FINAPRES NOVA

BASIC USER MANUAL

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CE 0344

In addition to this Basic User Manual the following documents come with the Finapres Nova:

- EC Declaration of Conformity
- Additional manuals of optional hardware modules and software applications

Customer support

If the product fails to function properly or when assistance, service, or recalibration is needed, please contact:

Finapres Medical Systems B.V.
Hogehilweg 8
1101 CC Amsterdam
The Netherlands

Phone: +31 20 609 0974
Fax: +31 20 609 0677
Internet: www.finapres.com
Email: info@finapres.com

The year of manufacture of the Finapres Nova is mentioned on the identification plate at the back side of the device. An example of a Finapres Nova identification plate is shown below.

Figure C-1: Identification plate of the Finapres Nova

If accessories for Finapres Nova are needed, such as extra cuffs please contact the Finapres Medical Systems B.V Sales Department:

Phone: +31 20 697 2228
Fax: +31 20 609 0677
Email: sales@finapres.com

The Finapres Nova contains no parts that can be serviced by others than Finapres Medical Systems B.V. Unauthorized repairs and modifications will void the warranty and may violate the conformity of the Finapres Nova with the requirements of the Medical Device Directive 93/42/EEC.

Warranty

Finapres Medical Systems B.V. issues a 12 month guarantee on the Finapres Nova. This guarantee is only valid if the Finapres Nova is operated in accordance with the specifications and the instructions for use and maintenance.

The guarantee of the Finapres Nova is void in the event of:

- Improper use
- Insufficient maintenance
- Improper maintenance
- Modifications without prior consent of Finapres Medical Systems B.V.

The guarantee does not apply to parts that need to be replaced periodically.

Disclaimer

Finapres Medical Systems B.V. is not liable for unsafe situations, accidents and injury or damage which are caused by:

- Neglecting warnings or prescriptions as shown on the Finapres Nova or stated in this Basic User Manual and/or additional hardware and software manuals.
- The use of the Finapres Nova for other applications or under other circumstances than stated in this Basic User Manual.
- Modifying the Finapres Nova in any way (including application of other spare parts and changing the control program).
- Insufficient and improper maintenance.

Finapres Medical Systems B.V. is not liable for resulting injury following Finapres Nova malfunctions, such as operation breaks etcetera.

(US) Federal law restricts this device to sale by or on the order of a physician.

Preface

This Basic User Manual informs the user about the safe operation and everyday maintenance of the Finapres Nova. Read this Basic User Manual carefully before starting to use the Finapres Nova. Only then optimal safety can be obtained. Operation (and everyday maintenance) of the Finapres Nova may only be done by qualified personnel.

The user must be acquainted with the entire contents of this Basic User Manual before starting to use the Finapres Nova.

Always keep this Basic User Manual near the Finapres Nova.

Contents

1 Introduction

1.1 Finapres Nova

The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals. Cardiac output derived from the flow signal requires a calibration with thermodilution.

The Finapres NOVA has the option to include additional modules to extend its functionality with ECG and SpO2 measurements and blood pressure calibration.

When the SpO2 module is present, the Finapres NOVA can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate.

When the ECG module is present, the Finapres NOVA can additionally monitor the ECG parameters of a patient and their pulse rate. Alarms concerning the pulse rate will be available from the monitor. The ECG module provides only a visual clinical alarm.

When the blood pressure calibration module is present, the Finapres NOVA can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The Finapres NOVA is intended to be used for subjects above 18 years of age.

The Finapres NOVA is intended for use in a professional medical environment.

Except of the ECG module, no visual clinical alarms are given by the Finapres Nova. The Finapres Nova can generate alerts for technical but not for clinical issues.

Data produced by the Finapres Nova and/or the accompanying software is intended as an adjunct in patient assessment. It should not be used as a sole means for determining a patient's diagnosis.

1.2 Intended use and environment

The Finapres Nova is a standalone device intended for desktop use. Measurements are to be performed under uninterrupted patient surveillance of the operator.

The Finapres Nova is used in a professional medical environment (i.e. hospitals, clinics and research institutions etc.). The Finapres Nova is suitable for use in an operating room in the non-sterile zone. The Finapres Nova is not intended for use in an oxygen rich environment.

The Finapres Nova should not be used in combination with systems that can cause electromagnetic interference. This includes devices such as defibrillators, MRI's, or electro-surgical units

The Finapres Nova should not be used in combination with HF surgery devices.

1.3 Intended user

The user of the Finapres Nova should be a qualified operator. The operator should have knowledge of the system and data interpretation, obtained via medical education, system manuals and/or specific courses. He/she is the person operating the Finapres Nova instrument.

1.4 Intended patient population

Age

18 years and up

Weight

20 up to 255 kg

Health

With respect to the measurement principle it is known that the application of the device in patients with Raynaud's disease is limited.

Condition

Provided the device can detect a sufficient pulsating artery (according to its own acceptance criteria) and the finger cuff is applied correctly, the measurement can be performed.

The Finapres Nova can be used with pregnant, pre-eclamptic patients with caution.

Diagnosis

The device has an added value for diagnosing a patient. However, an uninterrupted availability of measurement data cannot be guaranteed. Therefore, in situations where this is required additional patient monitoring equipment is needed.

Contraindications

Not known.

1.5 Device classification

- The Finapres Nova is class I ME equipment according to IEC 60601-1.

- The Finapres Nova has a protection degree against harmful ingress of water or particulate matter of IP31. This means that the Finapres Nova is protected against ingress of solid foreign objects having a diameter of ≥2,5 mm and against harmful effects of dripping water per IEC 60529.

1.6 Accessories

The Finapres Nova has the following accessories for measuring blood pressure:

- Frontend Unit
- Height correction unit
- Finger cuffs:
- **S(mall) finger cuff (white),**
- **M(edium) finger cuff (beige),**
- **L(arge) finger cuff (blue).**

! ***The Finapres Nova may only be used in combination with accessories provided by the manufacturer!***

2 Warnings and safety precautions

2.1 Safety and precautionary symbols

Suggestion to carry out tasks easier.

Draws attention to potential problems.

Draws attention to the danger of serious injuries to the user or patient if the instructions are not carried out carefully.

2.2 Warning pictorials

Consult instructions for use

General mandatory action sign

Dangerous voltage

Equipotentiality

USB connection

Type B applied part

Manufacturer

Year of Manufacture

Dispose as hazardous waste

IP31

Protection degree against harmful ingress of water or particulate matter

2.3 Warnings and cautions

Only qualified personnel is allowed to operate and maintain the Finapres Nova.

Measurements should always be performed under the supervision of a medical practitioner, who remains in the vicinity of the Finapres Nova

The operator should never touch both the patient and the Finapres Nova at the same time.

The functioning of the Finapres Nova should be checked prior to operation

The Finapres Nova should only be used with a properly grounded AC receptacle (100V - 240V, 50/60 Hz). Hospital grade line cords in AC-powered systems are preferred

To avoid the risk of electric shock, the equipment must only be connected to a mains supply with protective earth.

Damaged or defective parts should always be replaced before putting the Finapres Nova into use again

It is not allowed to make modifications to the Finapres Nova or its software without prior written approval of Finapres Medical Systems B.V.

Upon power down the Finapres Nova will immediately shut down.

The Finapres Nova may only be used in combination with the accessories and additional modules prescribed by Finapres Medical Systems B.V.

The finger cuff should not be applied over a wound, as this can cause further injury

To avoid the Finapres Nova to fall, make sure it is placed on a flat surface.

The Finapres Nova should be moved from one location to another using a trolley or similar means

After a patient connected to the Finapres Nova is defibrillated, the Finapres Nova needs 5 seconds recovery time.

When a patient needs to be defibrillated, remove all applied parts from the patient before applying the defibrillation pulse to the patient.

Any blood pressure reading can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition

Diseases or environmental conditions that result in reduced finger arterial compliance (diabetes, Raynaud disease, cold fingers), which causes reduced volumetric pulsations in the fingers, may lead to an inability to measure blood pressure or derived variables. This will be detected by the device which will report an error.

The Finapres Nova is not equipped with auditory alarm signals. Errors and warnings are displayed at the top of the screen.

Safety and effectiveness in children under the age of 18 and patients with Raynaud's disease have not been established.

3 Installation

3.1 Unpacking the Finapres Nova

Always check the packing of the Finapres Nova for damage before starting to unpack.

In case of damage of the packing contact Finapres Medical Systems B.V. before continuing.

3.1.1 Package contents

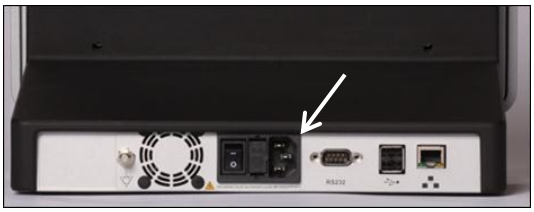
Verify the contents of the package with the delivery note.
In case of an incomplete delivery contact Finapres Medical Systems B.V.

3.2 Installation

3.2.1 Finapres Nova

1. **Place** the Finapres Nova on a flat surface.

2. **Connect** the power cable to the socket at the back of the Finapres Nova.



The Finapres Nova should be positioned such that the power socket at the back is easy accessible.

3. When the Finapres Nova is used in combination with other ME equipment, it is recommended to connect the potential equalization pin to a potential equalization busbar.

After installing, always check the functioning of the Finapres Nova before performing a measurement.

4 Finapres Nova description

4.1 Description of the Finapres Nova

Figure 4-1: The Finapres Nova

4.2 Connections and controls

On the front, back and on the right side of the Finapres Nova several connections and controls are positioned.

Controls on the front

On the front of the touch screen you will find the touch ON/OFF touch button:

Figure 4-2: ON/OFF touch button

Connection on the right side

The connection of the Frontend Unit can be found on the right side of the Finapres Nova.

Figure 4-3: Connection for the Frontend Unit

Controls and connections on the back

On the back of the housing general connections and the mains switch of the Finapres Nova can be found (Figure 4-4).

1. Equipotential connection
2. Mains switch
3. Mains connection
4. RS232 connection
5. USB connections
6. Network connection

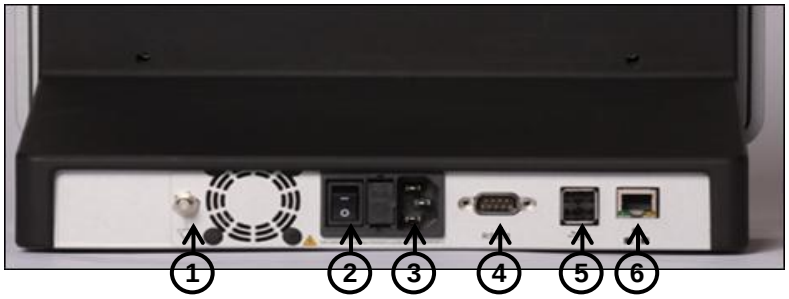


Figure 4-4: Connections on the back

4.2.1 Accessories

The Finapres Nova is provided with the following accessories:

1. Frontend Unit

2. Finger cuffs

3. Height correction unit

4.3 Graphical user interface

The Finapres Nova is mainly controlled via its graphical user interface using the touch screen. The graphical user interface allows the operator to set up the Finapres Nova, to perform measurements and to review stored data.

The graphical user interface is explained in detail in Appendix 1– ' Graphical user interface' on page 43.

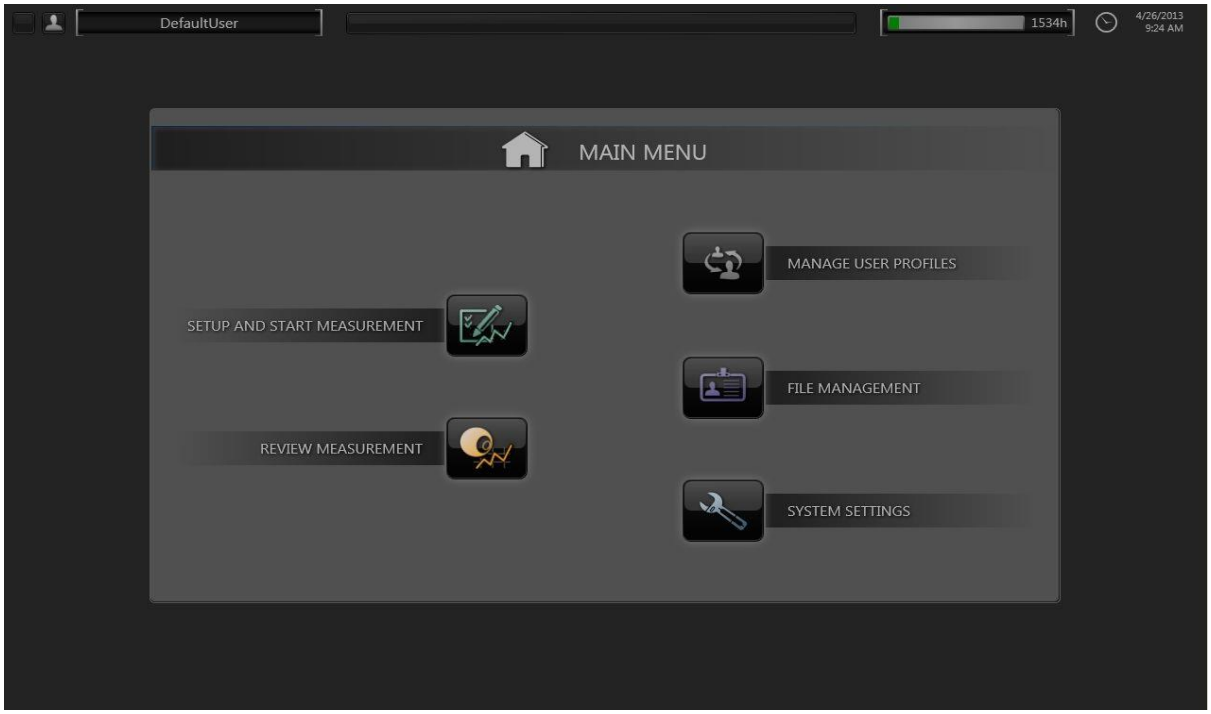


Figure 4-5: Main menu of the graphical user interface

5 Operation

5.1 Switching on

To switch on the Finapres Nova:

1. **Check** if the power cable is connected.
2. **Switch** the main switch on the back of the Finapres Nova to "1".

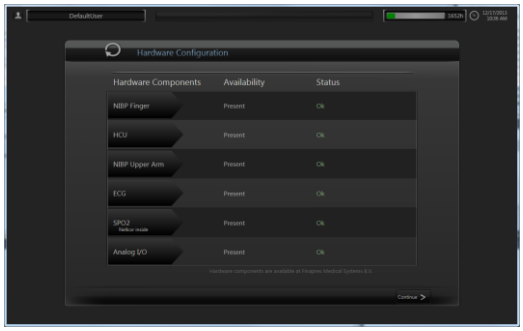
- The ON/OFF button on the front panel is lit orange to indicate the system is "IDLE".

3. **Touch** the ON/OFF button.

- The Finapres Nova starts up.
- The status button on the front panel is lit green to indicate the system is "Running".
- The startup will take about one minute and then…

4. The "MAIN MENU" appears.
…or…

5. The "HARDWARE CONFIGURATION" screen will appear when one or more additional modules report an important error
6. To start the Finapres Nova, **press** the "CONTINUE" button to open the "MAIN MENU"



See A1.5 for the error messages that appear on the "HARDWARE CONFIGURATION" screen

The "HARDWARE CONFIGURATION" screen will always appear when the Finapres Nova is not equipped with the additional modules.

5.2 Switching off

To switch off the Finapres Nova:

1. **Touch** the status button and confirm turning off the device.
- The Finapres Nova goes into "IDLE" state.

2. **Switch** the main switch on the back of the Finapres Nova to "0"

5.3 Disconnecting from the mains supply

If the Finapres Nova will not be used for a longer period or maintenance has to be performed, the Finapres Nova must be disconnected from the mains supply.

To disconnect the Finapres Nova from the mains supply:

1. **Ensure** the main switch on the back of the Finapres Nova is set to "0".
2. **Disconnect** the power cord from the mains outlet and the unit.

5.4 Measuring

5.4.1 Connecting the patient

Before the measurement is started, the finger cuff(s) and Frontend Unit must be connected to the patient (see Appendix 3 - 'Connecting the patient', page 93)

Ensure that the finger cuff is properly applied to the patient prior to starting a measurement. If a measurement is started without a finger in the finger cuff, the finger cuff may be damaged.

5.4.2 Connecting the Frontend Unit

To connect the Frontend Unit to the Finapres Nova:

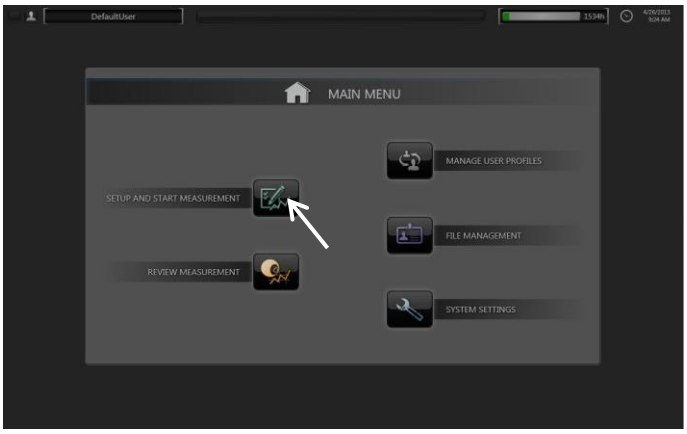
Push the plug of the Frontend Unit into the socket on the right side of the Finapres Nova marked with "FRONT END".

Be careful when connecting the Frontend Unit!
The pins of the plug are vulnerable.

5.4.3 Starting a measurement

To start a measurement:

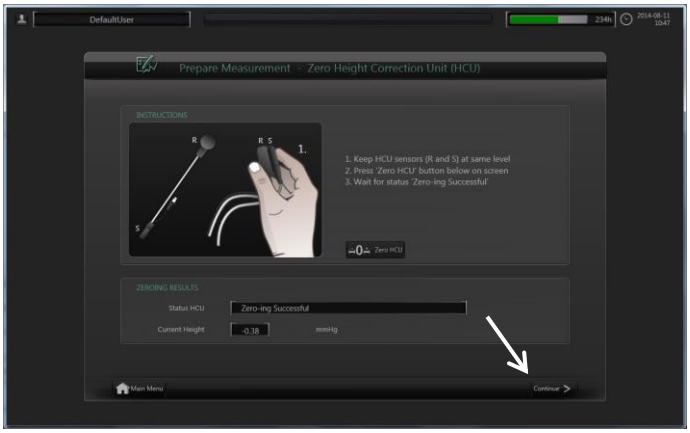
1. **Press** the "SETUP AND START MEASUREMENT" button on the "MAIN MENU" screen.



If the HCU is connected for the first time after the Finapres Nova is started up the "ZERO HEIGHT CORRECTION UNIT" screen appears:

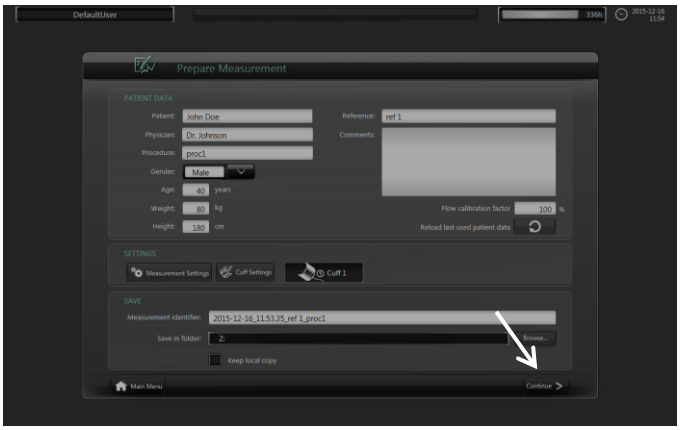
2. **Follow** the instructions on the screen and **wait** for the status "ZEROED" to show up.
3. **Press** the "CONTINUE" button.

- The "PREPARE MEASUREMENT" screen appears.



4. **Fill** in the patient data.
5. **Press** the "CONTINUE" button.

- The "MEASUREMENT" screen opens.



The on screen keyboard shows up automatically as soon as a text field is touched.

The "MEASUREMENT" screen is opened displaying the data according to the active user profile.

6. Press the button

- The finger blood pressure measurement is started automatically
- The measurement data is stored on the hard disk of the Finapres Nova.

