PHYSIOFLOW SOFTWARE V2

User Manual

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User Manual

PhysioFlow® Software V2

For MS-Windows® operating system

Software version PF-2.6.X

1. General Information

About this manual

This manual contains all the required information for installation and use for the PhysioFlow Software V2 associated to any of the PhysioFlow devices listed below:

- Enduro (Portable and standalone device)
- Q-Link (Compact desktop device)
- Lab1 (Desktop device)

It is designed for anyone involved in at least one activity described below.

Basic medical staff education associated to reading this manual is required to ensure a proper use of the medical device.

Basic technicians and maintenance staff education associated to reading this manual is required for any intervention on the medical device.

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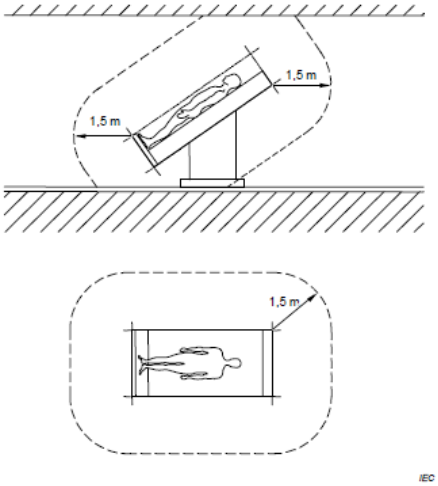
Definitions

Patient Environment	Any area in which intentional or unintentional contact can occur between a patient and parts of the medical equipment or between a patient and other persons touching parts of the medical equipment. For the PhysioFlow application, it equates to a 1.5m distance around the patient himself or of the surface he is in contact with (in any direction). 

Conditions of Use

The PhysioFlow is a noninvasive cardiac output measurement system which provides hemodynamic parameters using analysis of trans-thoracic bioimpedance signals. The system can be used at rest or while exercising.

For the enduro, the scheduled working time depend on batteries capacity up to 6 hours with rechargeable batteries and up to 8 hours with non-rechargeable Energizer Ultimate Lithium. For all devices, electrodes must be replaced after 24 hours.

The device is designed to be used by clinicians and/or qualified medical personnel.

The device can be used for real time monitoring purpose coupled with a computer (Wireless or wired connection) (desktop, laptop, tablet PC) and some devices like Enduro can also be used as a standalone device. The PhysioFlow devices are intended to place the computer out of the patient environment (cf. "*Definitions*" section). Under these conditions, computer and accessories specifications are given in Chapters 2 and 3.

	If the operator has to install/use the computer within the patient environment, the computer needs to have a medical grade (Comply with IEC 60601-1 standard).

The device cannot be used if the patient has an external/Implantable defibrillator.

The device is designed for the following environmental conditions:

- Temperature : +10 – +34° C
- Relative humidity : 30% – 70%
- Pressure : 700 hPa – 1060 hPa

Indications

The PhysioFlow system is indicated for use in patients with the following criteria:

- Non-invasive diagnostic and hemodynamic monitoring of known patients or suspected of having cardiovascular diseases.
- Differentiation between cardiac and pulmonary causes of acute dyspnea.
- Optimization of atrio-ventricular interval in patients having atrial and ventricular pacemakers.
- Patients in need of an indication of inotropic therapy.
- Heart transplant patients requiring a biopsy.
- Patients in need of blood volume control.

General Facts:

- PhysioFlow device can be used on adults or teenagers at rest, during cycloergometric exercise, or during exercise on a treadmill.
- PhysioFlow System and accessories are made to be used in strict compliance with instructions specified in this manual.
- PhysioFlow System is to be operated with single use sensors, which should be changed daily.
- PhysioFlow System is a Class IIa (European standards).
- PhysioFlow System is intended to be used only with the specific patient cable supplied and with PhysioFlow PF50 electrodes.
- For Enduro only: To measure during exercise and at rest: the device must be placed in its pouch and worn by the patient.
- Using any patient cable or electrode different from the ones specified above is inadvisable. Moreover, it can increase the electromagnetic emissions and reduce the immunity of the device.

Contraindications

PhysioFlow is not compatible with patients wearing pacemakers of « minute ventilation » type.

The use of the PhysioFlow system is contraindicated for use in patients with the following criteria:

- Patients with severe aortic insufficiency suspected or proven (cardiac output readings will be significantly overestimated in these cases)
- Patients under cardiopulmonary bypass assistance.
- Newborns or neonatal illnesses.

Functions

PhysioFlow System measures the following parameters:

- Contractility Index
- Heart Rate
- Ventricular Ejection Time
- Early Diastolic Filling Ratio

PhysioFlow System computes the following parameters:

- Stroke Volume / Index
- Cardiac Output / Index
- Systemic Vascular Resistance / Systemic Vascular Resistance Indexed
- Left Cardiac Work Index
- Ejection Fraction (estimation)
- End Diastolic Volume (estimation)

Measuring Technique Information

Trans-thoracic bio impedance is a technique which quantifies the heart's mechanical activity instead of its electrical activity (ECG). The fundamental theoretical principle of the trans-thoracic bio impedance use the direct measurement of the baseline impedance, the velocity index, the acceleration index, the ventricular ejection time and the heart rate, and the early diastolic filling ratio. These measured parameters are used to compute other hemodynamic parameters.

The PhysioFlow System application for the hemodynamic parameters determination is based on the following principles: the biological tissues, as the muscles, bones, fat and blood each have different electrical properties. Among them all, the blood is the most conductive body tissue in the thorax.

As the circulation is pulsatile and the arterial vessels are supple, the differences of pulsatile blood volume are made at the level of thoracic arterial system, mainly in the aorta, in connection with the ventricular function. This blood volume change makes an electrical conductivity change and consequently a change in the impedance of the thorax against the electrical current. The differences in thoracic electrical impedance are essentially created by changes of velocity and blood volume in the aorta.

