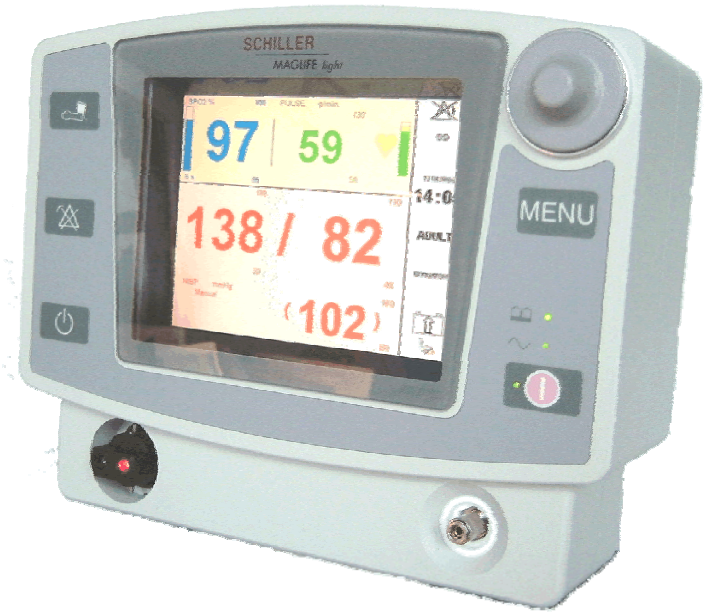
SCHILLER

MEDICAL S.A.S.

MAGLIFE *light*

User manual

Version 1.2 / October 2006



CE 0459

The Art of Diagnostics

Part No. 0-48-0080

Revision history

Version	Date	Comments
V1.0	June 2006	First edition
V1.1	July 2006	First release, Soft 3
V1.2	October 2006	Revision

Note: Distribution and maintenance information

SCHILLER has an international network of customer service, sales and consulting agencies. For details about your local representative, please contact the SCHILLER subsidiary near you. You will find a complete list of all the representatives and subsidiaries on our website at http://www.schiller.ch
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WARNINGS

This manual shall be deemed to be an integral part of the described unit.

Compliance with its content is a prerequisite for proper device performance and for patients and operators safety .

The manufacturer disclaims all responsibility for the safety, reliability and performance of the device if:

- **assembly, extensions, adjustments, modifications and repairs are not performed by the manufacturer or by manufacturer authorised persons.**

- **the electrical installation of the premises does not comply with locally applicable requirements.**

- **the device is not used in compliance with this instructions for use.**

This manual describes the device at the printing time.

Upon request, the supplier will provide circuit diagrams, lists of components, descriptions, calibration instructions or any other information required by the user's qualified technical personnel to repair those parts of the device that have been stated as "repairable" by the device manufacturer. The supply of such information shall not in any event constitute permission or approval to modify or repair a device.

The device is not designed for any use that is not specifically provided in this manual, which may be hazardous.

This **MAGLIFE *light*** manual provides the information required for proper device performance.

Knowledge of monitoring and the understanding of the characteristics and functions of **MAGLIFE *light*** are required for proper use of the device.

Do not use the monitor before you read these instructions.

Device maintenance information is provided in the service manual of the **MAGLIFE *light*.** For more information, please contact your nearest SCHILLER representative.

MAGLIFE *light* bears the CE-0459 mark in accordance with directive 93/42/EEC relating to medical devices and fulfils the essential requirements of annex I of that directive.

This product complies with the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic Compatibility-Medical Electrical Equipment » .

The radio interference emitted by this device is within the limits specified in the standard EN 55011, class B. When the device is connected to a printer, it is within the limits specified in the standard EN 55011 – class A.

WARNINGS, PRECAUTIONS AND NOTES

Please read and adhere to the following list of warnings, precautions and notes. Some of them have been repeated at appropriate areas throughout this manual.

Follow the warnings and precautions stated on the labels affixed on the monitor. Throughout this manual we have added specific notifications that offer additional information. These notations are designated as:

A **Note** is provided when extra general information is applicable.

A **Caution** is provided when special care is to be exercised by the user and/or patient, to avoid injury to the patient, damage to the device or damage to other property.

A **Warning** is provided when actions may result in a serious outcome (i.e. injury, serious adverse effect, death) to the patient or user.

Caution: **MAGLIFE *light*** is a monitor designed solely for use close to Magnetic Resonance Imagers of 0.2 to 3 T for monitoring of patients undergoing an MRI examination.

Caution: The continuous presence of a qualified person is imperative throughout the examination.

Warning: Before using the **MAGLIFE *light*** monitor, follow the safety instructions below:

- **MAGLIFE *light*** may only be used by trained healthcare workers who are familiar with its instructions for use.
- Make sure that the voltage and frequency of the electricity system match those stated on the identification plate.

Warning: Because the device is a class I device, it may only be used in premises with an electrical system comprising an earth connection.

Warning: Connecting other devices or sensors to the patient could lead to leakage currents that may be harmful to the patient. Consult SCHILLER before interconnecting with other equipment.

Warning: Take account of the physiological effect of the other devices connected to the patient.

Warning: This device may not be installed or operated in explosive environment.

Warning: This device is not designed for use with inflammable anaesthetic agents.

Caution: Use only sensors supplied by SCHILLER. They have been designed specially for use in MRI environments.

Warning: **MAGLIFE *light*** is designed for use with MRI systems with a magnetic field between 0.2 and 3 Tesla. Contact SCHILLER for use beyond that magnetic field range.

Warning: It is imperative the **MAGLIFE *light*** be installed in the area around the magnet where the magnetic leakage field is less than or equal to 40 mT (400 Gauss) (see typical installation drawings and labels on the device).

Note: The ambient temperature must be located within the following limits:
15°C ≤ Amb. T ≤ 35°C
60°F ≤ Amb. T ≤ 96°F

Note: The instructions specific to the installation and use of the **MAGLIFE *light*** monitor have been provided in section 4 of this manual, which must be read carefully before initial use of the monitor.

Caution: The safety instructions relating to the MRI environment must be followed at all times (during installation, use, repairs etc.). Any work on **MAGLIFE *light*** (e.g. repairs) must be done outside the area where the risk of magnetic attraction is non-existent.

Caution: No equipment that hampers blood flow (e.g. use of a cuff type sphygmomanometer) may be used on the limb of a patient undergoing oxygen saturation monitoring (SpO2), as it could disrupt the correct determination of the data.

Caution: Sensors and probes may not come in contact with conductive parts, including the earth.

Caution: Do not defibrillate on the accessories. Place the defibrillation electrodes as far away from the other accessories as possible.

Caution: The monitor is adapted for the MRI configuration upon power up. Any subsequent change in the MRI system can alter the performance of the **MAGLIFE *light*** monitor. Inform SCHILLER of any such change.

Caution: The device is designed to operate with electrosurgical devices. Place the accessories as far away from the electrodes of the electrosurgical device. That device must be installed and used in accordance with the manufacturer's instructions.

Caution: The device is designed to operate without any equipotential connection.

Contents

1. Description of MAGLIFE *light*

MAGLIFE *light* is a monitor designed solely for monitoring vital patient parameters during MRI (Magnetic Resonance Imaging) examinations.

Depending on the selected version, **MAGLIFE *light*** will monitor the following parameters:

- transcutaneous measurement of arterial oxygen saturation, SpO2 (pulse oximeter)
- pulse rate
- blood pressure (NIBP)

MAGLIFE *light* may be configured with all combinations of the above parameters

MAGLIFE *light* is fitted with batteries as standard and can move with the patient (e.g. to and from the examination room and the adjacent preparation room).

MAGLIFE *light* is designed to be placed on a non-magnetic mobile stand.

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2. Location and description of displays and controls

2.1 Front of MAGLIFE light

(see photo in section 11)

1. Main device on/off key.
2. Device “ON” indicator.
3. “MAINS” connection indicator.
4. “BATTERY” Indicator, showing that the battery is being charged (flashing), or is fully charged (steady).
5. Main “MENU” key. Access to the main menu and for exiting a menu from any other place.
6. Navigation button for menu selection.
7. Display for curves, parameters, menus and messages.
8. “NIBP” key, for starting up or stopping a measurement or a series of measurements of the blood pressure via a cuff.
9. “Alarm silence” key, enables or disables the two-minute or permanent audio alarm function (physiological and technical alarms).
10. Device “STANDBY” key.
11. SPO_2 optical oximeter sensor connector.
12. NIBP cuff connector.

2.2 Rear of MAGLIFE *light*

(see photo in section 12)

13. Connector for the low voltage cord for connecting to the mains power unit.
14. Loudspeaker
15. USB connector
16. RS 232 connector
17. Auxiliary connector compartment cover.
18. Identification label.

2.3 Mains power unit

(see photo in section 12)

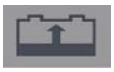
19. Mains plug.
20. Low voltage plug for connecting the **MAGLIFE *light***.

3. Device symbol identification

3.1 MAGLIFE *light* symbols

Main device on/off key

Mains power on



Battery charge

Entry into main menu or exit from any menu

Audio alarm enable/disable

Non-invasive blood pressure start/stop

CF type device, is protected against defibrillation shocks (device designed for direct heart applications).

Caution! Read the instructions for use of the device.

Electrical and electronic device identification symbol. The device components must be disposed of separately and the relevant parts must be sent to available recycle centres. Inappropriate disposal may be harmful to the environment and to public health as a result of the presence of hazardous materials in electrical and electronic devices.

Notified body for CE certification (G-MED)

3.2 Power symbols

Power connected

Power input

4. Use of MAGLIFE *light*

4.1 Installation

MAGLIFE *light* has been designed to operate at the patient's bedside. It is installed in the Faraday cage, i.e. in the room with the MRI system.

Minimum distances must be kept in relation to the measuring tunnel entrances. These depend on the magnetic field of the magnet and the type of magnet.
As a result, it is imperative the **MAGLIFE *light* be kept outside the area around the magnet demarcated by the 40 mT (400 G) line**. A magnetic field detector sets off an alarm if that value is reached. **Beyond the 40 mT limit, the monitor is exposed to a force of attraction (due to the magnetic field) that rises rapidly as the distance from the magnet decreases. This area must be indicated by markings on the floor.**

Caution: The monitor may be installed on a non-magnetic trolley supplied as an option by SCHILLER. The trolley has wheels for turning and moving the monitor. If the minimum distance is not kept, the performance of the device may be disrupted. **The trolley bearing the monitor may not be placed in or moved to an area where the field is greater than 40 mT (400G), regardless of whether the monitor is on or off.** The force of attraction of the magnet could pull the monitor against the walls of the tunnel.
The wheels of the trolley can be locked when the trolley is installed in the permitted area.

Important note: The magnetic field is always present, even when the imager is not being used for an examination.

Typical plan of an MRI system with a MAGLIFE *light* monitor

1) Faraday cage
2) **MAGLIFE *light*** monitor
3) Mains connector
4) Marking on the floor (40 mT line)