During the measurement all available signals, even those that are not visible on the screen, are recorded.

5.4.4 Actions during a measurement

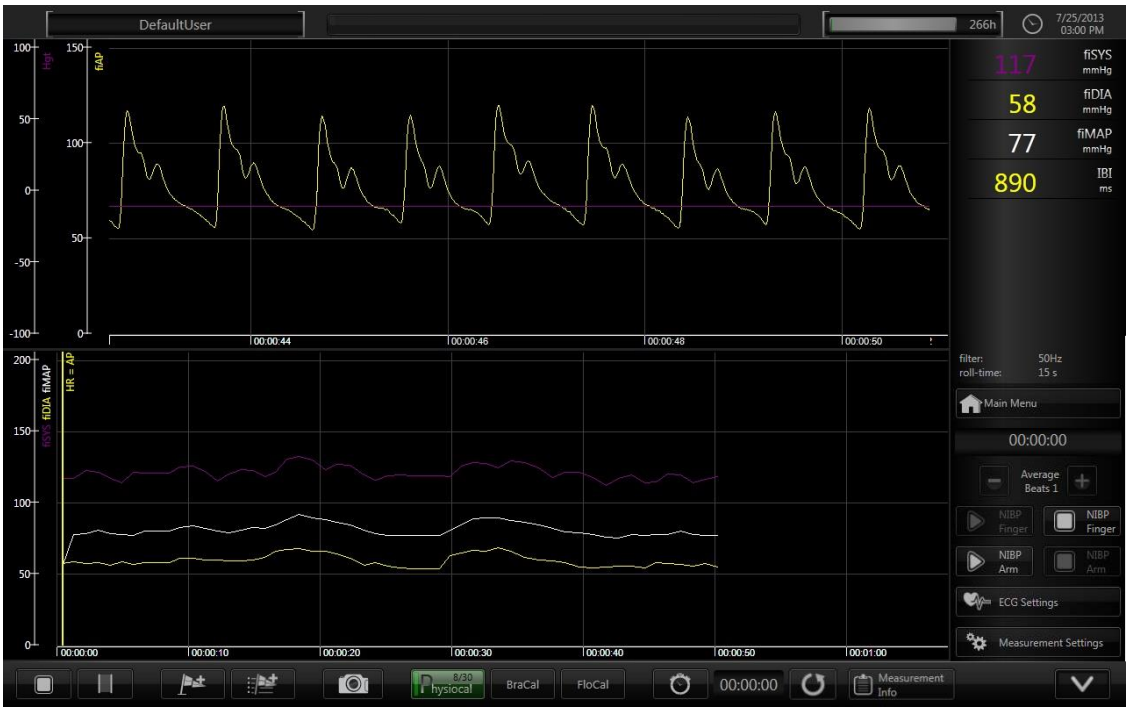


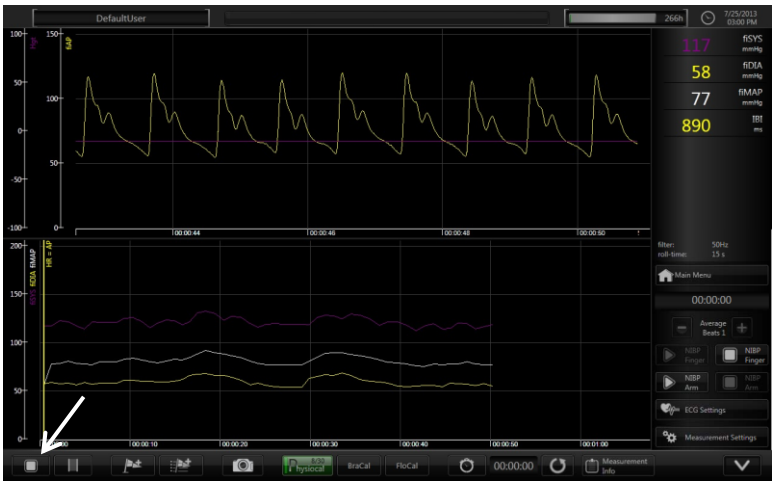
Figure 5-1: "MEASUREMENT" screen with a running measurement

While in measurement mode several actions are possible by means of the buttons at the bottom of the screen (e.g. placing markers, highlighting parts of the measurement, calibration, etc.). The functions of these buttons are explained in more detail in A1.4.

5.4.5 Stopping the measurement

To stop the recording of a measurement:

1. **Press** the "STOP" button .
- A confirmation pop-up is shown.



2. **Press** "YES" to stop recording the measurement.
- The "REVIEW MEASUREMENT" screen is opened with the recorded data shown.

..or..

3. **Press** "NO" to continue the recording.

..or..

4. **Press** "RESTART" to stop recording the measurement and to start a new recording for the same patient**.**

When "RESTART" is pressed, the data recorded up to the point of "RESTART" is stored under the given filename. The new recording will be stored under the same name with an additional index number appended to it.

5.4.6 Disconnecting the patient

After the measurement is finished the patient can be disconnected from the Finapres Nova by removing all accessories from the patient.

To disconnect the Frontend Unit to the Finapres Nova:

1. **Unlatch** the plug by pulling the ribbed part a few millimeter backwards
2. **Pull** the plug of the Frontend Unit out of the socket.

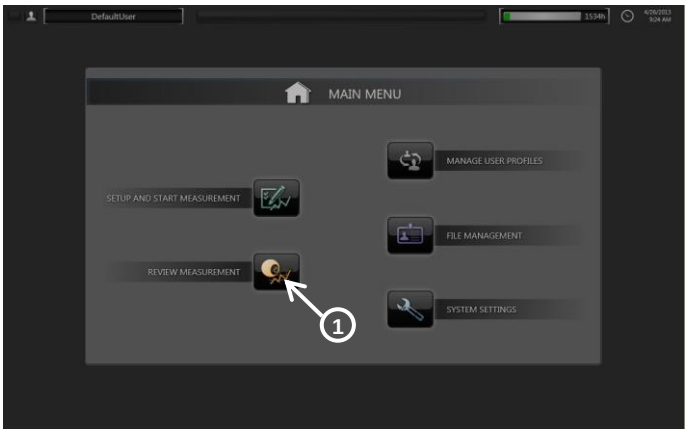
When disconnecting, pull on the plug itself, not on the cable.

5.5 Reviewing a measurement

In this chapter the most common actions when reviewing a measurement are explained. For more details about the functionality available in the "REVIEW MEASUREMENTS" screen see Appendix A1.4.1.

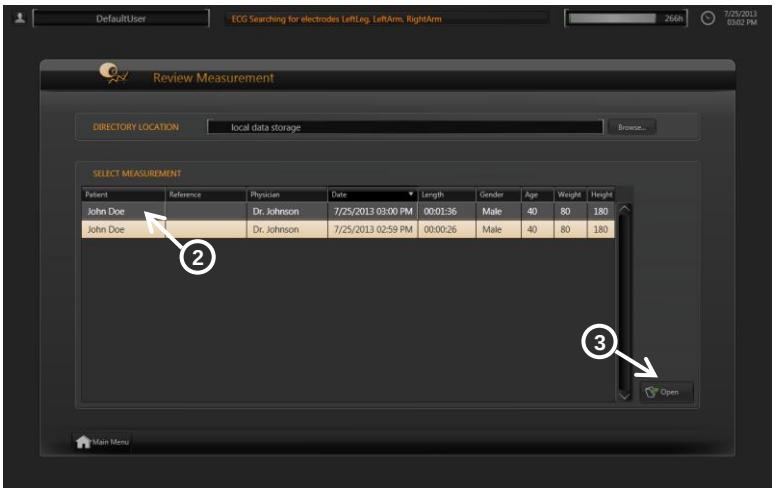
After a measurement is stopped, the data of that measurement is shown in the "REVIEW MEASUREMENTS" screen automatically. Alternatively, measurements can be reviewed via "REVIEW MEASUREMENT" in the "MAIN MENU".

1. **Press** the "REVIEW MEASUREMENT" button.
- A file selection screen appears.



2. **Select** a file.
3. **Press** the "OPEN" button.

- The "REVIEW MEASUREMENT" screen is opened and the data of the selected file is loaded.



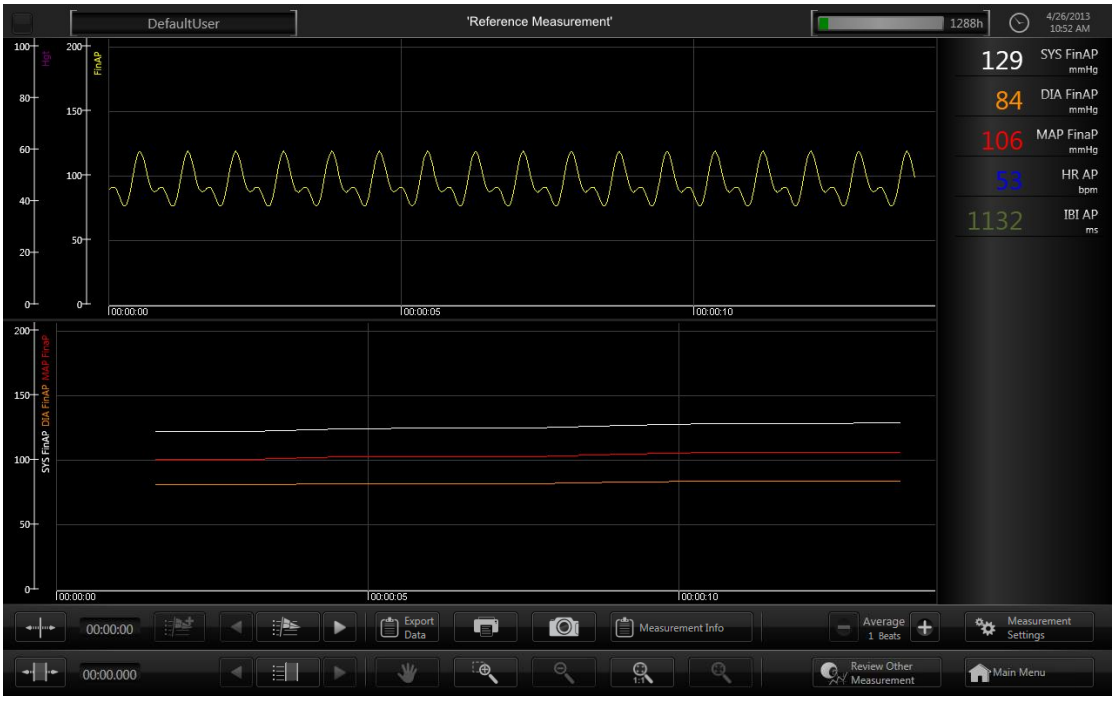


Figure 5-2: "REVIEW MEASUREMENT" screen with a measurement loaded

When a measurement is opened it is fully zoomed out so that the entire measurement is visible.

While in review mode several actions are possible by means of the buttons at the bottom of the screen (e.g. adding or removing signals, creating, editing and removing markers, zooming in and out, moving through the graphs, making prints and screen shots, exporting data, etc.). The functions of these buttons are explained in more detail in A1.4.1.

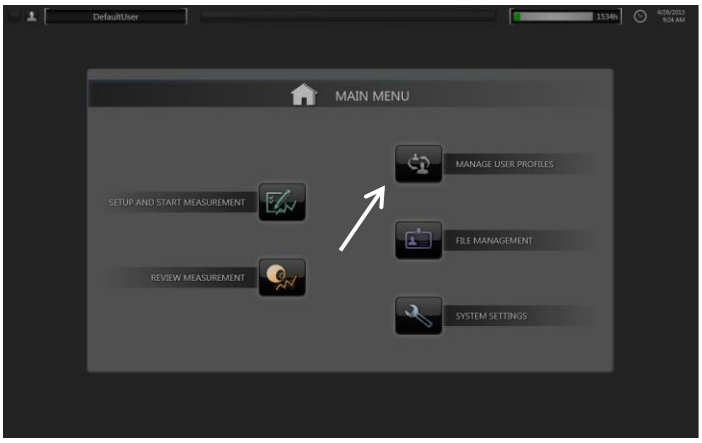
In general the button has to be selected and subsequently the graph has to be clicked in order to perform the action

5.6 Selecting a user profile

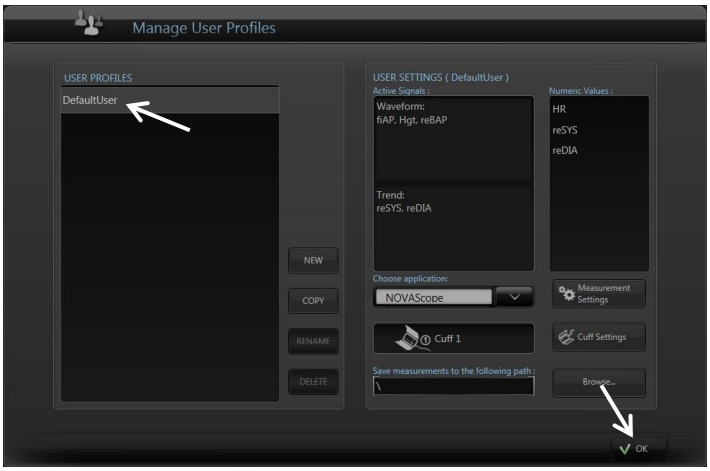
The appearance of the measurement and review screen is stored in user profiles. For creating, copying, renaming and deleting user profiles see A1.4.2.

1. **Press** the "MANAGE USER PROFILES" button of the "MAIN MENU".

- The "MANAGE USER PROFILES" screen appears.



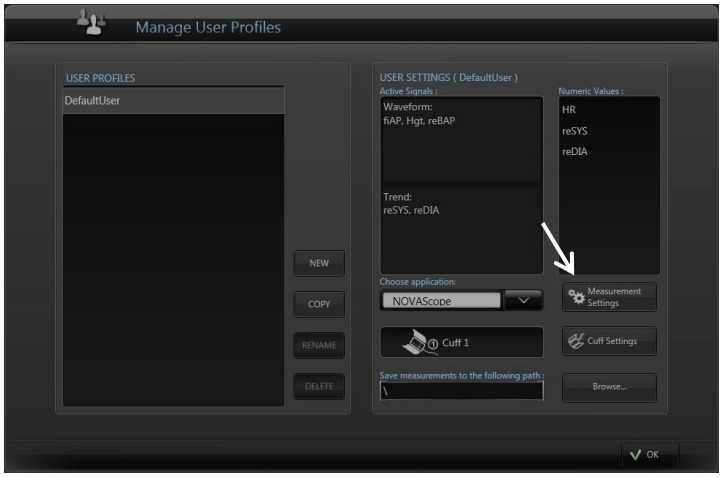
2. **Select** the desired user profile from the list and **press** the "OK" button.



5.7 Measurement settings

Measurement settings can be changed during measurement and review (see A1.4 and A1.4.1) or via the user profile settings:

Open the "MEASUREMENT SETTINGS" screen by pressing the "MEASUREMENT SETTINGS" button in the "MANAGE USER PROFILES" screen.



In the "MEASUREMENT SETTINGS" screen, settings for "WAVEFORM GRAPHS", "TREND GRAPHS", "NUMERIC VALUES", "SIGNAL SETTINGS" and "MARKER DEFINITIONS" can be made (A1.4.4).

If the measurement settings are changed, the new settings will be stored to the currently active user profile and will immediately be visible in the "MEASUREMENT" screen.

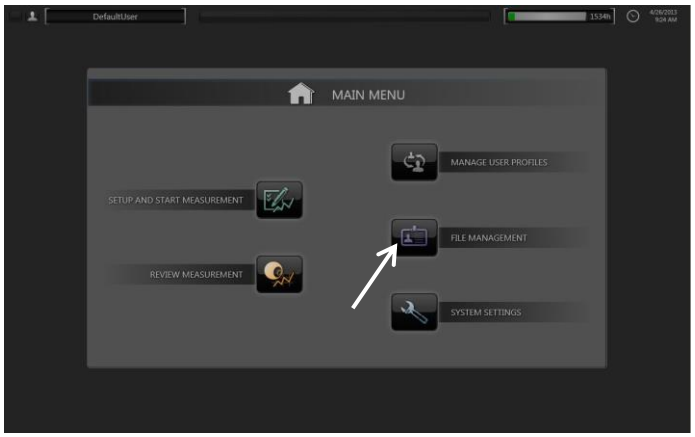
For all available signals and numeric values, see Appendix A2.3 "Signals". Additional signals may be available depending on the presence of hardware modules and software applications

5.8 File management

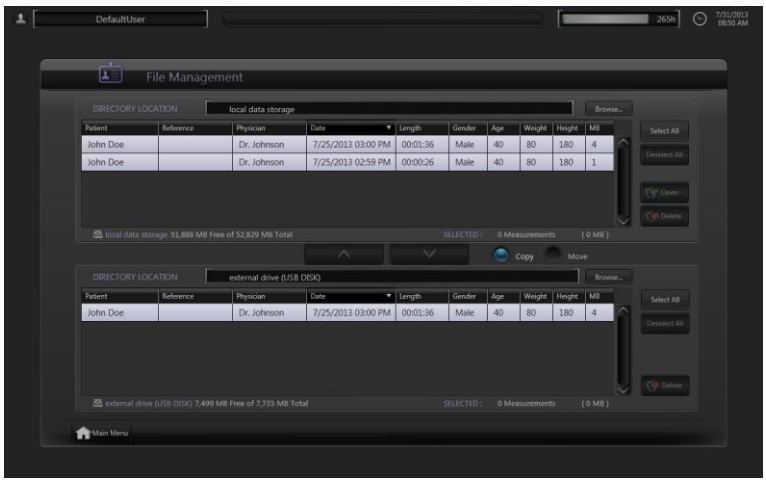
The measurements stored on the hard disk can be opened, deleted and moved or copied via the "FILE MANAGEMENT" screen.

The "FILE MANAGEMENT" screen can be opened as follows:

1. **Press** the "FILE MANAGEMENT" button of the "MAIN MENU".
- The "FILE MANAGEMENT" screen appears.



Refer to A1.4.5 on opening, deleting moving or copying files.



6 Maintenance & cleaning

6.1 Maintenance

The user is not allowed to perform technical maintenance on the Finapres Nova.

The housing contains components that are energized with high voltage. The housing may only be opened by Finapres Medical Systems B.V..

The Finapres Nova contains no parts that can be serviced or replaced by others than Finapres Medical Systems B.V..

Maintenance should only be executed by qualified persons.

6.1.1 Maintenance schedule

Finapres Medical Systems B.V. recommends that the device is returned yearly for a service and calibration check.

6.2 Cleaning

The Finapres Nova should be cleaned after each day of use. The Finapres Nova can be cleaned by whipping its surface using a soft, slightly moistened cloth. Cleaning fluid or any liquid should not be sprayed directly onto the device or its units. Detergents or strong chemical agents such as alcohol, refined petrol or thinner should never be used as they can damage the Finapres Nova housing.

The finger cuffs could be cleaned after each use by submerging the bladder end in a MidiClean ForteSolution (ChemischeFabrik Dr. Weigert GmbH & Co. KG) .

Do not allow any water to enter the device or finger cuff connectors at any time. Allow enough time to dry when water accidentally the finger cuff connectors.

Do not use other disinfecting agents (like alcohol) for cuff cleaning as they may compromise bladder integrity. Doing so may reduce measurement accuracy or lifespan of a finger cuff

7 Transport and storage

See Appendix A2.4.4 – "Environmental conditions" for the environmental storage and transport conditions.

7.1 Transport

When shipping back the Finapres Nova, please return the complete device and all its accessories. Use, if possible, the original cardboard box and protection buffers to avoid damage during transport. If this is not available make sure that the used box is compatible with the Finapres Nova and packed securely to help assure safe transportation, keeping in mind ordinary care in handling by couriers.

Figure 7-1: Transport box labeling

Prepare a Pro forma invoice to accompany the shipment mentioning "for customs use only", or "non-commercial invoice" and make sure to mention "repair return".

The Finapres Nova can be returned by a courier service, for instance FedEx or DHL, please do not use UPS for the return shipment. UPS doesn't work with the term "repair return" and it is not possible to perform a temporary clearance for a repair return shipment.

Always follow the instructions on the transport labeling while transporting the Finapres Nova in its transport box.

