PERFORM Centre

PERFORM Operating Document

Use and Cleaning Procedures for Nexfin

PC-POD-CP-007-v01

Revision History

Version	Reason for Revision	Date
01	New POD	August/21/2015

Summary

The content of this PERFORM Operating Document (POD) provides guidelines for the safe use and cleaning of the Nexfin as identified as equipment inventory at the PERFORM Centre, Concordia University.

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1. Definition of Terms

PERFORM operating document (POD)	Operating documents that are specific to an instrument or technique that require approval by area managers.
Protocol	Methods that are developed by users on specific instruments/equipment
Users	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.
Supervisor	Knowledgeable person regarding all or an aspect of a project or program and is familiar with PERFORM's best practices, that is responsible for ensuring that users conduct their activities in a safe manner and within scope of the project.
PERFORM Employees	Concordia employee that has been assigned to PERFORM.

2. Relevant Documents

This POD is governed by the following Concordia University policies, SOPs, and PODs:

- PC-POD-GA-001 "PERFORM Centre Booking System for Facilities and Equipment".
- PC-SOP-GA-002 "Handling of Biological Materials at PERFORM".
- PC-SOP-GA-007 "General Access to PERFORM Centre".
- PC-SOP-GA-009 "Emergency Response Procedures at the PERFORM Centre".
- PC-SOP-GA-011 "Guidelines for Management of Incidental Findings at PERFORM".
- PC-SOP-CP-001 "Cardio-Pulmonary Suite – Access, Use, and Training of Personnel".
- PC-POD-CP-002 "Use and Cleaning Procedures for Manual and Automatic Aneroid Sphygmomanometers".

3. Introduction

3.1 Background

The Nexfin is a monitoring system used to monitor continuous non-invasive blood pressure and to trend beat-to-beat hemodynamic parameters, including systolic blood

pressure, diastolic blood pressure, mean arterial pressure, pulse rate, stroke volume, cardiac output, systemic vascular resistance, and pulse rate. Nexfin uses a single finger sensor (finger cuff) wrapped around a participant's finger, to make necessary measurements.

3.2 Purpose

The objectives of the current POD are to 1) outline the procedure of using the Nexfin; 2) provide a set of standard practices for safe operation and training guide for new users of the systems at the PERFORM Centre, Concordia University; and 3) outline the procedure of cleaning/disinfecting of the cuffs and wires.

3.3 Scope

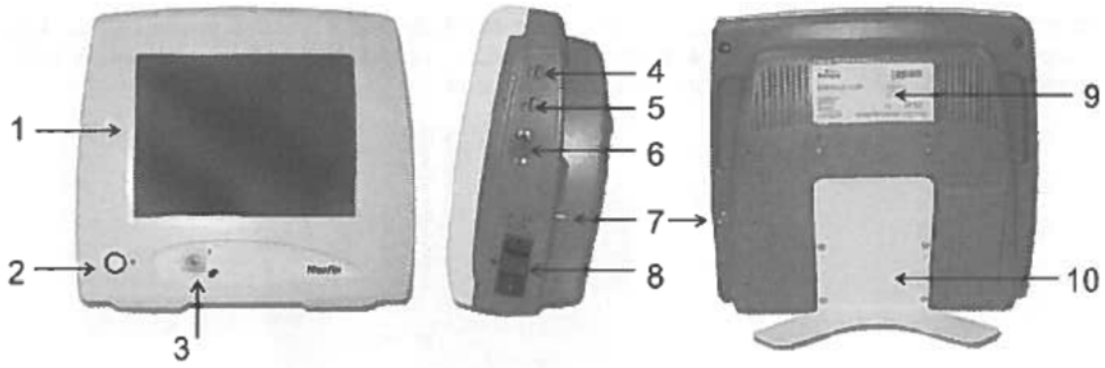
This POD applies to all users and supervisors using the Nexfin at the PERFORM Centre, Concordia University. Any other document other than this POD is out of scope for this operating procedure.

3.4 Responsibility

It is the responsibility of all users and supervisors to ensure that this POD is followed.

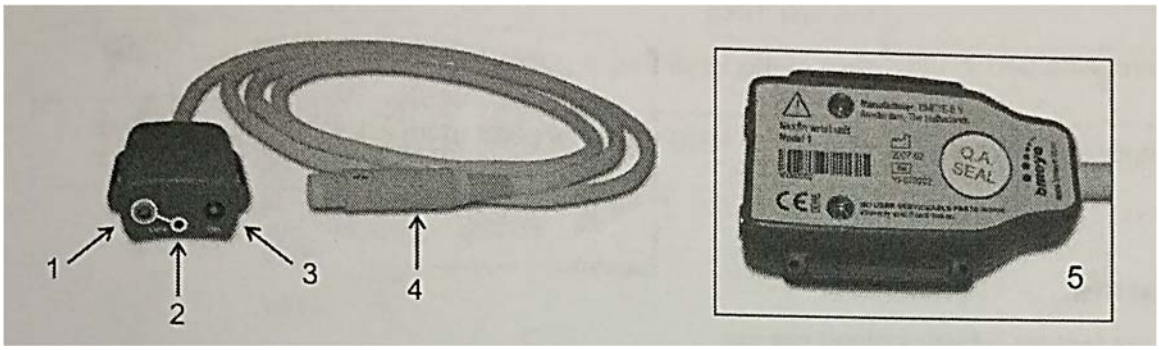
4. Main Components of Nexfin

4.1 Nexfin Monitor



1	Touch Screen	Color Screen with touch interface
2	Standby Button	Use button to standby/resume. - LED colored orange: monitor is standby. - LED colored green: monitor is switched on.
3	Wrist Unit Connector	Receptacle for the wrist unit.
4	USB Port	Connects to USB flash drive, Nexfin ECG cable.
5	USB Port	Connects to USB flash drive, Nexfin ECG cable.
6	I/O Connector	Port for analog output and output signals.
7	Equipotentiality connector	Used for grounding of the monitor in type 2 rooms (IEC 60364-7-710)
8	Power Inlet and Main Power Switch	Connects to wall outlet via the power cord. Use the power switch to switch the instrument on or off.
9	Monitor Serial Number Label	Serial Number and Manufacturer information. NOTE: This information is needed when contacting BMEYE customer service.
10	Desk Stand Mount	Always use the desk stand mount (or the rolling mount) when using the device.

4.2 Wrist Unit



1	Cuff Electrical Connector	Receptacle for the finger cuff electrical connector.
2	Cuff Air Connector	Receptacle for the finger cuff air hose connector.
3	Heart Reference System (HRS) Connector	Receptacle for the HRS.
4	Wrist Unit Connector	For connection of the monitor.
5	Wrist Unit Serial Number Label	Serial number and manufacturer information. NOTE: This information is needed when contacting BMEYE customer service.

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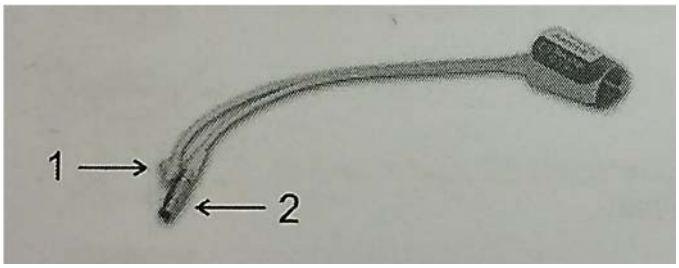
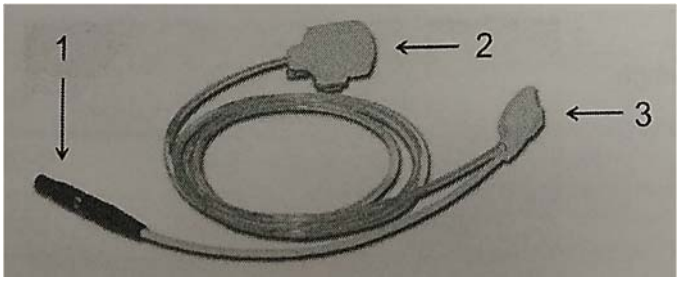
4.3 Finger Cuff (small, medium, and large)



1	Air Hose Connector	Connects to the air outlet of the wrist unit.
2	Cuff Connector	Connects to the silver colored receptacle on the wrist unit marked "CUFF".

4.4 Heart Reference System (HRS)



1	HRS Connector	Connects to the black receptacle on the wrist unit marked "HRS".
2	The Heart Side Part of the HRS	Part of the HRS that is positioned at heart rate.
3	The Finger Side Part of the HRS	Part of the HRS that is applied to an adjacent finger using a finger strap.

4.5 Analog Output Module (AO) – OPTIONAL

The AO module can be used to connect the Nexfin monitor to external systems. This module provides 4 configurable analog output signals. Output plugs: BNC jacks. Output signals have a delay of 250ms, yet can optionally be changed to a delay of 3 secs under the "System Setup" button in the main menu. An additional tab  will appear on the screen when AO is detected.

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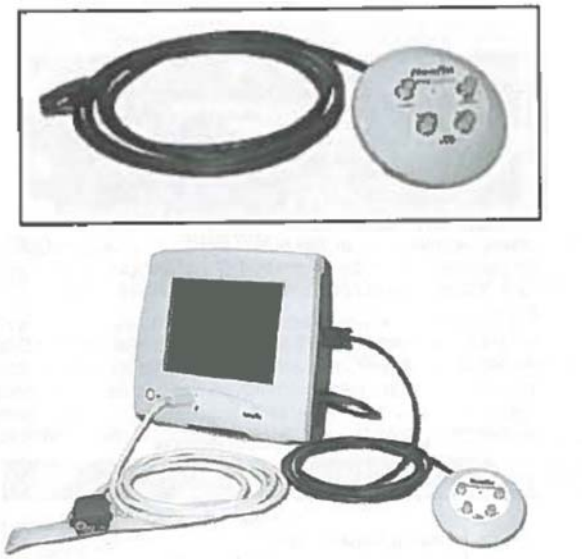
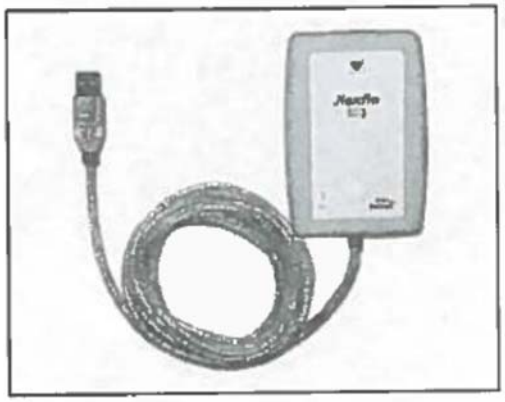
NOTE: This option is only available when either the analog output option or the analog input/output option is enabled under the "System Setup" button in the main menu.



4.6 ECG - OPTIONAL

The 6-lead ECG option with 4-lead wires allows for the electrical activity of the heart, sensed by electrodes on the skin surface, to be monitored. This option provides additional information that helps understanding physiological processes during blood pressure and hemodynamic measurements. The ECG option does not feature arrhythmia detection, waveform interpretation (other than an indicative R-top detection), or alarms. An additional ECG tab will appear on the screen when ECG is detected. Leads and heart rate derived from the ECG will be automatically stored in the Nexfin data file.

NOTE: This option is only available when the ECG option is enabled under the "System Setup" button in the main menu.