Unlike other trans-thoracic bio impedance systems, PhysioFlow System does not rely on impedance baseline measurements to compute parameters. This tends to reduce the limitations of standard Trans-thoracic bio impedance.

PhysioFlow System uses a non-invasive technique to determine the Trans-thoracic bio impedance. By performing the analysis of Trans-thoracic bio impedance recordings in association with the ECG signal, PhysioFlow System provides information related to the cardiac function.

PhysioFlow System measures the change in impedance by injecting a high frequency alternating electrical current (66 kHz) of low magnitude (4.5 mA peak to peak) towards the thorax between two electrodes positioned on the neck and another two positioned on xiphoïd process.

The use of a high frequency current eliminates the risk of interference with heart and brain bioelectrical activity. In addition, as the impedance of skin-electrodes is very low at high frequency, tissues will not endure any thermal effects and the patient feels nothing.

By detecting and measuring the difference of thoracic impedance over time, PhysioFlow System noninvasively measures the systolic volume, the cardiac output and several other hemodynamic parameters. By comparison, thermo dilution measures differences in temperature in function of the time for measuring systolic volume and cardiac output in an invasive way.

Warnings

- **The patient cable and the device are not designed to withstand defibrillation shocks. When defibrillator is used, THE PATIENT CABLE MUST BE UNPLUGGED FROM THE PATIENT. Do not let the device or patient cable be in contact with the patient when the defibrillator is in use.**
- **Use the electrodes recommended in this manual (cf. Accessories section). PhysioFlow cannot provide customer support if any other electrode is used.**
- **Before use, ensure the electrodes are not expired, damaged or dry.**
- **Patient's skin must be carefully prepared prior to any measurement (preferably using Nuprep Skin preparation gel).**

- Explosion hazard: do not use in the presence of flammable anesthetics.
- The conductive gel of sensors must not be in contact with other conductive products of objects when patients are monitored.
- Sensors must be positioned on the skin; they must not be directly positioned on the heart.
- The specific patient cables supplied with all PhysioFlow devices have no particular protection against effect of defibrillators and electrosurgical devices; it should be unplugged from the device before any defibrillator shock is performed.
- Do not use another type of cable with the device.
- Disposal of this product and/or its accessories shall be made in accordance with all locally enforced laws.
- PhysioFlow devices should not be used stacked with or close to any other device. If it cannot be avoided, users must ensure that the PhysioFlow device function properly in this configuration.
- PhysioFlow devices are designed to evaluate the patient's cardiovascular state. It is not a diagnostic device. The PhysioFlow parameters shall **NEVER** be used individually or out of context. They must be combined with other parameters measured by other systems (ECG SPO2, VO2, etc.), together with the clinical valuation of a physician, and never in lieu and place of these.
- If the device is used in exercise testing on a treadmill, please secure cable leads with tape or a fishnet.
- PhysioFlow devices need extra caution regarding electromagnetic compatibility (EMC). It shall be setup and put on regarding the EMC information specified in this service manual of the device.
- Manatec Biomedical considers itself responsible for effects on basic safety, reliability and characteristics of any PhysioFlow device only if:
  – The relevant room's electrical installation complies with the

	appropriate requirements, and if – The device is used in accordance with the operating instructions. ▪ Any change of any electro medical PhysioFlow device is forbidden. ▪ PhysioFlow devices are designed to be reliable, effective and mechanically robust. However handheld devices like Q-Link or Enduro must be used with care. ▪ PhysioFlow devices have no particular protection against the penetration of liquids. Do not allow liquids to get into the device. ▪ Only patient cable provided by PhysioFlow must be used. ▪ Any other use of the patient cable is forbidden. ▪ FOR ACCURATE MEASUREMENTS, IT IS ESSENTIAL THAT THE OPERATOR UNDERSTANDS THE DIFFERENCE BETWEEN ACCEPTABLE SIGNAL AND POOR SIGNAL QUALITY. (cf. *" Calibration"* section)

Precautions

Some clinical circumstances may impair accuracy of measurements, such as:

- Tachycardia with heart rate above 250 bpm
- Untimely movement of neck
- Patients running on treadmill
- Patients under 120cm (48 in.)
- Patients under 25 Kg (67 lbs.)
- Presence of aortic balloon pumps
- Presence of ultrafiltration systems
- Presence of pacemakers with external leads
- Open chest surgery
- Use of electrical cutlery and electrosurgical devices
- Morbidly obese patients, such as those weighting over 600 pounds.
- Re-calibration can take place at the same time that the electrodes are replaced as a function of normal nursing protocol. After 24 hours electrodes must be replaced.
- Use a damp cloth with soap to clean the device and patient cable.
- The device must not be sterilized

When any of the PhysioFlow handheld devices (Enduro or Q-Link) if the enclosure is in contact with the patient for more than one hour, it is recommended to use the pouch provided with the device in order to avoid any discomfort.

Symbols and Marks

Symbols and Marks for the manual

Symbol	Signification
	In the manual this symbol indicates that one or several conditions could damage the equipment itself and/or impact patient's and/or users' and/or environment's safety.
	Important information to consider for an efficient and optimized use of the system.