Appendix 1 Graphical user interface

A1.1 General screen description

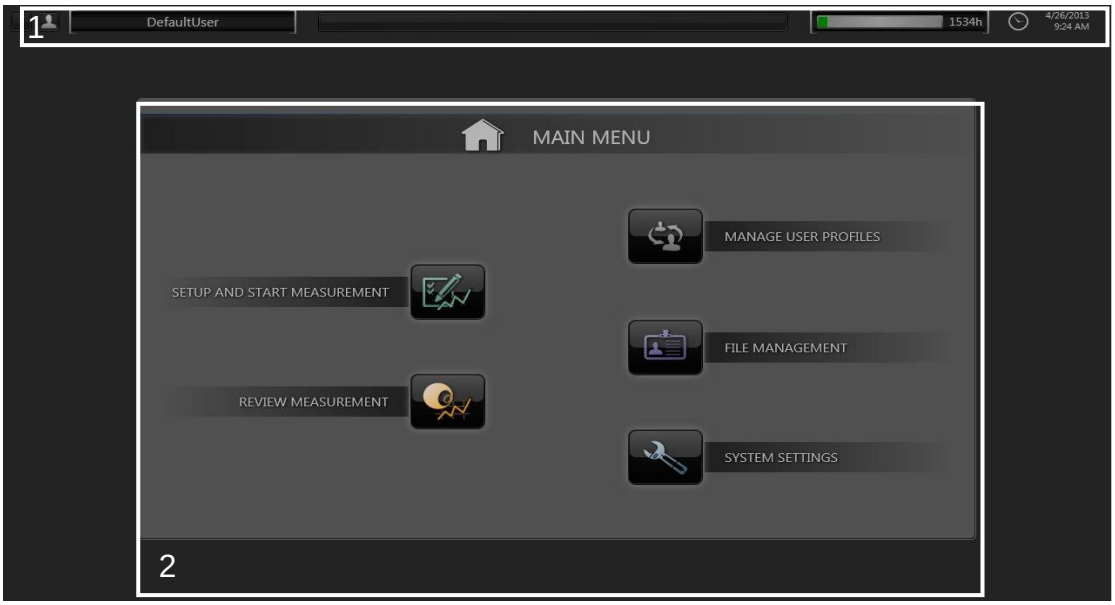


Figure A1-1: General screen description

All screens of the graphical user interface consist of a STATUS BAR (1) on top of the screen and a CONTENTS BOX (2) in the middle (see Figure A1-1).

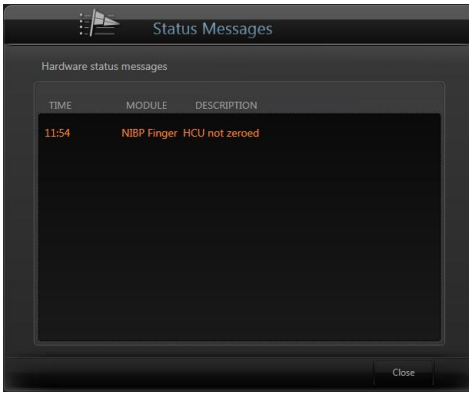
Status bar

Figure A1-2: Status bar

On the STATUS BAR (see Figure A1-2) the following information is displayed:

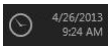
1. The active user profile.

2. Notification of occurring errors or warnings. The total number is indicated between brackets (number of current warning or error / total number of warnings or errors)
   - Clicking the message will cause the "STATUS MESSAGES" pop-up screen to appear. In this screen a list of the generated error and warning messages is shown.



3. An estimation of the remaining recording time.

4. The actual time and date.



Contents box

Inside the CONTENTS BOX the different screens are displayed. Based on its contents the CONTENTS BOX can vary in size. In Figure A1-1 the CONTENTS BOX is shown with the MAIN MENU loaded.

A1.2 On-screen keypad

To be able to enter text in text fields, the Finapres Nova graphical user interface is provided with an on-screen keypad. This on-screen keypad shows up automatically after a text box is touched (see Figure A1-3).

Figure A1-3: On screen key pad

After the button is pressed, the entered text is transferred to the text box and the on-screen keypad is closed.

A1.3 Main menu

After the Finapres Nova is started the MAIN MENU of the graphical user interface is shown. Via this screen tasks can be started and the other screens accessed.

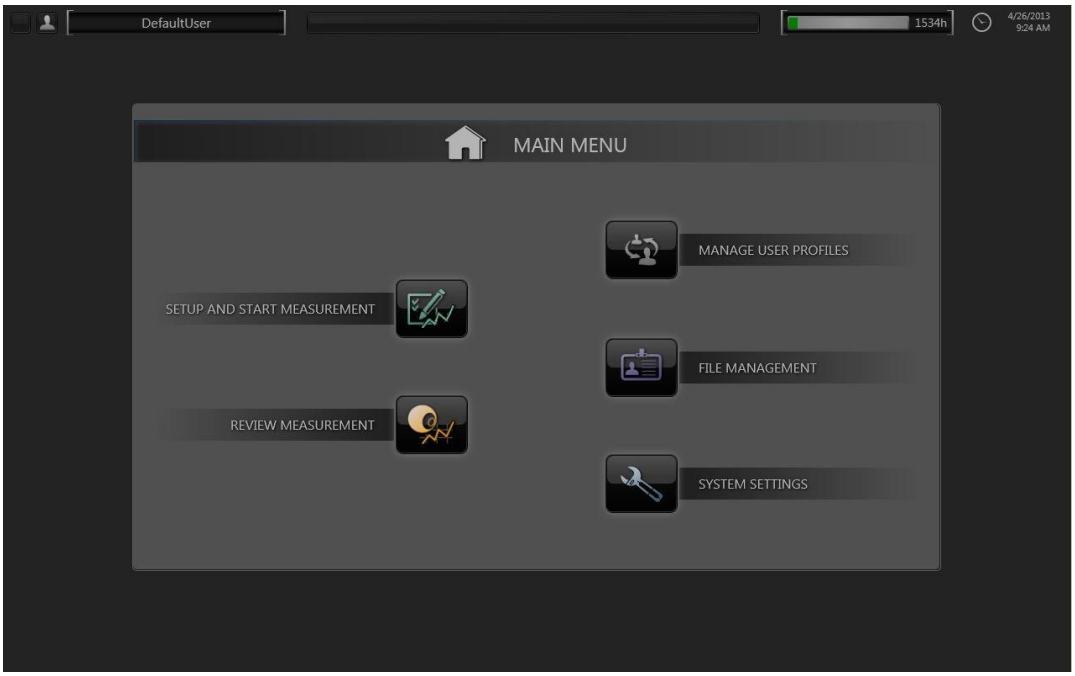


Figure A1-4: Main menu

The elements of the "MAIN MENU" screen have the following meaning:

Item	***Description***
	SETUP AND START MEASUREMENT Starts the procedure to enter patient data and start a measurement. Refer to A1.4 for more information.
	REVIEW MEASUREMENT Opens the REVIEW MEASUREMENTS screen that enables the user to open and review measurement results that are stored on the hard disk of the Finapres Nova. Refer to A1.4.1 for more information.
	MANAGE USER PROFILES Opens a screen that shows the available USER PROFILES and enables the user to add, alter and remove USER PROFILES. Refer to A1.4.2 for more information.
	FILE MANAGEMENT Allows the user to handle (open, delete, move and copy) the files with measurement data. Refer to A1.4.5 for more information.
	SYSTEM SETTINGS Opens the SYSTEM SETTINGS SCREEN. Refer to A1.4.6 for more information.

When additional applications are available on the Nova, these are accessible via an additional button. When only one application is available, this button is replaced by the button specific for that application.

A1.4 Setup and start measurement

The SETUP AND START MEASUREMENT option on the MAIN MENU SCREEN opens the first preparation screen of the measurement procedure.

The procedure starts with showing the "ZERO HEIGHT CORRECTION UNIT" screen. This is a screen that enables the user to zero the Height Correction Unit (HCU).

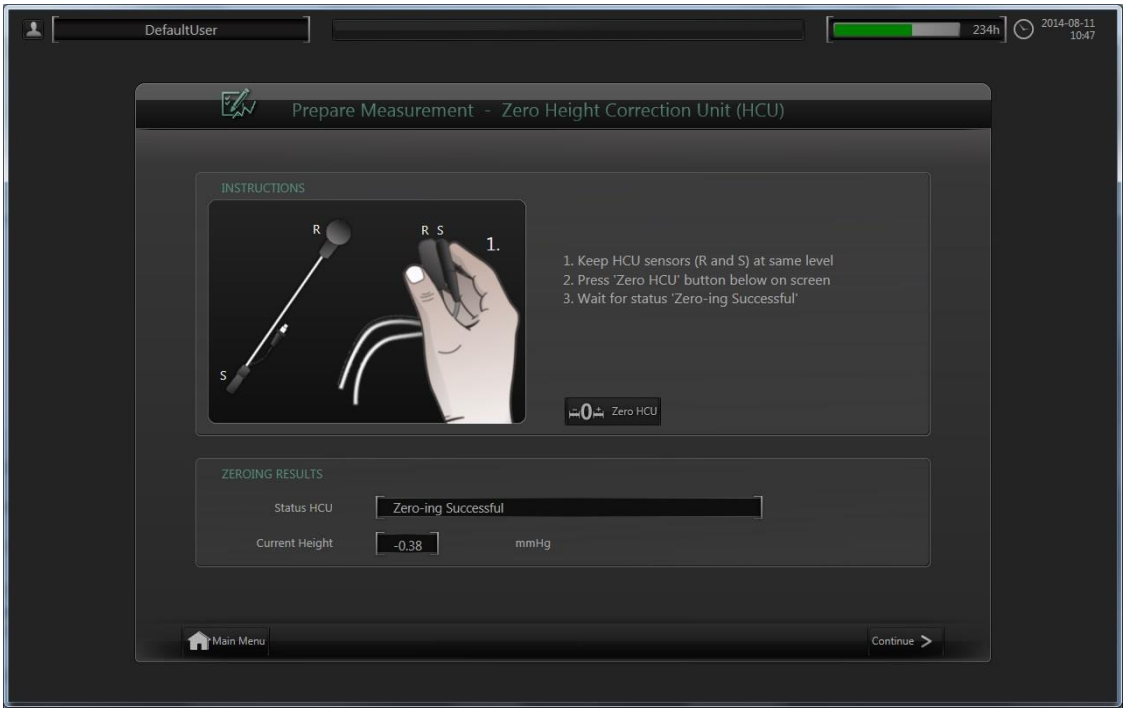


Figure A1-5: The "ZERO HEIGHT CORRECTION UNIT" screen when a HCU is connected

The elements of the first "ZERO HEIGHT CORRECTION UNIT (HCU)" screen have the following meaning:

Item	***Description***
Zero HCU	ZERO HCU To be pressed to zero HCU after following onscreen instructions
	STATUS HCU Displays the status of the HCU; "NOT CONNECTED", "'NOT ZEROED", "ZERO-ING", ZERO-ING FAILED" or "ZERO-ING SUCCESSFUL"
	CURRENT HEIGHT Displays the difference in height between the patient's heart and the patient's finger (provided that the HCU is connected).
Main Menu	MAIN MENU Returns to the MAIN MENU.

Continue >	CONTINUE Continues to the next step of the measurement preparation procedure.

When no Height Correction Unit is connected to the Finapres Nova, the "ZERO HEIGHT CORRECTION UNIT (HCU)" screen will instruct the user to keep the hand of the patient at heart level during the measurement.

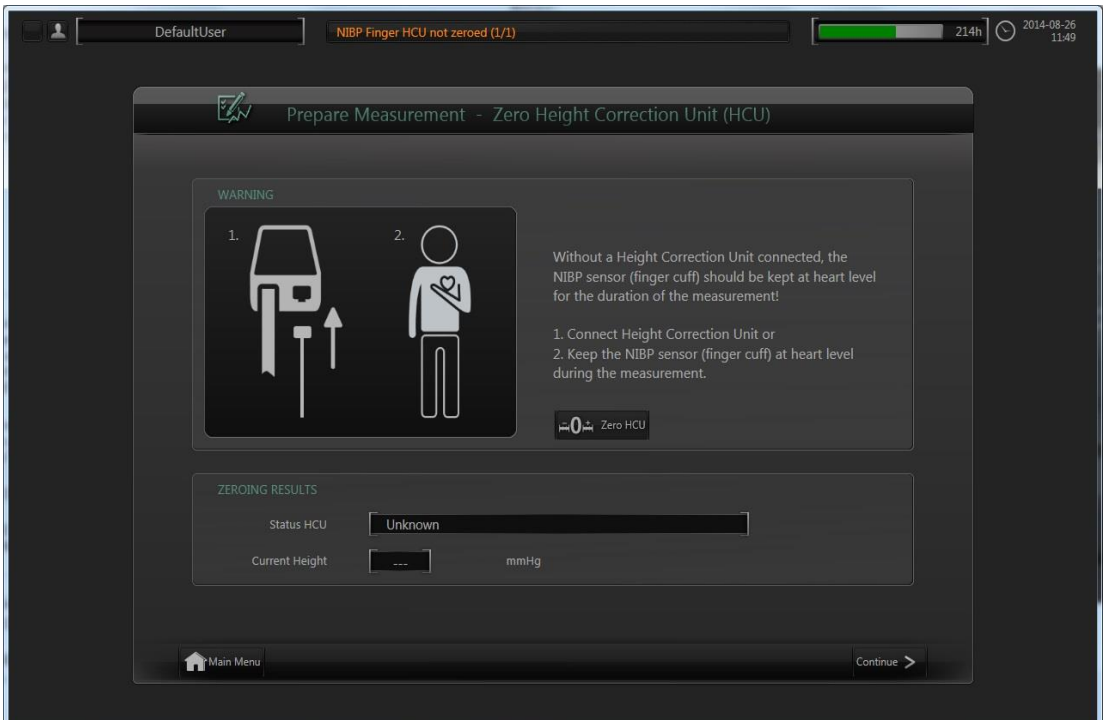


Figure A1-6: The "ZERO HEIGHT CORRECTION UNIT" screen when no HCU is connected

After the "CONTINUE" button is pressed, the "PREPARE MEASUREMENT" screen is shown. In this screen the patient data is to be entered.

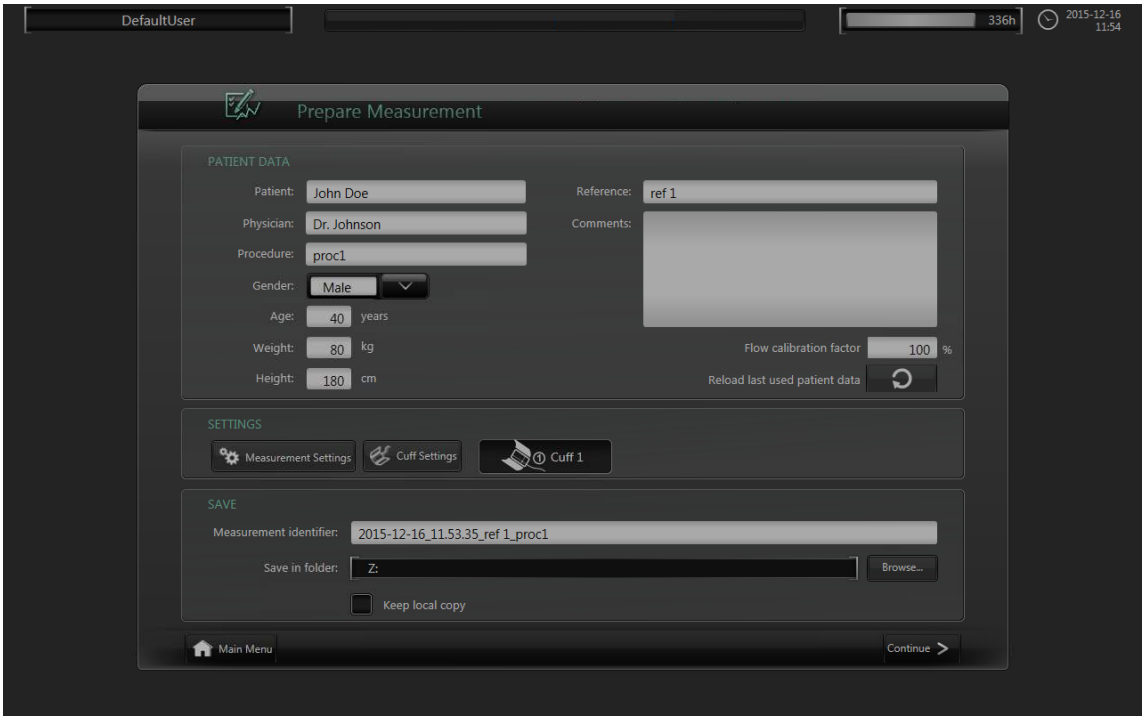
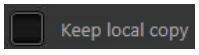


Figure A1-7: The "PREPARE MEASUREMENT" screen

The elements of the second "PREPARE MEASUREMENT" screen have the following meaning:

Item	***Description***
Measurement settings	
	Opens the MEASUREMENT SETTINGS screen that allows the user to review and change the measurement settings (these are automatically stored in the user profile).
	Opens the CUFF SETTINGS screen that enables the user to review and alter the cuff settings (these are automatically stored in the user profile).

Patient data	
	PATIENT, PHYSICIAN, PROCEDURE, GENDER, AGE, WEIGHT, LENGTH, REFERENCE, COMMENTS Fields in which the patient related data is to be entered. The on-screen keypad will appear as soon as a text field is tapped. **Gender, age weight and length are required fields**. If these are not or incorrectly filled out, a red warning text will appear next to it.
	RELOAD LAST USED PATIENT DATA Fills in the patient data fields automatically with the data of the last patient.
Save	
	In the MEASUREMENT IDENTIFIER field the name of the file can be entered. Standard name is the current time concatenated with the reference and procedure entry.
	Opens a screen to select the directory in which the file has to be stored. The selected directory is shown in the text box SAVE IN FOLDER.
	When a USB or network drive has been selected, the option to keep a local copy becomes available. In case transfer to the external drive fails, a local copy is stored irrespective of this setting.
General	
	Returns to the MAIN MENU.
	Continues to the next step of the measurement procedure.

After all fields are filled out and the “CONTINUE” button is pressed, the “MEASUREMENT” screen opens.