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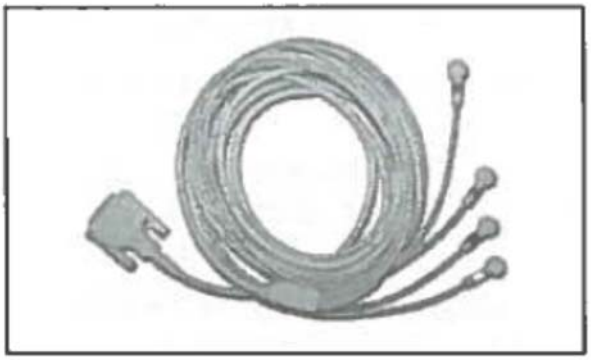

5.0 Screen Symbols, Screen Layout, and Screen Abbreviations

5.1 Screen Symbols

	Attention, read accompanying documents
	Continuous, non-invasive arterial blood pressure
	Type B applied part
	Type CF applied part
	Defibrillation-proof type CF applied part
	ECG
CE 0086	Indicates compliance to the Medical Device Directive 93/42/EEC
	Indicates compliance with applicable Canadian and US standards.
	Warning: dangerous voltage
	Indoor use only

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Standby


Equipotentiality


USB


Input / Output


Finger circumference (measured at the center of the middle phalanx of the finger)

Serial number


Date of manufacture

IP20

Extent of protection against the ingress of objects or water


Follow Waste Electrical and Electronic Equipment regulations.

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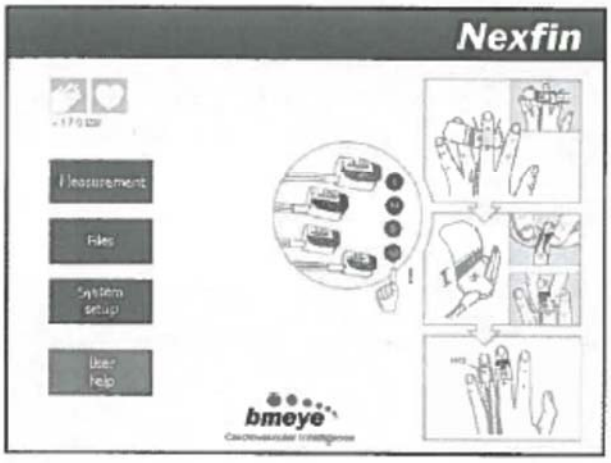
5.2 Screen Layout

5.2.1 Main Menu

After switching the power on the instrument displays the main menu, with the following buttons:

- **Measurement**: to start a measurement
- **Files**: to copy, review and print previous recordings
- **System setup**: to setup the device
- **User help**: to show the Nexfin Getting started manual



The icons on the main menu refer to the activated options in the monitor.

 : Blood pressure

 : Hemodynamics (optionally available)

 : Analog output (optionally available)

 : Analog input (optionally available)

 : ECG (optionally available)

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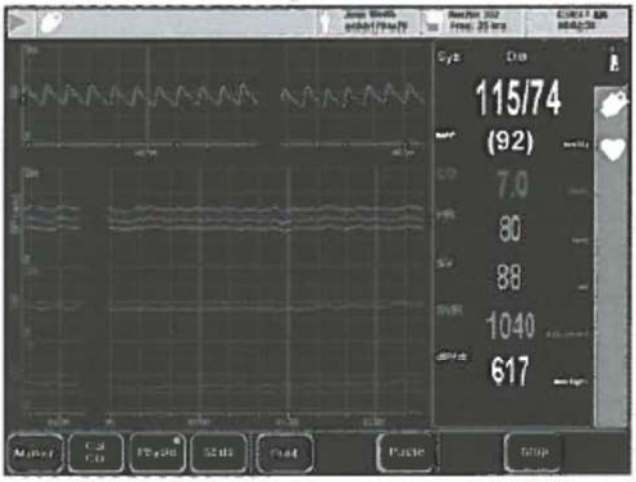
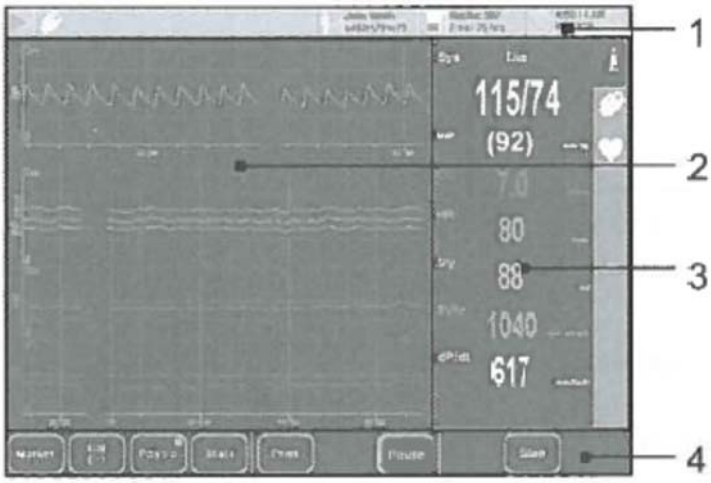
5.2.2 Screen Options During Data Acquisition

The figure below shows a typical Nexfin screen during a measurement.



The screen is divided into different sections, with different functions.



1 : Status panels
2 : Graphical signal view
3 : Numerical beat data
4 : Button control bar

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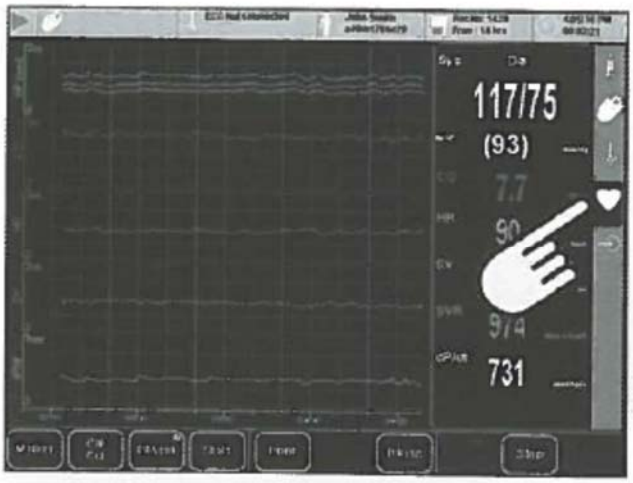


: Overview tab

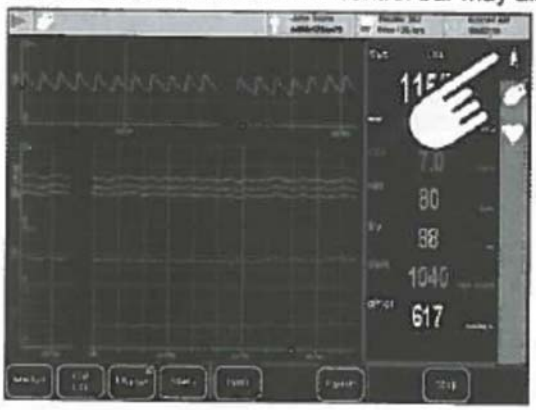
: Finger pressure tab

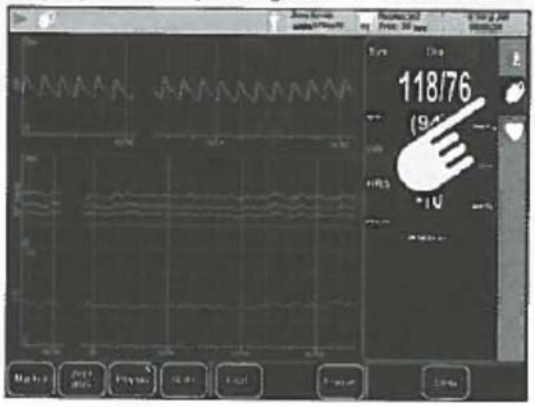
: ECG tab

: Hemodynamics tab

: Analog input tab

By tapping a tab a different view of the recording will be displayed. The graphical signal view and the numerical beat data form a set. By tapping a tab the beat data and associated graphical signal view are activated. The button control bar may also slightly differ, depending on the selected view.





In the top line of the measurement screen a number of status panels are available to give the user a quick overview of the status of the measurement and the internal status of Nexfin. Normally the background color of status panels is grey:

If a warning or error condition is detected the associated panel flashes:

- yellow for warnings
- red for errors

If this is the case the panel can be tapped to display additional information and corrective actions for the detected problem.

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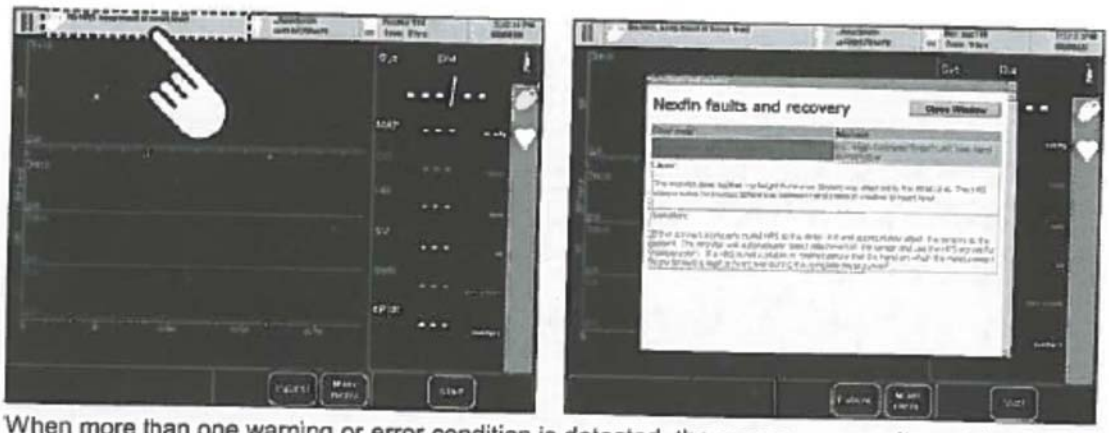
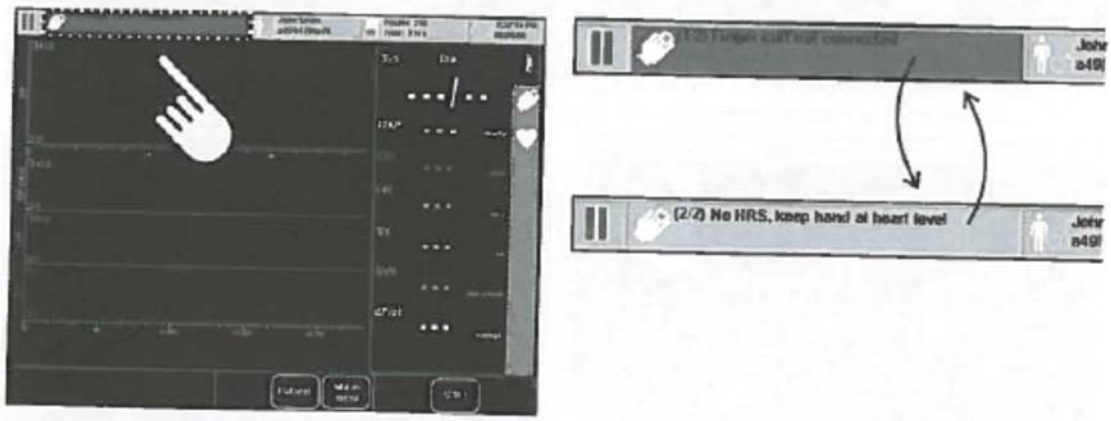
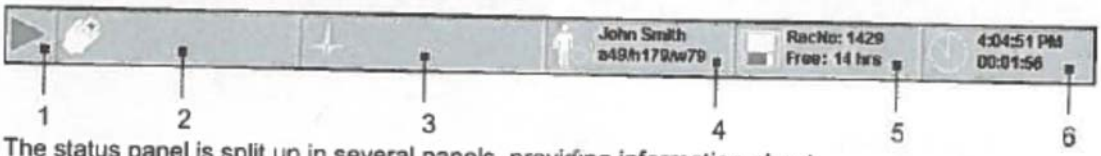


When more than one warning or error condition is detected, the messages are alternately displayed:





The status panel is split up in several panels, providing information about:

1 : View mode
2 : Wrist unit status
3 : ECG status (optionally available)
4 : Patient data
5 : Internal disk status
6 : Time status

View mode

The top left panel displays an icon indicating the view mode of the device:

 : not measuring

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: measuring


: review mode (when no measurement is running)


: pause mode (temporary review mode during measuring)

Wrist unit status

In normal operation - when no error condition is detected - this panel will show a gray box with the wrist unit icon. During a measurement this status panel will provide information regarding the Physiocal status (section About Physiocal 109).