Symbols and Marks of the software

The software icons must not be confused with the previous marks that regard only the user manual. Those icons help user to identify the kind of message displayed by the software:

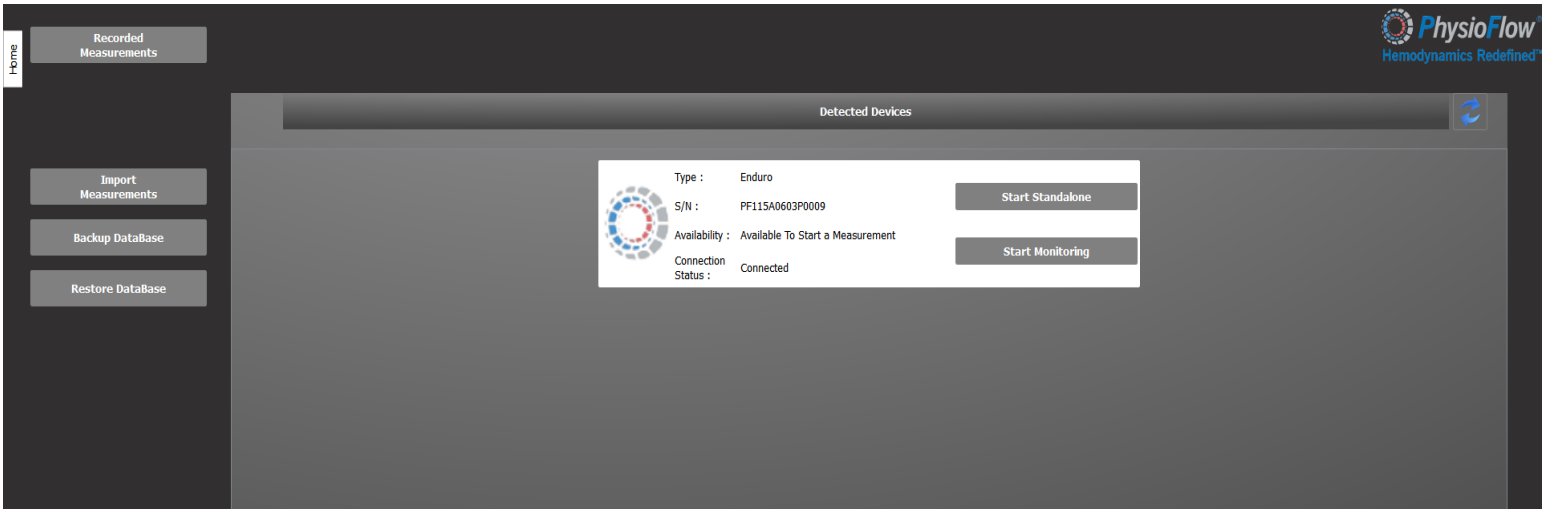
Symbol	Signification
	Warning message or/and displaying important tips for user. User must pay attention to any messages with this mark to avoid issue. During signal preview this mark is bilking to increase the attraction of user attention.
	Information message.

2. Device Installation:

During software setup all needed drivers for all PhysioFlow devices are installed. Users only need to plug the device and wait for the MS-Windows operating system to install the drivers and display the popup message confirming the correct setup of drivers.

⚠	If drivers have not been installed correctly or not found by the operating system an internet connection may be needed! Users just need to unplug and plug back the device after they make sure of internet access. The device will not be detected if the drivers are not installed properly!!

All PhysioFlow devices are automatically detected and configured and then displayed in main screen of the PhysioFlow Software V2 when connected to the PC or in the range of wireless connection around the host PC. (Here an example with an Enduro)



⚠	In some cases automatic detection will not work so users have to make sure that: - Only accessories provided by PhysioFlow are used (Bluetooth antenna, USB/Serial converter, patient cable etc.) - That the device is turned ON - That the drivers are installed properly or that no other drivers or internal device to the host PC (like internal Bluetooth antenna) are interfering with the provided accessories by PhysioFlow. In this case users may disable those internal antenna or drivers. PhysioFlow only support Mircosoft Bluetooth and BlueSoleil drivers. All other drivers like Toshiba, WidCom etc. are not supported. PhysioFlow can only provide support for the USB to serial adapter model delivered with the device. **Note:** Once all those points checked user may use the refresh device list button (Blue arrows button) to see if new devices are detected.

3. Software Installation & configuration / Removal

Minimum configuration requirements

For a correct installation and use of the software, the computer must have at least the following characteristics:

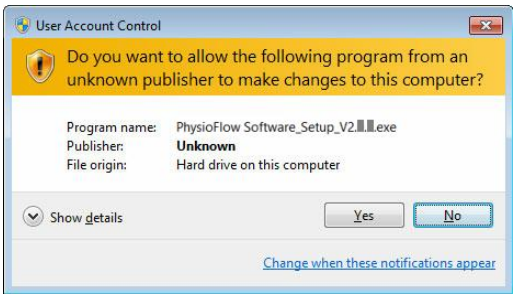
- Operating system: Microsoft Windows XP, Vista, Seven and eight (For windows 8 the software is launched in Desktop mode and not with new windows metro mode)
- 2GHz dual core X86 or X64 Processor
- 4GB RAM
- 250MB Free hard disk space for installation
- Minimal size screen advised : 15'' XGA (1024 x 768)

⚠	10GB free space on the hard drive is recommended to store monitoring data. User has to make sure to have enough disk space for every measurement session! If the disk space is less than 250MB the software are no more usable please refer to Disk space warning message section for more details.

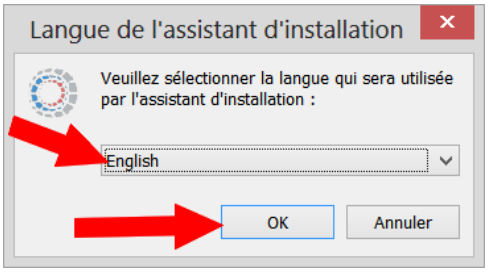
Installation

- Switch on the computer
- When Windows is loaded, launch the PhysioFlow installer from a CD-ROM, a flash drive or an electronic copy downloaded from PhysioFlow website.