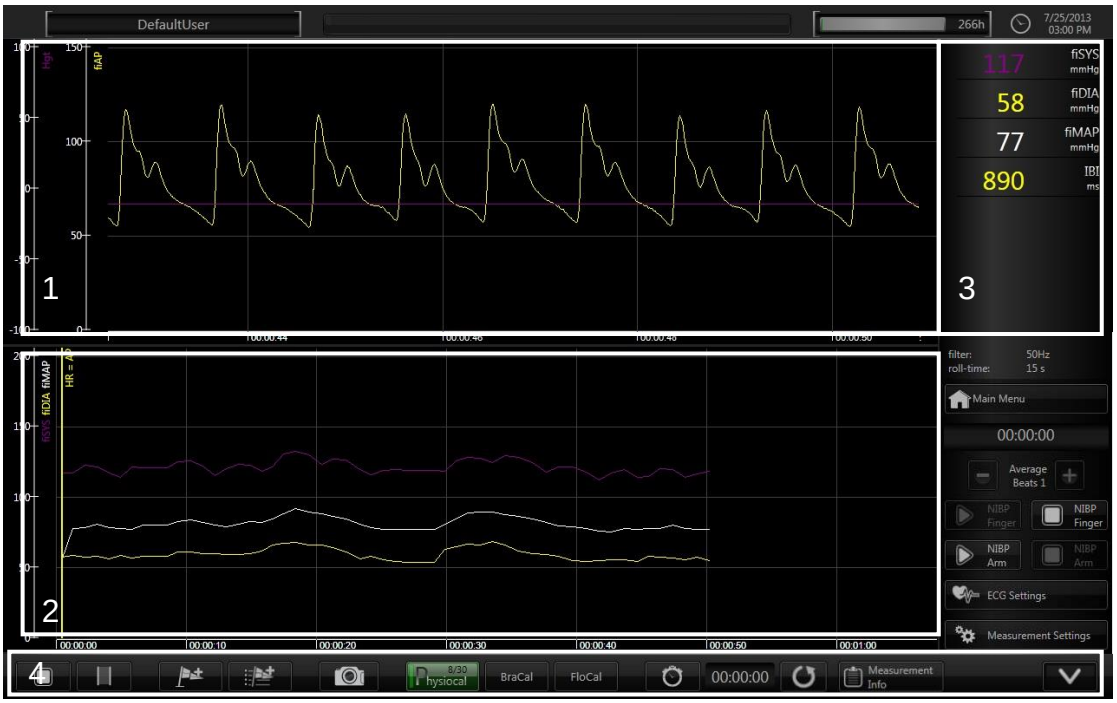
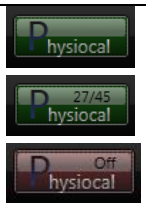
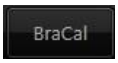


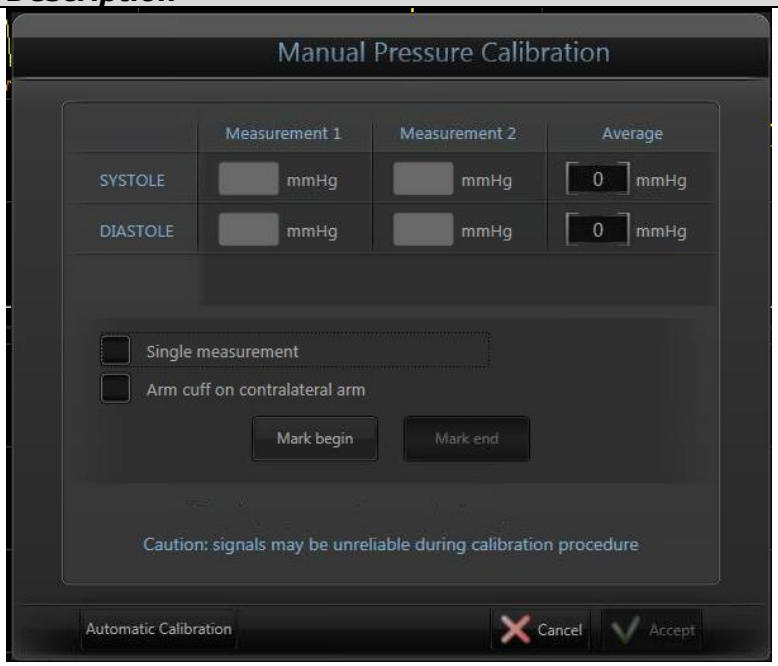
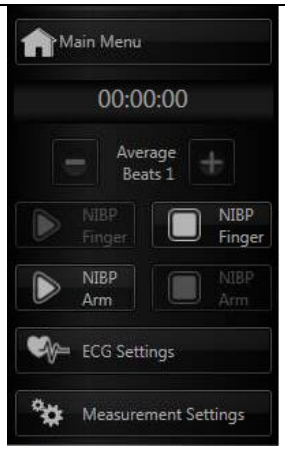
Figure A1-8: The "MEASUREMENT" screen

The "MEASUREMENT" screen is divided into four parts (see Figure A1-8):

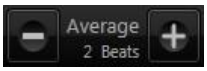
1. **Trend Graphs**
   In this area the trend graphs defined in the "MEASUREMENTS SETTINGS" screen (refer to A1.4.3) are shown.
2. **Wave form graphs**
   In this area the wave form graphs defined in the "MEASUREMENTS SETTINGS" screen (refer to A1.4.3) are shown.
3. **Numeric signals**
   In this area the numeric values of the signals defined in the "MEASUREMENTSSETTINGS" screen (refer to A1.4.3) are shown.
4. **Controls**
   The controls of the "MEASUREMENT" screen have the following functionality:

Item	***Description***
	Toggle button to start and stop the measurement.
	Highlights a period during a measurement.
	QUICK MARKER Immediately adds a standard marker to the graph when to indicate a sudden interesting event. In review mode the marker can be renamed if desirable.
	MARKER LIST Opens a pop-up screen that shows the predefined markers. After selecting a marker or entering a new name for the marker it can be added to the graph by clicking the OK button.

Item	*Description*
	The marker will appear on the time index the MARKER LIST button was pressed. In review mode the marker can be renamed if desirable.
	SCREEN SHOT Takes a screen shot. The picture will be saved with the actual date and time as filename in the subfolder Screenshots in the measurement data folder. It is automatically exported with a measurement file when it is downloaded to an external storage medium.
	TIMER The button starts and stops the timer. The elapsed time is shown on the display on the right of this button. By means of the  button the timer can reset to "0".
	MEASUREMENT INFO Shows measurement info and allows to add general comments
	PHYSIOCAL Postpones the automatic calibration of the finger cuff(s). This may be desirable when the user wants to avoid the calibration to occur at a moment when it is important to have readings (e.g. when certain procedures are carried out). If active, the number of beats to go prior to the next automatic calibration of the finger cuff(s) is stated on the button. Disabling the "PHYSIOCAL" option for a longer period may have a negative effect on the accuracy of the readings. When not active the "PHYSIOCAL" button is colored red.
	PRESSURE CALIBRATION Starts the pressure calibration procedure with the aid of the arm cuff. A pop-up is shown after the button is pressed in which the systole and diastole pressure need to be filled in twice. These values have to be obtained with two manual measurements. To properly calibrate the reconstructed brachial pressure the start of manual inflation of an upper arm cuff needs to be indicated. Therefore the "Mark begin" button needs to be pressed the moment the upper arm cuff starts to inflate. The end of the second manual measurement needs to be indicated by the "Mark end" button. By subsequently pressing the "Accept" button the reconstructed brachial pressure will be calibrated according to the manual measurement results. Pressing the "Cancel" button will cancel the calibration procedure.

Item	Description
	
	QUICK MENU TOGGLE A selection menu that allows the operator quick access to several functions and settings 

The controls of the "QUICK MENU TOGGLE" have the following functionality:

Item	Description
	MAIN MENU Opens the "MAIN MENU" screen
	MEASUREMENT TIME Indicates the time the measurement has run
	AVERAGE BEATS Determines, by means of the "+" and "-" controls, the number of beats used in the averaging of the trend graphs.
	NIBP FINGER START (Re)starts the finger blood pressure measurement. This action does not affect the state of recording.

Item	*Description*
	NIBP FINGER STOP Stops the finger blood pressure measurement. This action does not affect the state of recording.
	NIBP ARM START Starts the upper arm blood pressure measurement.
	NIBP ARM STOP Stops the upper arm blood pressure measurement.
	MEASUREMENT SETTINGS Opens the "MEASUREMENT SETTINGS" screen that allows the user to review and change the user bound measurement settings.

If the finger cuff needs to be re-adjusted during a recording, the  ***button can be used to pause the finger blood pressure measurement without interrupting the recording of the other signals. After re-adjustment the finger blood pressure measurement can be restarted using button*** 

If an error occurs which pauses the finger blood pressure measurement, it can be restarted using the button without stopping the recording.

In case the measurement is prolonged (e.g. due to patient movement) it is the user's responsibility to verify that the upper arm measurement is finished successful or manually aborted within acceptable time.

An upper arm measurement on the contralateral arm is less accurate.

A1.4.1 Review measurement

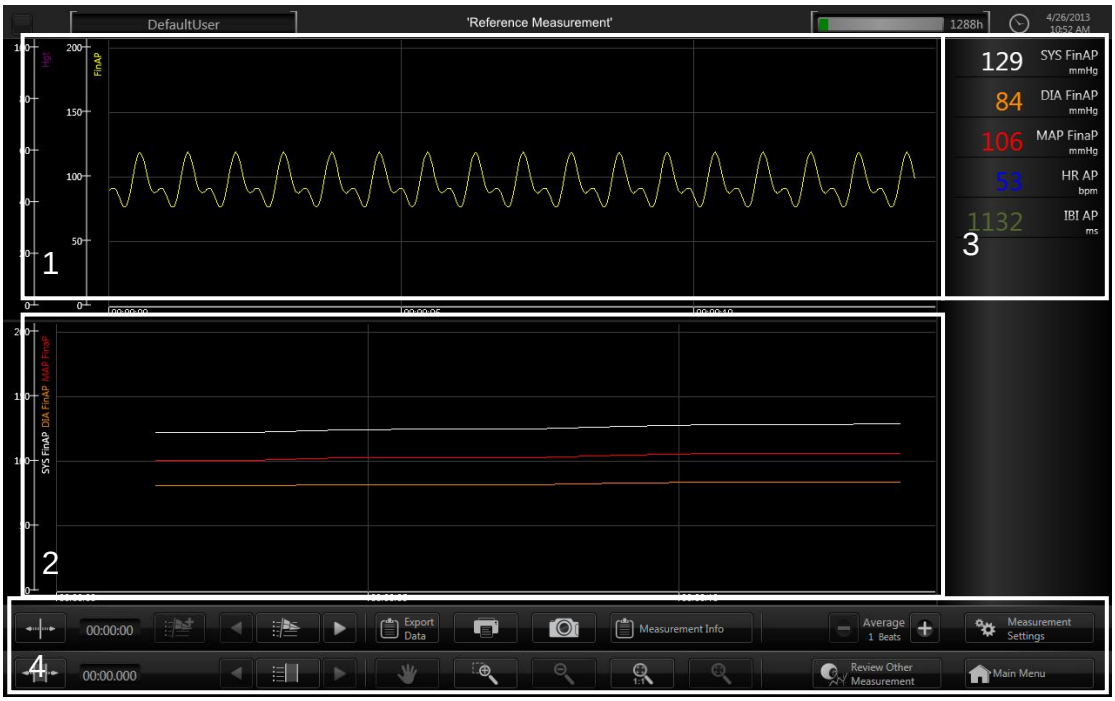


Figure A1-9: The "REVIEW MEASUREMENT" screen

The "REVIEW MEASUREMENT" is divided into four parts:

1. **Trend Graphs**

   In this area the trend graphs defined in the "MEASUREMENTS SETTINGS" screen (refer to A1.4.4) are shown.

2. **Wave form graphs**

   In this area the wave form graphs defined in the "MEASUREMENTS SETTINGS" screen (refer toA1.4.4) are shown.

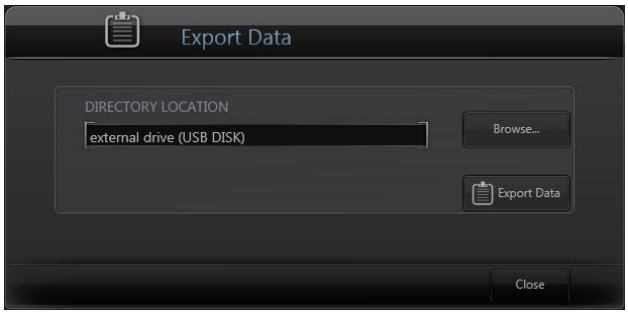
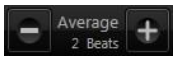
3. **Numeric signals**

   In this area the numeric values of the signals defined in the "MEASUREMENT SETTINGS" screen (refer to A1.3.5) are shown.

4. **Controls**

   The controls in review mode have a toggle function. They have to be clicked to be activated, after which the user can perform the selected action in the measurement screen (nr 1 and 2 indicated above). When done, the button has to be clicked again or another button has to be clicked to disable it function. The controls of the "MEASUREMENT" screen have the following functionality:

Item	***Description***
	PLACE CURSOR After selecting the user can place a cursor on screen. When placed, the numerical values are shown of that time index.
	ADD MARKER Adds a marker to the graph at the location of the cursor.

Item	*Description*
	MARKER LIST Shows a list of the present markers. Enables the user to alter the marker descriptions and to delete markers.
	MARKER LIST BUTTONS By means of the buttons the user can quickly move to the previous or next marker in the recording without having to zoom out.
	EXPORT DATA Allows the operator to export the measurement data in CSV format. A pop-up screen will open allowing the user to select the directory (via the button) where the data will be exported to. When pressing the button, the data is exported. 
	PRINT Opens a screen that enables the user to print the data of the measurement. Besides the printer selection and printer options the user can select the following options: • Print the complete measurement or only the WAVEFORM or BEAT-TO-BEAT graphs. • Whether or not to print FRONT SUMMARY PAGES, and if selected which information should be on it. • Determine the scale of the print out.
	SCREEN SHOT Makes a screen shot of the screen. The picture will be saved as yyyy-MM-dd_HH_mm_ss.jpg in the subfolder Screenshots in the measurement data folder. It is automatically exported with a measurement file when it is downloaded to an external storage medium.
	AVERAGE BEATS Determines, by means of the "+" and "-" controls, the number of beats used in the averaging of the trend graphs.
	RANGE SELECTION Allows the user to measure the time interval between two points on the screen. After the button is clicked, the user can start dragging his finger from the start to the end point. The elapsed time of the selected interval is shown on the display on the right of this button.

Item	Description
	HIGHLIGHT LIST Shows a list of the highlights. Enables the user to alter the highlight descriptions and to delete highlights. By means of the button one can move quickly from highlight to highlight.
	MOVE By clicking this button and subsequently dragging a finger over the screen the user can move the graph to the left and right.
	ZOOM TO AREA Enables to enlarge a certain part of the graph by dragging the cursor over the graph.
	ZOOM OUT Scales the image down.
	ZOOM 1:1 Scales the image to the trace speed used during the measurement. The graphs will have the same scaling as in the "MEASUREMENTS" screen.
	ZOOM ALL Shows the entire recording after subsequently clicking this button and the graph.
	MEASUREMENT INFO Shows the patient data and measurement data.
	Opens the file browser to select the next file to review.

All signals available during a measurement are stored. The showed signals and graphs in the "REVIEW MEASUREMENT" screen can be altered by means of the "MEASUREMENT SETTINGS" screen.

Screenshots are stored in the same directory as the recording and can be downloaded as described in section 5.8 or using the network connection

A1.4.2 Manage user profiles

The "MANAGE USER PROFILES" screen displays the available user profiles. In the right window a short summary of the details of the selected user profile is shown.

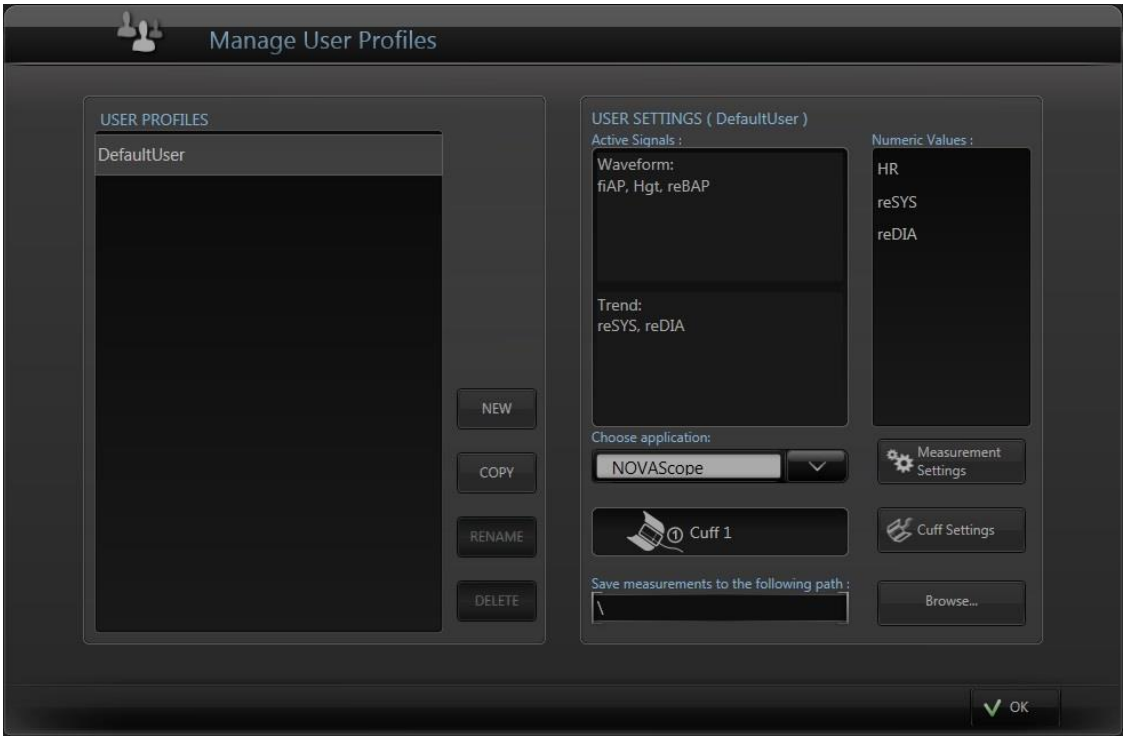
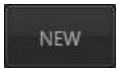
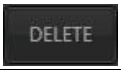
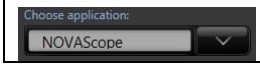
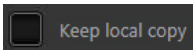


Figure A1-10: The "MANAGE USER PROFILES" screen

The elements of the "MANAGE USER PROFILES" screen have the following meaning:

Item	***Description***
	NEW Opens the ON-SCREEN KEYPAD to enable the user to enter the name of the USER PROFILE to be created. After pressing the button the new USER PROFILE is created.
	COPY Allows the user to create a new USER PROFILE based on an existing user profile.
	RENAME Renames the selected USER PROFILE.
	DELETE Deletes the selected USER PROFILE.
	CUFF SETTINGS Opens the CUFF SETTINGS SCREEN that enables the user to review and alter the cuff settings for the activated user profile.
	MEASUREMENT SETTINGS Opens the "MEASUREMENT SETTINGS" screen that allows the user to review and change the user bound measurement settings.
	CHOOSE APPLICATION Some Finapres NOVA applications require application-specific

Item	Description
	settings. These can be accessed by selecting the application and then pressing the button MEASUREMENT SETTINGS. Application-specific settings will be addressed in their respective manuals. General settings can be altered by selecting NovaScope and pressing the MEASUREMENT SETTINGS button.
	BROWSE Opens a pop-up that allows the user to select the directory to be shown in the pane in which the measurements should be stored.
	When a USB or network drive has been selected, the option to keep a local copy becomes available. In case transfer to the external drive fails, a local copy is stored irrespective of this setting.
	After selecting the user profile and clicking the OK button, the selected user profile is activated.

The new user profile is based on the Default User.

A1.4.3 Finger cuff settings

The "CUFF SETTINGS" screen displays the cuff settings for the measurement.

Figure A1-11: The "CUFF SETTINGS" screen

The elements of the "CUFF SETTINGS" screen have the following meaning:

Item	*Description*
	SINGLE CUFF OR DUAL CUFF MEASUREMENT Allows the operator to choose between single and dual cuff measurements
	CUFF SELECTION Only visible when a single cuff measurement is selected. Allows the operator to choose with which cuff to perform the single cuff measurements
	CUFF SWITCHING INTERVAL Only visible when a dual cuff measurement is selected. Allows the operator to select a cuff switching interval of 1, 15 or 30 minutes.

Correct finger cuff application is essential for a correct measurement (see Appendix 3).

A1.4.4 Measurement settings

The "MEASUREMENTS SETTINGS" screen allows the selection of signals for "WAVEFORM GRAPHS", "TREND GRAPHS" and "NUMERIC VALUES" to be shown in the "MEASUREMENT" and "REVIEW" screen. "SIGNAL SETTINGS" and "MARKER DEFINITIONS" can also be set here.

On the left hand side of the screen the tab can be selected to make adjustments to:

Waveform graphs

Selection of number of waveform graphs and its containing signals.

Trend graphs

Selection of number of trend graphs and its containing signals

Numeric values

Selection of the signals for which the numeric value has to be shown on the right hand side of the "MEASUREMENT" screen and the "REVIEW" screen.

Signal settings

Definition the signal properties.

Marker definitions

Definition of the preset marker descriptions.