Warnings and errors related to the blood pressure measurement or occurring in the wrist unit will be displayed in this area and subsequently the color will be changed as indicated above.

ECG status

In normal operation - when no error condition is detected - this panel will show a gray box with the ECG icon. Warnings and error messages related to the ECG measurement (e.g. 'Lead fault') will be displayed in this area and subsequently the color will be changed as indicated above.

Patient data

The text in the patient data panel is formatted as follows:

- On the first line: patient name
- On the second line: age/height/weight

The icon in front of the text indicates:


: Gender not specified


: Male


: Female

CAUTION: Accurate measurements of cardiac output can only be obtained if the following patient data are properly entered: gender, age, weight and height. When the patient data status panel displays the warning 'Patient data incomplete', go to the Patient menu to fill in the missing patient data.

Internal disk status

The internal disk status panel displays:

- On the first line: the current recording number
- On the second line: the total number of available recording hours on the internal disk.

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If an error or warning is detected in the data storage (e.g. disc full), the disk status field will be colored red.

Time status

The time status panel displays:

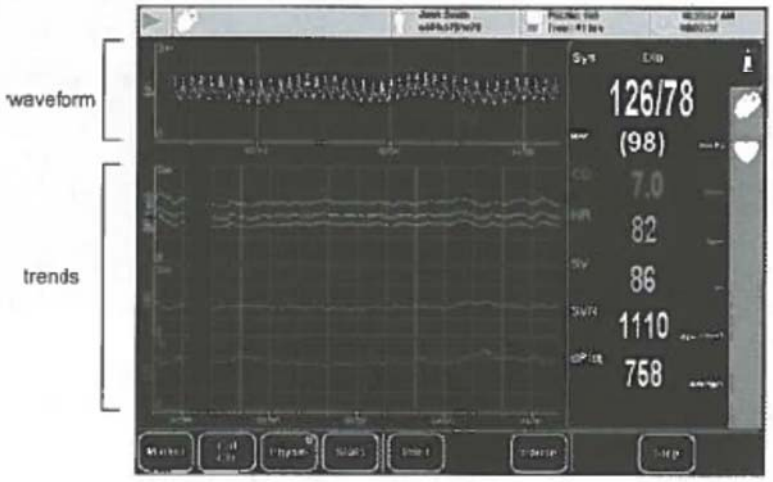
- On the first line: the current system time
- On the second line: the current recording time

5.2.3 Graphical View

This graphical signal view displays a fixed lay-out of signal graphs. Two types of graphs can be presented:

- Waveforms
- Trends (trended beat-to-beat data, no averaging)

The waveform panel normally displays the blood pressure waveform, but can also display other waveforms. The waveform and trend graphs have different time scales which can be adjusted independently.



Most parts of the waveform and trend panels on screen can be customized. You can:

- adjust the time scale and vertical scale
- change the signals displayed in the waveform and trend panel
- change the signal colors.

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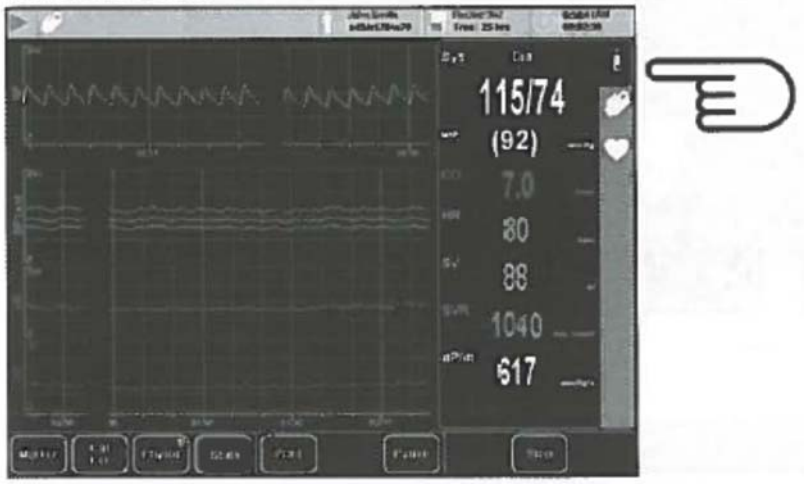
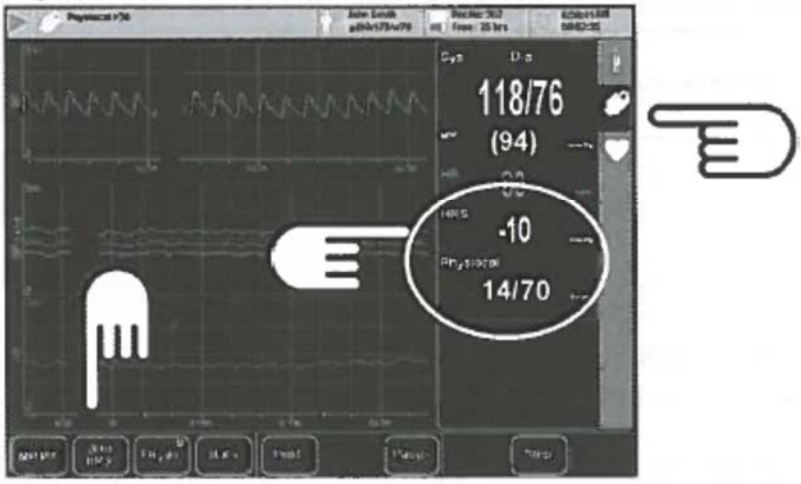
5.2.4 Numerical Beat Data

At the right of the measurement screen numerical beat data are shown. The beat data shown in numerical beat data panel are updated every two seconds. The numbers are the averaged results of the last 5 beats.



Depending on the selected view (tab) the content of the numerical beat data panel may differ. The numerical beat data panel however is fixed and cannot be modified. Note that when the finger pressure view is selected, the numerical beat data panel will display information focussing on the blood pressure recording itself (the Nexfin methodology), providing e.g. information about the Physiocal interval and the correction by the heart reference system (HRS).



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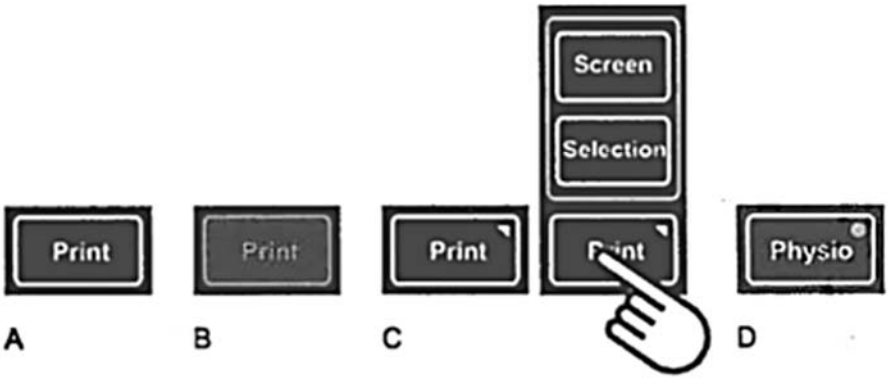
5.2.5 Button Control Bar

In many screens the bottom screen area displays a button bar which adapts to the context of the monitor state. The buttons may have the following appearance:



Type	Description
A	Active button (button colored black): Tapping the button will provoke an action.
B	Inactive button (button colored gray): This functionality is not accessible or already activated.
C	Menu button: button with underlying submenu
D	Toggle button: • Green light visible: option is active • Green light not visible: option is inactive

Toggle buttons are :

- Physio (On/Off)
- Select (Select/Scroll)

6.2.4.1 Select button (Select/Scroll toggle)

The Select button is a special kind of toggle button and toggles between select and scroll:

Select mode: The Select button is active (green light visible).
You can make selections of recorded data while moving your finger horizontally over the screen.

Scroll mode: The Select button is inactive (no green light visible).
You can browse through a file when moving your finger horizontally over a graphic panel.

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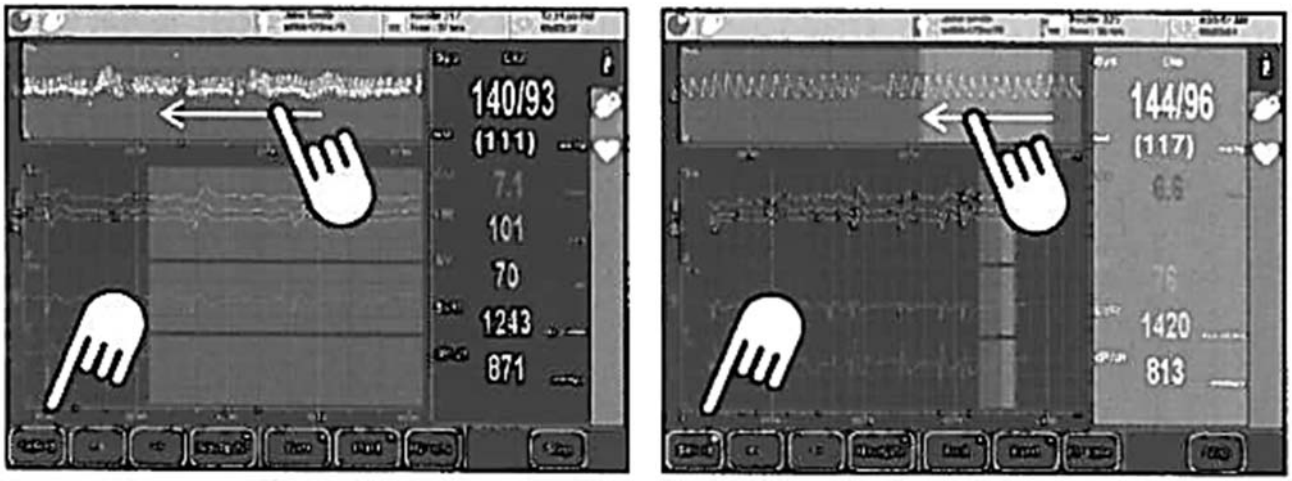

5.3 Screen Abbreviations

Abbreviation	Description	Unit	Note
AD-1	Analog input channel 1	V	IO
AD-2	Analog input channel 2	V	IO
AD-3	Analog input channel 3	V	IO
AD-4	Analog input channel 4	V	IO