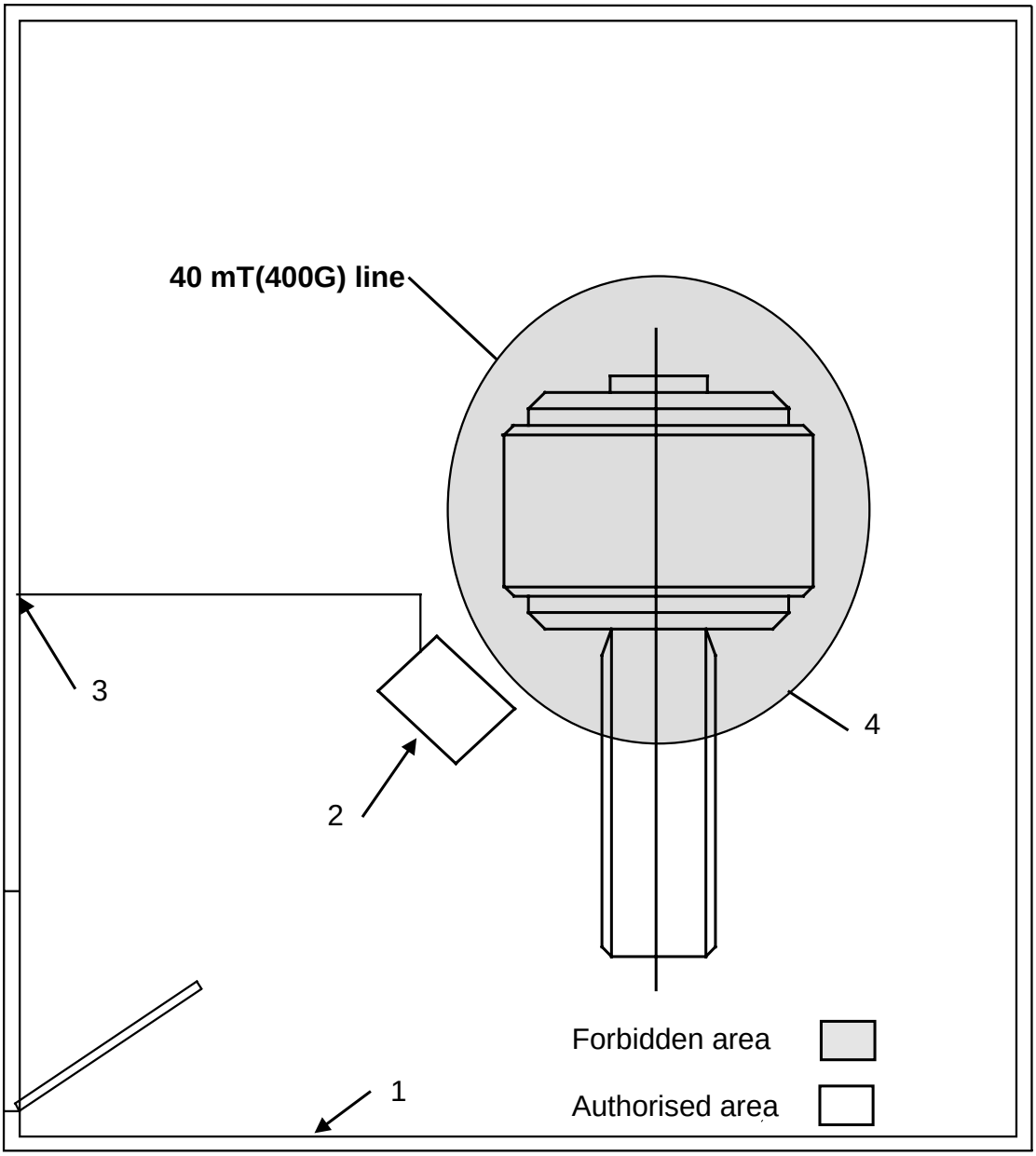
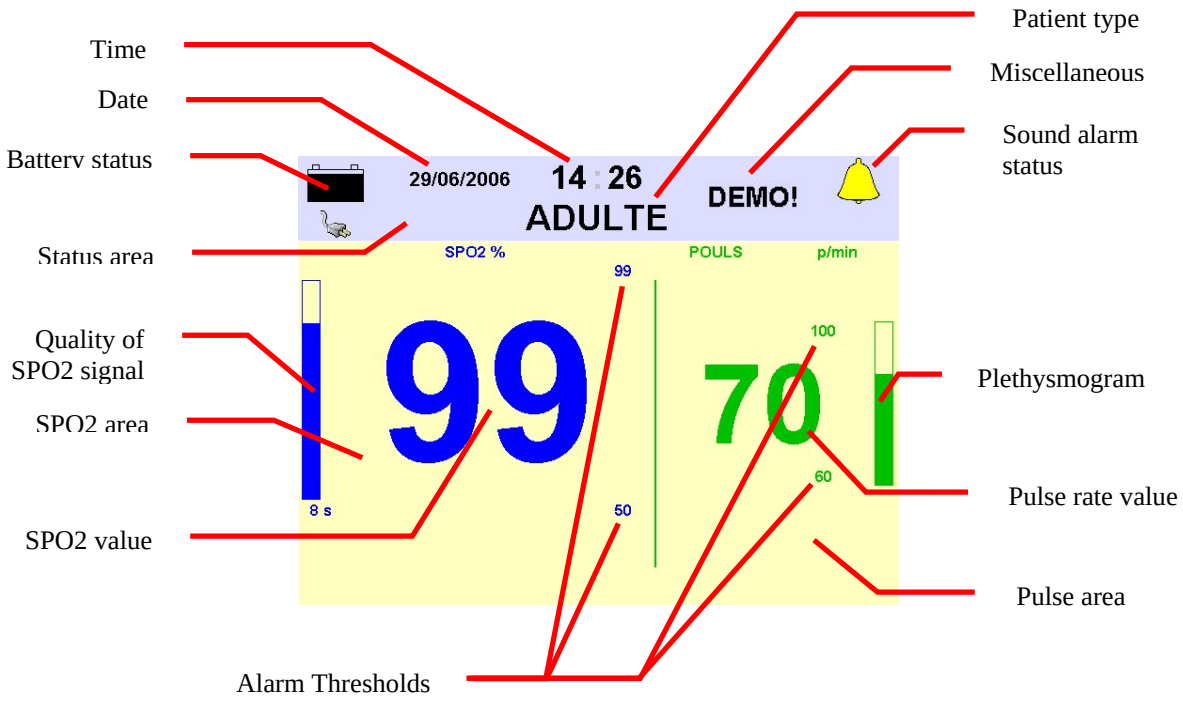


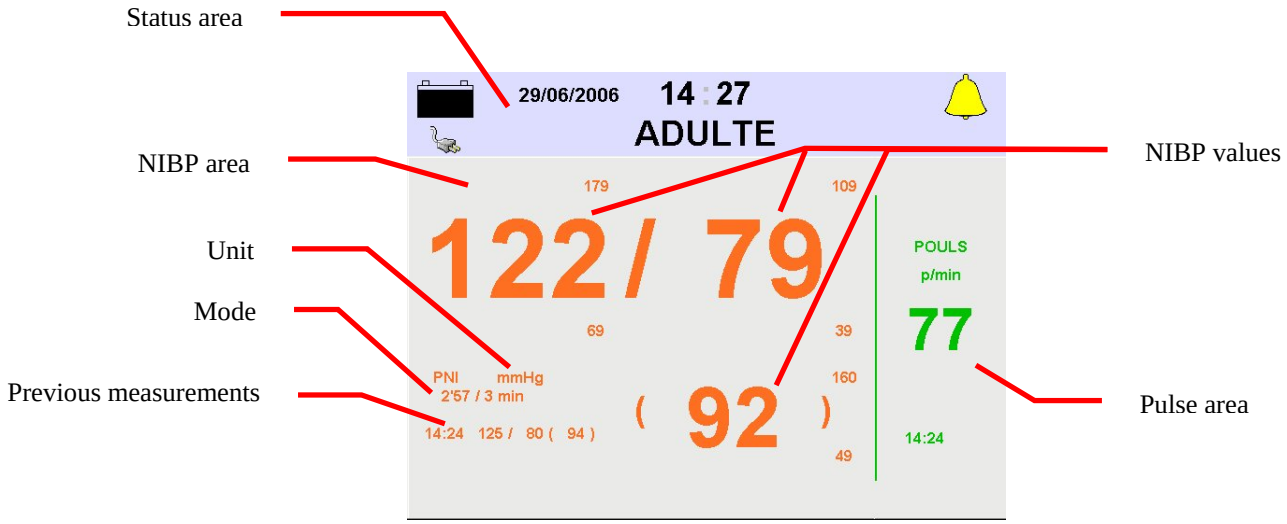
Figure 1

4.2 Display screens

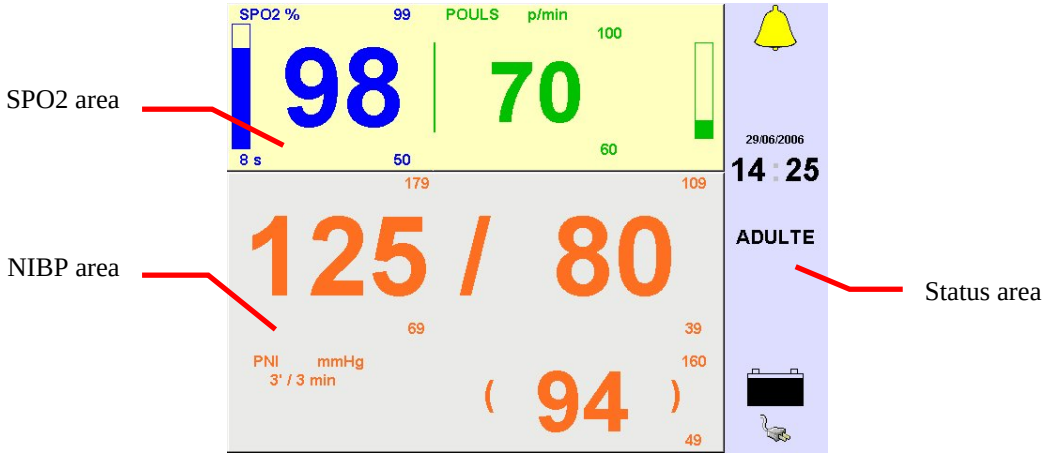
4.2.1 SPO_2 option only



4.2.2 NIBP option only



4.2.3 SPO_2 and NIBP options



4.3 Placing of probes and sensors

Warning: The recommendations relate to the type of sensors and probes to be used, the positioning of the sensors and probes on the patient and the placing of the cables that connect the sensors and probes on the patient and the device.

The following rules must be followed **precisely** to avoid the problems described below:

4.3.1 Absolute rule

Use only the cables, sensors and cuffs supplied by SCHILLER.

4.3.2 Probes and sensors to be used and positioning instructions

4.3.2.1 SpO2 sensor

1. Make sure that the Oximeter function is on and that the oximeter parameters are set correctly.

Caution: Use only the sensors from the list of accessories supplied by SCHILLER.

2. Connect the oximeter patient cable to the oximeter connector and give the connector a quarter turn to the right-hand side to lock it in place (to disconnect, turn the connector to the left and pull it out).

3. Place the sensor over the nail of the index finger or equivalent site; place the cable on the top of the hand and fix it using Velcro™ strap or secure to the patient's wrist without tightening it.

Warning: Be cautious in placing the cable correctly so as to prevent damage or injury (tangling and/or strangulation).

Warning: Remove nail polish or false nails before placing the sensor on the patient's finger, as they could lead to inaccurate oximeter measurements. Cut long nails, as they could hinder the placing of the sensor.

Warning: If the sensor is secured with tape, do not tighten the tape excessively. If the tape is too tight, it may affect the measurement accuracy of the device and blisters may form on the patient's skin (due to the lack of circulation in the skin and not because of a source of heat).

Caution: Do not place the sensor on an extremity with an invasive probe or a blood pressure cuff.

Caution: Do not place the cuff on the same limb that the oxygen saturation is being measured, as it could disrupt the correct determination of the data (resistance that hinders the blood flow).

Warning: The oximeter measurement may be modified by the presence of strong ambient light. Cover the sensor (e.g. with a surgical sheet) if required.

Warning: The incorrect application or improper use of the sensor can lead to measurement inaccuracies, as can the presence of significant levels of dysfunctional haemoglobins (e.g. carboxyhaemoglobin or methaemoglobin) or intravascular dyes such as indocyanine green or methylene blue, the exposure to excessive light such as with surgical lamps (especially lamps with xenon sources), bilirubin lights, fluorescent lamps, infrared heating lamps or direct sunlight, excessive movement by the patient, vein pulsations, the installation of a sensor on a limb with a blood pressure cuff, an arterial probe or an intravascular line.

Warning: In some cases, when the perfusion and signal are weak, e.g. with patients with a thick or dark skin, the device may produce abnormally low oximeter readings. Oxygenation should be verified before starting therapies and interventions, especially in preterm babies and patients with chronic lung diseases.

Warning: It often happens that patients suffer from low peripheral perfusion due to hypothermia, hypovolaemia, serious vasoconstriction or reduced cardiac output etc. These symptoms may lead to a loss in the oximeter readings.

Warning: The temperature of the patient and the room must not be too low since it will affect the measurement outcome.

Caution: Do not use the oximeter alone while monitoring vital parameters.

4.3.2.2 Sphygmomanometer cuffs (Non-Invasive Blood Pressure)

1. Make sure that the NIBP function is on and that the NIBP parameters are set correctly.

2. Connect the NIBP tube connector to the NIBP measurement connector **(12)**. Use only the cuffs listed in section 8.

Warning: If the cuff is placed too tightly on the limb, the results will be excessively high readings. Among other considerations, the use of a cuff suited to the patient has a direct bearing on the accuracy of the NIBP measurements obtained. Select the cuff according to the circumference of the patient's limb.

Warning: Cuffs can soften over time and get permanent creases that may mark the limb temporarily. Replace any cuffs which have that characteristic.

Caution: Make sure that the pressure connectors are not flattened or blocked.

Caution: Position the cuff slightly above the elbow, the Velcro™ turned up. Since the cuff does not contain a microphone, specific positioning is not necessary.

Warning: The cuff must be tightened around the arm, but must not apply pressure on the blood vessels before the measurement. Roll the cuff around the arm and close the Velcro™.

Caution: Check to ensure the hose is not tangled (check any incorrect placement of the arms, legs or body of the patient, any clamps etc.), as device operation will be disrupted by a flattened or restricted hose.

Warning: Check that the blood is flowing correctly in the relevant limb (arm, leg) (except during the measurement).

Caution: A cuff type sphygmomanometer must not be used on the patient's limb undergoing oxygen saturation measurement as it could disrupt the correct determination of the data.

Several cuff models are available, including:

- Adult cuff
- Child cuff
- Neonate cuff

Extension hoses are also available.

4.4 Start up

Connect the mains cord to the mains connector **(19)** and the low-voltage connecting cord to connectors **(20)** and **(13)**. Indicator **(3)** will light up to show that the device is connected to the mains.

Caution: Indicator **(4)** will illuminate and the battery will be charge automatically while the device is connected to the mains, even if it is not in operation.

Press key **(1)**; the associated indicator **(2)** will illuminate.
After a few seconds, the screen will activate and the system initialised. The initialisation sequence will last about 10 seconds. After that time, the parameters will be displayed.

For battery operation (with the mains cord disconnected), just press key **(1)** (the battery is integrated in the device). If the battery is charged, associated indicator **(2)** illuminate and the device will start up. With a fully charged battery, the device can operate for at least two hours.

Note: The operating of key **(1)** is disabled during the initialisation phase.

4.5 Battery charge

MAGLIFE *light* may be powered by the internal battery to accompany the patient as the patient is moved, or if the mains power is absent. The battery charges automatically whenever the device is connected to the mains, whether or not it is operating. While the battery is charging, indicator **(4)** flashes. Once the battery is fully charged, it stays on and steady.
MAGLIFE *light* can operate on the battery (new battery, fully charged) for two hours (one hour if intensive use is made of the NIBP function).
An alarm message is displayed about 5 to 10 minutes before the battery is completely discharged and the automatic device shutdown occurs,

4.5.1 Operating during a mains failure

MAGLIFE *light* manages its power supply automatically. If the mains supply fails or is of poor quality, the battery will automatically start supplying power to the device regardless of the duration of the disruption.
Indicators **(3)** and **(4)** will go off and the mains present indicator (see section 4.2) and the battery charge indicator will reflect the new situation in the Status zone after three seconds.