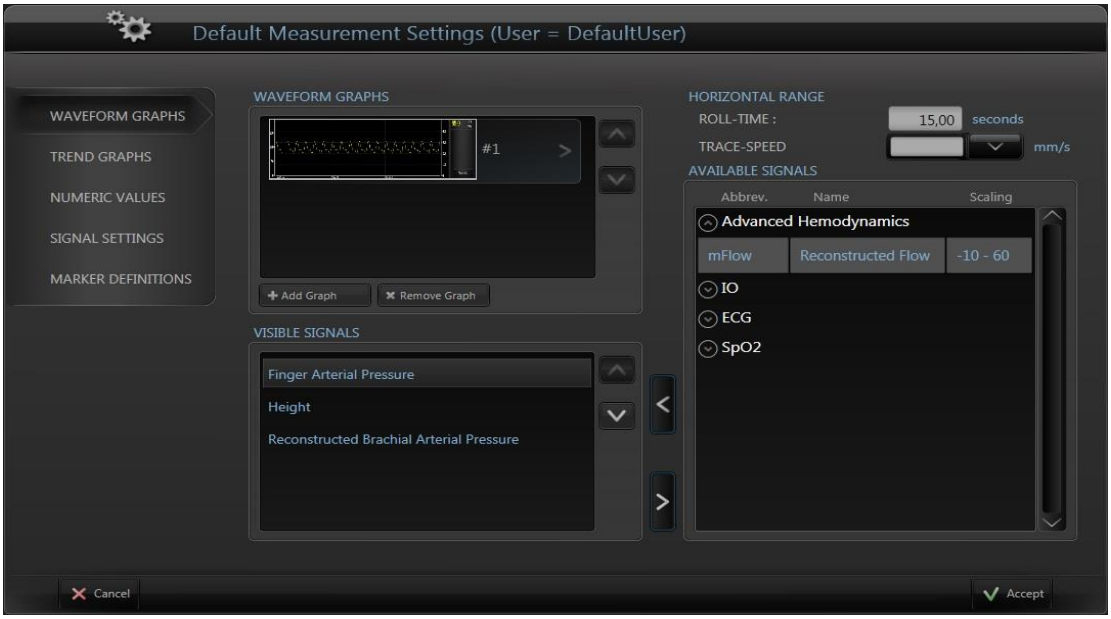
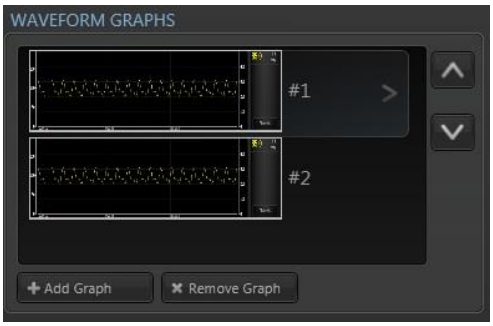
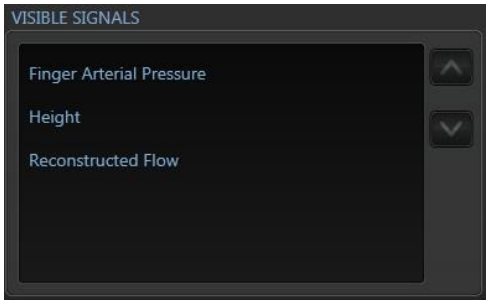
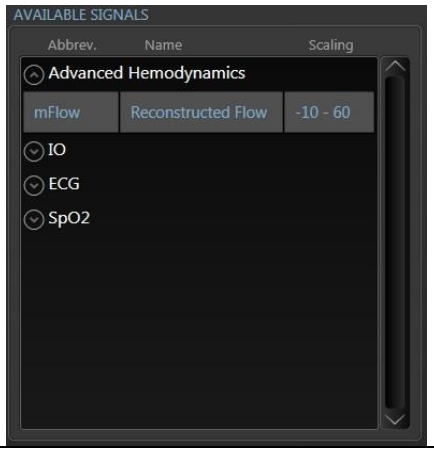


Figure A1-12: The "MEASUREMENT SETTINGS" screen, waveform tab

Item	***Description***
	WAVEFORM GRAPH Shows the different waveform graphs that will be visible on the MEASUREMENT screen and REVIEW MEASUREMENT screen. With the buttons + Add Graph and ✖ Remove Graph it is possible to add and remove graphs to the screen. With the ^ and v button it is possible to change the position of the graph on the screens.
	VISIBLE SIGNALS Shows the different signals that will be shown in the selected waveform graph. With the ^ and v button it is possible to change the order of the y-scales on the left side of the graphs (the amount of different y-scales is limited to three, when more signals with different scaling settings are visible the lower ones will not have their y-scale available on the screen).

Item	*Description*
	AVAILABLE SIGNALS Shows all signals that can be displayed in the waveform graphs. The signals are sorted per available module or application.
	Moves the selected signals from the available signals to the visible signals list
	Moves the selected signals from the visible signals to the available signals list
	HORIZONTAL RANGE Changes the x-scale. The user can either enter the number of seconds that will be plotted on the screen for the waveform graphs in the roll-time field or select one of the available trace speeds (12.5, 25 or 50 mm/s).

When signals have the same y-scale setting, only one y-scale will appear with the short names of the accompanying signals next to it. The names will have the same color as the signal they belong to.

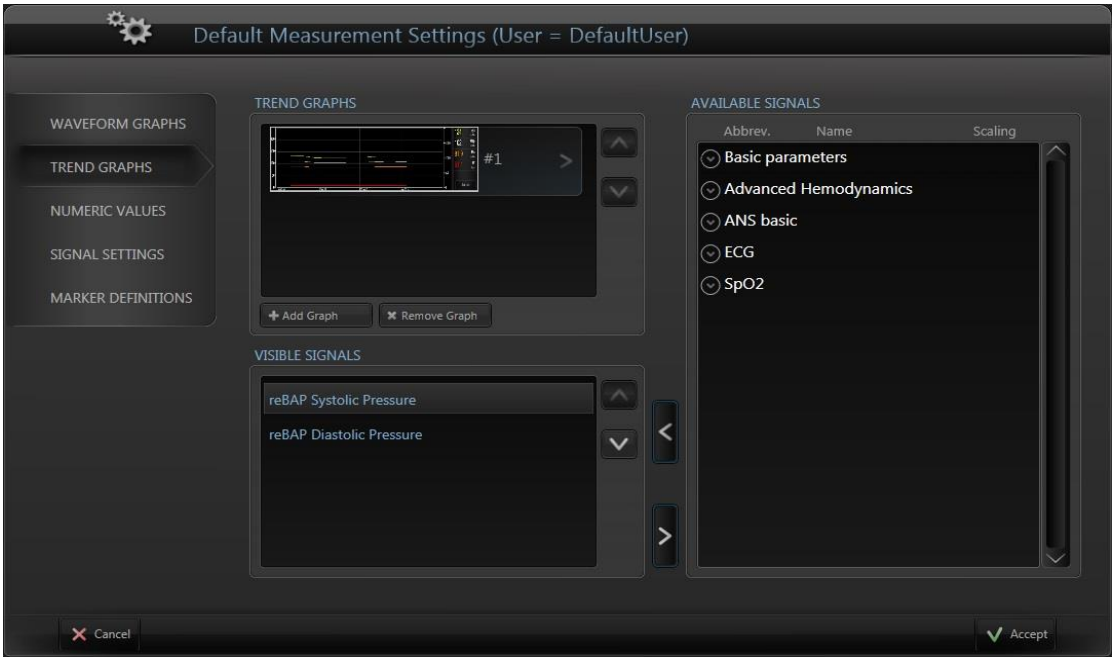
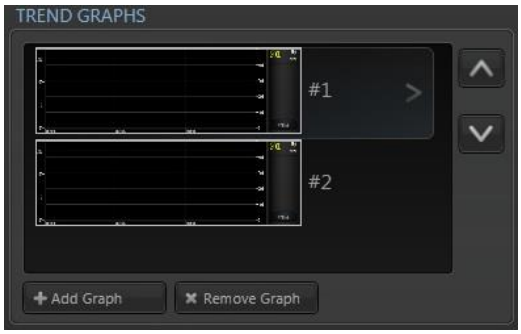
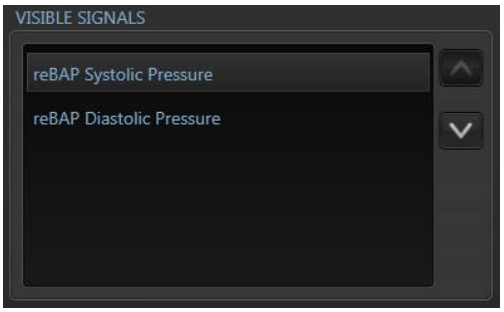
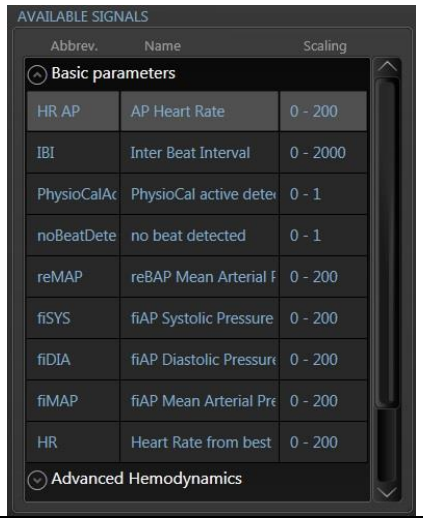


Figure A1-13: The "MEASUREMENT SETTINGS" screen, trend graph tab

Item	***Description***
	TREND GRAPH Shows the different trend graphs that will be visible on the MEASUREMENT SCREEN and REVIEW MEASUREMENT SCREEN. With the Add Graph and Remove Graph buttons it is possible to add a graph to the screen. With the ^ and v buttons it is possible to change the position of the graph on the screens.
	VISIBLE SIGNALS Shows the different signals the will be shown in the selected trend graph. With the ^ and v buttons it is possible to change the order of the y-scales on the left side of the graphs (the amount of different y-scales is limited to three, when more signals with different scaling settings are visible the lower ones will not have their y-scale available on the screen).

Item	Description
	AVAILABLE SIGNALS Shows all signals that can be displayed in the trend graphs. The signals are sorted per available module or application.
	Moves the selected signals from the available signals to the visible signals list
	Moves the selected signals from the visible signals to the available signals list

When signals have the same y-scale setting, only one y-scale will appear with the short names of the accompanying signals next to it. The names will have the same color as the signal they belong to.

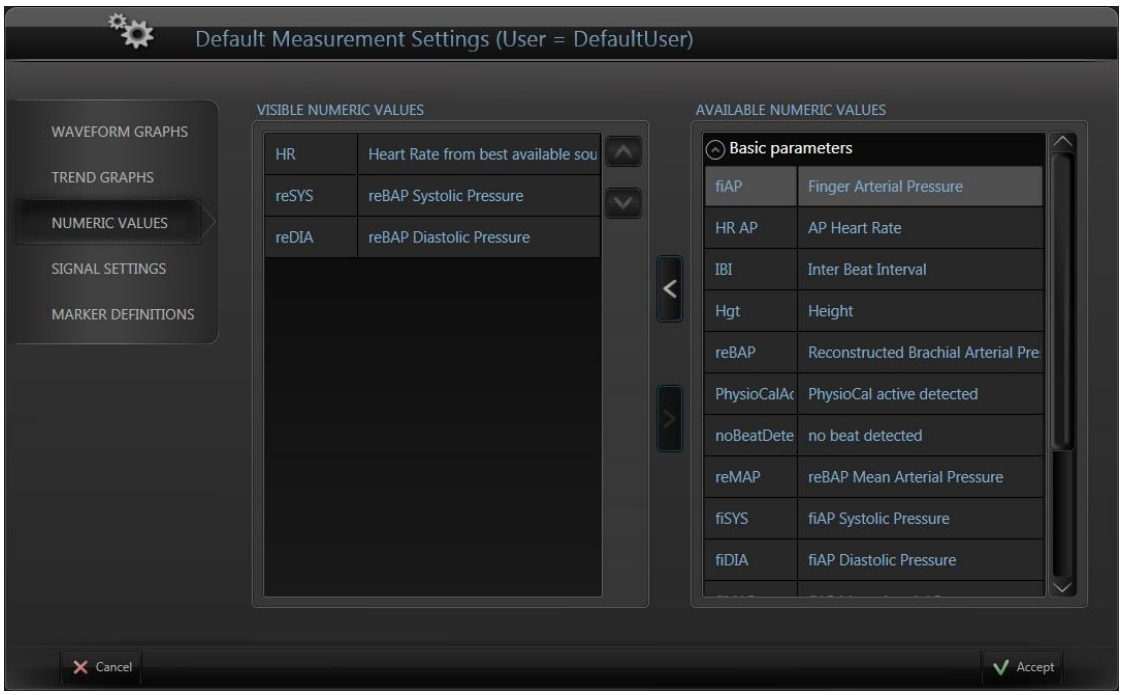
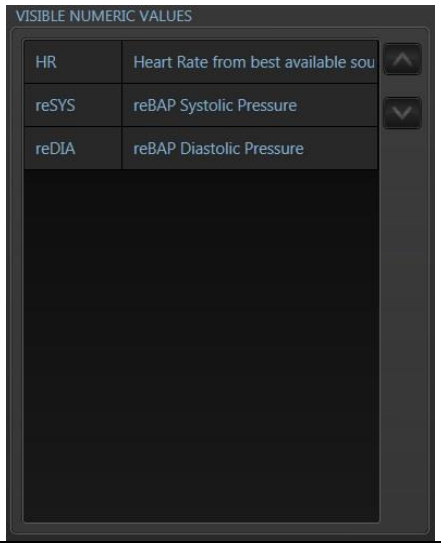
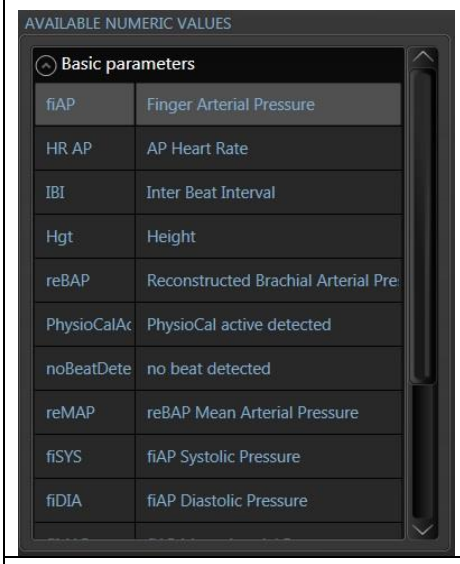


Figure A1-14: The "MEASUREMENT SETTINGS" screen, numeric values tab

Item	Description
	NUMERIC VALUES Shows the different signals that will be shown as numeric values.
	AVAILABLE NUMERIC VALUES Shows all values that can be displayed as numeric values. The signals are sorted per available module or application.
	Moves the selected signals from the available signals to the visible signals list
	Moves the selected signals from the visible signals to the available signals list

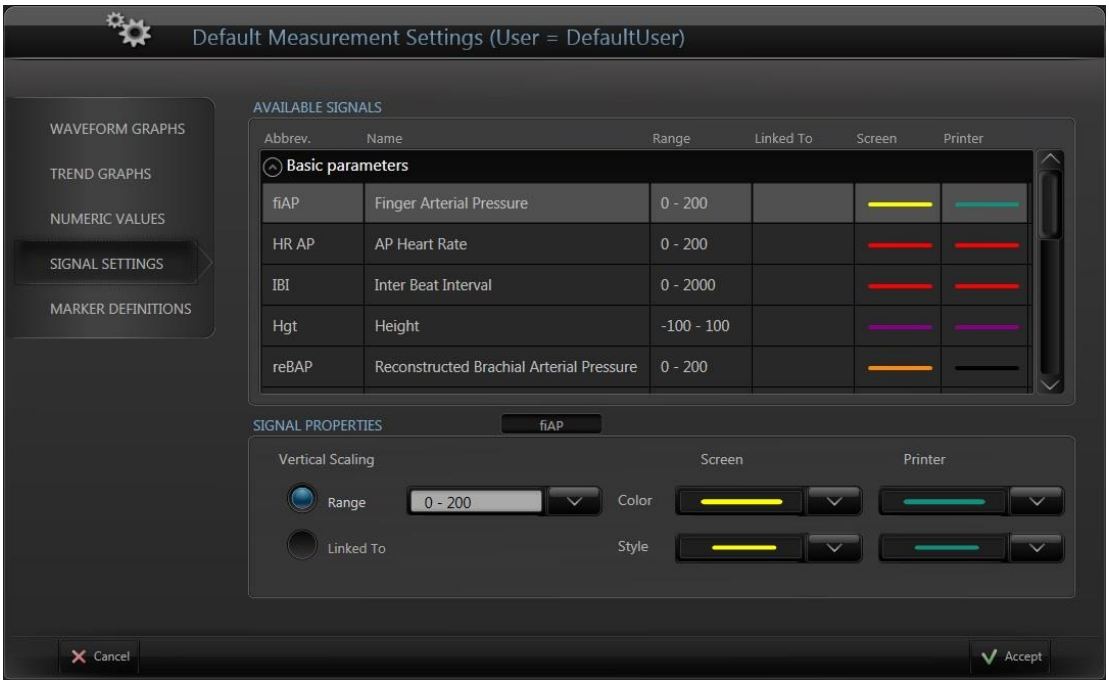
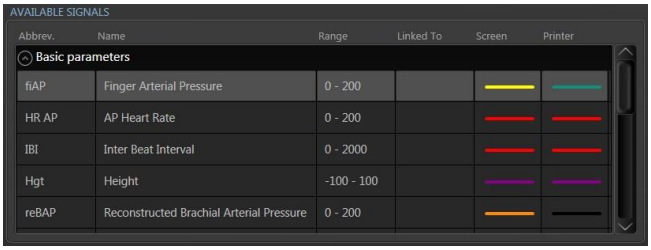
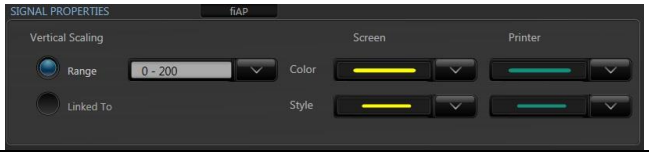


Figure A1-15: The "MEASUREMENT SETTINGS" screen, signal settings tab

Item	***Description***
	AVAILABLE SIGNALS Shows how the available signals will be represented on screen and after printing. When selecting a signal, the settings can be changed in the SIGNAL PROPERTIES window below.
	SIGNAL PROPERTIES Enables changing the signal properties of the selected signal (see description below).
	VERTICAL SCALING Allow the user to select the vertical scale by selecting the "Numeric" option and one of the available scales in the pull down menu. …or… Allow the user to select from which signal the scaling settings should be copied by selecting the "linked to" option and selecting the appropriate signal (in this way only one scaling setting has to be changed to change all scaling which are

Item	Description
	linked to the first one and only one y-scale will appear in the graph)
	COLOR and STYLE Allows the user to select the color and style of the selected signal both on screen and for printing

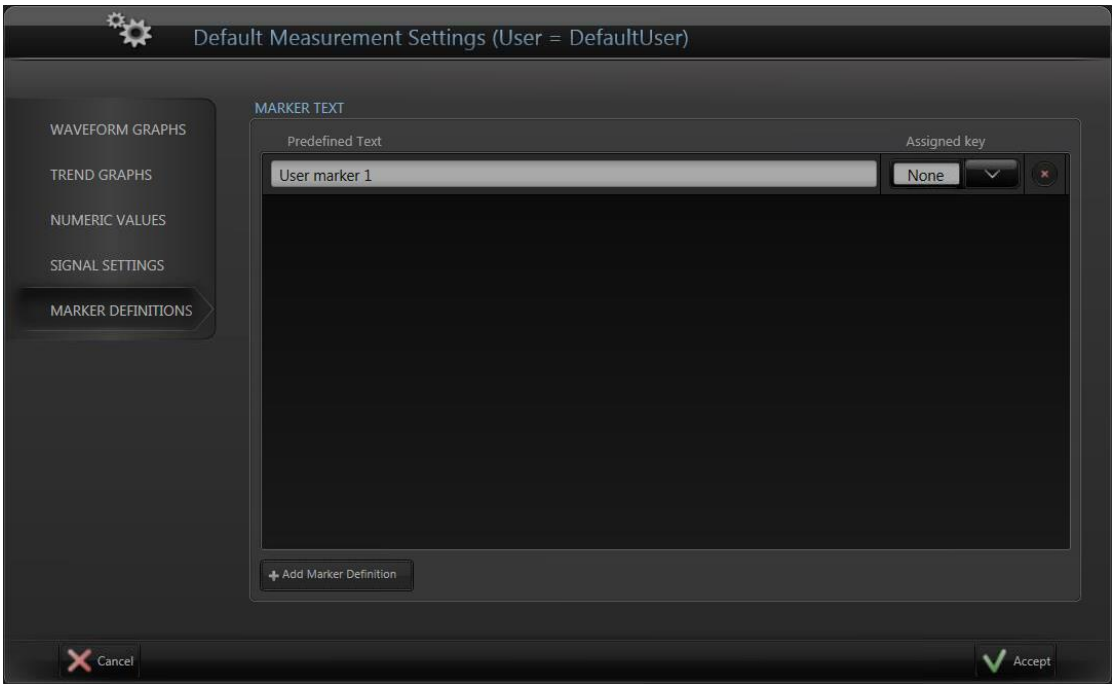
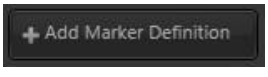


Figure A1-16: The "MEASUREMENT SETTINGS" screen, marker definitions tab

Item	Description
	MARKER TEXT Allows the user to add predefined marker texts to the MARKER LIST. By clicking on the marker text, the ON-SCREEN KEYPAD appears and the text can be altered. By clicking on the button, the accompanying marker on the left is deleted.
	ADD MARKER DEFINITION Opens the ON-SCREEN KEYPAD to enable the user to enter the marker text for a new marker.
	ASSIGNED KEY Allows the user to assign one of the F1 to F12 keys of a keyboard to the marker,

Item	Description
	setting the marker when pressing that key.