Abbreviation	Description	Unit	Note
aVF	ECG lead aVF	mV	E
aVL	ECG lead aVL	mV	E
aVR	ECG lead aVR	mV	E
BMI	Body mass index	kg/m2	-
BP (trend)	Blood pressure (trend)	mmHg	-
BSA	Body surface area	m2	-
cal	Calibrated signal (at least one CO calibration performed)	-	HD
CI	Cardiac index	l/min.m2	HD
CO	Cardiac output	l/min	HD
Dia	Diastolic pressure	mmHg	-
dP/dt	Maximum pressure slope during systole	mmHg/s	HD
HR	Heart rate (derived from blood pressure)	bpm	-
HR 	Heart rate (derived from ECG)	bpm	E
HRS	Hydrostatic compensation of the heart reference system (HRS)	mmHg	-
I	ECG lead I	mV	E
IBI	Inter beat interval (time between consecutive heart beats, derived form the the blood pressure)	s	-
II	ECG lead II	mV	E
III	ECG lead III	mV	E
MAP	Mean pressure	mmHg	-
Physio	Physiocal interval, indicated as: xx/yy, where: xx = Number of beats to the next Physiocal calibration yy = Physiocal interval	beats	-
RR	Interval between consecutive R-peaks	s	E
SV	Stroke volume	ml	HD
SVI	Stroke volume index	ml/m2	HD
SVR	Systemic vascular resistance	dyn.s/cm5	HD

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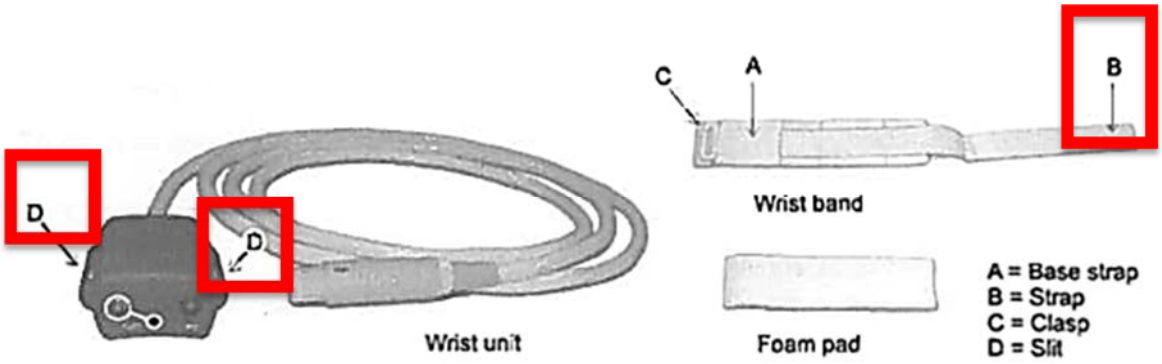
Abbreviation	Description	Unit	Note
SVRI	Systemic vascular resistance index	dyn.s.m2/cm5	HD
Sys	Systolic pressure	mmHg	-

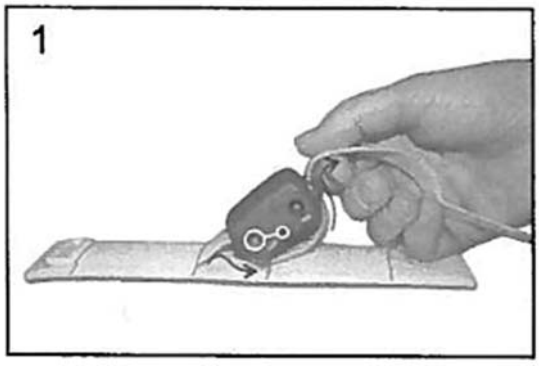
6. Nexfin Hardware Setup

6.1 Applying the wrist band to the wrist unit

Before starting measurement with the Nexfin, the wrist band must be applied to the wrist unit.

6.1.1 Take the wrist band and guide the strap through the first slit opening by folding the end of the strap (labeled B in Figure), then through the sides of the wrist unit labeled D as shown below.





6.1.2 Fold the end of the strap of the wrist band again.

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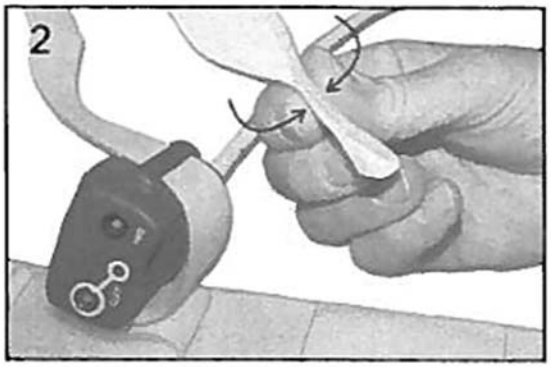
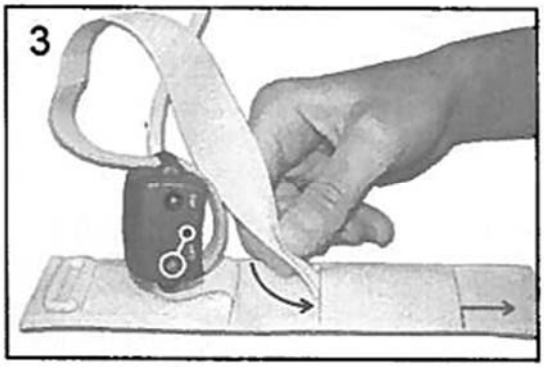
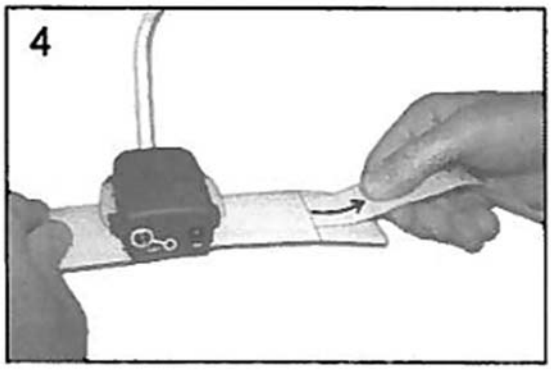


6.1.3 Guide the end of the strap through the second slit of the wrist band.

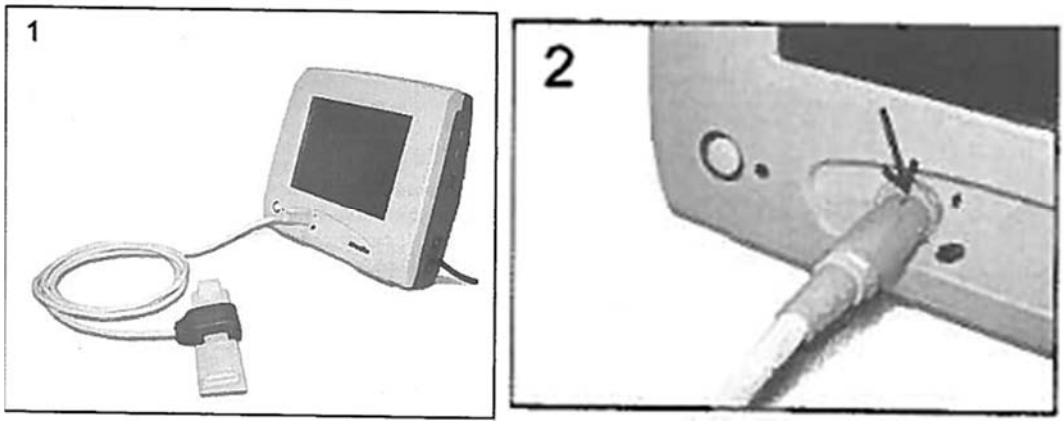


6.1.4 Secure the wrist unit to the base strap by pulling the strap as far as possible.

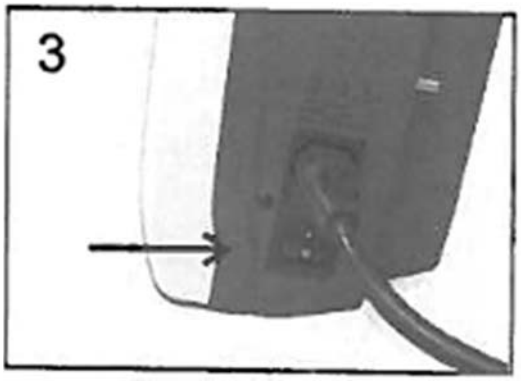


6.2 Setting up the Device

6.2.1 Connect the wrist unit to the Nexfin monitor. Make sure the red mark on the connector is aligned with the corresponding red mark on the receptacle.



6.2.2 Connect the power cord of the Nexfin monitor.
6.2.3 Connect the power cord to the power outlet.
6.2.4 Turn the device on by pressing the power switch on the bottom right side of the Nexfin.



7. Measurement Conditions and Participant Instructions

7.1 Measurement Conditions

7.1.1 Measurements should be done in a quiet room at a comfortable temperature.
7.1.2 Remain seated during measurements with legs uncrossed.
7.1.3 If the participant has cold hands, warm the hand with a loosely wrapped towel.

NOTE: Should participant have cold hands, measurement may not be obtained.

7.1.4 Refrain from talking to the participant during measurements since this can significantly affect blood pressure.

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7.2 Participant Instructions

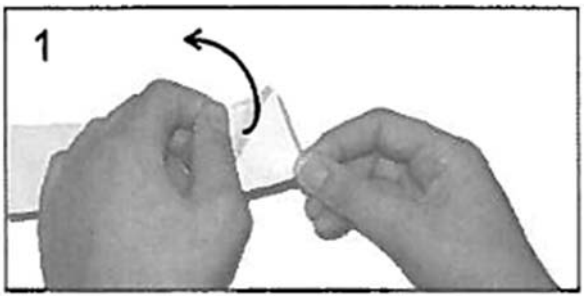
Before setting up the participant, advise them during measurement they should:

7.2.1 Keep the measurement arm relaxed and do not overstretch the hand.
7.2.2 Avoid unnecessary movement of the fingers.
7.2.3 If they are resting their arm on a hard surface, avoid pressing their hand down, which may cause obstruction of blood flow to the hand.
7.2.4 During measurement, the participant will notice a slight pulsation in the finger where the cuff is applied. This is normal.
7.2.5 During measurement the distal part of the finger inserted in the cuff might become red. This is normal and coloring will go back to normal after cuff is removed.

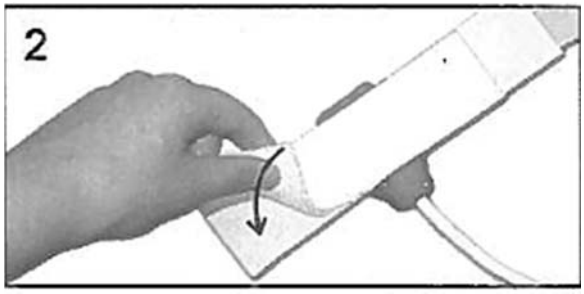
8.0 Participant Setup

8.1 Applying the Wrist Unit

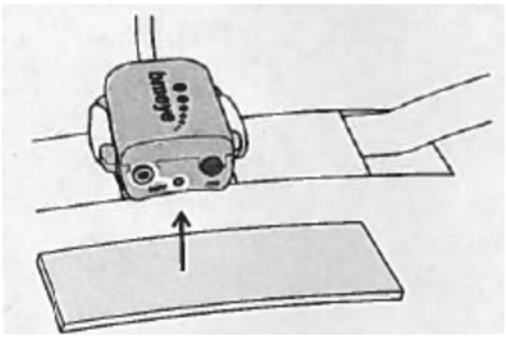
8.1.1 Take the foam pad (see Appendix II for e-mail to distributor regarding re-use of foam pads) and remove the adhesive protection layer or use a clean foam pad.