4.6 Use of the menu

All the functions other than those accessible via the controls on the unit are selected from the menus displayed on the screen.

You can enter the main menu in two ways:
- by pressing rotary button **(6)** or
- by pressing key **(5)**.

Caution: The displayed menus depend on the parameters defined as active in the configuration (see paragraph 4.7.2).

The rotary button is used to:
- confirm a choice in the menu (when the line is highlighted in blue)
- make a choice
- switch to the digital entry mode by making the cursor flash
- move from one selected field to another without making any change
- select a status in a toggle function

Double clicking (two clicks in rapid succession) is used to exit any menu. It has the same function as key **(5)**.

Button rotation is used to:
- move in a menu
- increase or decrease the value of an entry field

Caution: Menus disappear if no action is taken for more than 10 seconds.

4.7 Description of menus

4.7.1 Main menu

The main menu is as follows:

It is used to select submenus.

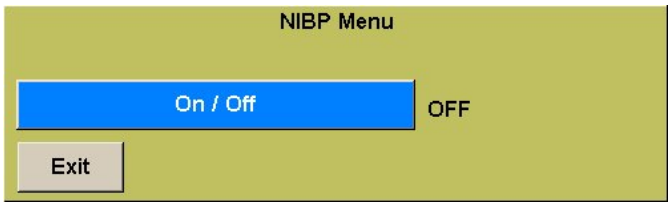
Note: Only the labels corresponding to the installed parameters are displayed.

The main menu contains the following submenus:

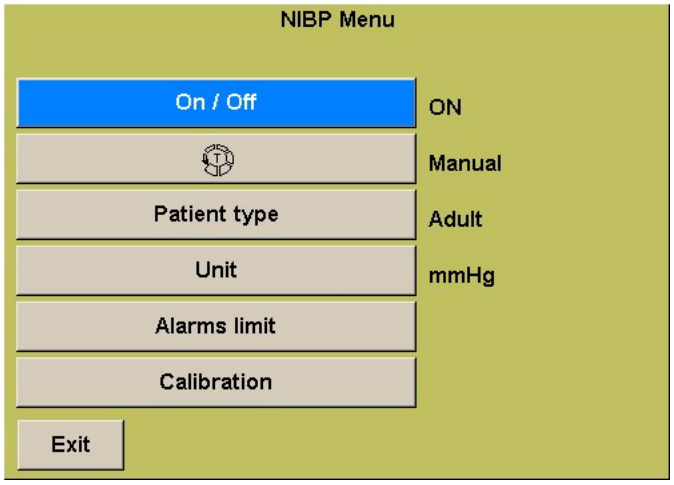
4.7.1.1 NIBP (Non Invasive Blood Pressure) menu

Windows displayed

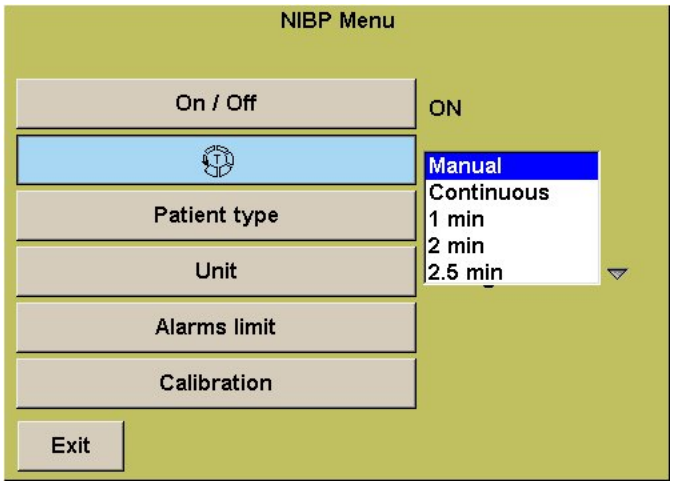
– with the NIBP parameter disabled (select NIBP On/Off to enable)



– with the NIBP parameter enabled (select NIBP On/Off to disable)



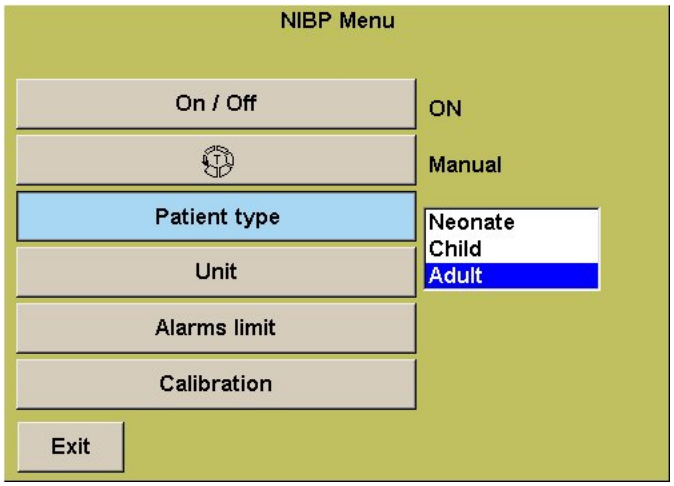
- **Cycle selection**
  to select a cycle value from 1 minute to 90 minutes, activate symbol , then select the appropriate value by rotating button **(6)** and confirm by pressing the button.



- **Patient type selection**

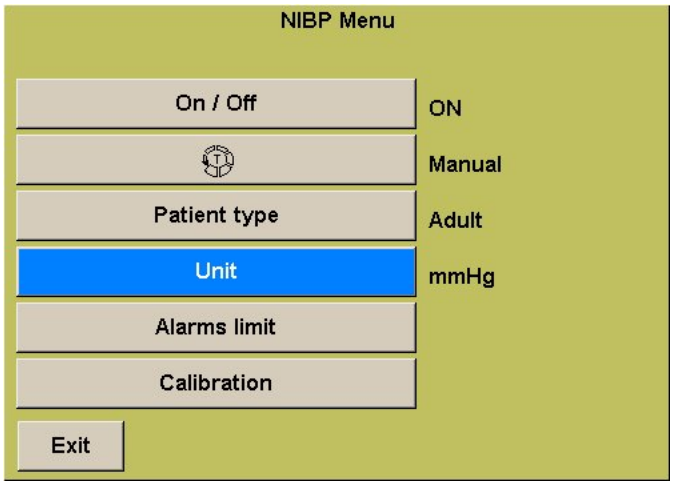
  Depending on the type of patient, the initial inflating pressure is automatically selected (180mmHg for Adult/Child and 120mmHg for Neonate.

Note: For subsequent measurements, the inflating pressure is automatically selected (about 50mmHg above the measured systolic pressure for Adult/Child and 30mmHg for Neonate.

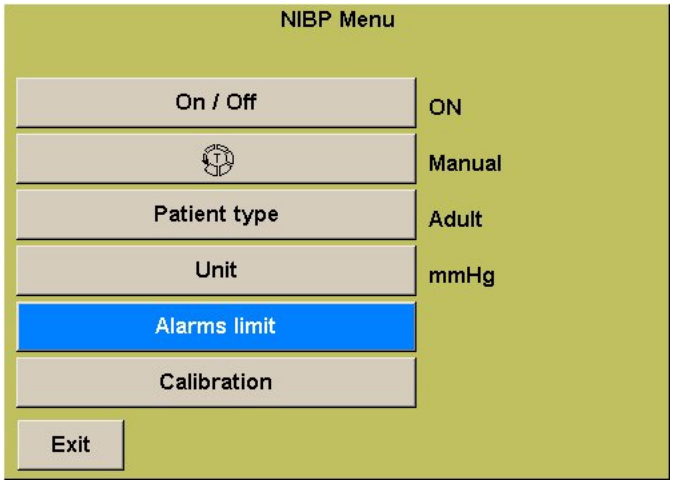


- **Measuring unit selection**

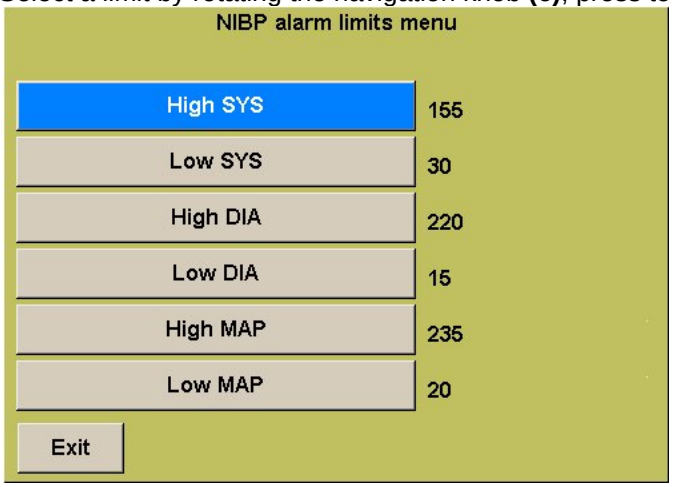
  The Unit button is used to switch between the two units - kPa and mmHg.



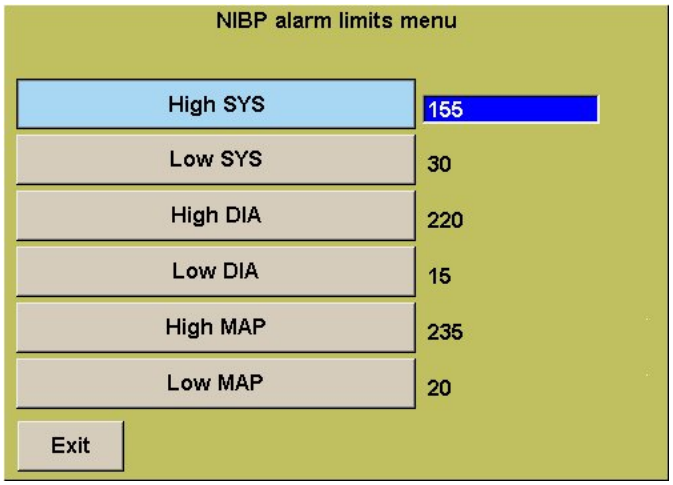
- Use the **Alarm limits** button to manage thresholds. For more details, refer to section 4.7.1.3 Alarm limits and 4.9 Alarms



- **NIBP alarm limit setting**
  Select a limit by rotating the navigation knob **(6)**, press to confirm



  Select the limit value by rotating the navigation knob **(6)** again, press to confirm the selected value.

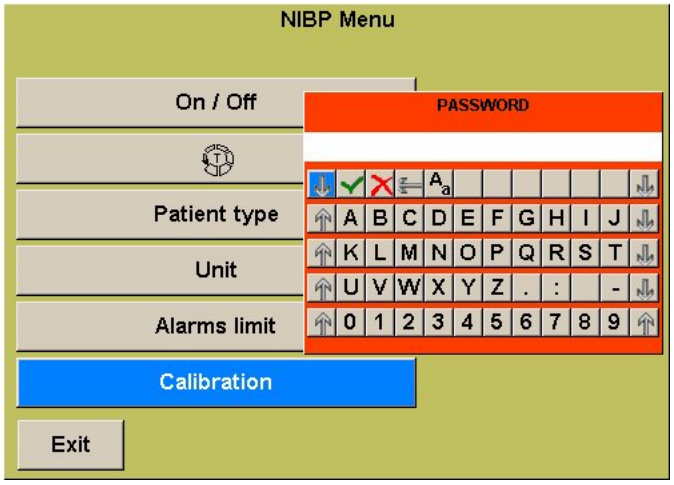


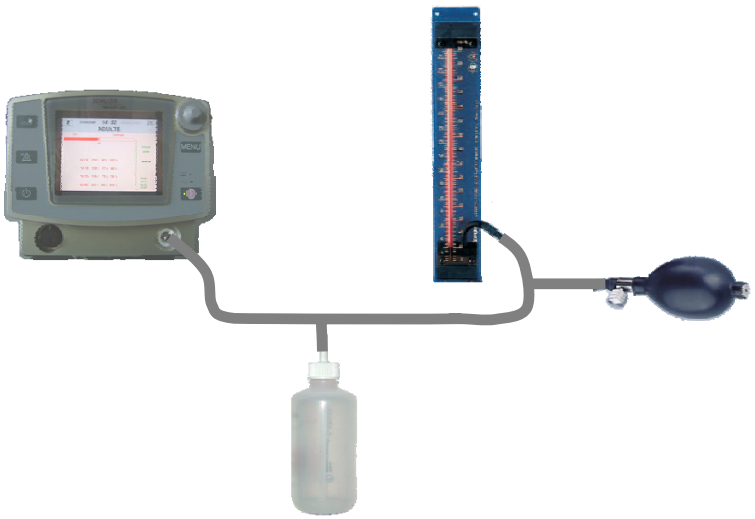
Note: At the switch on time, the alarm levels corresponds to the standard values of the selected patient. The operator selection is done in general alarm limit management window refer to section 4.7.1.3 Alarm limits

- The **Calibration** submenu is used to check if the NIBP pressure module is measuring the pressure correctly. Connect the external verification system with an expansion vessel of at least 75 cl and a pressure measuring device. If required, add an inflating bulb with a deflating valve. Activate **Calibration**; the display on the screen will show the pressure value measured by the NIBP module. Make several comparisons between the measurements by **MAGLIFE *light*** and those by the external measuring device over the entire measurement range.

  Note: Calibration is regulated in some countries. Comply with applicable laws and regulations.

  Note: The **Calibration** submenu is locked by a password.
  The password is communicated to the people who followed the technical training.