A keyboard and mouse can be connected to the Finapres NOVA using a USB hub. USB ports can be found at the back side of the device.

A1.4.5 File management

By means of the "FILE MANAGEMENT" screen the files containing the measurement data can be opened for reviewing or deletion. Furthermore it enables the user to copy or move the files to another directory or external storage medium.

The screen is divided into two panes, each representing a directory. At the top of the pane the current directory location is shown. After being selected, files can be copied or moved between the panes.

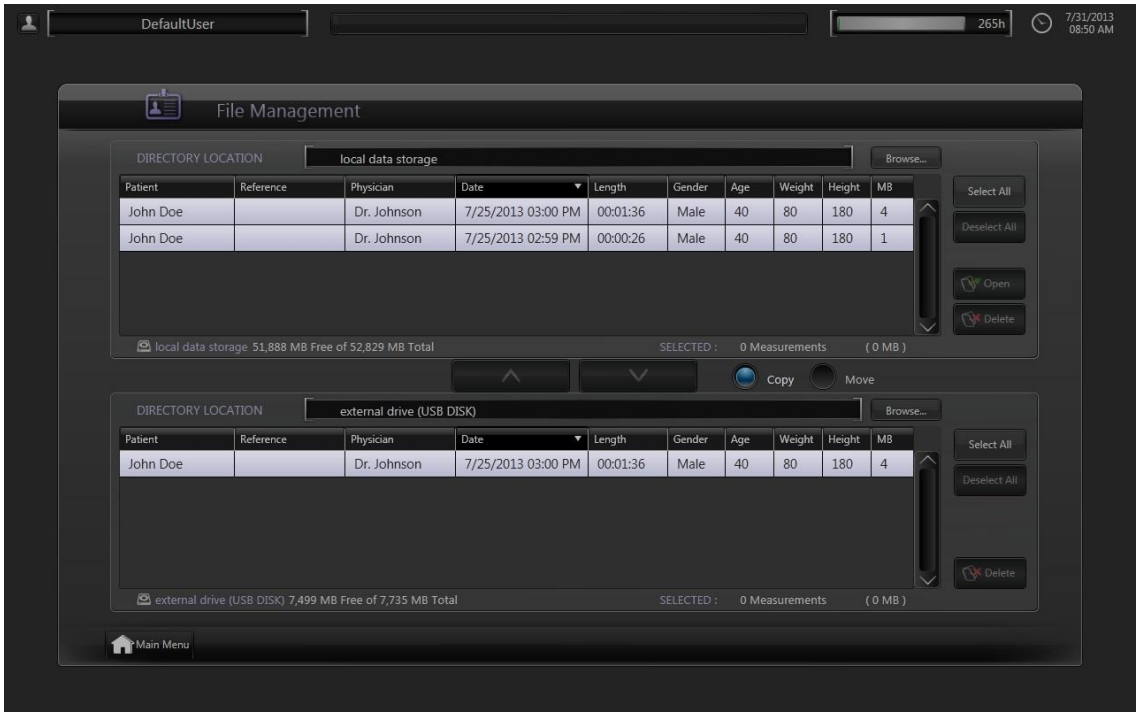
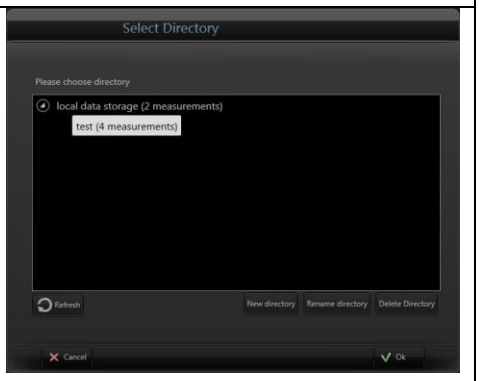
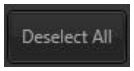
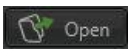
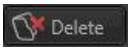


Figure A1-17: The "FILE MANAGEMENT" screen

The components of the screen have the following meaning:

Item	*Description*
Controls of the panes	
	BROWSE Opens a pop-up that allows the user to select the directory to be shown in the pane. When needed, a new directory can be created by pressing the button Create new Directory. A folder can be renamed by pressing the button Rename directory. The on screen key pad opens where the new directory name can be entered. 
	SELECT ALL Pressing the "SELECT ALL" button will select all files present in the directory.
	DESELECT ALL Pressing the "DESELECT ALL" button will deselect all files present in the directory.
	OPEN The "OPEN" button is enabled when a single file is selected. Pressing this button will load the selected file in the "REVIEW MEASUREMENT" screen (refer to A1.4.1).
	DELETE The "DELETE" button is enabled when one or more files are selected. Pressing this button will remove the files from the disk after asking for user confirmation.
File control buttons	
	UP Moves or copies the selected files from the lower to the upper pane.
	DOWN Moves or copies the selected files from the upper to the lower pane.
	COPY / MOVE Selects whether files are to be copied or moved to the other pane. In case "MOVE" is selected, the user will be prompter with the question whether he wants to remove the file from the source.

A1.4.6 System settings

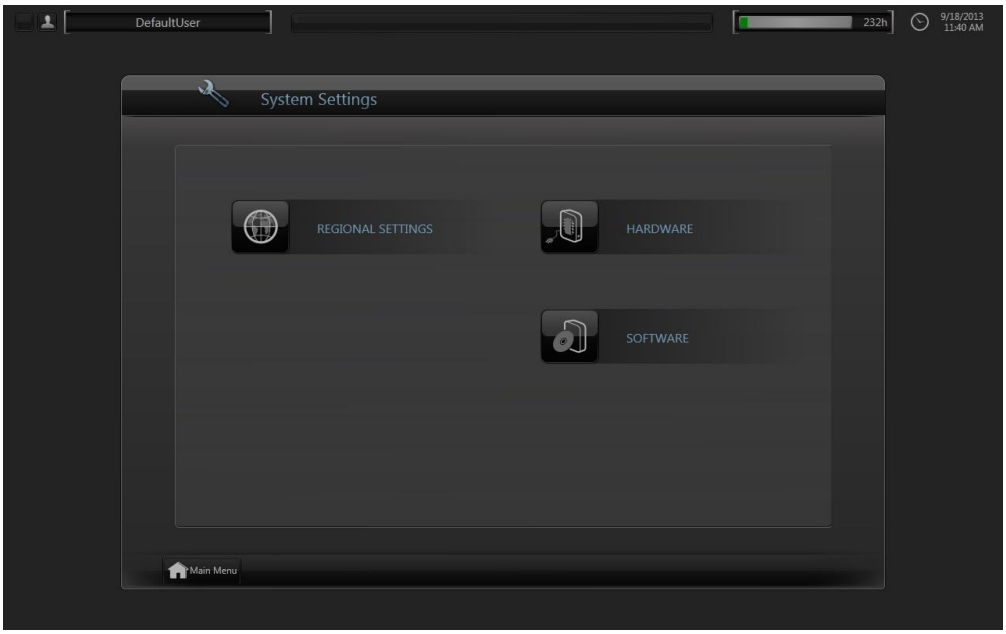


Figure A1-18: The "SYSTEM SETTING" screen

The items of the SYSTEM SETTINGS SCREEN have the following meaning:

Item	***Description***
	REGIONAL SETTINGS Opens the "REGIONAL SETTINGS" screen.
	HARDWARE Opens the "HARDWARE" screen.
	SOFTWARE Opens the "SOFTWARE" screen.

Regional settings

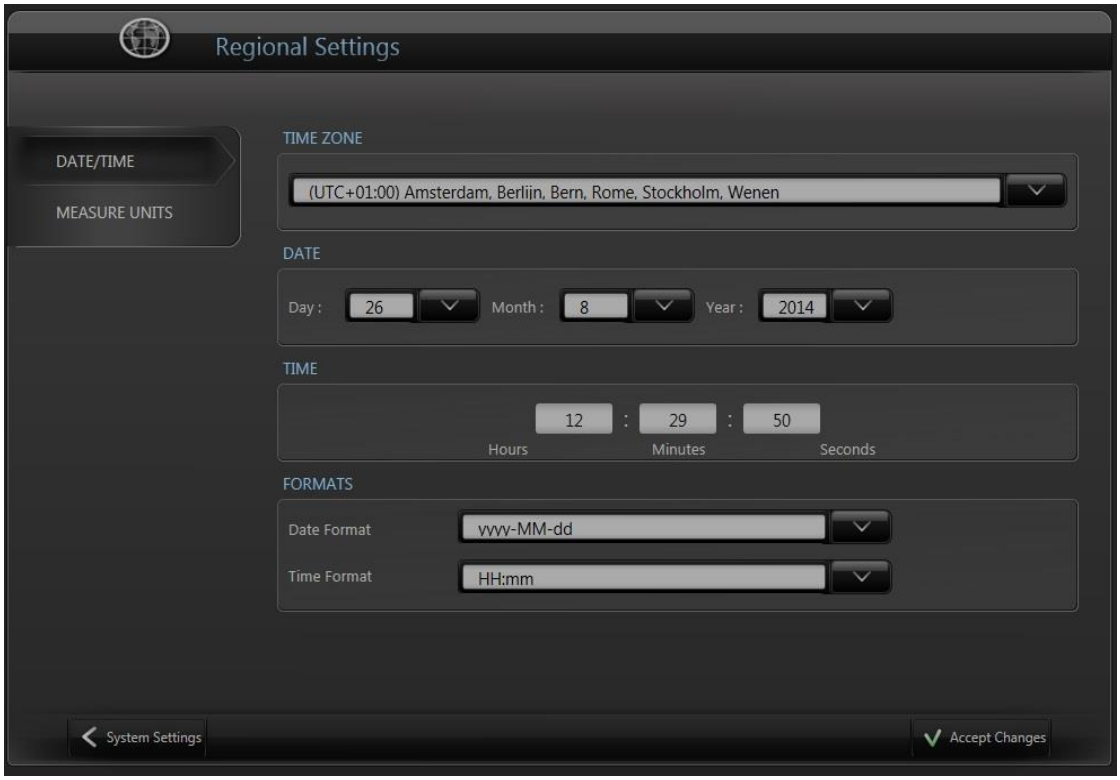


Figure A1-19: The "REGIONAL SETTING" screen

The "REGIONAL SETTINGS" screen allows the operator to alter the regional settings of the FINAPRES Nova.

Settings that can be changed are:

- **Time zone, date and time**

  In the Date/Time tab the time zone as well as date, time and their representation can be altered
- **Measure units**

  In the measurement units tab the choice can be made between metric or SI notation for weight and length

Hardware

Through the tab column of the "HARDWARE" screen gives the user access to:

- **Status**

  The "STATUS" tab of the "HARDWARE" screen shows the presence and status of the (optional) hardware of the Finapres Nova.
- **Network**

  The network tab displays the network information and allows the user to setup the network connection.
- **Printers**

  The Printers tab displays the installed hardware printers drivers and allows the user to install printer drivers

- **Maintenance**
  Gives access to the maintenance screens of the Finapres Nova. The "Maintenance" screen is restricted to Finapres Service personnel.
  Via the maintenance tab a user can download logfiles if so requested for by service personnel. This helps service engineers to solve user reported problems. The logfiles can only be downloaded to an external drive (either USB or network drive)

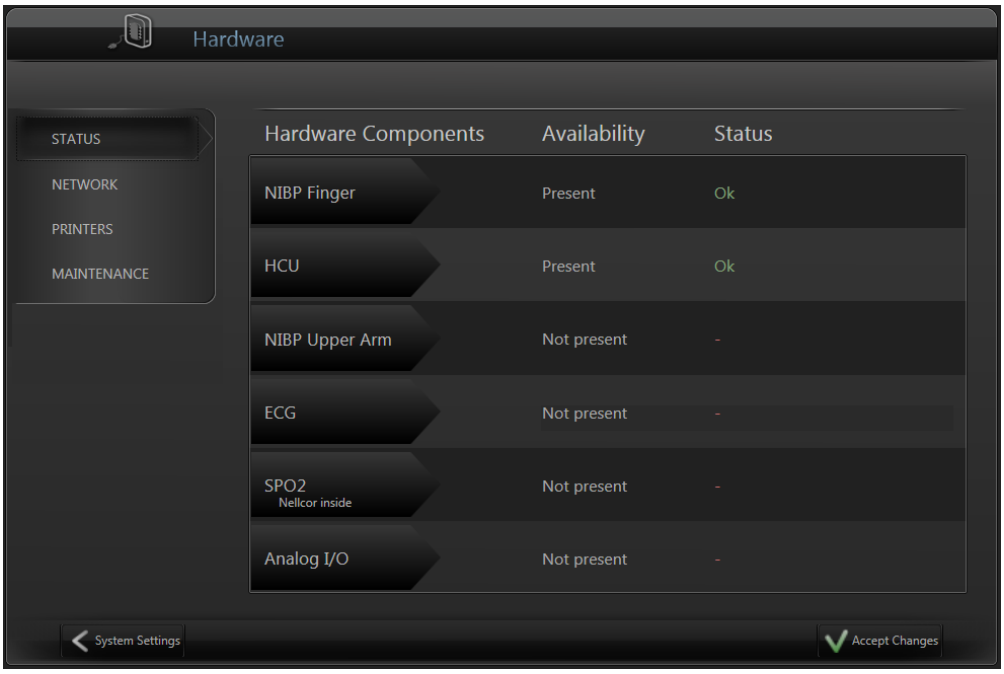


Figure A1-20: The "HARDWARE" screen – status tab

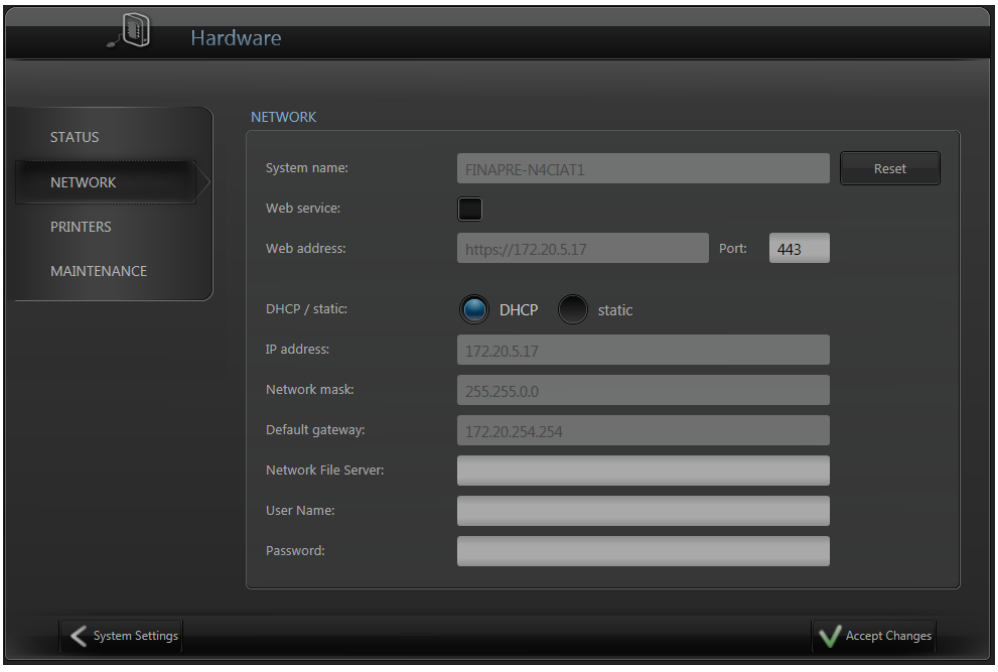
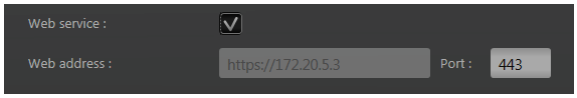
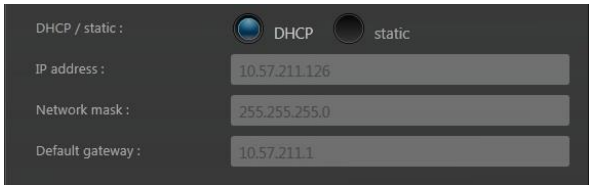


Figure A1-21: The "HARDWARE" screen – network tab

Item	*Description*
	SYSTEM NAME Displays the name with which the Finapres Nova will appear on the network
	WEBSERVICE When the webservice checkbox is selected, it becomes possible to remotely access the Finapres Nova to download measurement data via the indicated web address and port. In order to access the Finapres Nova via a web browser, type the following in address bar: "*web address:Port*"
	IP ADDRESS Allows users to let the Finapres Nova obtain an IP address dynamically (by selecting the DHCP option) or to use a fixed IP address (by selecting the static option). In the latter case, the user should enter the correct IP address, Network Mask and Default gateway.
	NETWORK FILE SERVER A connection to the network drive will be established when providing a valid network address in the Network File Server field and, if applicable, an User Name and Password in their respective fields. This network drive will show up in the directory selection windows as an external drive.

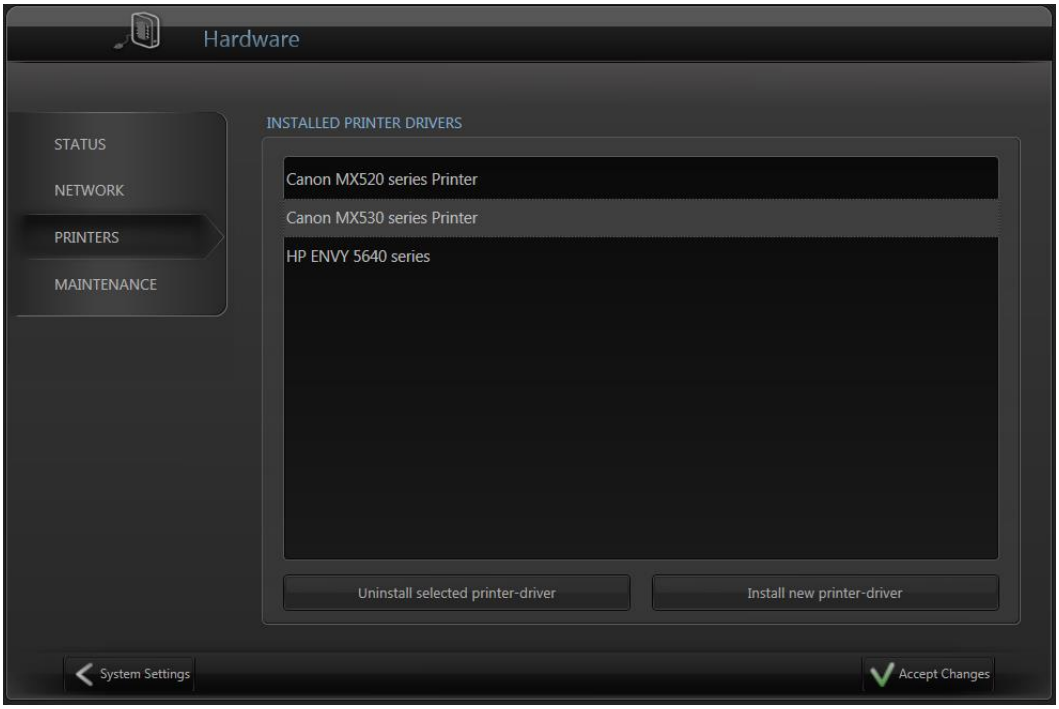
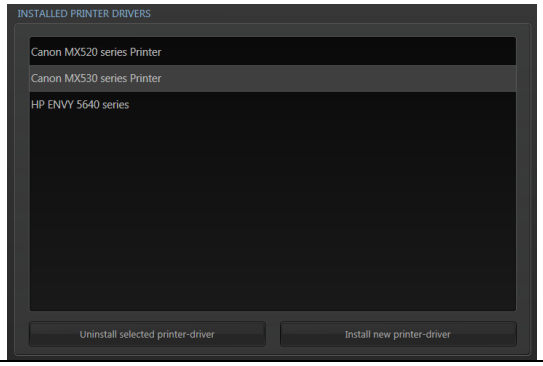
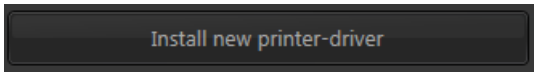
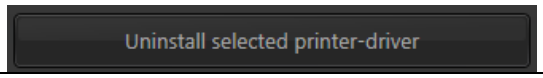


Figure A1-22: The "HARDWARE" screen – printer tab

Item	***Description***
	The main window shows all installed hardware printer drivers. For printing the appropriate printer should be connected via USB.
	Allows to install new printerdrivers. printerdrivers available on the Finapres Nova are • Canon MX520 series • Canon MX530 series • HP Envy 5640 series Other printerdrivers can be created by Finapres Medical Systems upon request
	Uninstalls the selected printerdriver

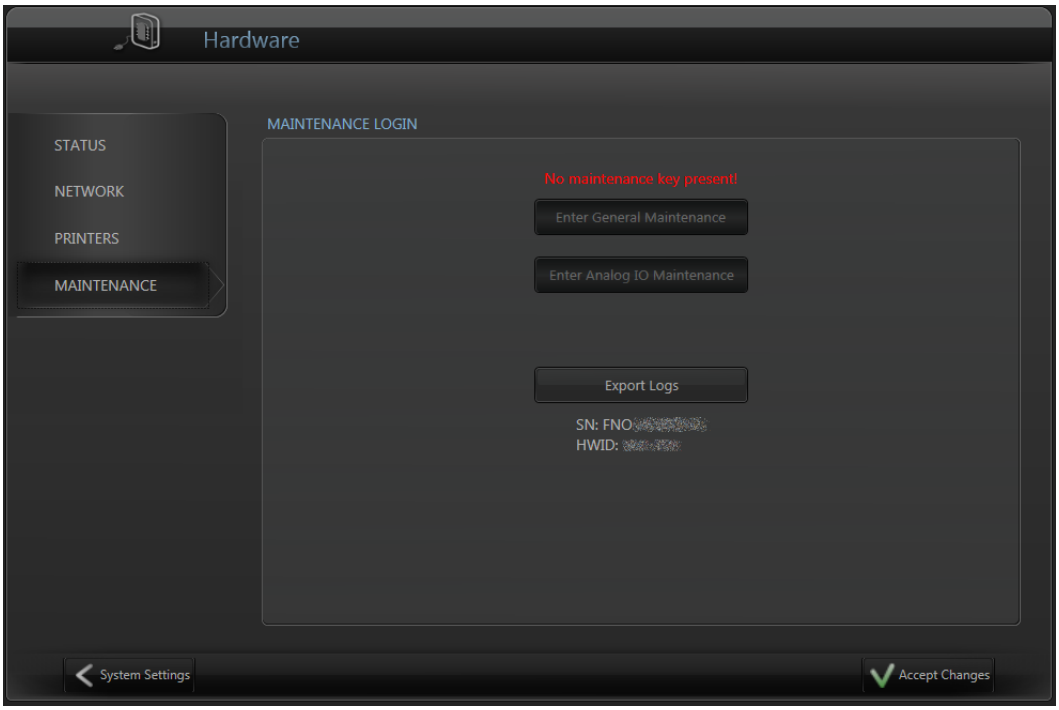


Figure A1-23: The "HARDWARE" screen – maintenance tab

Software

The "SOFTWARE" screen displays information about the version and license of the software of the Finapres Nova. These will be further elaborated below.