For windows Vista and further version click "Yes" when the following window is displayed:

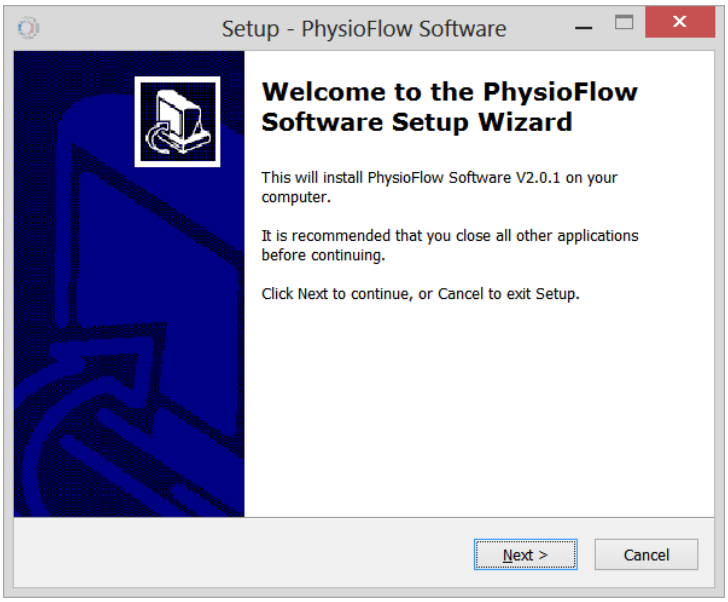


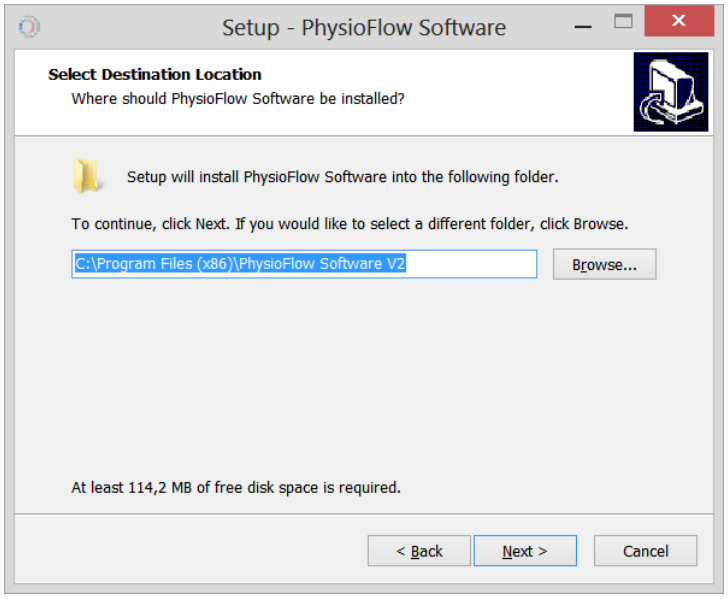
Choose the language :



Note: Selected language is applicable for the installer and the software.

Installation will immediately start. Follow every step of the procedure by clicking on the *"next"* and *"install"* button when appropriate. The process ends by creating and loading files in "C:\Program Files \PhysioFlow Software V2".

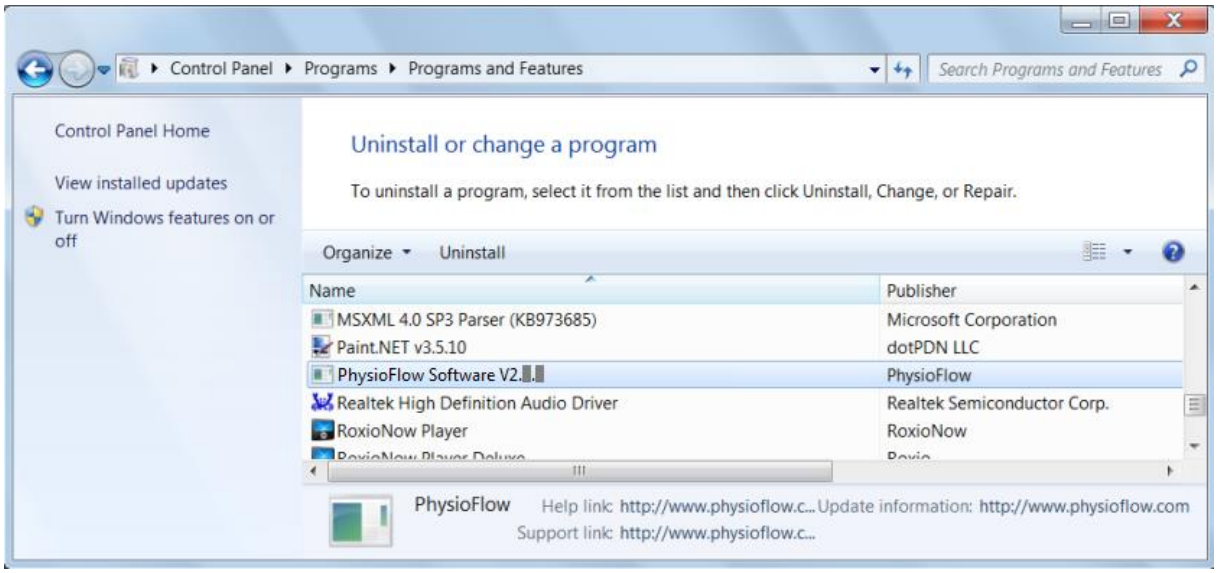




⚠	License must be accepted in order to install the software

Uninstallation

To uninstall the PhysioFlow software click on *"Start"* (tool bar on the bottom of the screen). Select *"Control Panel"*, select "*Programs*", and "*Uninstall a program*", then select PhysioFlow, click on the "*Uninstall*" button and follow instructions.