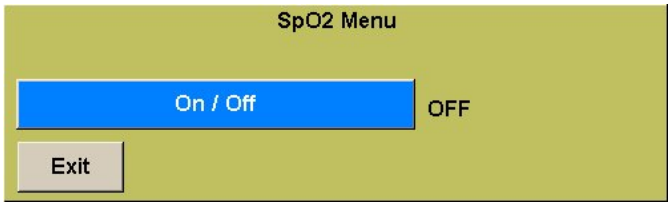




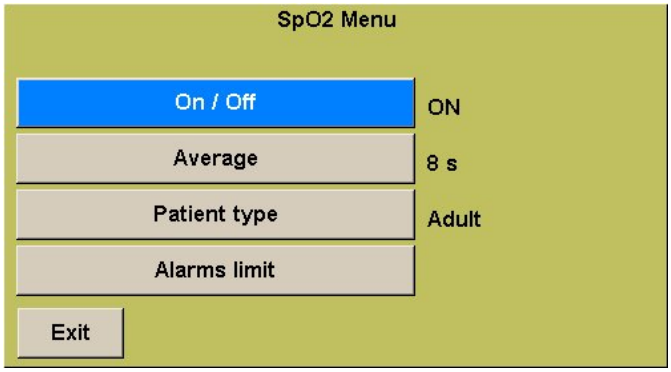
4.7.1.2 Oximeter (SpO2) submenu

Windows displayed

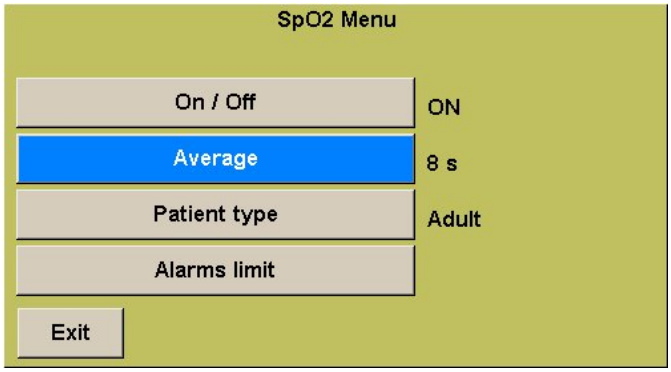
– with the SpO2 parameter disabled (select SpO2 On/Off to enable)



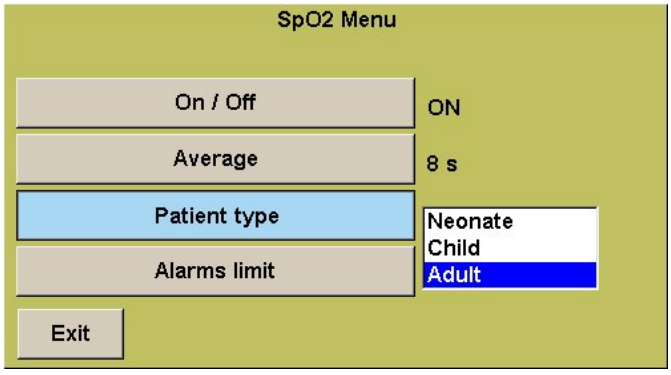
– with the SpO2 parameter enabled (select SpO2 On/Off to disable)



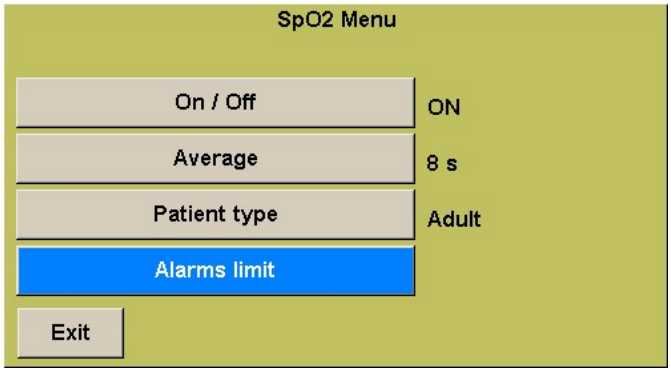
- Select the **averaging time** to be taken into account while calculating the SpO2 value and the pulse rate. The choice between the two values - 8 s and 16 s - is made by activating the **Average** tab.



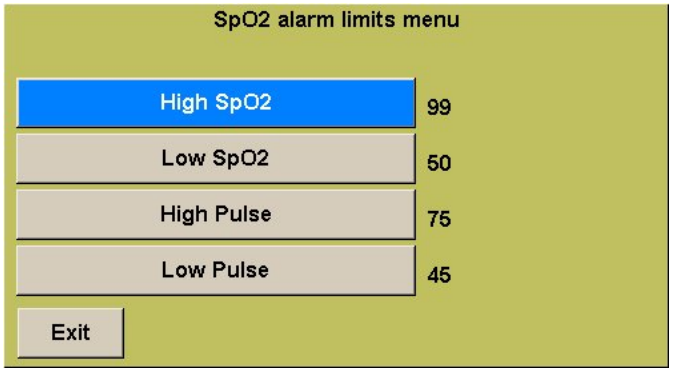
- Patient type selection. The patient type selection only affects the thresholds.



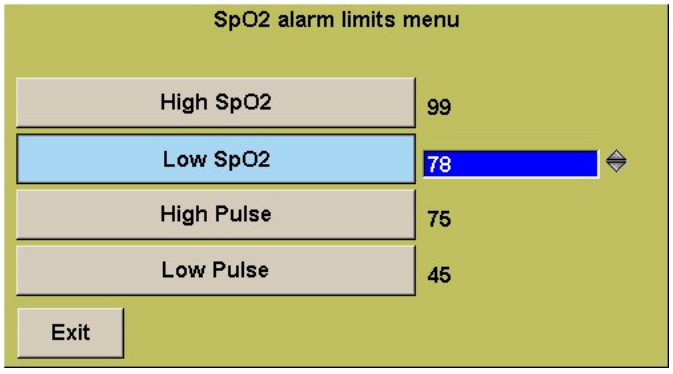
- Use the **Alarm limits** tab to manage thresholds. For more details, refer to section 4.7.1.3 Alarm limits and 4.9 Alarms



- **SPO2 alarm limits setting**
  Select a limit by rotating the navigation knob **(6)**, press to confirm



Select the limit value by rotating the navigation knob **(6)** again, press to confirm the selected value.



Note: At the power up time, the alarm levels corresponds to the standard values of the selected patient. The operator selection is done in general alarm limit management window refer to section 4.7.1.3 Alarm limits

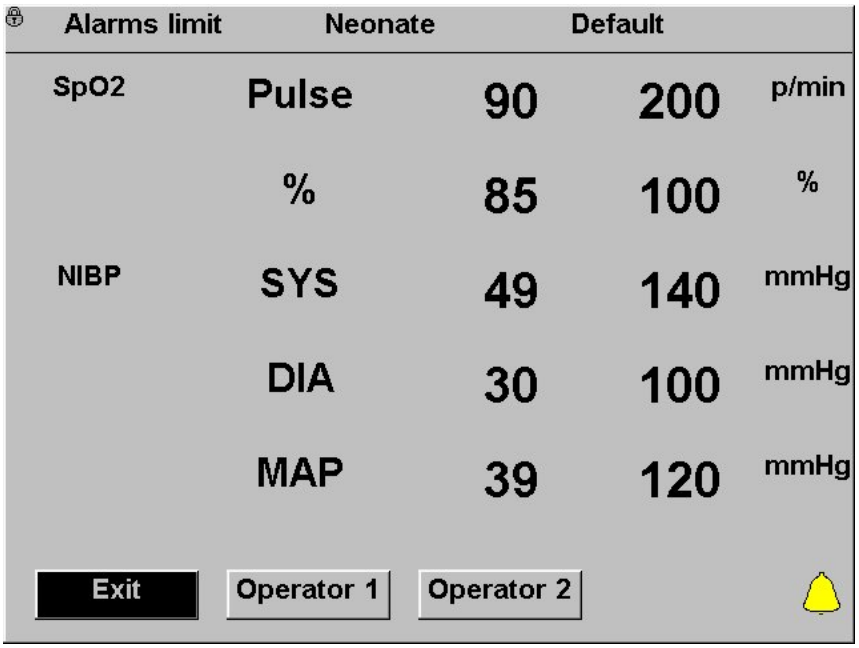
4.7.1.3 Alarm limits menu

The **Alarm limits** menu is used to set the thresholds for triggering alarms relating to the different parameters.

Caution: The **Thresholds** menu only displays the thresholds for the parameters present in the configuration.

Caution: If one or more alarms have been disabled, an icon with a crossed-out bell and the word OFF is displayed in the upper right-hand corner of the screen.

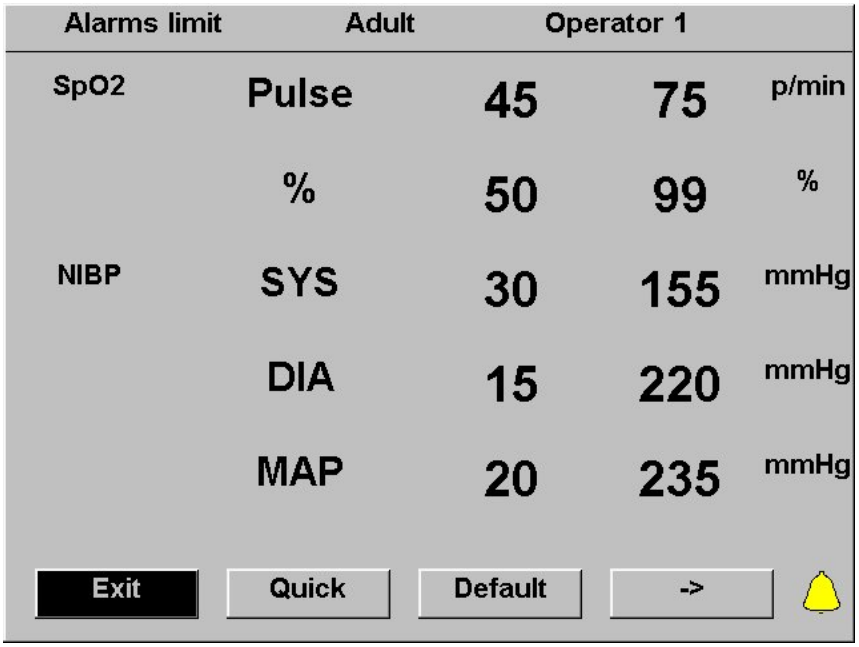
The following submenus are available:



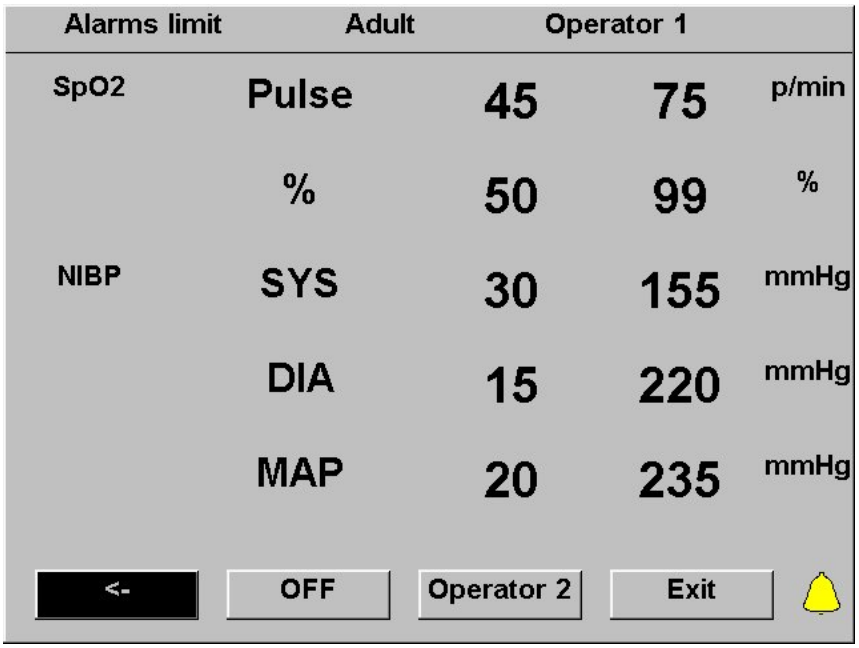
When the device is powered up and when it comes out of the standby mode, the threshold values are the default values for the type of patient selected (Adult, Child or Neonate).
. See section 4.7.1.3.1 Power up and standby mode

Three different sets of default values are available for each type of patient. These values can be set from the **Device configuration** menu (see section 4.7.2)

The Operator 1 choice gives access to the following submenu, which is used to set the thresholds from the values selected by the operator when the function was last accessed.



- The **Quick** selection is used to set all the values in relation to the measured physiological values of the patient. The upper values are set to 20% above and the lower values are set to 20% below those physiological values.
- The **Default** selection is used to go back to the default values for the selected patient type.
- -> provides access to the following submenu:



<- Is used to go back to the previous submenu

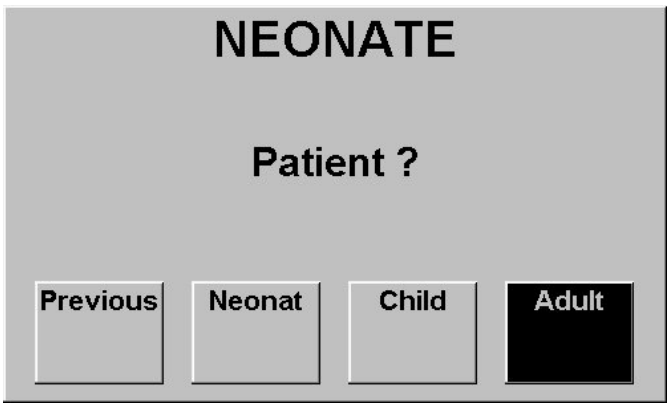
- OFF is used to disable all the audio and visual physiological alarms

Caution: Failure to monitor the condition of the patient may lead to death.