- **Current version**

  Displays the current and previous version of the installed software, and allows the user to install new versions.

- **License**

  Displays the license information of the software of the Finapres Nova and enables the user to enter a new license code to unlock software functions.

- **Company Logo**

  Allows the user to replace the Finapres Medical Systems logo with their own logo

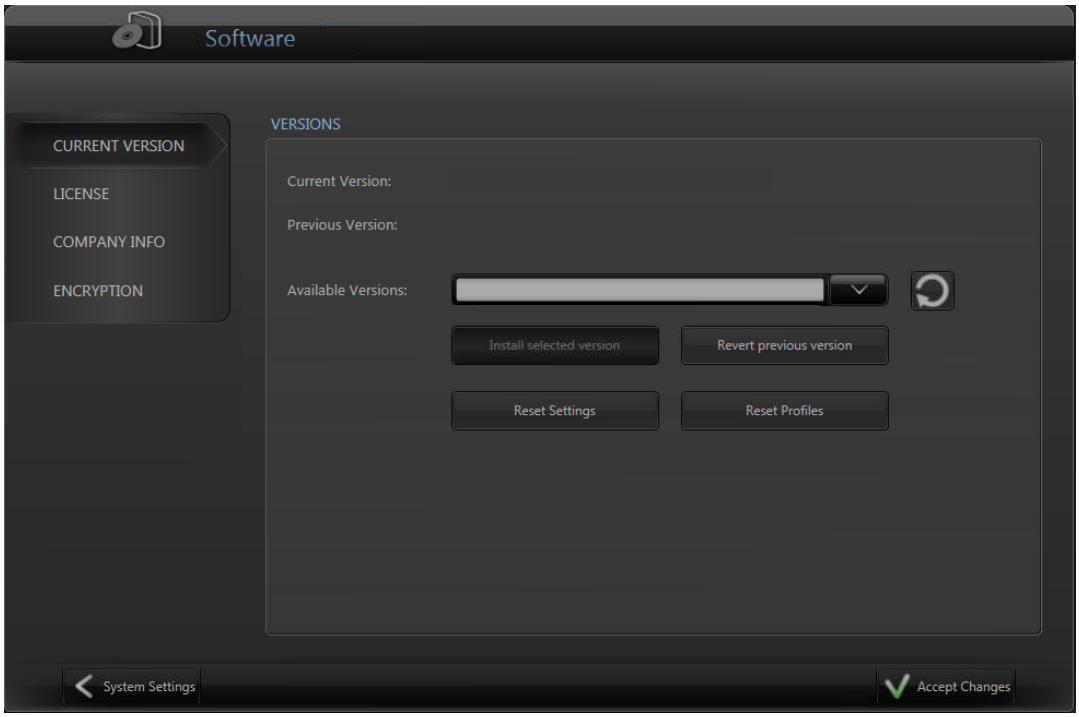
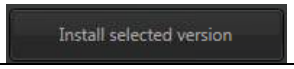
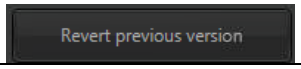
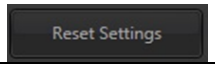
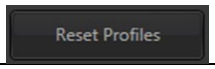


Figure A1-24: The "SOFTWARE" screen – current version tab

Item	***Description***
	Shows software installation files available on a connected USB drive
	Refreshes the list of available software installation files
	Installs the selected software installation file.
	Reverts the software to the indicated software version.
	Resets all module related settings to a default setting.
	Removes all user profiles.

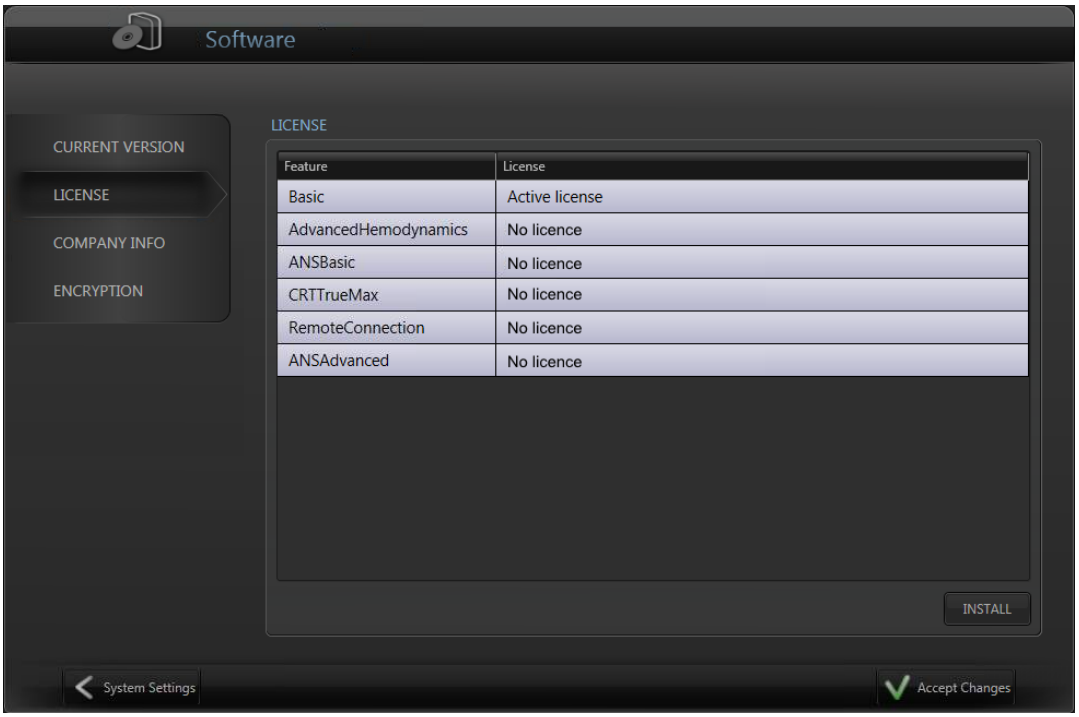
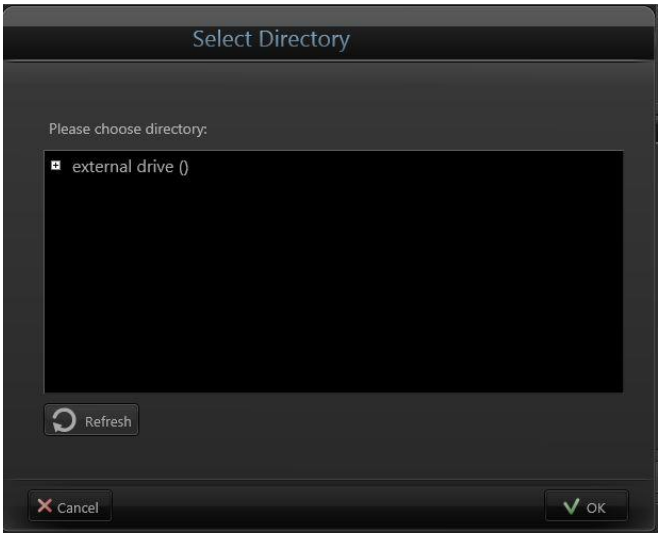


Figure A1-25: The "SOFTWARE" screen – license tab

Item	***Description***
	INSTALL LICENSE Allows the user to install a new license code from a license file to unblock software functions. When the  button is pressed a location on an external drive can be selected in which the license file is located. The license file will have the following extension: *".V2C"* 

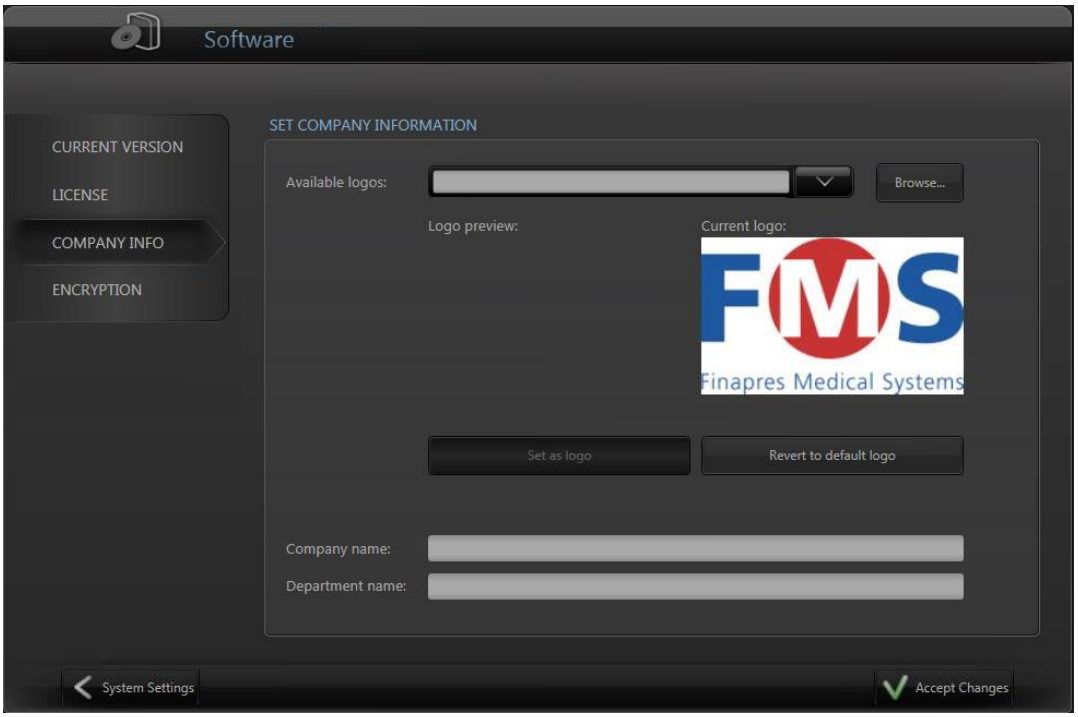
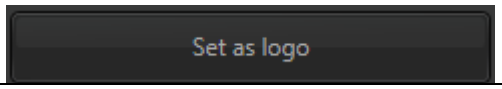
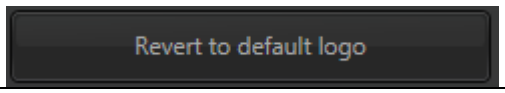
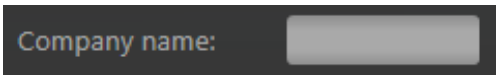
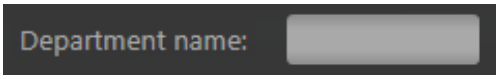


Figure A1-26: The "SOFTWARE" screen – company logo tab

Item	***Description***
	Shows logo picture files available on a connected USB drive
	Refreshes the list of available logo picture files on USB disk
	Installs the selected logo
	Sets the default Finapres Medical Systems logo
	Allows the user to enter the company name, which is used for printing
	Allows the user to enter the department name, which is used for printing

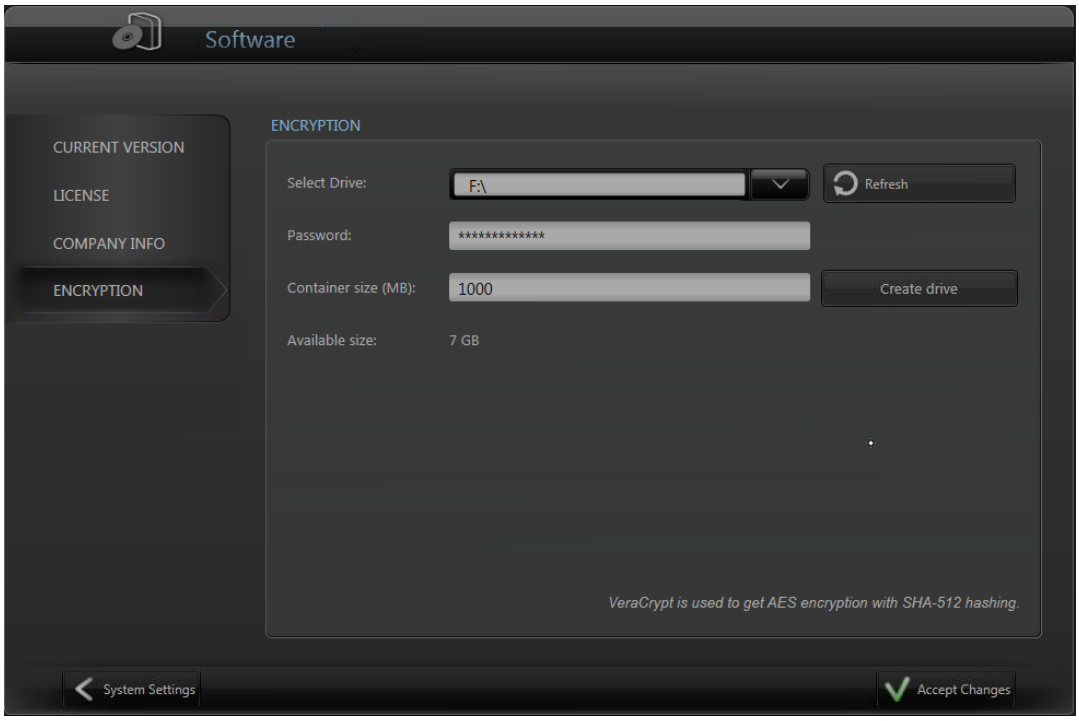
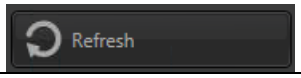
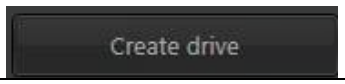
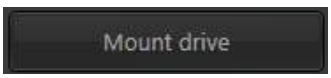
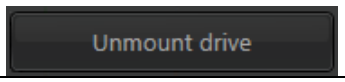


Figure A1-27: The "SOFTWARE" screen – encryption tab

Item	***Description***
	Allows the user select the drive to create an encrypted drive on (if not present) or to mount (if the drive has an encrypted partition)
	Refreshes the list of available USB disks
	Sets the password which is used to create or mount an encrypted drive
	Creates an encrypted partition on the selected drive (if none is present) or indicates the size of the encrypted drive (if present)
	Creates an encrypted partition on the selected USB drive
	Mounts the selected USB drive (only available if the selected drive contains an encrypted partition)
	Unmounts the encrypted drive (only available if the selected drive is mounted)

If a mounted drive is removed without properly unmounting it, the encrypted partition on the USB drive could be corrupted without the option of retrieving any of the data stored on the encrypted partition.

When an encrypted USB drive is inserted, it can be mounted and unmounted from the main menu using respectively the Mount Encrypted Drives ***and*** Unmount Encrypted Drives ***button on the bottom of the screen (provided that the stored password corresponds to the password used to encrypt the drive).***

The encrypted drive is indicated as such in the file management screens. If the user wants to store data on the encrypted data storage drive they should take care in selecting the correct location.

A1.5 Basic warnings and error messages

This paragraph describes the warnings and error messages that might be shown on the display of the Finapres Nova:

The following warnings will appear in the "HARDWARE CONFIGURATION" screen or in the status bar.

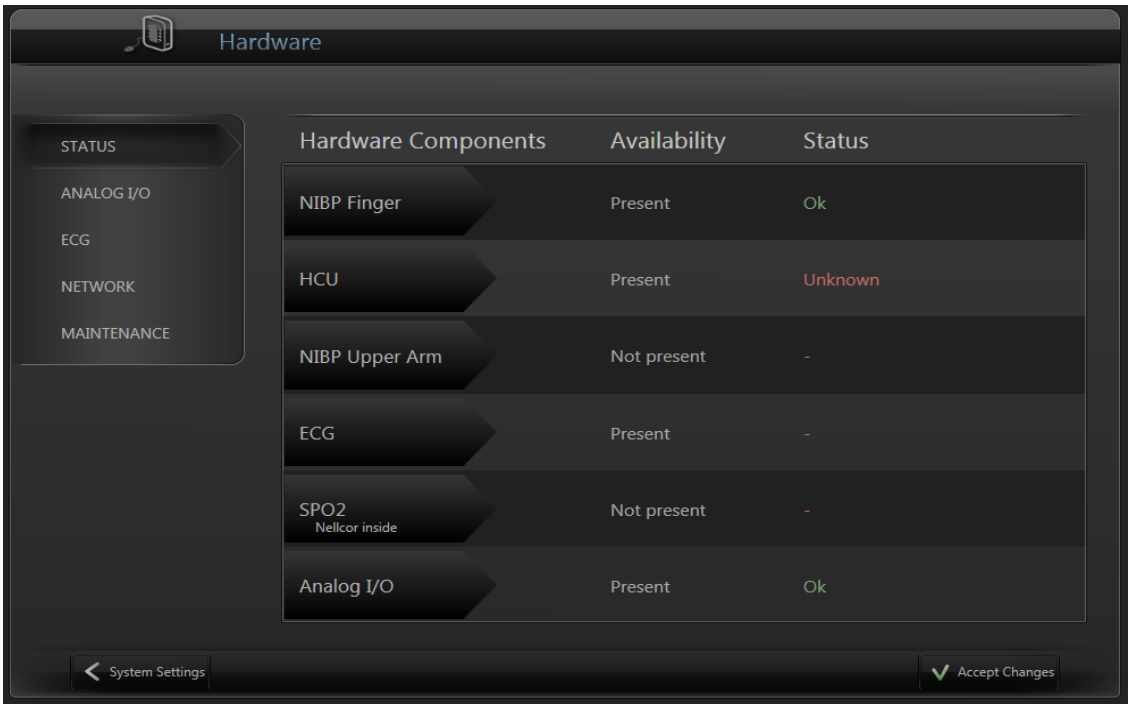


Figure A1-28: The "HARDWARE CONFIGURATION" screen.