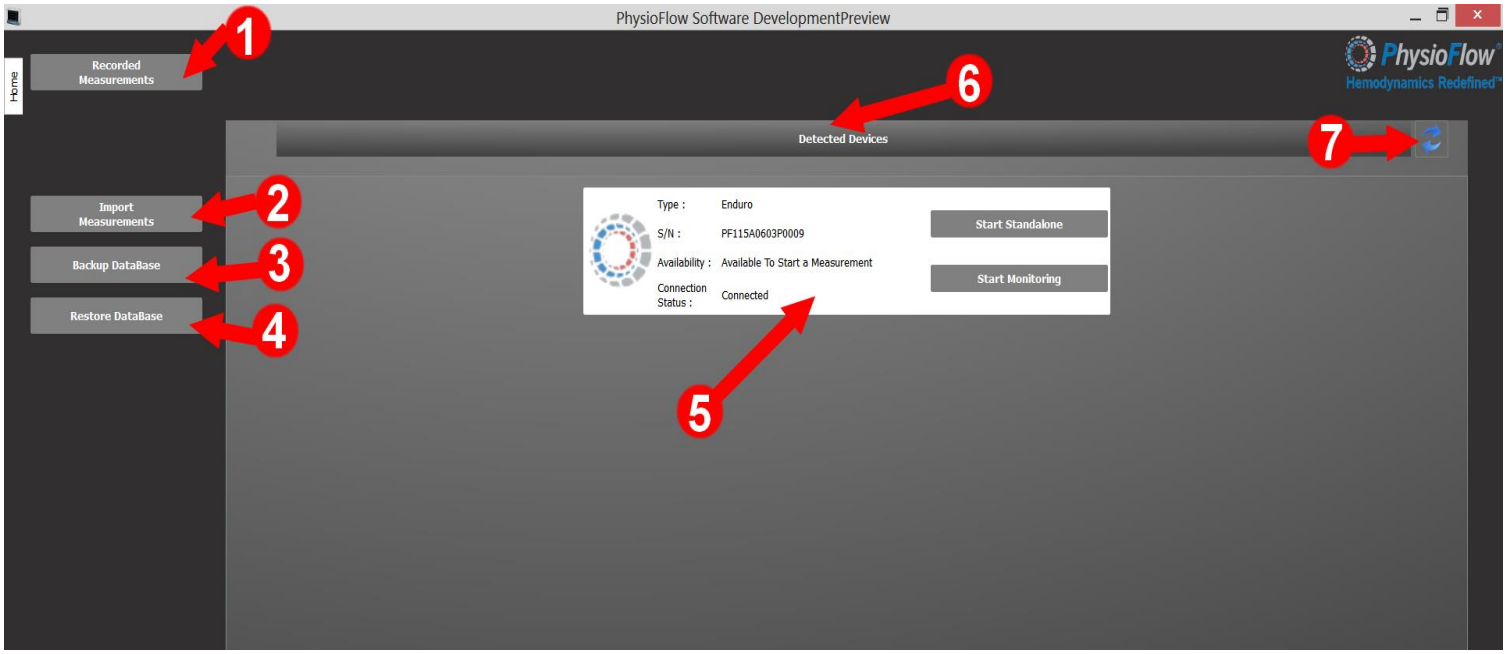


4. Software overall usability / concept

This section introduces main ergonomic concepts used to enhance user experience and make the system easy to use.

Home screen

- The home page provides to the operator the following information and controls:



1. Open a dialog with a list of all previously recorded measurements. Cf Reviewing acquisition section for more details.
2. Allow to import all measurement from data base of previous PhysioFlow software (PF1.0.X versions). Cf Import data from previous physioFlow software version section for more details.
3. Allow to save a copy of current database to the desired path chosen by users. Cf Backup software data base section for more details.
4. Load a previously saved copy of data base to current data base. Cf Restore software data base section for more details.
5. Device information section: gives all information and status related to the identified PhysioFlow device. It also lists all possible actions/functions the operator can perform on the system.

   Note: Available actions depend on the PhysioFlow device type and status. (for instance only Enduro allows standalone measurements)

6. Detected devices section: all detected compatible devices will be displayed in this list.
7. Device list refresh button: if for some reasons the device is not detected after the first scan the operator has the opportunity to update the list by clicking the refresh button. (It usually occurs when the software is launched before the device is powered)

Validation Icons

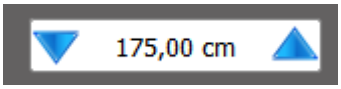
Important parameters must be selected and validated before moving to next steps. The next button remains disabled until all mandatory fields are validated. In this case all fields have a green marks. Note: Optional fields do not have “Validation Icon”:

- The red icon with a white cross means that the parameters are not validated: it is impossible to move to the next step if at least one of these sign is displayed.

- When the entered parameters are in the expected range and are validated, they have the green icon with the white check mark.