- Selection Operator 2 provides access to the second set of values defined by the operator when the function was last accessed. The values can then be edited.
- **Exit** is used to close this submenu.

4.7.1.3.1 Power up and standby mode

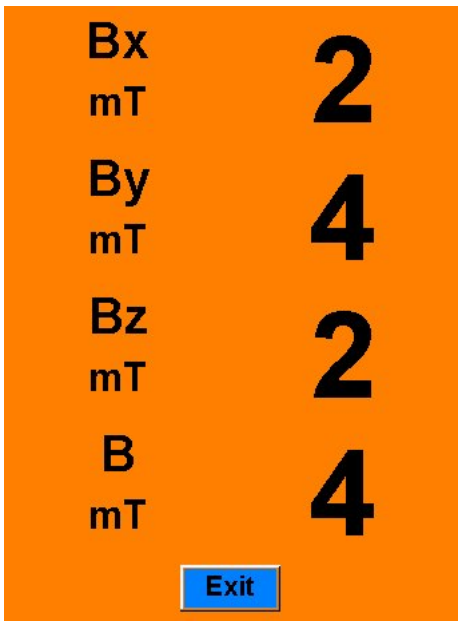
When the device is powered up, the threshold values are the default values for the type of patient selected, and therefore not necessarily the values used when the device was last used for monitoring. (The default thresholds are factory set and can be adapted from the configuration menu). Patient type selection is offered for 12 seconds after device power up and also when the device comes out of standby mode. If the operator does not select the patient type, the default values of the neonatal type are selected automatically. The possibility to select the values used last is available with the **Previous** button.



Note: Selecting the **Previous** option makes it possible to obtain trend continuity, as all the other selections result in the insertion of a separating mark between patients in the trends.

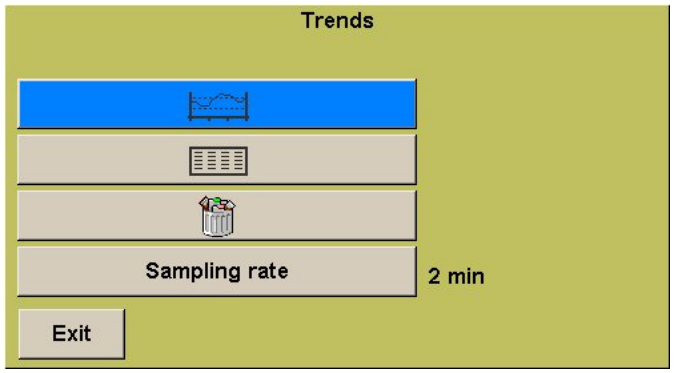
4.7.1.4 Magnetic field display

The B0 display button is used to display the magnetic field measurement on the screen. Values Bx, By and Bz show the value of the magnetic field in mT along the three orthogonal directions in space. The B value shows the corresponding vector modulus.



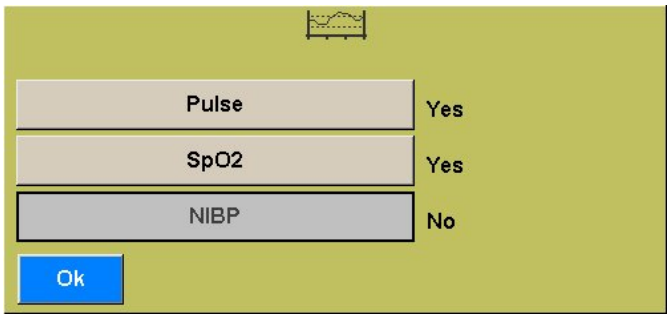
4.7.1.5 Trends menu

The Trends menu contains two main submenus - Graphs and Tables - and two options. It enables the user to erase the trends and select the period for trend tables.

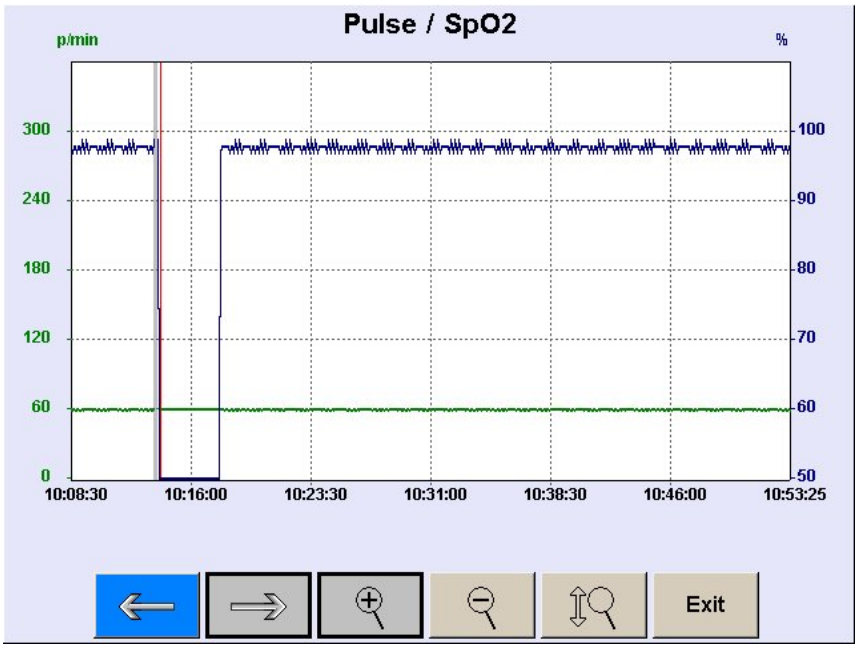


4.7.1.5.1 Trend graph submenu

The Trend graph menu is used to select the trend curves to be displayed and contains the following tabs:



Note: Only two waveforms can be shown at the same time.



Navigation buttons


Back one page


Forward one page


Reduce time line from 24 hours to 1 hour

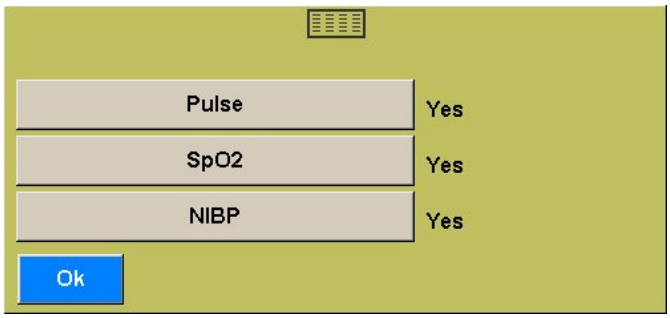

Increase time line from 1 hour to 24 hours


Adapt graph scale

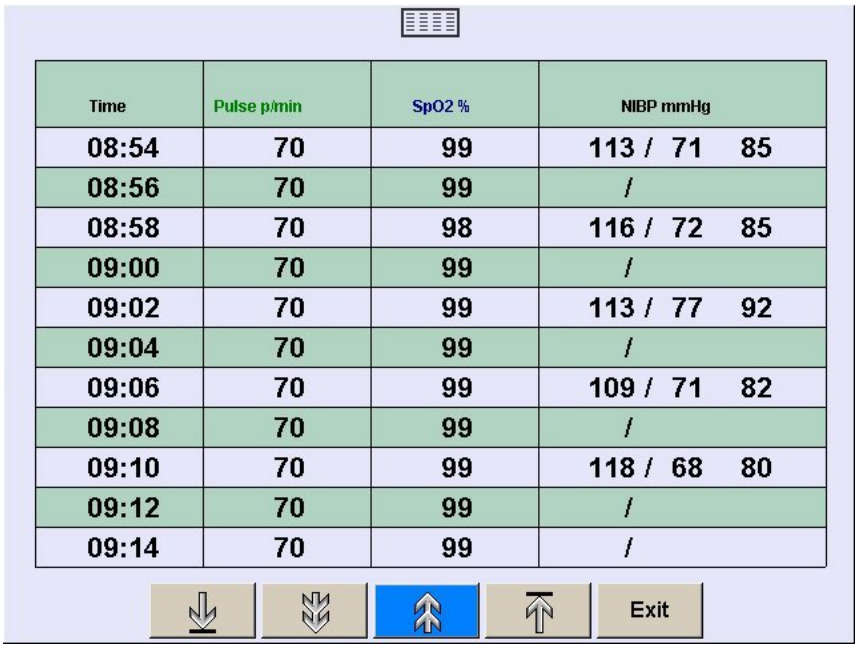
Exit the trend graphs display

4.7.1.5.2 Trend table submenu

Trend table show the numerical values of the physiological parameters according to the frequency that has been defined earlier from the trend type selection menu.



The display varies according to the selected parameters



Navigation buttons


Forward to the end of the table (most recent value)


Forward to next line

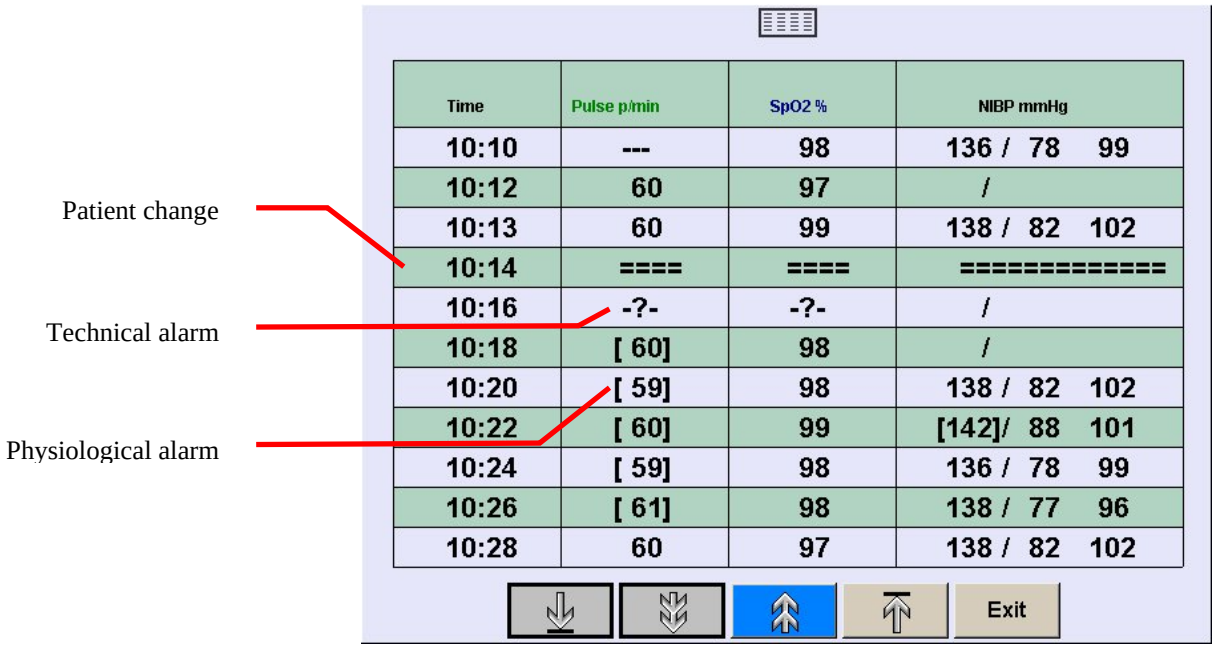

Back to previous line


Back to the start of the table (oldest value)

Exit the trend tables display

Note: If a non-invasive pressure measurement does not strictly follow the table frequency rules, it is inserted at the appropriate location.

Special displays

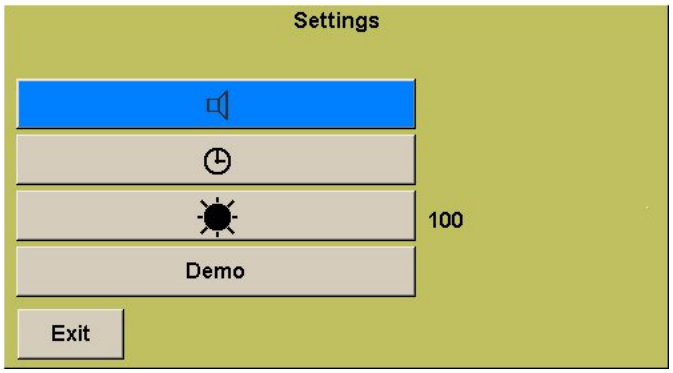


4.7.1.6 Edit menu

(To be written)

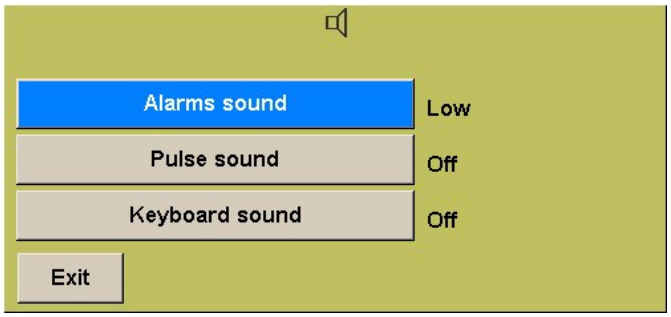
4.7.1.7 Settings menu

The **Settings** menu is used to set the general parameters of **MAGLIFE *light*** and to access the demonstration mode.