In the column "Availability" it is indicated for each hardware component whether it is "present" or "not present".

In the column "Status" the following messages can appear:

Status	Description	Action
NIBP Finger		
Connecting	The module is busy connecting to the system	• If after one minute this message has not disappeared, turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V.
Error	Another error than the ones described here has occurred	• Turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V.
Frontend Unit not connected	Frontend Unit is not connected	• (Re)connect the Frontend Unit.
Internal communication error	Internal communication problem	• Turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V..
Ok	The module is connected	
Please reconnect Frontend Unit	Finapres Nova is in an error state that can only be resolved by reconnection Frontend Unit while power is on	• Reconnect the Frontend Unit. If the error persists, have the device checked by Finapres Medical Systems B.V..
HCU		
Not connected	The HCU is not connected to the Frontend Unit	• Connect the HCU
Ok	The HCU is connected	
Unknown	The Frontend Unit is not connected or an unknown error occurred	• Connect the Frontend Unit
NotZeroed	HCU is connected but not zeroed	• Zero the HCU
Zeroed	HCU is connected and zeroed, height can be read	

Status	***Description***	***Action***
Zeroing Failed	HCU zero-ing failed	• Try again • Try another HCU If the error persists, have the device checked by Finapres Medical Systems B.V.

The following warnings and error messages will appear in the STATUS BAR.

Warnings

Warnings	***Description***	***Action***
Artery contracted	No pressure measurement due to contracted artery	• Retry. • Try another finger. • Warm the hand.
Communication time out	Internal communication problem	• Turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V..
Connect Frontend	No Frontend Unit connected in ready mode	• (Re)connect the Frontend Unit
CPU overloaded	CPU cannot process the amount of work within the required interval	• Turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V..
Fan error	System fan failed, might cause high internal temperature, see warning below	• If no temperature warning is given the device can be used as normal, otherwise turn off the device.
No pulse detected	No pulse detected	• Retry. • Try another finger. • Warm the hand.
Physiocal error	During Physiocal, an error was detected, probably due to movement artifact	• Retry. • Minimize finger movement and movement artifacts.
Physiocal off	Physiocal is turned off	• Reactivate Physiocal by pressing Physiocal button in the GUI.
Plethysm low	Problem with plethysmogram	• Retry. • Try another finger.

Warnings	***Description***	***Action***
		• Warm the hand.
Temperature high	High internal temperature	• Turn off the device. • Make sure the rear end of the device has access to fresh air (i.e. don't use the device inside a closed cabinet). • Move device to cooler location.
NIBP Finger HCU not zeroed	HCU is connected but not zeroed	• Zero the HCU
NIBP Finger HCU not connected	HCU is not connected	• Connect the HCU

Errors

Errors	***Description***	***Action***
Check air supply	Generated air pressure is not high enough which may be caused by an air hose kinked, leaks, or deteriorated control valve.	• Check if the finger cuff air hose is inserted in the Frontend Unit. • Check if you are using the correct finger site (C1 or C2). • Check for leaks or kinks. If the error persists, have the device checked by Finapres Medical Systems B.V..
Check electronics	A short-circuit, zero offset or power supply unbalance developed. The error may also occur if you disconnect the Frontend Unit e.g. during a measurement.	• Turn off the device immediately. • Retry power-on briefly without finger cuff. • Reconnect the Frontend Unit and try again. If the error persists, have the device checked by Finapres Medical Systems B.V.
Connect cuff cable	Cuff electrical cable not connected, or has a faulty wire.	• Insert the connector, and try again. • Check if you are using the correct finger site (C1 or C2). • A wire in the cuff cable may be broken. Try another finger cuff.
Cuff artifact	Odd plethysmogram detected, probably due to	• Retry.

Errors	***Description***	***Action***
	pressing the cuff or finger-tip.	• Minimize finger movement
Finger too thin	The infrared level transmitted through the finger is too high. This may occur on very thin, nearly bloodless fingers.	• Retry. • Try a smaller finger cuff. • If this fails wrap some thin cloth around the finger and replace the cuff. Use darker cloth when necessary.
Frontend connection lost	Frontend Unit has been disconnected during measurement.	• Reconnect the Frontend Unit.
No device	No NIBP Finger device connected (internally).	• Turn device OFF wait a few seconds and turn it ON again. If the error persists, have the device checked by Finapres Medical Systems B.V..
No plethysmograph	No plethysmogram can be detected during startup; probably the arteries are fully contracted.	• Retry. • Try another finger. • Warm the hand.
Pressure out of range	Pressure outside range 5..250[mmHg] for >2.5sec.	• Retry. • Check if the finger cuff is wrapped tight enough around the finger. • See 'check air supply' and' connect cuff cable errors.
Pressure unstable	During the pressure staircase procedure at start-up or during a Physiocal, constant pressure levels were not stable enough.	• Retry. • Check if the finger cuff air hose is inserted in the Frontend Unit. If the error persists, have the device checked by Finapres Medical Systems B.V.
Reconnect Frontend	Finapres Nova is in an error state that can only be resolved by reconnection Frontend Unit while power is on.	• Reconnect the Frontend Unit. If the error persists, have the device checked by Finapres Medical Systems B.V.

Appendix 2 Technical specifications

In this annex the technical specifications of the Finapres Nova are described.

A2.1 Characteristics

Item	***Value***
Product category	Finapres Nova finger blood pressure measuring device, with optional hardware modules and software applications.
Product type	Finapres Nova
Measurement method	Arterial volume-clamp method of J. Peñáz and the Physiocal criteria of K.H. Wesseling
Cuff pressure	Max. 350 mmHg
Pressure measurement accuracy	1% of full scale (max. 3 mmHg)
Clinical Accuracy	Meets accuracy requirements of AAMI/ANSI/ISO 81060-2:2009 and EN1060-4:2004 only if a calibration with the optional Upper Arm Calibration module has been done.
Rate accuracy	(Rate [bpm] / 60) %
Interbeat interval accuracy	Max 10 ms (non-accumulating)

A2.2 Finger cuffs

A2.2.1 Protective measures for finger cuff

Cuff pressures on the finger up to 350 mmHg are practically painless and do no harm unless applied for long periods. Electrical circuits of the Finapres Nova do not touch the skin, and are not in contact with body fluids. The following measures are taken for the safety and comfort of the patient monitored and the convenience of the operator.

A2.2.2 Electrical

- Low cuff LED current (<30 mA), voltage (<1.8 V) and power dissipation (<50mW) prevent undue heating or skin irritation, or electrical hazard.
- An electrical short circuit in the cuff or the instrument depressurizes the cuff within 1 second.
- An interrupted Frontend cable or cuff cable depressurizes the cuff within 1 second.
- All analog signal outputs are fully short circuit proof.

A2.2.3 Cuff pressure

- A cuff pressure greater than 250 mmHg sustained for 2.5 s depressurizes the cuff within 1 second.
- During the start procedure cuff pressure is limited to a maximum of 295 mmHg lasting less than 2 s.

A2.2.4 General

- If cuff pressure oscillates when measuring finger pressure, although this presents no hazard or discomfort to the patient, software takes action to remove the oscillation.
- Fully contracted finger arteries do not allow pressure monitoring. A warning is send to the Finapres Nova and the finger cuff is depressurized when this is detected. The Finapres Nova waits maximally 100 s and starts up again.

A2.3 Signals

The table below gives an overview of the available signals.

Abbreviation	***Name***	***description***	***min***	***max***	***unit***
reBAP	Reconstructed Brachial Arterial Pressure	reconstructed brachial pressure from finger pressure waveform	0	300	[mmHg]
reSYS	reBAP Systolic Pressure	systolic brachial pressure (based on reBAP)	0	300	[mmHg]
reDIA	reBAP Diastolic Pressure	diastolic brachial pressure (based on reBAP)	0	300	[mmHg]
reMAP	Mean arterial pressure	mean arterial pressure (based on reBAP)	0	300	[mmHg]
fiAP	Finger Arterial Pressure	finger arterial pressure	0	400	[mmHg]
fiSYS	FinAP Systolic Pressure	SYStolic pressure (from BP signal)	0	400	[mmHg]
fiDIA	FinAP Diastolic Pressure	DIAstolic pressure (from BP signal)	0	400	[mmHg]
fiMAP	FinAP Mean Arterial Pressure	Mean Arterial Pressure (from BP signal)	0	400	[mmHg]
HR	Heart rate	Pulse Rate derived from best signal	0	300	[beats/ min]
HR AP	AP Heart rate	Pulse Rate derived from arterial pressure signal	0	300	[beats/ min]
IBI	Inter Beat	Inter Beat Interval	0	2000	[ms]

Abbreviation	*Name*	*description*	*min*	*max*	*unit*
	Interval	derived from BP signal			
height	Height	Difference between the two sensors on the HCU	-250	250	[mmHg]
PhysioCalActive	PhysioCal active detected	indicates detection that physioCal calibration algorithm is active (only for finger-pressure)	0	1	[bool]
noBeatDetected	No beat detected	indicates no beats can be detected	0	1	[bool]

A2.4 Technical description

A2.4.1 Connectivity

USB port:

The USB ports should only be used to connect a key board, mouse or USB stick. The USB ports are powered, use only devices capable of being connected to such a powered USB port.

When a USB drive has caching enabled and has been removed improperly from a computer/device it may no longer be recognized by the Finapres NOVA. Please ensure that the used USB storage device has caching turned off (in Windows → File Explorer → right mouse click on USB drive → properties → hardware tab → properties → (change settings) → Policies → disable Write caching policy).

Repairing the drive in Windows will solve the issue.

RS232:

Only to be used for data transfer according to the DatexOhmedaRS232 protocol. For more information about the RS232 protocol, please contact Finapres Medical Systems B.V. at support@finapres.com.

LAN:

Only to be used for data transfer according to standard Ethernet protocols.

A2.4.2 Mechanical

Unit:	*Outer dimensions [mm]:*	*Console weight [kg]:*
Main unit	333 x 277 x 260	5
Frontend Unit	65 x 50 x 30	0.75

A2.4.3 Electrical

Power cord:	IEC 60320 C13 to local mains plug
AC power:	100 - 240 Vac, 50 / 60 Hz, 2A - 1A
Protection against electric shock:	According EN 60601-1
Degree of protection:	Finger cuff, HCU, type B applied part Type of protection: Class I equipment
Protection against ingress of water and/or objects:	IP31
Power consumption:	In main unit: < 50 W, in Frontend Unit: 1 W, in finger cuff: < 50 mW

The following power supply cords can be used for the countries specified in the table.

Object / part NO	Manufacturer / trademark	Type / model	Technical data	Standard
Cord set (Europe)	Eurlectric, Different Manufac-turers	2pole, class I H05VV-F	Plug: 10/16 A, 250V Cord: 3xmin 0,75 mm2 appliance Coupler: 10A, 250V	IEC60320 HD21
Cord set (UK)	WELL SHIN	2pole, class I H05VV-F	Plug: 10A,250V Cord: 3xmin 0,75 mm2 appliance Coupler: 10A,250V	IEC 60320 C13
Cord set * (USA,CAN)	Ta Hsing, Different Manufac-turers	2pole, class I SVT	Plug: 10A, 125V Cord: 3 x AWG 18 appliance Coupler: 10A, 125V	IEC60320 C13

* For patient care equipment, where a "Hospital Grade" or "Hospital Only" MAINS PLUG exist for the particular electrical rating in question, the MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT with a protective earth connection shall comply with the requirements for a hospital grade attachment plug (mains plug) or the non-hazardous location locking type designated "Hospital Only" as specified in the Standard for Attachment Plugs and Receptacles UL 498.

A2.4.4 Environmental conditions

Operation temperature:	0 °C to 35 °C
Storage temperature:	-20 °C to 70 °C
Humidity:	5 to 90 % non-condensing
Atmospheric pressure:	700 to 1100 hPa

Note: The device may not meet its performance specifications if stored or used outside the ranges specified above.

A2.4.5 EMC Guidance and manufacturer's declaration tables

This section describes the information regarding potential electromagnetic or other interference and advice regarding avoidance.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Finapres Nova is intended for use in the electromagnetic environment specified below. The customer or the user of the Finapres Nova should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Finapres Nova uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable (< 75 W power)	The Finapres Nova is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable (low power/limiting switching)	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Finapres Nova is intended for use in the electromagnetic environment specified below. The customer or the user of the Finapres Nova should assure that it is used in such an environment.			
Immunity test	*IEC 60601 test level*	*Compliance level*	*Electromagnetic environment - guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_t (>95 % dip in U_t)for 0,5 cycle 40 % U_t (60 % dip in U_t) for 5 cycles 70 % U_t (30 % dip in U_t) for 25 cycles <5 % U_t (>95 % dip in U_t) for 5 sec	0 % U_t (100 % dip in U_t)for 0,5 cycle 40 % U_t (60 % dip in U_t)for 5 cycles 70 % U_t (30 % dip in U_t) for 25 cycles 0 % U_t (100 % dip in U_t) for 5 sec*	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Finapres Nova requires continued operation during power mains interruptions, it is recommended that the Finapres Nova be powered from an UPS or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Finapres Nova is intended for use in the electromagnetic environment specified below. The customer or the user of the Finapres Nova should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Hz outside ISM bands a 3* Vrms 150 KHz to 80 MHz in ISM bands a	3V 3V	
Radiated RF IEC 61000-4-3	3* V/m 80 MHz to 2,5 GHz	3V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a) The ISM bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 to 27,283 MHz; and 40,66 MHz to 40,70 MHz

b) The compliance levels in the ISM band between 150 kHz and 80 MHz and in the total frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason an additional factor of 10/3 is used calculating the recommended separation distance for transmitters in this ranges]

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Finapres Nova is used exceeds the applicable RF compliance level above, the Finapres Nova should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Finapres Nova

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

* 10 V/m for life supporting or 3 V/m for NOT life supporting

Recommended minimal separation distances between portable and mobile RF communications equipment and the Finapres Nova (Not Life supporting: V1 = 3V & E1 = 10V/m)

The Finapres Nova is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Finapres Nova can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Finapres Nova as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance d according to frequency of transmitter in meters**		
	150 kHz to 80 MHz $d = \frac{3,5}{V1}\sqrt{P}$	80 MHz to 800 MHz $d = \frac{3,5}{E1}\sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{7}{E1}\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

Appendix 3 Connecting the patient

A3.1 Using finger cuffs

Proper finger cuff application is critical to the success of the Finapres Nova finger arterial pressure measurement. Therefore read the following sections about finger cuff selection, handling and application with care!

A3.1.1 Finger cuff selection

There are 3 different finger cuff sizes: small (S), medium (M) and large (L). Each size has its own color. The finger cuff(s) should be applied to the middle phalanx of one or two fingers, depending on the selected finger switching interval. The best results can be gained with the middle and ring finger (combination), but the index finger can be used equally well in most cases.

The pre-formed conical finger cuffs are not designed for application to the thumb. However, you may apply the finger cuff to the thumb when it is impossible to measure finger arterial pressure on any other finger.

Select the proper finger cuff size by using the table below or by using the Cuff Size Guide. When in doubt, use the smaller size finger cuff.

Finger circumference * [mm]	***Finger cuff size***	***Finger cuff Color***
45 - 55	S (small)	White
55 - 65	M (medium)	Beige
65 - 75	L (large)	Blue

* measured at the centre of the middle phalanx of the finger

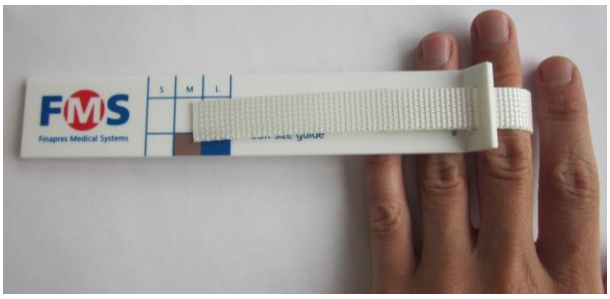


Figure A3-1: Cuff size guide

Finger cuffs are available in different sizes. Make sure to use the appropriate sized finger cuffs for each patient.

To obtain a good transmission of pressure from the air bladder to the underlying tissues both sides of the air bladder should just make contact (Figure A3-2).

Cuff too large Cuff OK Cuff too small

Figure A3-2: cuff application and cuff size guide

A3.1.2 Notes on cuff handling

Take into account the following notes to prevent finger cuff damage:

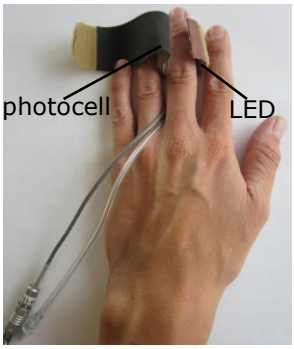
- Don't remove the finger cuff from a finger before stopping the measurement or before disconnecting the air hose from the Frontend Unit. You may damage the finger cuff even though Finapres Nova automatically takes pressure away when the finger cuff unwraps.
- Don't apply air pressure to a finger cuff, when it isn't wrapped around a finger or any other solid object! This may damage the finger cuff.
- Don't bend finger cuffs outwards to a flat shape since this may damage the bonding and the electrical shielding. Finger cuffs are preformed around a conical mandrel during manufacturing.
- Do not try to repair defective finger cuffs with e.g. adhesive tape, this will substantially affect measurement accuracy.

A3.1.3 Cuff application

To wrap the finger cuff around the finger:

1. **Bend** the finger cuff open just enough to see the LED and photocell.
2. **Place** the finger in the cuff such that the LED and photocell are symmetrically placed on each side of the finger's soft parts in the center of the middle phalanx.

   The cuff cable and air hose are now at the back of the hand and should point towards the Frontend Unit.



3. **Make** sure the finger cuff is placed in the middle between the two knuckles, touching each knuckle.
4. **Wrap** the finger cuff tightly for best performance. The finger cuffs are designed in such a way that correct wrapping is almost natural.
5. **Check** that it is not easy to rotate the finger cuff after application. A common mistake is to wrap the finger cuff not tight enough.
6. **Guide** the cuff cable and air hose between the fingers to the back of the hand and connect them to the Frontend Unit which is worn on the wrist (see Figure A3-3).

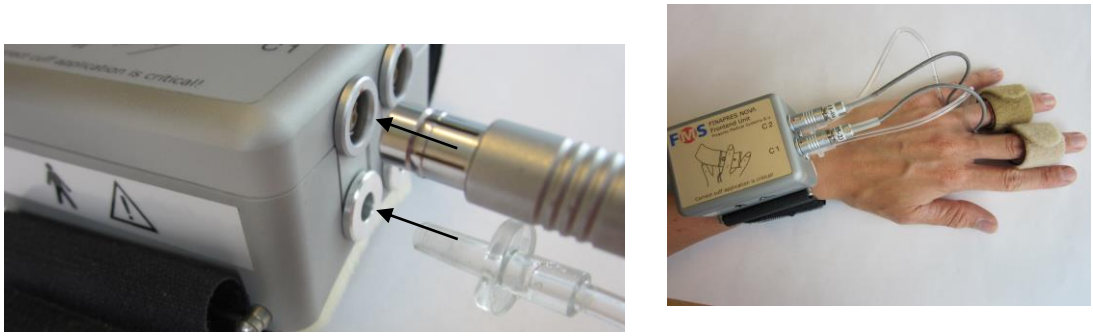


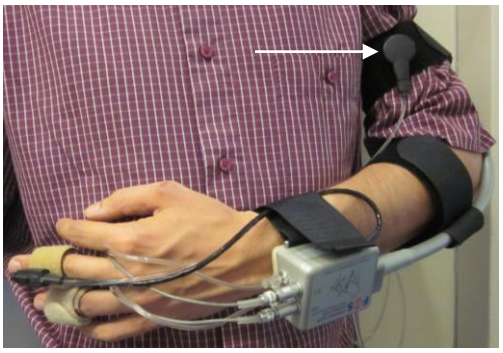
Figure A3-3: Connecting the finger cuffs to the Frontend Unit

7. **Repeat** step1 to 6 for a second finger, when finger switching measurement mode has been selected.

Make sure to connect a finger cuff to the air and electrical connections that are positioned above each other on the Frontend Unit.

A3.2 Connecting the height correction unit

1. **Fix** the reference ending of the height correction unit to the patient's arm at heart level near the body.



2. Connect to height correction unit connector to the connector on the Frontend Unit.

3. The other ending of the height correction unit, the transducer ending, should be fixed to one of the finger cuffs.