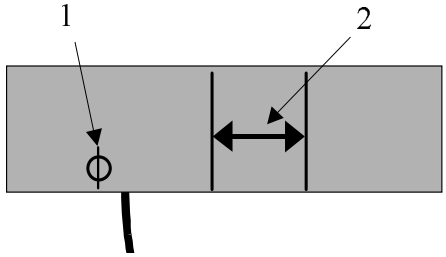

Figure 27. The cuff

To obtain accurate measurements, the point of measurement should be kept at the same height as the heart. Measurements taken above the height of the heart gives lower values, and measurements taken below the heart level give higher values.

Neither the hose nor the cuff may be subjected to any physical influence when measurement takes place, for which reason the extremity should rest on a pillow or the like.

5.3 Start an NIBP measurement

The patient should keep still during the entire measurement procedure.

Measurement can take place in three ways:

1. As a single measurement. Single measurements are started by pressing the **NIBP button** on MobiMed 300c or by pressing **F1** on the functions keyboard or from NIBP settings, see “NIBP settings” on page 43.
2. As periodic measurements at regular intervals. Periodic measurements are started from NIBP settings. The time between measurements can be selected at 2, 5, 10, 15, 20, or 30 minutes.
3. As a STAT measurement. STAT measurement entail that measurements take place repeatedly over a five-minute period. It is started from NIBP settings.

NIBP function when no pulse is detected:

1. If no pulse is detected during inflation, the inflation stops at 150 mmHg.
2. The measurement is restarted.

3. If no pulse is detected during the second inflation (stops at 150 mmHg) the measurement stops.

5.4 Stopping an NIBP measurement

The following alternatives can be used to stop all existing and impending NIBP measurements and release the cuff pressure:

- Press the **NIBP** button on MobiMed 300c.
- Press **F1** on the keyboard.
- Press **Stop** in the NIBP settings (see “NIBP settings” on page 43).

Important: *Stopping a current measurement stops all impending measurements.*

5.5 NIBP alarms

Clinical alarms

Message	Priority
Sys bp low <	***
Sys bp high >	**
Dia bp low <	**
Dia bp high >	**
Mean bp low <	**
Mean bp high >	**

Technical alarms

Message	Priority
Cuff is not deflating	##
Calibration error	##
Pressure too high	##
Too long measurement	##
Wrong cuff used	##
Cuff leakage	##
Measurement failed	##

5.6 NIBP settings

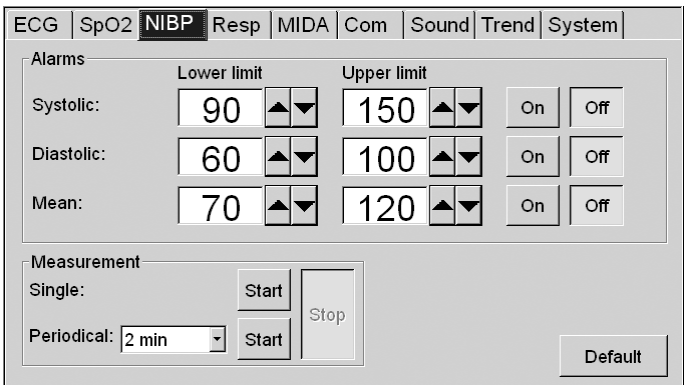

Figure 28. NIBP settings

NIBP settings are accessed by clicking on the NIBP parameter data in the monitor view or by selecting **More:Settings:NIBP**. In the NIBP view the upper and lower alarm limits can be set for the Systolic, Diastolic and Mean Pressures. The alarms can be turned On or Off and single NIBP measurements can be started. Periodic measurements (2, 5, 10, 15, 20 and 30 minutes) and STAT (repeated measurement during 5 minutes) can be started or stopped by pressing the **Start/Stop** buttons. Pressing, **Stop** interrupts the current and all impending NIBP measurements.

To return to the default settings select the **Default** button.