8.1.2 Attach the foam pad with the Velcro surface contacting the wrist band.

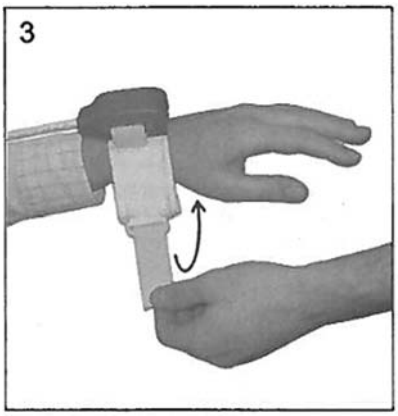


PERFORM Centre



8.1.3 Wrap the wrist band around the participant's wrist and secure.

NOTE: Do not wrap too tightly.

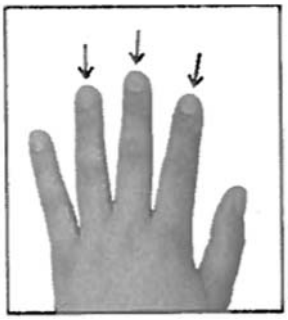


8.2 Select the Cuff Size

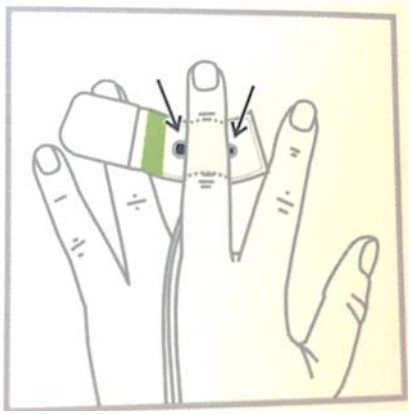
NOTE: Best results are usually obtained when the cuff is wrapped around the middle phalanx of the middle, ring, or index finger.

NOTE: Do not select a finger that had suffered a bone fracture or skin damage or a skin disorder.

8.2.1 Select the finger you want to measure on.



8.2.2 Select the finger cuff where the finger fits exactly between the optical components.

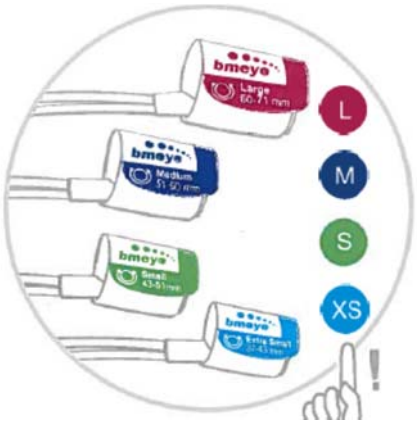


8.2.3 Use the table below to select the appropriate cuff size.

NOTE: When selecting the appropriate size, the air bladder inside the finger cuff should fully enclose the middle phalanx of the finger, when the cuff is tightly wrapped around the finger.

NOTE: Always try to find a cuff size that fits best to the finger. When in doubt, use a smaller size.

Cuff size:	Cuff color:	Art. No.	Finger circumf.[1]
Extra small	Light blue	FCUFXS1	37 - 43 mm
Small	Green	FCUFS1	43 - 51 mm
Medium	Navy blue	FCUFM1	51 - 60 mm
Large	Burgundy	FCUFL1	60 - 71 mm



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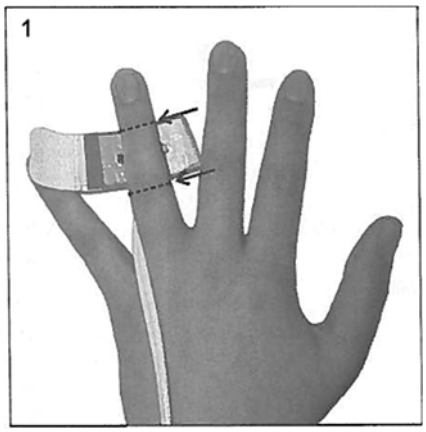
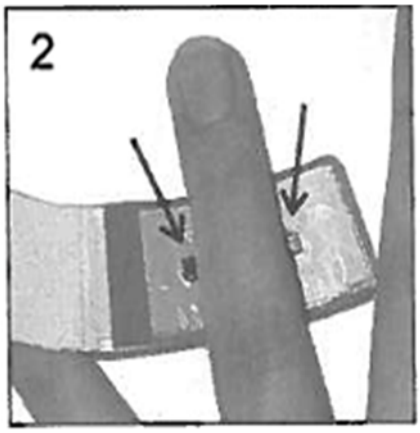
8.3 Apply the Finger Cuff

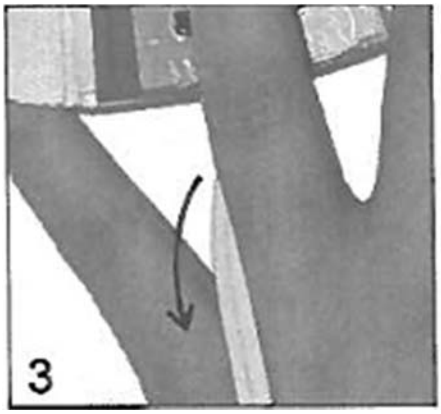
8.3.1 Open the finger cuff and place the finger in it. Make sure that the cuff is centered between the 2 knuckles.



8.3.2 Place the finger between the two optical components.



8.3.3 Gently lead the cuff cable and air hose in between two fingers to the back of the hand.



8.3.4 Wrap the finger cuff tightly following the contour of the finger.

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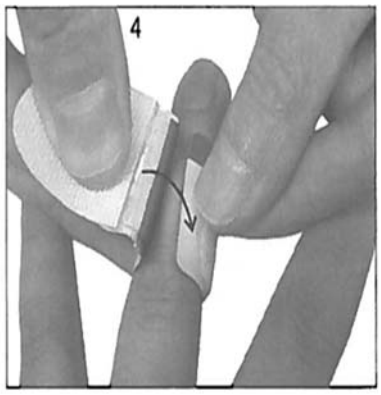
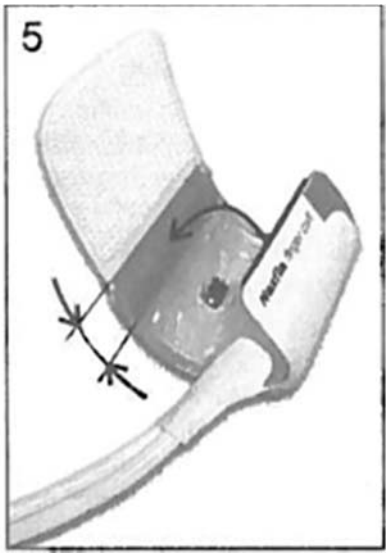
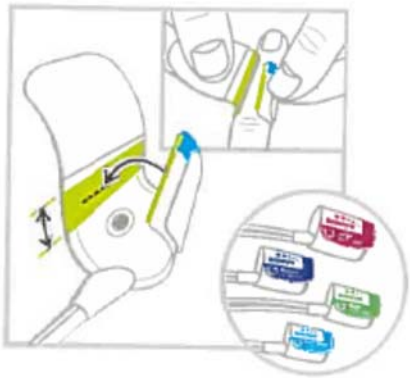


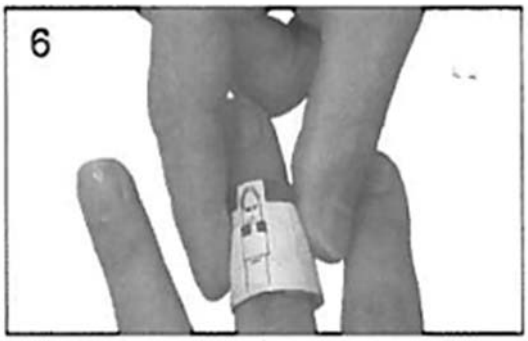
8.3.5 When wrapped around the finger, the outer edge has to be within the shaded/lined area.





8.3.6 Make sure that the cuff cannot be twisted or shifted.

NOTE: If the cuff can be twisted or shifted reapply the cuff.



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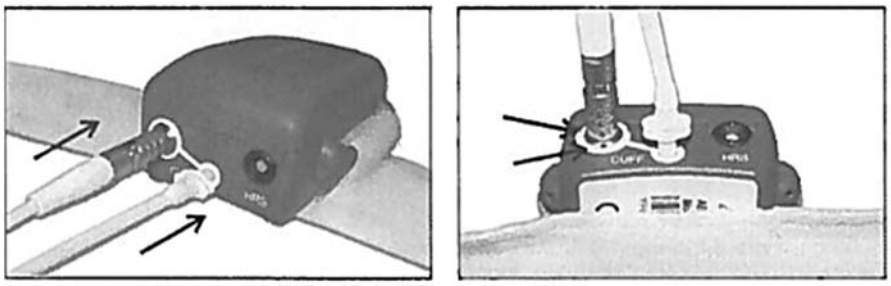
8.4 Connect the Finger Cuff to the Wrist Unit

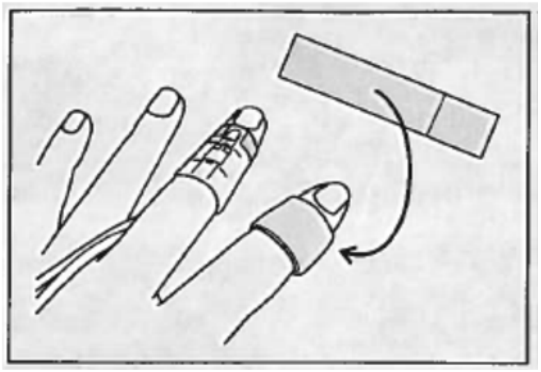
8.4.1 Connect the cable with silver outlet making sure that it is connected to the silver receptacle and that the red dot on the connector is aligned with the one on the receptacle. Connect the air hose to the air outlet.



8.5 Apply the HRS

NOTE: The manufacturer recommends the use of the HRS in all measurements. If the HRS is not used, ensure that the participant's hand with the finger cuff on it is at heart level during the entire measurement.

8.5.1 Attach the heart reference box of the HRS to the participant's arm or chest at heart level near the body using the attached clip.
8.5.2 Wrap a finger strap around the middle phalanx of an adjacent finger on which the finger strap is attached, with the Velcro on the outside.



8.5.2 Attach the finger side of the HRS to the finger strap with the Velcro.

NOTE: Make sure that the finger side is placed at the same height level as the finger cuff.

8.5.3 Connect the HRS connector to the black connector receptacle on the wrist unit labeled "HRS" making sure that the red dot on the connector is aligned with the one on the receptacle.