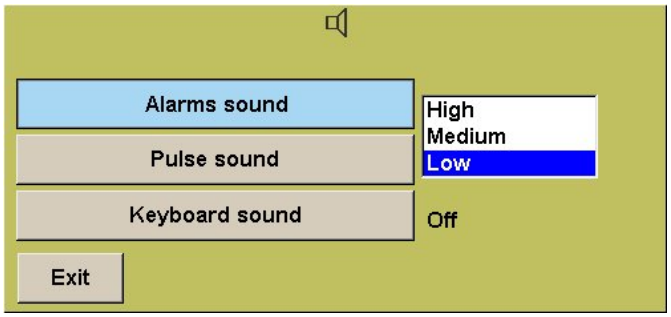


4.7.1.7.1 Sound submenu

The sound submenu is used to set the level of the sound for alarm signals, pulse bip or keyboard clics

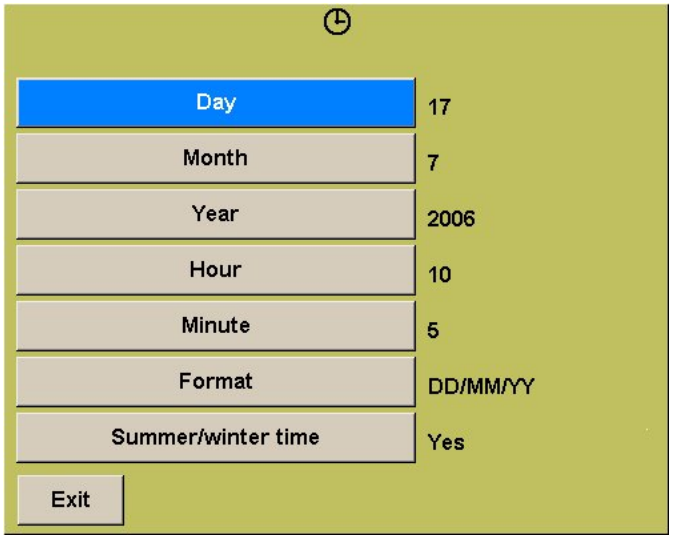


Sounds may be High, Medium, Low or Off, with the exception of alarms, which can never be Off.



4.7.1.7.2 Clock submenu

The various buttons are used to set the date and time. The daylight saving option can be disabled. The clock change date is pre-set.

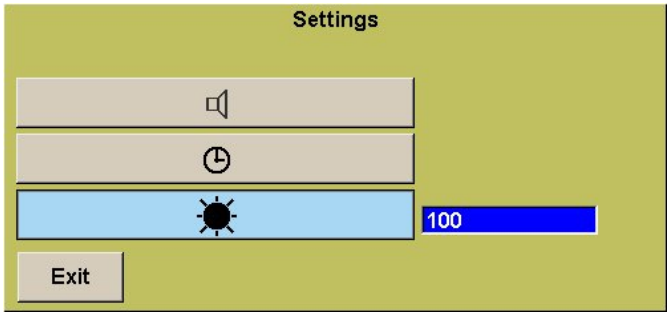


Example of date setting. Only plausible values can be selected.

Note: A time or date setting will erase all trends.

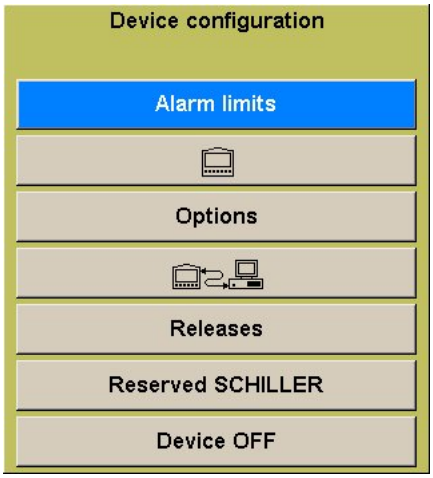
4.7.1.7.3 Screen brightness setting

You can set the screen brightness from 50 to 100%.



4.7.2 Device configuration menu

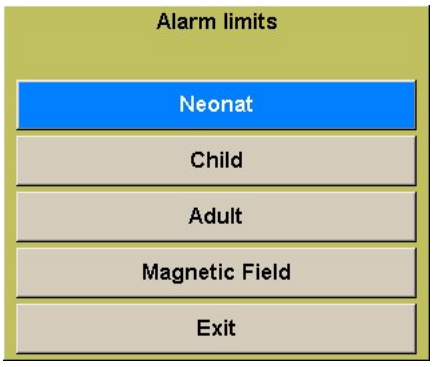
The configuration menus are hidden during normal operation. Access is initiated by pressing the navigation button **(6)** when the device is switched on and keeping it pressed until the configuration menu is displayed.



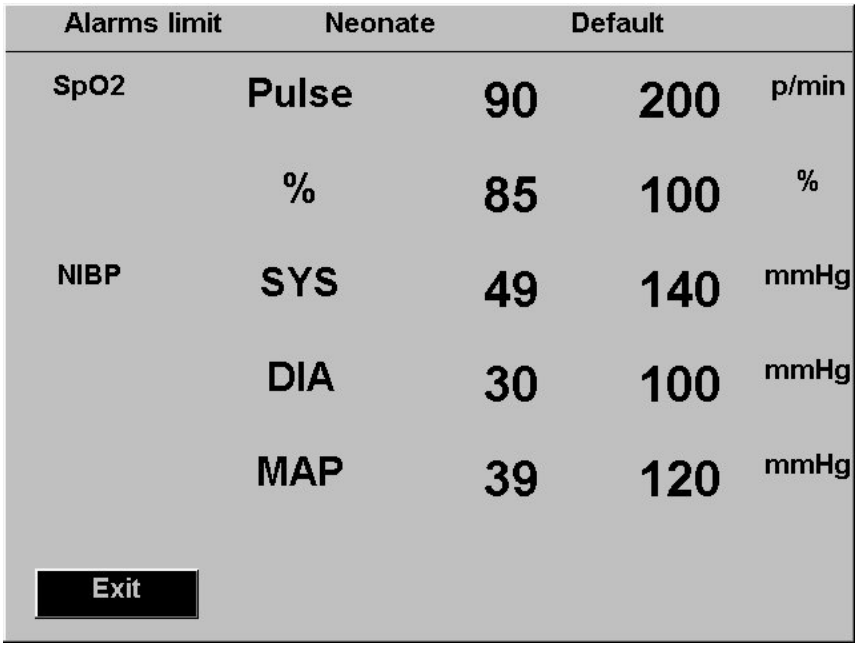
Note: To exit the **Device configuration** mode, the device must be switched off.

4.7.2.1 Alarm limits submenu

The default thresholds are set for the three type of patients - Adult, Child and Neonate. Select one type of patient, press button **(6)** and make the setting in the following tab



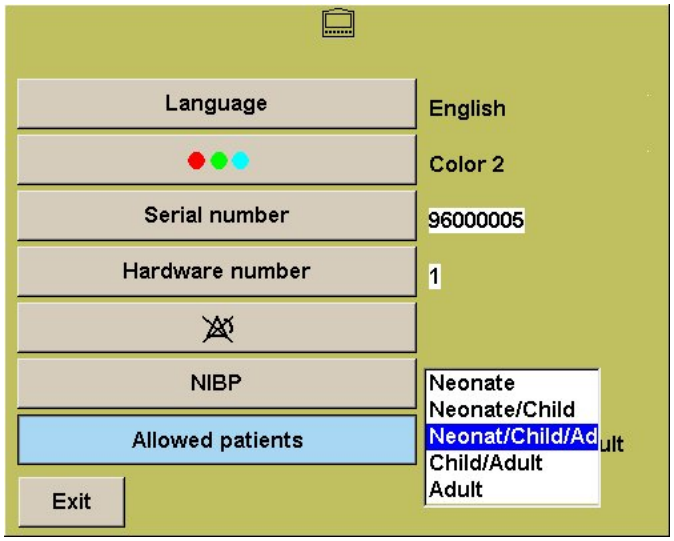
Select the parameter by navigation button **(6)** counter clockwise and confirm by pressing button **(6)**. The first value will flash. Turn as required to modify the value. Save the value by pressing button **(6)**. The next value is automatically selected. When the last parameter value has been entered, the selection cursor goes back to the parameter selection column.



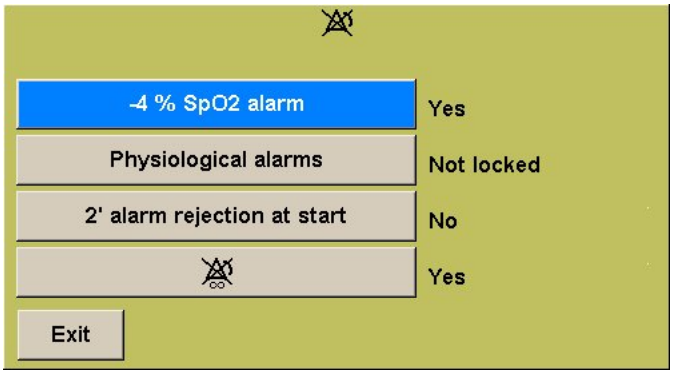
4.7.2.2 Monitor submenu

Note: The **Language**, **Colour**, **Alarms**, **NIBP** and **Patients selection list** buttons are used for settings, whilst the **Serial number** and **Hardware number** buttons are provided for information only and cannot be modified by the user.

- A certain number of languages are available. The language selection does not affect the operating of **MAGLIFE *light***.
- The screen colour combination can be selected with button .You cannot define a customised colour combination.
- The allowed **patient selection** button is used to restrict or extend the patient selection list.



Button: is used for special alarm configuration. It opens the following submenu:



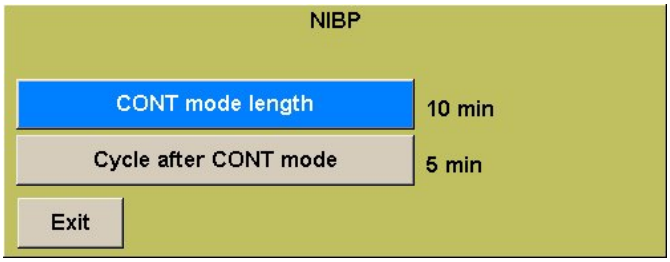
-4 % SpO2 alarm Enabling or disabling the alarm function if the SPO_2 drops more than 4%.

Physiological alarms A physiological alarm may be latched, i.e. confirmation by pressing key **(9)** is required to stop it, even when the value of the parameter has exceeded the threshold and is back in the non-alarm range. If the alarm is not latched, it stops as soon as the value is back within the non-alarm range.

2' alarm rejection at start This option is used to disable audio alarms for two minutes after the device is switched on, allowing for time required to apply the sensors for the measured values to stabilise.

This button is used to permit or prevent the ability to mute audible alarms permanently with key **(9)**. If the alarms are permanently muted, a reminding audio signal (double beep) is emitted after every two minutes.

Button: NIBP is used to define the parameters of the NIBP measurement in the continuous mode.



CONT mode length Is used to select the duration of the continuous mode.

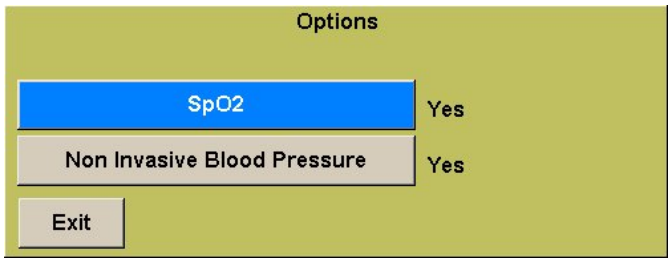
Caution: To ensure the correct vascularization of the member on whom the blood pressure is measured, the repetition of the continuous mode is not advised.

Cycle after CONT mode Is used to select the frequency of automatic measurements after the end of the continuous mode.

Caution: These configuration settings must be in accordance with the laws applicable in the country of use.

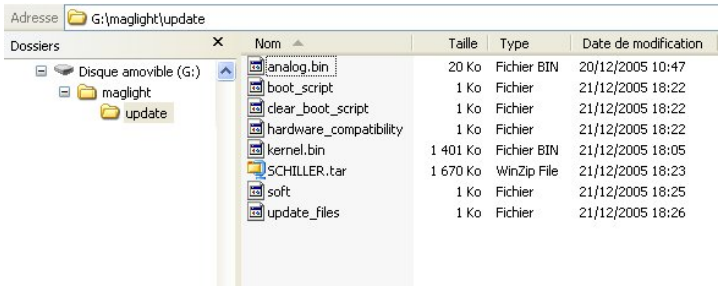
4.7.2.3 Options submenu

The **Options** menu is used to enable or disable one or both parameters of **MAGLIFE *light***

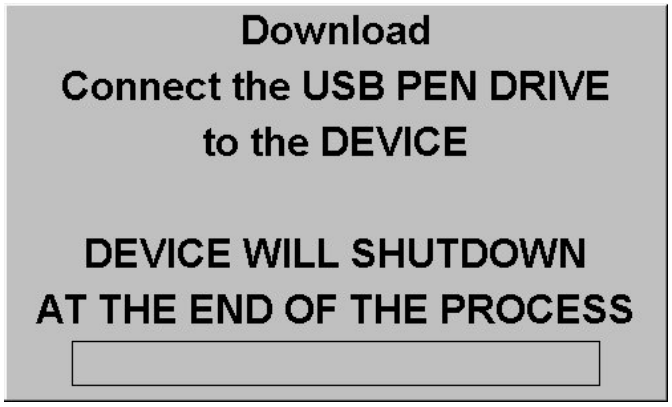


4.7.2.4 Software update submenu

The person performing the update must have the requisite skills to make the relevant functional and safety checks and **is entirely responsible for such checking.**
The software is updated by means of a USB key, standard 1.1 or above. Make sure that the software on the USB key in the root directory (only that software) is compatible with the device you want to update.