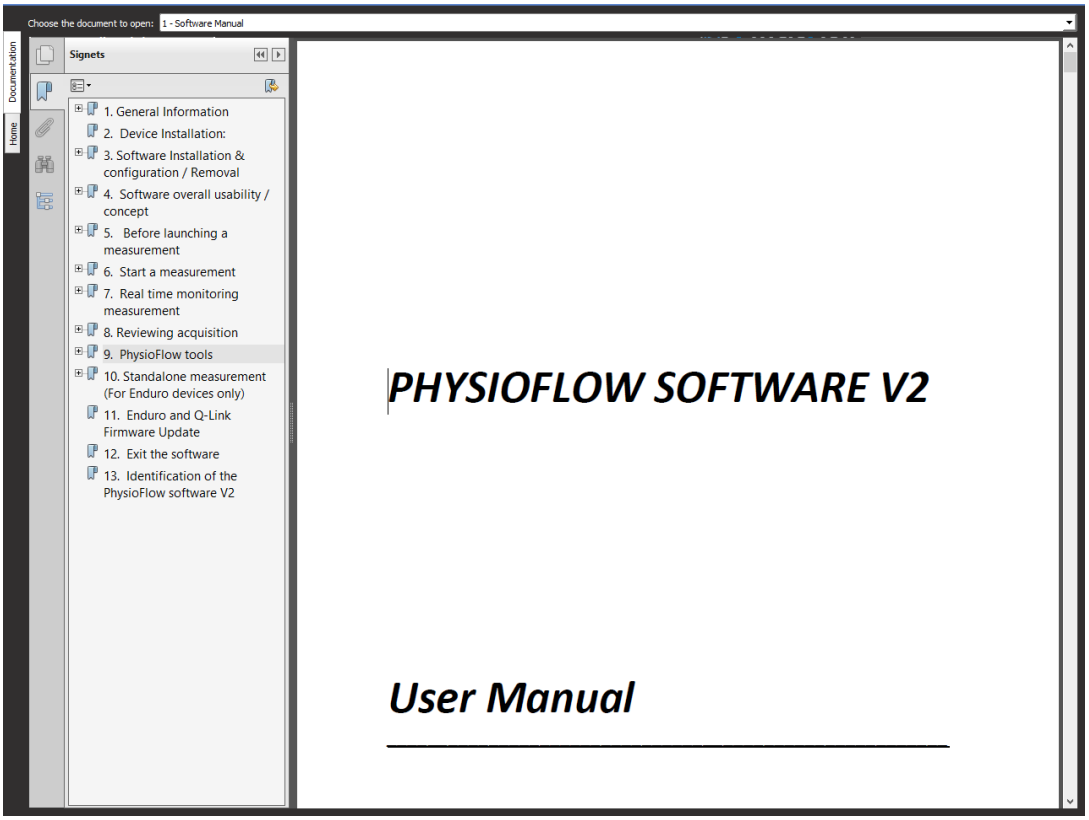
Spin Boxes

Data input are made easier for numerical value even with touch screen. After entering the value by keyboard user have the possibility to adjust the value by pressing the up or down arrow. For floating value only the integer part can be adjusted.



Software documentation and help

The software and device documentation is always available by clicking on the “Documentation” tab at the top right of the screen, or by pressing the F1 key on the keyboard, even while a measurement is opened or monitoring is in progress:



The software and devices documents can be open by choosing in the list at the top of the screen.

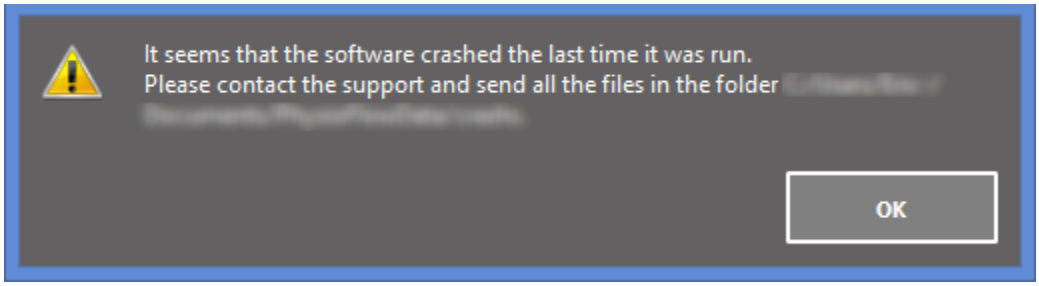
If Adobe® Reader® is installed on the computer, the selected document is displayed directly in the PhysioFlow Software. Otherwise it will be openned in the default pdf file viewer on the computer.

Miscellaneous

- The main functions of the software are displayed with clear text to easily identify their function.
- Main procedures are simple and straightforward (just follow the steps).

⚠	**However user must pay attention to all information displayed, read carefully all texts and avoid clicking quickly to switch to the next window before understanding the information displayed.**

- When some parameters are selected some images related to the chosen configuration are displayed. It allows having a quick and visual overview of all selected parameters before moving to the next step.
- All compatible devices are automatically detected and shown in a list with their status and associated functions. No configuration is required.
- If for any reason, the software is not closed properly, the following message will be displayed during the next software startup:



In this case, please send all these files to PhysioFlow support (support@physioflow.com)

- It is always possible to save the current active window of the PhysioFlow Software as an image, by pressing the “Print screen” key on the keyboard. Then a window allows to select the folder in which the image file will be saved, along with the file name and file type. When the save button is clicked, the image is automatically opened by the default image viewer installed on the computer.

5. Before launching a measurement

Subject Setup

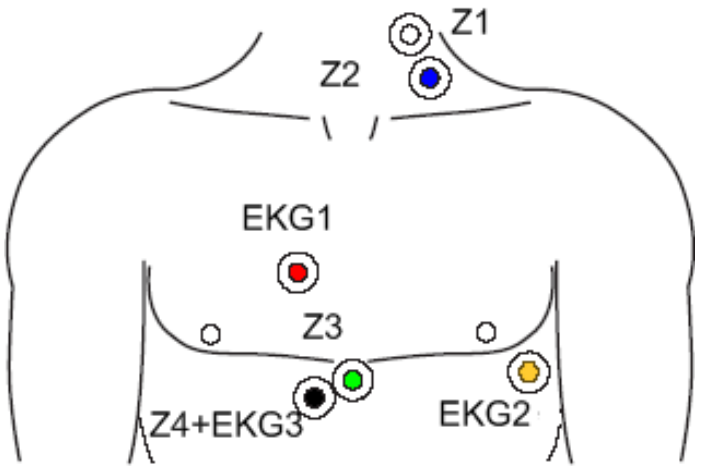
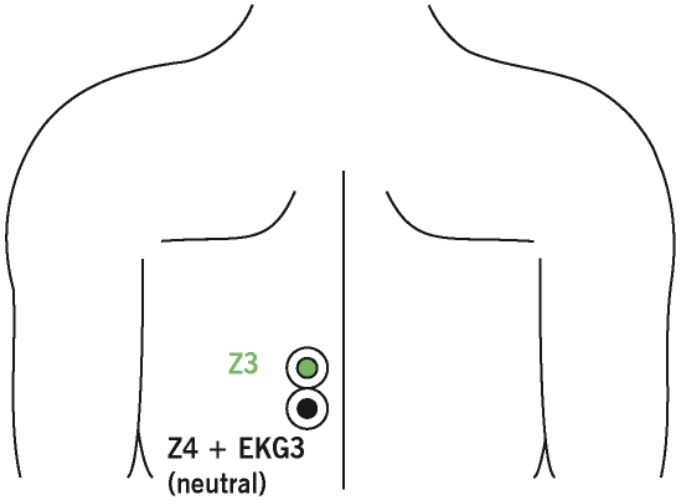
To ensure a stable signal and proper data acquisition, it is critical that the electrodes and Physioflow patient cable probes be setup and configured correctly. Follow these steps when setting up a subject:

1. Shave the areas required for probe placement (as seen below), if need be with a disposable surgical razor.

2. Clean off the sites with an alcohol prep pad and dry with a paper towel. Then rub the skin with some Nuprep abrasive gel using gauze. Remove the excess gel when done. Skin color must turn bright pink.