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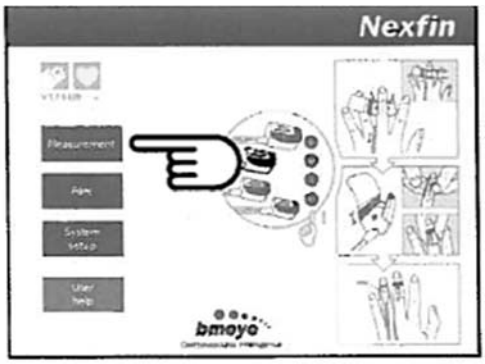
9.0 Calibration

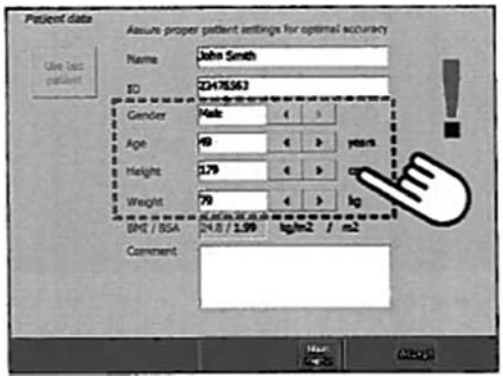
9.1 Zeroing the HRS

9.1.1 On the Nexfin monitor, select "Measurement"



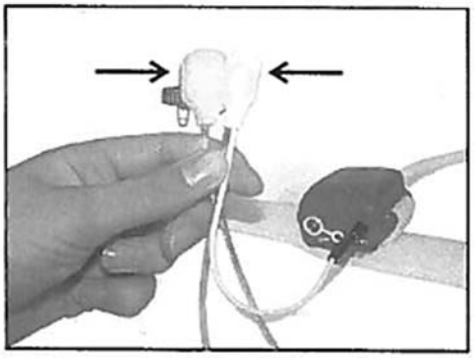
9.1.2 Enter participant information. Click "Accept".

NOTE: For accurate data acquisition, the participant's gender, age, weight (kg) and height (cm) must be entered.

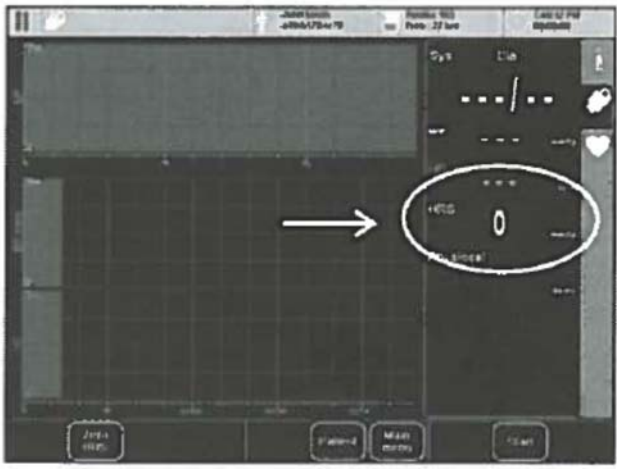


9.1.3 Select  .

9.1.4 With the HRS connected to the wrist unit, keep both endings of the HRS at the same vertical level.



9.1.5 When aligned make the HRS equal to 0 mmHg. Once at 0, click the "Zero HRS" button on the control bar.



9.1.6 Click the "Next" button on the window that appears.
9.1.7 Click the "Zero!" button in order to start the zeroing procedure, while keeping both endings of the heart reference system at the same level.
9.1.8 Wait until the message "HRS zeroed" is displayed.
9.1.9 Click the "Finish" button to close the HRS zeroing window.
9.1.10 Place both endings of the HRS.

9.2 Calibrating Cardiac Output (CO) - OPTIONAL

This option allows for the calibration of CO using a reference CO, such as thermodilution. This procedure can only be performed during a measurement.

NOTE: Nexfin should be calibrated to ensure optimal accuracy of CO.

NOTE: In order for CO calibration to be performed, you must have already entered the participant's age, gender, height, and weight before starting measurement.

9.2.1 Before starting calibration, make sure that the blood pressure measurement is sufficiently stable (Physiocal interval ≥ 30 beats).
9.2.2 Click the "Cal CO" button on the bottom panel of the measurement page.
9.2.3 Select, in the averaging time panel, a period to determine an average Nexfin CO value. Select a period that best matches the corresponding period of the reference CO.
9.2.4 Prepare the reference CO measurement.
9.2.5 In the averaging panel, click the "Start" button to start averaging Nexfin CO.
9.2.6 Enter the "Reference CO (Ref. CO) in the Calibration panel.
NOTE: The calibration factor (Cal factor) will automatically be displayed, and is updated if the Ref CO field is changed.
9.2.7 Click the "Accept" button to accept the calibration.
NOTE: Clicking the statistics button in the Calibration panel, reveals additional statistics about the Nexfin CO averaging and absolute CO calibration factor.

10.0 Acquiring Measurements and During Measurement Options

10.1 Measurement Quality and Stability

10.1.1 Checking the stability of a blood pressure measurement can be done by checking that there are none of the following warnings are shown:

- EXTRA PHYSIOCAL SCHEDULED
- VASO CONSTRICTION
- SEVERE VASO CONSTRICTION
- PHYSIOCAL OFF TOO LONG
- OSCILLATIONS IN THE FINGER CUFF

If one of these warnings appear in the top left hand corner, click on the warning displayed in the status panel to get some additional information and corrective actions for the detected problem. Refer to the Error Code and Corrective Actions in Appendix I.

10.2 Starting Measurement

NOTE: Before starting measurement, ensure that there are no error messages or warnings (on a red or yellow background) displayed in the status panels before starting.

10.2.1 Click the start button on the Nexfin monitor.

NOTE: Data should not be interpreted until the "Physiocal interval" at the top left hand of the monitor reads "Physiocal > 30" in grey.

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10.3 Measurement Options - Calculating Statistics during a Measurement using the "Stats Button"

This option allows you to obtain descriptive statistics of almost all signals over a certain period of time during a measurement. The descriptive statistics are displayed in a "Measurement statistic" dialogue box that can be printed. This box shows the average (Avg), standard deviation (SD), minimum (Min), and maximum (Max) value for the selected period of measurements.

NOTE: The statistics feature can also be used in review mode when measurement is stopped, however calculated data will not be stored in Nexfin nor can it be printed.

10.3.1 Make sure that the measurement is stable (Physiocal interval > 30 beats).
10.3.2 Click the "Stats" button in the control bar on the bottom on the Nexfin monitor.
10.3.3 Under "Averaging time", select a time period.
10.3.4 Click the "Start" button.
10.3.5 When averaging is done, click the "Close" button to close the dialogue box. The calculated data is stored in the Nexfin data file and the average period is clearly marked.

10.4 Measurement Options - Creating Event Markers

This option allows you to mark specific events during measurement, for example the beginning and end of a protocol. Markers can only be inserted during a running measurement.

NOTE: When you insert a marker, you can type in the marker label yourself by clicking on the "Label text". When this is done, a keyboard will appear where you can type the text for the marker label.

10.4.1 Click the "Marker" button on the control button bar.
10.4.2 Click the "Label" text field.
10.4.3 Enter the marker label using the keyboard that appears.
10.4.4 Click "Enter".
10.4.5 Click the "Create" button to insert the even marker in the file.

10.5 Measurement Options - Creating a Marker using Marker Sets

NOTE: This option should be used when the same type of markers are frequently used. Marker sets contain several preset marker buttons. Marker sets can be changed or added in the "System setup" menu under "Custom Marker Settings".

10.5.1 Click the "Marker" button.
10.5.2 Select a marker set from the preset marker buttons displayed.

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10.5.3 Click the desired marker button. The text label will appear in the "Label" text field.
10.5.4 Click the "Create" button to create the marker.

10.6. Measurement Options - Physiocal off/on

Physiocal is the name of the procedure that fully automatically performs a physiological calibration from time to time that is required for accurate blood pressure readings. This is used by Nexfin to optimally adjust to the participant's physiology.

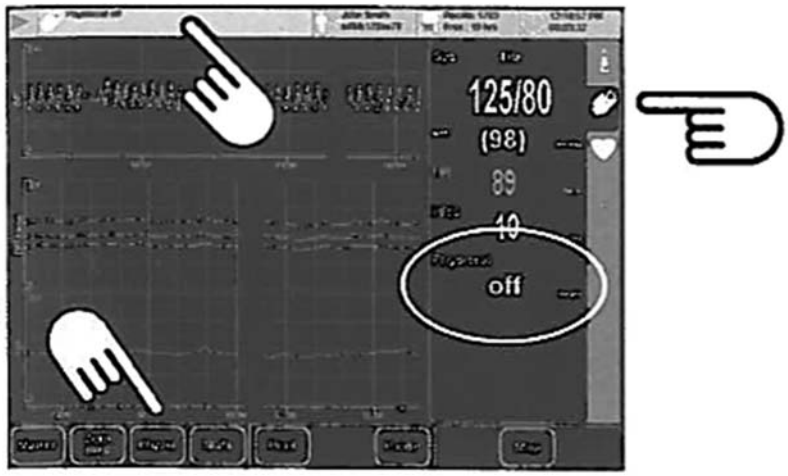
NOTE: It is advised to wait for interpretation of the measurement until the physical interval is at least 30 beats or more (the larger the interval the better).

NOTE: Information about the physical interval is displayed in the numerical data panel of the  tab indicated as: xx/yy. "xx" is the number of beats to the next Physiocal procedure, and "yy" is the Physiocal interval (number of heart beats between two successive Physiocals).

10.6.1 Switching Physiocal Off

NOTE: Temporarily disabling Physiocal is only acceptable after Nexfin has established a stable measurement (Physiocal >30).

10.6.1.1 Make sure that the monitor has established a stable measurement (Physiocal interval > 30).
10.6.1.2 Click the "Physio" button



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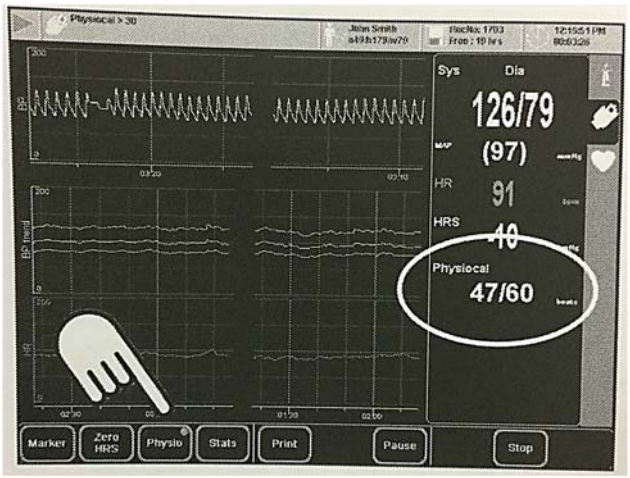
10.6.2. Switching Physiocal On

10.6.2.1 Click the "Physio" button.

NOTE: The green light on the "Physio" button will light up. This indicated that the automatic Physiocal procedure is activated.



11.0 Measurement Options during Pause

11.1 Pausing a measurement

11.1.1 Click the "Pause" button to switch to review mode.

11.2 Calculating Statistics for a Selected Period

11.2.1 Scroll through the file to the period of interest by either using the arrow buttons (<< or >>) or by moving your finger horizontally over a waveform.
11.2.2 Click the "Select" button to switch to select mode.

NOTE: When the select option is active, the "Select" button will appear in green.

11.2.3 Select the waveform panel of interest by clicking on the screen and dragging your finger across the screen.

NOTE: The area you have selected will change color.

11.2.4 Click the "Tools" menu.
11.2.5 Click the "Stats" button. The "Measurement statistics" dialog is displayed.

11.2.6 Click the "Mark" button to mark and store the statistical data.

11.3 Marking Selected Periods when Measurement is paused

11.3.1 Click the "Pause" button to switch to review mode.
11.3.2 Scroll through the file to the period of interest by either using the arrow buttons (<< or >>) or by moving your finger horizontally over a waveform.
11.3.3 Click the "Select" button to switch to select mode.