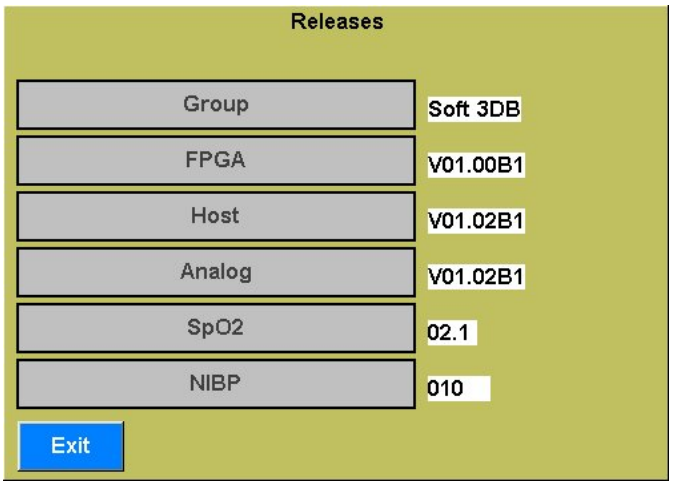
Insert the USB key in the connector **(15)** provided, select the update button and loading will start automatically. Follow the instructions. At the end of the loading process, the device will go off automatically.



Note: The procedure has been described in detail in the Service Manual of the device. For more information, please contact the technical service network of Schiller Medical.

4.7.2.5 Version submenu

The Version tab will show detailed info about used software versions and releases in MAGLIFE *light*

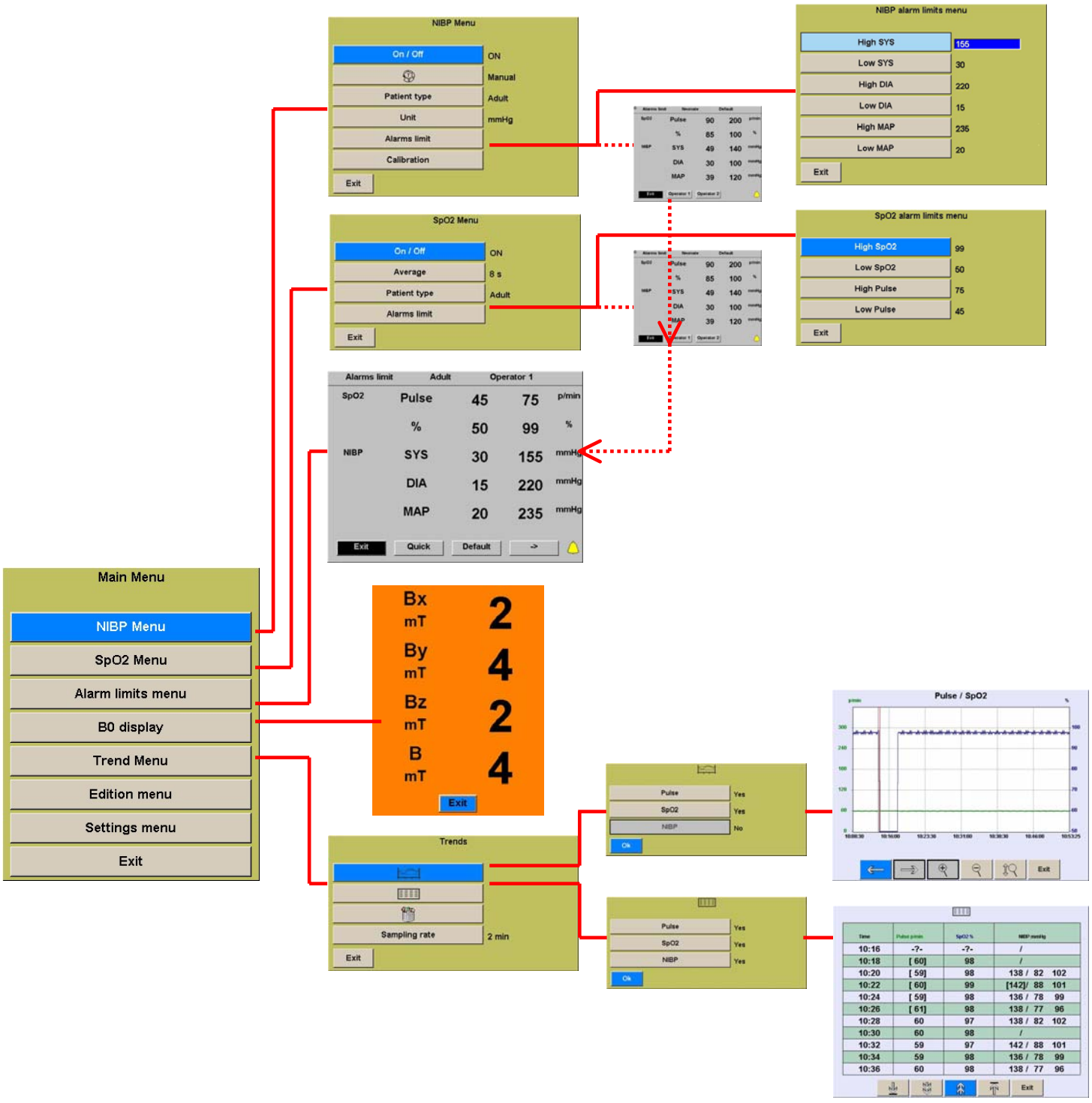


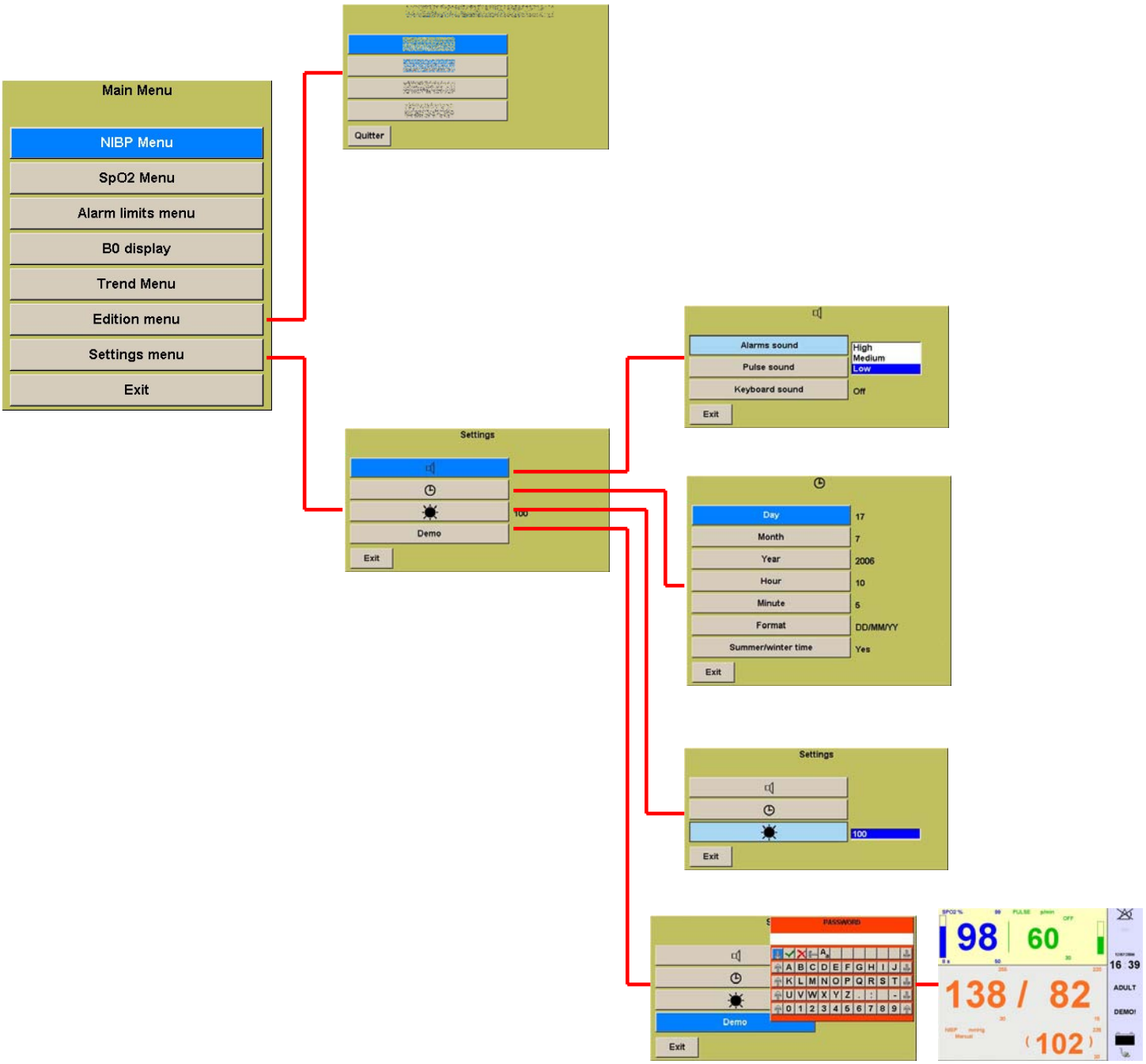
4.7.2.6 Reserved SCHILLER submenu

This submenu is only for technical purpose and is described in a separate manual.

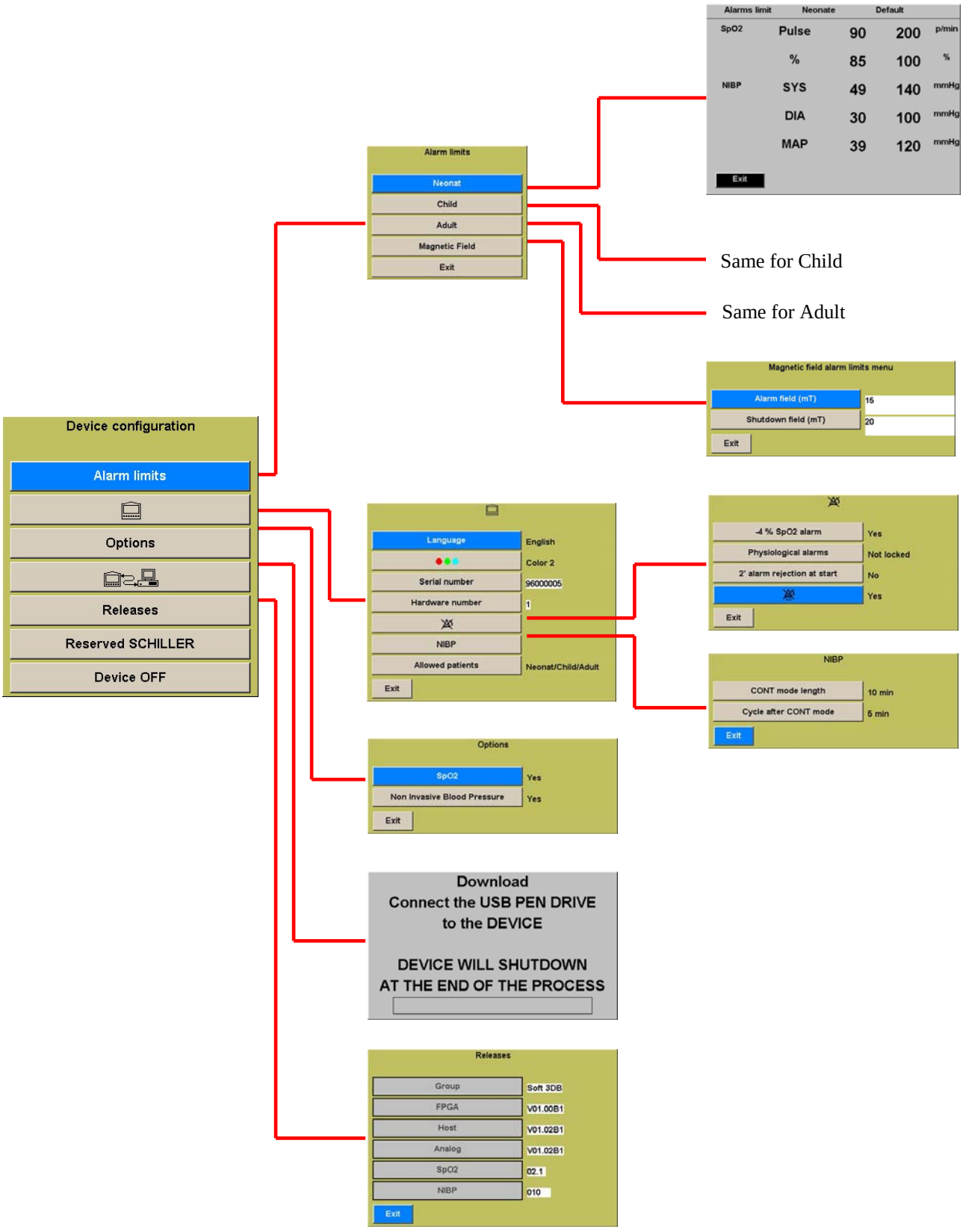
4.8 Structure of menus

4.8.1 User menus




Main Menu
NIBP Menu
SpO2 Menu
Alarm limits menu
B0 display
Trend Menu
Edition menu
Settings menu
Exit
Quitter
Settings
100
Demo
Exit
Alarms sound
Pulse sound
Keyboard sound
High
Medium
Low
Off
Exit
Day
17
Month
7
Year
2006
Hour
10
Minute
5
Format
DD/MM/YY
Summer/winter time
Yes
Exit
Settings
100
Exit
PASSWORD
Demo
Exit
98
60
138 / 82
102
16 39
ADULT
DEMO!

4.8.2 Configuration Menus



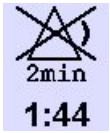
4.9 Alarms

4.9.1 Screen alarm symbols

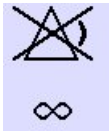
S1  Audible alarms enabled

S2 

Alarm sound disabled!
Displayed when at least one monitoring threshold is disabled. Technical alarms will go off all the same.