3. Connect the appropriately colored PhysioFlow probes on the patient cable to the PhysioFlow PF50 AgCl electrodes (6 in total)

4. Apply the PhysioFlow PF50 AgCl electrodes (6 in total) on the patient to the proper locations (refer to the diagram below)

For measurement with patient at rest the electrodes are to be placed on the thorax as shown:	
NB: For the exercise tests, apply the black and green electrodes on the back as shown, the green one being at the same level as the xiphoid process and not above:	

VERY IMPORTANT:

Before applying the electrodes, *skin of the patient must be shaved and cleaned with some alcohol and abrasive gel (Nuprep).*

From this moment until the end of the calibration phase, the patient has to be calm and at rest without moving.

Please use PhysioFlow PF50 electrodes only. Any other electrode will decrease the signal/noise ratio and impair the performance of the device.
IMPORTANT: *Please make sure the electrodes are in good condition (expiration date, electrode bag not opened for more than a few days).*

When applying the electrodes, ensure that the gel pad in the center of the electrodes contacts the skin before the rest of the electrode. Do this by lifting up the sides of the electrode while placing the gel pad in the center flush against the skin. Then firmly push down on the sides of the electrode making sure no air pockets exist between the skin and the electrode.

System preparation

This procedure is an overview of the main points to check on the device before launching a measurement.

Note: The system setup is specific to every PhysioFlow device so users have to refer to the Service Manual provided with the device for specific details and exact procedure applied to the type of device delivered.

1. Connect the patient cable to the PhysioFlow device.

2. Switch the device ON:

   According to the device it may be:

   - plugging the device to the host PC by USB (Q-Link),
   - putting fully charged batteries in the device (Enduro)
   - connecting the power cable to main supply, then connecting the USB to serial adapter from the host PC to the PhysioFlow device, and switching ON the power button in the back of the device (Lab1)

Note: This step can be validated by checking that the device has a green led light.

3. Launch the PhysioFlow Software 2.X

4. The software will start scanning for all PhysioFlow compatible devices around (Wireless) or connected to the PC.

5. If the device is operational it should be detected and displayed in the device information section with all available functions.

	In some cases automatic detection will not work so users have to make sure that: - Only accessories provided by PhysioFlow are used (Bluetooth antenna, USB/Serial converter, patient cable etc.) - That the device is turned ON - That the drivers are installed properly or that no other drivers or internal device to the host PC (like internal Bluetooth antenna) are interfering with the provided accessories by PhysioFlow. In this case users may disable those internal antenna or drivers. PhysioFlow only support Mircosoft Bluetooth and BlueSoleil drivers. All other drivers like Toshiba, WidCom etc. are not supported. PhysioFlow can only provide support for the USB to serial adapter model delivered with the device. **Note:** Once all those points checked user may use the refresh device list button (Blue arrows button) to see if new devices are detected.

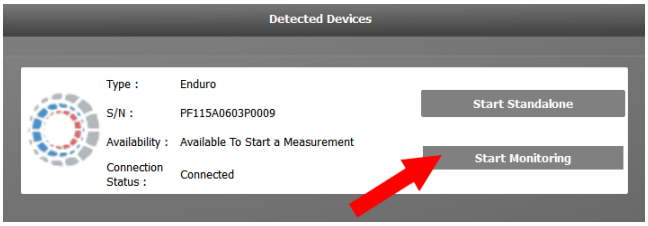
6. Start a measurement

⚠	*At any step of the following procedure can be stopped by just pressing the "cancel" button. To return to the home screen and start again the procedure (if for instance signal quality is not satisfying).*

Device selection

The new generation of PhysioFlow software are enable to detect all the PhysioFlow devices connected to same PC (even if they are of different type) so first step is to select on which device the measurement have to be done. The selection is done by pressing the "Start Monitoring" button of the chosen device in the "Detected Devices" list.

Here an example with and Enduro. **Note:** only have the Enduro have the "Start Standalone" for information about particularity of this mode please see Standalone measurement (For Enduro devices only))



PhysioFlow terms of use

For regulatory purpose before starting a measurement user must validated all the check points of the PhysioFlow terms of use to proceed to the data acquisition. User may read this carefully most of the issues that he may encounter can be avoided if the following are checked before the measurement.

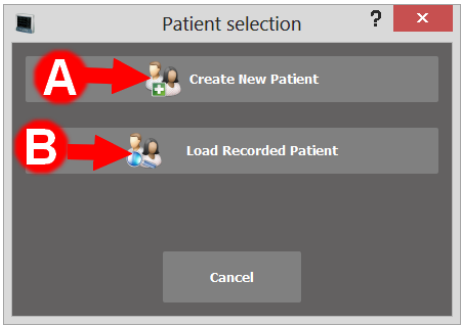
A document describing how to make a good patient skin preparation and how to optimize electrodes position according to measurement parameters can be displayed by pressing the "Instruction for attaching leads" button.