NOTE: When the select option is active, the "Select" button will appear in green.

11.3.4 Select the waveform panel of interest by clicking on the screen and dragging your finger across the screen.

NOTE: The area you have selected will change color.

11.3.5 Click the "Tool" menu.
11.3.6 Click the "Marker" button.
11.3.7 Add a marker by clicking the "Label" text field or by clicking a "Marker" button.
11.3.8 Click the "Create" button.

11.4 Browsing through Markers when Measurement is paused

11.4.1 Click the "Pause" button to make sure you are in review mode.
11.4.2 Click the "Navigate" menu button.
11.4.3 Click the "Browse markers" button.
11.4.4 Click on a marker label.

NOTE: the selected marker will be displayed in the middle of the screen.

11.4.5 Click the "Close" button to close the Markers dialog.

12. Stopping Measurement and Options

12.1 Stopping Measurement

12.1.1 Click "Stop" when data collection is complete.

NOTE: Do not click "Standby" since this can cause data corruption.

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12.1.2 Wait until the device indicates that the saving was successful before continuing.

12.2 Calculating Statistics when the Measurement has stopped

NOTE: When measurement is stopped, calculated data will not be stored in the Nexfin data file.

NOTE: In this mode, Nexfin displays the averaged data calculated for the selected period in the numerical beat data panel on the right hand side of the screen.

12.2.1 Click the "Tool" button then the "Stats" button in the control bar on the bottom on the Nexfin monitor.
12.2.2 Under "Averaging time", select a time period.
12.2.3 When averaging is done, click the "Close" button to close the dialogue box. The calculated data is stored in the Nexfin data file and the average period is clearly marked.

12.3 Browsing through Markers after Measurement has stopped

12.3.1 Click the "Pause" button to make sure you are in review mode.
12.3.2 Click the "Navigate" menu button.
12.3.3 Click the "Browse markers" button.
12.3.4 Click on a marker label.

NOTE: the selected marker will be displayed in the middle of the screen.

12.3.5 Click the "Close" button to close the Markers dialog.

13. Reviewing, Deleting and Exporting Data

13.1 Reviewing Files

13.1.1 Click the "Files" option on the main screen.
13.1.2 Select the file to be reviewed.
13.1.3 Click the "Review" button.

13.2 Deleting Files from Internal Disk

To free up disk space on the internal flash disk of the monitor, selected files can be deleted.

NOTE: Files that have been deleted from the internal disk of the Nexfin monitor, cannot be restored on the monitor. Nexfin data files on a USB flash drive cannot be moved back onto the Nexfin's internal disk.

13.2.1 Click the "Files" option on the main screen.
13.2.2 Select the files that you want deleted.
13.2.3 Click the "Delete" button.
13.2.4 Click "Yes" to confirm.

This feature will transfer data files from the Nexfin onto the desired USB flash drive into a folder that automatically appears titled "Nexfin data".

13.2.5 Connect a USB flash drive to a USB port.
13.2.6 Click the "Files" option on the main screen.
13.2.7 Click to select the files that you want copied.
13.2.8 Click the "Copy" button.
13.2.9 Click "OK" on the dialog window that appears.

13.3 Copying Files to USB Flash Drive

NOTE: Only one USB flash drive at a time is supported. A second device will be ignored.

13.3.1 Connect a USB flash drive to a USB port at the right side of the Nexfin monitor.
13.3.2 In the File management menu, select the files that you want to copy to the USB flash drive by clicking the files or by making use of the Select drop-down list.
13.3.3 Click the Copy button.

NOTE: A window will appear, asking if you really want to copy the selected files to the USB flash drive.

13.3.4 Click "OK" to confirm.

13.4 Exporting Files

13.4.1 Copy the Nexfin data files to a USB flash drive.
13.4.2 Copy the files from the UBS flash drive to a PC.
13.4.3 Install FrameInspector on the PC.
13.4.4 Export the Nexfin according to the FrameInspector instructions.

14. Reports

14.1 Creating Single Reports

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14.1.1 Click the "Files" option on the main screen.
14.1.2 Select the file of interest.
14.1.3 Click the "Report" button.
14.1.4 Select a report template.

NOTE: You can preview the report by clicking the "Preview" button.

14.1.5 Insert a USB flash drive.
14.1.6 Click the "PDF" button to save the report as a PDF file on the USB flash drive.

14.2 Creating Multiple Reports

14.2.1 Click the "Files" option on the main screen.
14.2.2 Select the files of interest.
14.2.3 Click the "Report" button.
14.2.4 Select one or more report templates.
14.2.5 Insert a USB flash drive.
14.2.6 Click the "PDF" button to save the report as a PDF file on a USB flash drive.
14.2.7 Click "Yes".

14.3 Uploading New Report Templates

New report templates can be uploaded to the Nexfin monitor using a USB flash drive. New templates are downloaded from the BMEYE website (www.bmeye.com).

14.3.1 Copy the new report template(s) to a USB flash drive.
14.3.2 Connect the USB flash drive to a USB port on the Nexfin Monitor.
14.3.3 In the main menu, click the "System setup" button.
14.3.4 Click the "Report" menu button.
14.3.5 Click the "Templates" button.
14.3.6 In the lower panel, select the report templates that you want to upload onto the monitor.
14.37 Click the "Copy" button.

15.0 Cleaning of the Cuffs and Wires

15.1 Cleaning of Wires and Monitor

15.1.1 Wipe the Nexfin monitor and cables with a soft, slightly moistened cloth.

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15.1.2 Use a soft, dry cloth to clean the display. If this is inadequate, use a soft cloth with a neutral detergent to clean the display.

15.2 Cleaning of Wrist Unit

15.2.1 Wipe the wrist unit with a soft, slightly moistened cloth.
15.2.2 The foam pad on the wrist unit is disposable, and typically for single use.

15.3 Cleaning of Finger Cuff

Finger cuffs are designed for limited re-use.

NOTE: Never apply any liquid directly to the finger cuff.
NOTE: Do not immerse the finger cuff in liquid

15.3.1 Wipe with soft cloth damped with a mild disinfectant.
15.3.2 Make sure no liquid enters the tubing. If this happens, allow enough time to dry.

15.4 Cleaning of HRS

The HRS is designed to be re-used with the exception of the finger strap.

NOTE: Never apply any liquid directly to the finger cuff.

NOTE: Do not immerse the finger cuff in liquid

15.4.1 Discard the used finger trap.
15.4.2 Wipe the HRS with a soft damped cloth with a mild disinfectant.

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APPENDIX I

Error Codes and Corrective Actions

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The status panels in the measurement screen shown the status of the device. If the monitor is not ready to start or when the measurement stops due to an error, always check the status panels. See tables below, which describe the error messages, the potential cause(s), and steps to solve the problem.

Blood Pressure Related Errors:

Error Message	Potential Cause(s)	Recommended Action
Bad waveform	The monitor failed to detect normal pressure waveforms	• Verify that the finger cuff is properly applied. • Verify that the finger cuff is not leaking. • If available, take another finger cuff and restart the measurement.
Calibration/Zeroing Mode	Calibration mode failed	• Power device off and on. • Retry calibration procedure. Have the device checked by BMEYE if the error persists.
Check HRS fixation	The HRS signal values exceeds the normal range. This can be caused by: • Odd patient gesture • Detachment of HRS reference unit from heart level	Check that the HRS reference unit is properly attached at heart level.
Communication problem	• The communication with the monitor was interrupted. • The connections between the wrist unit and the monitor are failing.	• Switch the monitor off and on. • Check if the connector between wrist unit and monitor is properly inserted. Have the device checked by BMEYE if the error persists.
Cuff transducer cal failed	Malfunctioning electronics	• Power device off and on. • Try, if available, another wrist unit on this device. Have the device checked by BMEYE if the error persists.
Cuff transducer zeroing failed	Malfunctioning transducer	• Power device off and on. • Try, if available, another wrist unit on this device. Have the device checked by BMEYE if the error persists.

Error in BP measurement	Movement artifacts during measurement	• Let the participant omit significant movements with the hand and fingers. • Make sure the participant does not strain hand or fingers. • Try to measure on another finger or with another cuff.
Error reading configuration	An error condition was detected in the wrist unit.	• Disconnect and reconnect wrist unit. • Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Error saving configuration	An internal error occurred in the wrist unit, unable to continue.	• Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Error: Watchdog	Error occurred causing a time out in one of the processes.	During the measurement the monitor may have stopped the measurement. In general it should be possible to normally restart the measurement. However, it is advised to reboot the monitor completely. If the problem persists contact BMEYE for further assistance.
Extra Physiocal scheduled	Poor plethysmograph quality during physiocal	• Let the participant omit significant movements with the hand and fingers. • Make sure the participant does not strain hand or fingers. • If warning persists try to measure on other finger or with other cuff. • If warning persists warm the hand.
	Physiocal procedure failed probably due to motion artifact.	• Let the participant omit significant movements with the hand and fingers. • The physiocal procedure will automatically be repeated.

Failed to Upgrade Firmware	A failure occurred during an upgrade of the internal firmware of the wrist unit.	• Do NOT switch the monitor off during the entire procedure. • Retry the last upgrade firmware attempt. Have the device checked by BMEYE if the error persists.
Finger Cuff Air Supply Failure	Finger cuff air hose not connected or air leakage.	• Check the finger cuff connection to the wrist unit. • Try another finger cuff, the air bladder in the finger cuff may have a leak. • Check the connector between wrist unit and monitor. • Check for leaks or kinked tubes. Have the device checked by BMEYE if the error persists with different finger cuffs.
	Wrist unit detected a problem in the feeding air pressure. • Wrist unit cable not properly inserted in monitor. • Leak in air hose in wrist unit cable. • Defective or damaged wrist unit connector.	• Check the finger cuff connection to the wrist unit. • Check the connector between wrist unit and monitor. • Check for leaks or kinked tubes. Have the device checked by BMEYE if the error persists with different finger cuffs.
	Cuff air pressure not stable enough during Physiocal constant pressure periods.	• Let the device retry a few times. • Make sure the participant's hand and fingers are relaxed. • Check if the cuff air hose is firmly inserted. • Check if the wrist unit connector is firmly inserted. • If the error persists there may be a problem with the writs unit or with the pump unit. Have the device checked by BMEYE if the error persists.

Finger Cuff Detected on HRS Connector	A cuff is detected on the HRS connector of the wrist unit.	• Check if the cuff is connected to the correct inlet.
Finger Cuff not Connected	The finger cuff is either not connected to the wrist unit or defective.	• Make sure the finger cuff connector is properly inserted in the wrist unit. • Try another finger cuff, the finger cuff may be defective.
HRS Connected to Finger Cuff Connector	A wrist unit was detected on the cuff connector of the wrist unit.	• Detach HRS and connect to the correct inlet.
HRS not Active	Calibration of zeroing of HRS failed.	• Redo the zeroing procedure, make sure to level the two ends of the HRS. • Try, if available, another HRS. Have the HRS checked by BMEYE if the error persists.
HRS Zeroing Failed	• Movements during zeroing procedure of HRS. • Defective HRS.	• Retry the HRS zeroing and assure a stable level of the HRS. • Try, if available, another HRS.
Internal Device Failure	An error condition was detected in the wrist unit.	• Disconnect and reconnect the wrist unit. • Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Internal Electronics Failure	Power in wrist unit unstable or failing.	• Disconnect and reconnect the wrist unit. Have the device checked by BMEYE if the error persists.
	Malfunctioning of wrist unit electronics.	• Power device off and on. • Check if the wrist unit connector is firmly inserted. Have the device checked by BMEYE if the error persists.
Internal Status Mismatch	Interruption of communication with the wrist unit.	• Disconnect and reconnect the wrist unit. • Check if the wrist unit connector is firmly inserted. • Power device off and on.