S3 

Alarm sound disabled for 2 minutes.
Displayed when you press key **(9)** (for less than three seconds). The remaining time is displayed under the symbol.

S4 

Alarm sound disabled permanently.
Displayed when the alarm off key (**9**) is held down for more than three seconds.

Alarm muting function

Key **(9)** is used to mute the alarms.

- When this key is pressed briefly, alarms stay disabled for two minutes and the symbol **(S3)** shows the time remaining in minutes up the end of the disabling of the alarm.
- If you press key **(9)** for three seconds or more, alarm sounds remain disabled permanently or until the key **(9)** is pressed again. Symbol **(S4)** is displayed, the symbol "∞" flashes and a beep is emitted once in every two minutes to remind the user.

Caution: **Audible alarm enabling/disabling**
The permanent disabling of audible alarms is not permitted in some medical facilities. That is why that function can be configured. (See Permanent muting section 4.7.2.2)

4.9.2 Physiological alarms

If the measured value of a parameter exceeds a threshold for over three seconds, an alarm goes off and:

- the display of the measured value flashes in red
- an intermittent audible alarm sounds (sequence of four digital sounds that is repeated)
- the window of the parameter over the threshold flashes on a red background and the display colour are inversed
- Depending on the choice made while configuring (see section 4.7.2.2) the alarm stops:
  - As soon as its cause stops (non latched)
  - After the causes disappears and key **(9)** is pressed (latched)

4.9.3 Technical alarms

When a technical alarm is triggered:
- an error message is displayed in the display field of the parameter in question
- an intermittent audible alarm goes off (sequence of two audible signals that is repeated); it depends on the audible alarm configuration criteria
- a question mark (**-?-**) is displayed instead of the measured value.

Note: going beyond of the measurement limits of the device.
In this case no error message is displayed:
- technical alarm sounds;
- 3 fixed indents (- - -) are displayed in the place of the measured value.

These alarms go off automatically when their causes disappear.

5. Technical specifications

5.1 System specifications

Manufacturer	SCHILLER Medical S.A.S.
Device name	**MAGLIFE *light***
Dimensions	
main unit	270 x 216 x 116 mm; 10.6” x 8.5” x 4.6”
power supply	180 x 84 x 68 mm; 7” x 3.3” x 2.7”
Weight	
main unit	6 Kg
power supply	1.3 Kg
Protection class of the enclosure	IP 21
Electricity supply	100, 115, 230 VAC, 50/60Hz Factory defined voltage
Power consumption	25 VA
Fuses	2 x 100 mA (T) - 230 VAC; 2 x 200 mA (T) - 100 - 115 VAC
Battery	12 V, 2 Ah Lead
Autonomy	2 hours
Environmental conditions	
Operating	
Temperature	15°C - 35°C; 60°F - 96°F
Relative humidity	30 – 95% non condensing
Pressure	500 - 1060 hPa
Magnetic field	≤ 40mT
Storage	
Temperature	-10°C - 50°C; 13°F - 124°F
Relative humidity	30 – 95% non condensing
Pressure	500 - 1060 hPa
Magnetic field	≤ 40mT

Display	Colour TFT screen: 6.8”; 98 x 132mm; 480 x 640 dots
Connections	SPO_2 and NIBP
Interfaces	RS232, USB 1.1 for connecting the equipment specified by SCHILLER
Safety standards	IEC 60601-1
EMC	IEC 60601-1-2 CISPER 11 Class B; with printer connected, class A The device may be subject to the following interference without being affected: Static discharge up to 8 kV Radio frequency 10 V/m (80 – 2500 MHz, 5 Hz modulating)
CE marking	According to directive 93/42/EEC class IIb
Protection class	Class I according to IEC 60601-1

5.2 Technical specifications of modules

5.2.1 Pulse oximeter

OEM module	BCI
Connection	Fibre optic
Class	CF
SPO2 accuracy	± 2 % from 70 to 99 % ± 3 % from 50 to 69 %
SPO_2 display range	0 – 99%
Pulse accuracy	5 b/min
Pulse display range	30 – 250 b/min
Blocking by defibrillator shock	10 seconds maximum
HF protection	protection from electro surgery devices

5.2.2 NIBP Non-Invasive Blood Pressure

OEM module	CAS
Connection	Fast snap
Class	CF
Measuring principle	Oscillometric
Mode	Manual, Automatic, Continuous

Types of patient	Neonate, Child, Adult
Sensor accuracy	± 3mmHg or ± 2 %
Pulse accuracy	5 b/min

Display range

Adult / Child:	systolic:	30 - 255 mmHg
	diastolic:	15 - 220 mmHg
	mean:	20 - 235 mmHg
	Pulse :	30 - 240 P/min
Neonate:	systolic:	30 - 135 mmHg
	diastolic:	15 - 110 mmHg
	mean:	20 - 125 mmHg
	Pulse :	40 - 240 P/min

RF protection	protection from electro surgery devices

5.3 Threshold ranges

The upper and lower alarm thresholds are adjustable according to the values in the table below.
The lower limit setting may never be greater than the upper limit setting and vice versa.

Parameter		Lower limit	Upper limit
Neonate patient			
SPO2	Pulse	30-245	35-250
	Saturation	50-98	51-99
NIBP	SYS	30-130	35-135
	DIA	15-105	20-110
	MAP	20-120	25-125
Child patient			
SPO2	Pulse	30-245	35-250
	Saturation	50-98	51-99
NIBP	SYS	30-250	35-255
	DIA	15-115	20-220
	MAP	20-230	25-235
Adult patient			
SPO2	Pulse	30-245	35-250
	Saturation	50-98	51-99
NIBP	SYS	30-250	35-255
	DIA	15-215	20-220
	MAP	20-230	25-235

6. Cleaning

MAGLIFE *light* can be cleaned with common cleaning and disinfecting agents (BURATON, INCIDIN. GG. KORSOLIN or LYSO FORMIN 2000).

Follow the manufacturer's instructions for use.

Switch the device off and disconnect from the mains before cleaning.
Do not remove any covers.
If any liquid does penetrate into the device, the device must be cleaned completely and inspected.

Do not expose the device to temperatures above 50 °C.

The use of an autoclave is not permitted.

The device and its accessories need to be decontaminated (risk of pathological contamination) before disposal.

The batteries of **MAGLIFE *light*** must be disposed of using a special procedure and not merely scrapped.

7. Troubleshooting

7.1 General errors

Error	Cause	Remedy
The screen does not activate when the device is switched on	• Mains not connected • Battery discharged • Magnetic field too great • Device faulty	• Check and correct the connections - LED (3) must be on • Connect the mains - LED (4) flashes • Place the device outside the field (<40mT) • Replace the device
The screen activates but the device initialise sequence is not carried out	• Device faulty	• Replace the device
The device shuts off automatically	• Battery discharged • Magnetic field too great	• Connect the mains • Place the device outside the field
No printing	• Non specific printer • No power to printer • Connecting cable loose	• Replace the printer with a printer specified by SCHILLER • Connect the printer to the power source and switch on • Check and remedy the connections

7.2 Errors of modules

Error	Cause	Remedy
No SPO2 measurement	• Optical probe faulty • Ambient light artefacts • No perfusion • Module faulty. (no light in the SPO2 connector)	• Replace the probe • Cover the sensor holder on the finger • Change the signal taking location • Replace the device
SPO2 signal disturbed	• Incorrect sensor installation • Compression of the measurement location • Poor perfusion	• Move the sensor • Remove the compression • Move the sensor
The cuff will not inflate	• Pump motor magnetised, because the device has been subject to an excessive magnetic field • Faulty cuff or tube	• Replace the device • Replace and check tightness
Doubtful NIBP measurements	• Incorrect cuff installation • Inappropriate cuff • System not airtight • Not locatable	• Check and adjust the cuff • Replace with an appropriate cuff • Replace the leaking part • Replace the device

8. Maintenance

- Before each use:
  - check all the device functions
  - simulate an alarm
  - check if all the connectors and cable insulators are in good condition
- Once a year:
  - check the leakage current according to paragraph 19 of standard IEC 601-1.

8.1 Alarm simulation

To simulate an alarm for verification, proceed as follows:

- connect a device that simulates a physiological signal to the device (e.g. SPO_2); wait for the value to stabilise and take the reading
- select the corresponding parameter with button (6) and select the **Thresholds** button
- modify one of the threshold values so that the value of the physiological parameter read earlier exceeds it
- confirm by pressing button **(6)**

After 3 seconds, an alarm will go off.

9. Additional accessories and indications

MAGMOVE *light*	Amagnetic trolley with storage basket for **MAGLIFE *light***
0-13-0010	Adult finger SpO_2 sensor, 5.2 m - fibre optic
0-13-0011	Child finger SpO2 sensor, 5.2 m - fibre optic
0-13-0012	Universal Y SpO2 sensor, 5.2 m - fibre optic
0-13-0008	Adult finger SpO2 sensor, 4.2 m - fibre optic
0-13-0002	Child finger SpO2 sensor, 4.2 m - fibre optic
0-13-0001	Universal Y SpO2 sensor, 4.2 m - fibre optic
0-13-0009	Adult finger SpO2 sensor, 3.5 m - fibre optic
0-13-0004	Child finger SpO2 sensor, 3.5 m - fibre optic
0-13-0003	Universal Y SpO2 sensor, 3.5 m - fibre optic
0-22-0003	5 m cuff tube
W1404413	3.5m m cuff tube
U50143	2.5 cm neonate cuff
U50142	4 cm neonate cuff
U50130	6 cm child cuff
U50129	7 cm child cuff
U50140	9 cm child cuff
0-40-0002	12 cm adult cuff
U50128	14 cm adult cuff
U50141	16 cm adult cuff
3-10-0118	Shielded **MAGLIFE *light*** power cable

10. Disposal

10.1 Battery disposal

Important

In normal use, the battery requires no maintenance.
After five years, the battery must be replaced, whether or not the device has been used.

Caution: Explosion hazard! The battery may not be incinerated or disposed of with household waste.

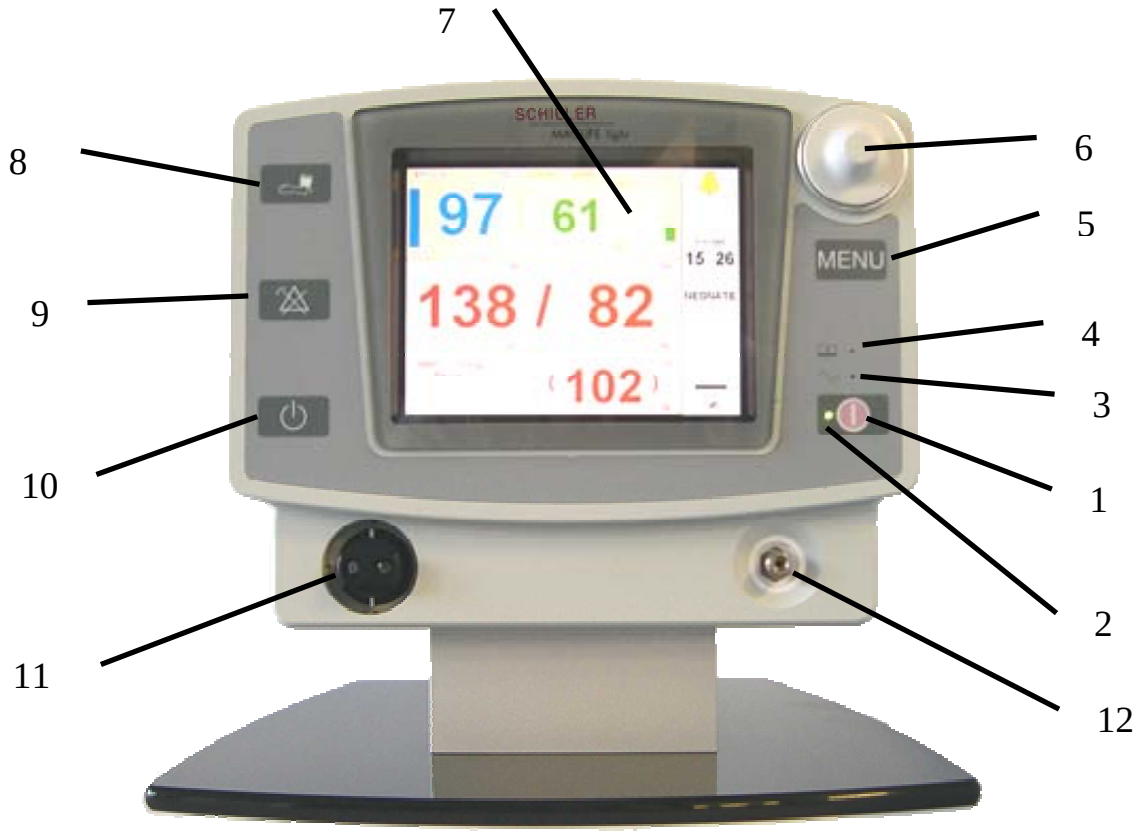
Caution: Acid burn hazard! Never open or overheat the battery!

In accordance with national law, the battery may only be disposed of in an approved disposal facility or sent back to SCHILLER.

10.2 Device disposal

The device components must be disposed of separately and the relevant parts must be sent to appropriate recovery and disposal centres.
If you do not know of such a recovery and disposal system, you may return the device to the distributor or manufacturer, who will take charge of disposing of the device in accordance with applicable regulations. In that way, you will contribute to the recycling and recovery of old electrical and electronic devices and their reuse in other forms.
Inappropriate disposal may be harmful to the environment and to public health as a result of the presence of hazardous materials in electrical and electronic devices.

11. Front



12. Rear and power supply