		Have the device checked by BMEYE if the error persists.
Invalid Pressure Zero	The pressure transducer in the wrist unit could not be zeroed.	• Let the device retry a few times. Have the device checked by BMEYE if the error persists.
Keep Finger Cuff at Heart Level	The monitor detected that no HRS was attached to the wrist unit. This HRS compensates hydrostatic differences between hand position relative to heart level.	Either connect a properly zeroed HRS to the wrist unit and appropriately attach the sensors to the participant. The monitor will automatically detect attachment of the sensor and use the HRS signals for compensation. If a HRS is not available or desired assure that the hand on which the measurement is performed is kept at heart level during the complete measurement.
Low Power	Low power detected in wrist unit electronics.	• Reconnect the wrist unit. Have the device checked by BMEYE if the error persists.
Measurement time on finger exceeds 8 hours.	Measurement on the same finger exceeded maximum duration (8h)	• Apply finger cuff to another finger.
No BP Waveform Detected	The monitor failed to detect pressure waveforms. Usually when pressure pulsation in finger diminishes for instance due to applying external pressure to the upper arm, elbow or wrist.	• Check if the blood flow in the arm of the participant is free of obstructions. • Check the blood pressure waveform. • Reapply the finger cuff.
No HRS, keep hand at heart level.	The monitor detected that no HRS was attached to the wrist unit. The HRS compensates hydrostatic differences between hand position relative to heart level.	Either: • Connect a properly zeroed HRS to the wrist unit and appropriately attach the sensors to the participant. The monitor will automatically detect attachment of the sensor and use the HRS signals for compensation. If HRS is not available or desired: • Assure that the hand on which the measurement is performed is kept at heart level during the complete measurement.

No plethysmogram	During the start-up procedure no measurable plethysmogram was detected. This is often caused by contracted arteries.	• Let the device retry a few times, while comforting the participant. • Try another finger cuff, the cuff may be defective. • Ask the participant to raise hand above heart level for a minute, to relax smooth muscle. • Try the finger cuff on another finger. • Warm the hand.
Oscillations in finger cuff	• Contracted arteries, or • Cuff too loose, or • Motion of participant (for example when exercising)	Usually the device automatically solves the problem. If oscillations keep repeating: • Reapply finger cuff (not too loose) • Warm the hands Have the device checked by BMEYE if the error persists.
Physiocal interval <30. Consider postponing calibration until stable measurement.	Physiocal interval was less than 30 beats. This possibly indicates an unstable measurement which may jeopardize calibration success.	• Click on the finger tab next to numerial panel. • Wait and check whether the Physiocal interval increases, indicationg stability. • If the Physiocal interval does not increase, stop measurement and reapply cuff. • If no success, try applying cuff on other hand.
Physiocal off too long	User switched off Physiocal.	Regularly switch on Physiocal again; measurement accuracy is compromised when Physiocal is awitched off for prolonged periods.
Pump Control Problem	Internal communication failed.	• Power device off and on. Have the device checked by BMEYE if the error persists.
Pump Pressure Low	Loose or defective connection of wrist unit air hose connector. • Pump failure • Internal tubing problem	• Check wrist unit connector for proper insertion. • Check wrist unit connector for leaks. Have the device checked by BMEYE if the error persists.

Servo Problem	The digital servo control is unstable or failing	• If warning persists restart the device. Have the device checked by BMEYE if the error persists.
Severe vaso constriction	Bad measurement conditions due to vaso constriction	• Raise the heand above the head for 1 minute to relax smooth muscle in the hand before starting a measurement. • Try the cuff on another finger. • Warm the hand.
Too few beats detected (number) to calibrate. Please redo procedure.	The number of detected beats during averaging was less than 8. This is the minimum number of beats required to obtain an acceptable calibration.	• Restart averaging. • Avoid premature cancelling of averaging process. • In case of very low heart rates consider increasing the averaging time.
Too much light (small fingers)	The finger cuff pletysmogram received too much light.	• Let the device retry a few times. • In case of cold fingers, try to warm fingers by covering them by e.g. using a towel. • If current cuff size M you may try to use size S. • If above fails remove the cuff, wrap a thin cloth around the finger, and reposition the cuff over the cloth. Use a darker colored cloth when needed.
Transducer not connected	Malfunctioning of wrist unit electronics.	• Power device off and on. • Check if the wrist unit connector is firmly inserted. Have the device checked by BMEYE if the error persists.
Unexpected Plethysmogram	Electrical connections may be failing.	• Check the connection between finger cuff and wrist unit. • Try another finger cuff. Have the device checked by BMEYE if the error persists.

Unidentified System on HRS Connector	A cuff is detected on the HRS connector of the wrist unit.	• Check if the cuff is connected to the correct inlet.
Unstable Cuff Led Current	Defective finger cuff • Bad connection with cuff • Failing electronics	• Try another finger cuff. • Reinsert cuff connector. Have the device checked by BMEYE if the error persists.
Vaso Constriction	Possibly contracted arteries	• Raise the arm above the head for 1 minute to relax smooth muscle in the hand before starting a measurement. • Try the cuff on another finger. • Warm the hand.
Wrist Unit not Connected	An internal error occurred in the wrist unit, unable to continue.	• Switch the monitor off and on. Have the device checked by BMEYE if the error persists.

Cardiac Output Related Errors:

Error Message	Potential Cause(s)	Recommended Action
No measurement running. Press monitor start button…	A calibration can only be started of a measurement is running.	• Click on start button bar to start the measurement. • Wait for stable measurement. • Start CO calibration.
Too few beats detected (number) to calibrate. Please redo procedure	The number of detected beats during averaging was less than 8. This is the minimum number of beats required to obtain an acceptable calibration.	• Restart averaging. • Avoid premature cancelling of averaging process. • In case of very low heart rate consider increasing the averaging time.
Total calibration factor (number) out of range. Please re-adjust Ref CO or repeat procedure	The entered reference CO resulted in a calibration factor that falls outside the allowed range (0.25-4.0).	• Verify that the correct ref CO was entered. • Repeat the calibration procedure. • If the problem persists, check the pressure waveforms. • Verify quality of reference CO measurement.

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Participant Data Related Errors:

Error Message	Potential Cause(s)	Recommended Action
Age outside intended range	The device is intended for adult participants.	Be cautious with evaluation of measurement results when participant age is less than 18 years.
Age < 2 yrs	This device is intended for use in adults.	Do not use in pediatric participants.
BMI out of range	The combination of participant weight and height results give a BMI value outside the normal range.	BMI is estimated from participant height and weight. Its value ranges between 10 and 65; the current value lies outside this range. • Select the participant data property page again and check whether the entered parameters are correct. Please ignore the warning if participant weight and height are correct.
Patient data incomplete	Not all participant data was properly entered.	Proper participant data is required to obtain acceptable accuracy of the CO method. You can proceed with the recording. However, it is highly recommended to enter correct participant data as measurement results will be more accurate.
Patient data not complete. Calibration procedure only allowed if all patient data properly defined.	Not all participant data was entered at start of the measurement.	• Close CO calibration dialog. • Click on patient button in button bar. • Edit missing participant data. • Return to CO calibration dialog.

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Device Related Errors:

Error Message	Potential Cause(s)	Recommended Action
AD/DA Failure	An internal error occurred, unable to continue.	• Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Could not Create File	An error occurred in the internal storage of the measurement data.	• Try to start a new measurement. • If the error persists, restart the monitor. Have the device checked by BMEYE if the error persists.
Disk Almost Full	The amount of internal free disk space is running low.	Please save and remove old recordings: • If situation permits stop the running recording. • Switch to files view. • Copy the files from the internal disk to a USB flash drive, and • Free up internal disk space by deleting recordings on the internal disk.
Disk Full	The internal disk is full. The current recording was terminated.	Please save and remove old recordings: • Switch to files view. • Copy the files from the internal disk to a USB flash drive, and • Free up internal disk space by deleting recordings on the internal disk. Have the device checked by BMEYE if the error persists.
Error: Watchdog	Error occurred causing a time out in one of the processes.	During the measurement the monitor may have stopped the measurement. In general it should be possible to normally restart the measurement. However, it is advised to reboot the monitor completely. Have the device checked by BMEYE if the problem persists.
Internal Electronics Failure	An internal error occurred in the electronics of the monitor.	• Immediately turn off the device.

		• Briefly retry power-on without a wrist
Memory Running Low	During for example a lengthy recording the device memory may run low.	If situation permits: • Stop the running recording. • Power off and on the device, and • Restart the measurement.
Monitor Power Error	An internal error occurred, unable to continue.	• Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Out of Memory	The system is running out of memory.	• Switch the monitor off and on. Have the device checked by BMEYE if the error persists.
Required DLL is Missing	One of the software components that is required for proper function of the monitor was not found or could not be loaded.	• Power the device off and on. Contact BMEYE if the error persists.

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APPENDIX II

E-mail to Distributor Regarding Re-Use of Foam Pads

PERFORM Centre

Hello Marylen,

Thanks for your email.

I am checking on our side if those can be even ordered for future reference.

However, for research purposes I don't think you have to change the pad with every patient. It does not affect the measurement at all. It is used to hold one end of the Heart Reference System....Changing the pad itself is more a question of esthetics.
In the hospital setting though or when used on patients in isolation(i.e. MRSA positive) -I would suggest to change the set (including finger cuff) to prevent the spread of infection.

I will get back to you with details once I get confirmation.

Regards,

Klaudia Pawlik, RN
Territory Manager / Gestionnaire de Territoire
Enhanced Surgical Recovery (ESR) / Récupération Rapide Après Chirurgie (RRAC)
Critical Care / Soins Critiques
Edwards Lifesciences (Canada) Inc.
6750 Century Ave., Suite 303
Mississauga, ON L5N 2V8
Cell: 514-923-6703
VM: 1-888-865-8896
Customer Service: 1- 800-268-3993
klaudia_pawlik@edwards.com
www.edwards.com

From: marylen youssef [mailto:marylen_youssef@hotmail.com]
Sent: Wednesday, May 13, 2015 2:16 PM
To: Klaudia Pawlik
Cc: Amanda Rizk
Subject: Nexfin foam pads

Hello Klaudia,

My name is Marylen, we spoke yesterday on the phone and I am writing to you in regards to the finger pads for the Nexfin serial number: YM101123. In the Nexfin's user manual it says that the foam pads onto which the HRS finger end is connected to must be replaced after it is used with each subject. I currently have about 5 foam

pads and will be doing my research on a total of 30 participants. I have attached a picture of the foam pad in the e-mail. This is the picture directly from the manual.

I have cc'd Amanda Rizk in the e-mail. She is the coordinator of the CardioPulmonary Suite at PERFORM where the equipment is found.

Please let us know if this is something we can order from you, in addition to what the cost would be.

Thank you for your time,

Marylen

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APPENDIX III

POD Training Record Form

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POD Title

Use and Cleaning Procedures for Nexfin

POD Code

Ownership	Document type	Area	POD Number	Version
PC	POD	CP	007	01

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

Sign here

Date