Note: This window can be hidden for 20 measurement

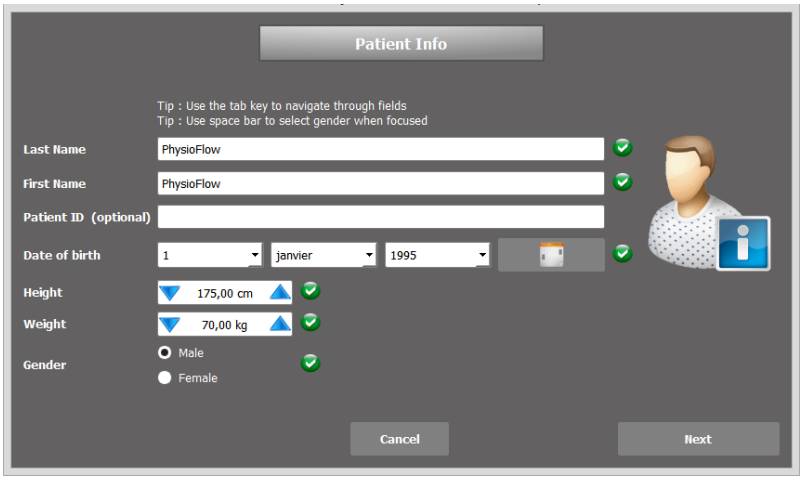
Measurement options/parameters

The following procedures apply to both real time monitoring and standalone acquisition.

Patient selection:



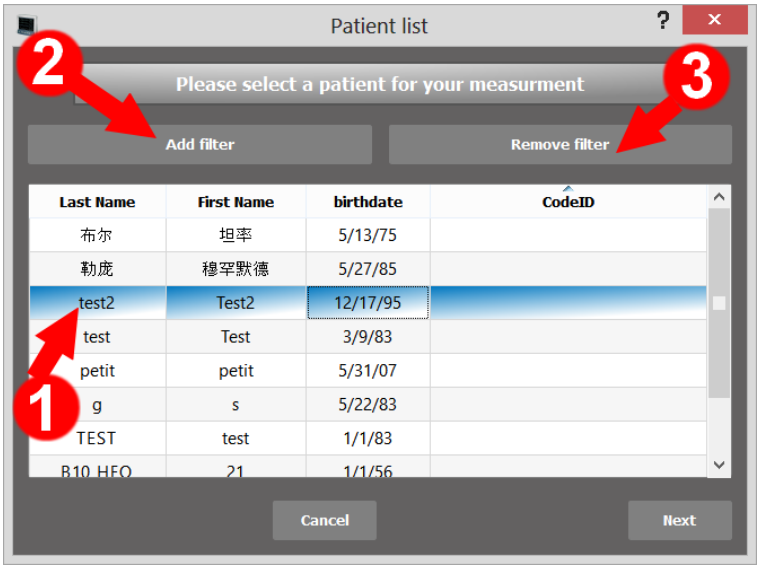
A. Create a New patient:



- When all mandatory information is filled all green validation icons are displayed and the next button is enabled.
- Data out of range stay with the red validation icon until a correct value is entered

B. Select an already registered patient:

By default all Patients are sorted by Code ID. This can be changed by left clicking on any column title. Columns can be added or removed by right clicking on any column title.

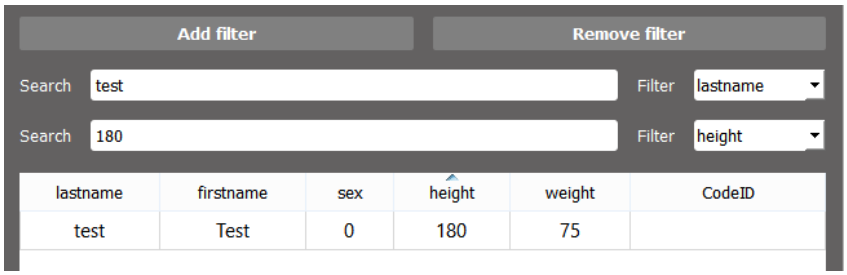


1) All recorded patients are displayed in this list. A patient is selected when a line is clicked and is highlighted in blue. The next button is then activated for final validation (Equivalent to double click on a patient). Right click on a patient gives access to delete and update functions.

2) Filters can be used by clicking on "Add Filter". For advanced filtering it is possible to add more than one criterion. The following example (see below) uses a double criteria filter using patient last name and height.

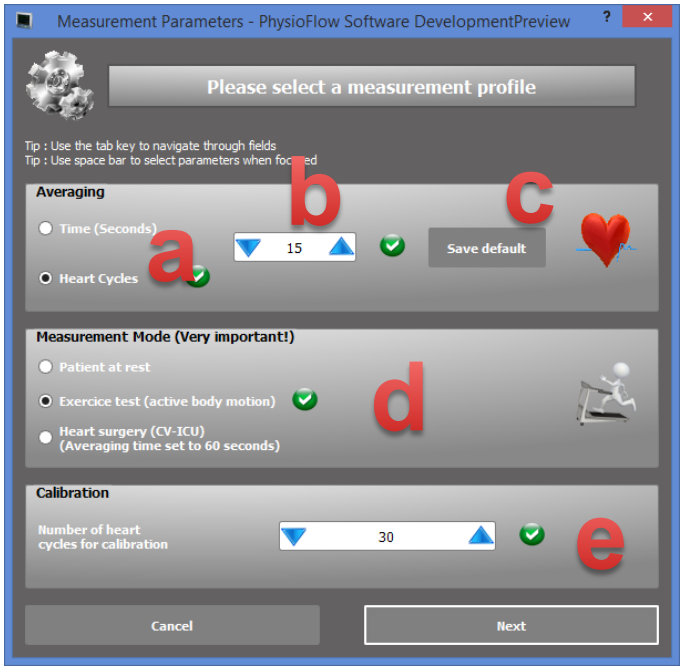
3) This option is used to remove last added filter.

Filters example:



⚠	*It is impossible to store measurement or patient anywhere else than in the default PhysioFlow Software data base!* ***Only the software has access to this data base. It is not possible to manually access its data.*** *However a backup of the data base can be done and stored to user selected path cf Backup software data base section "PhysioFlow Tool" chapter* *All data is encrypted ensuring privacy of electronic recordings.*

Measurement parameters selection



a) Measurement averaging type: seconds or heart cycles

b) Averaging value by default set to 10 (10 seconds or cycles according to user choice of averaging type)

c) Save averaging type and value as default for next measurements

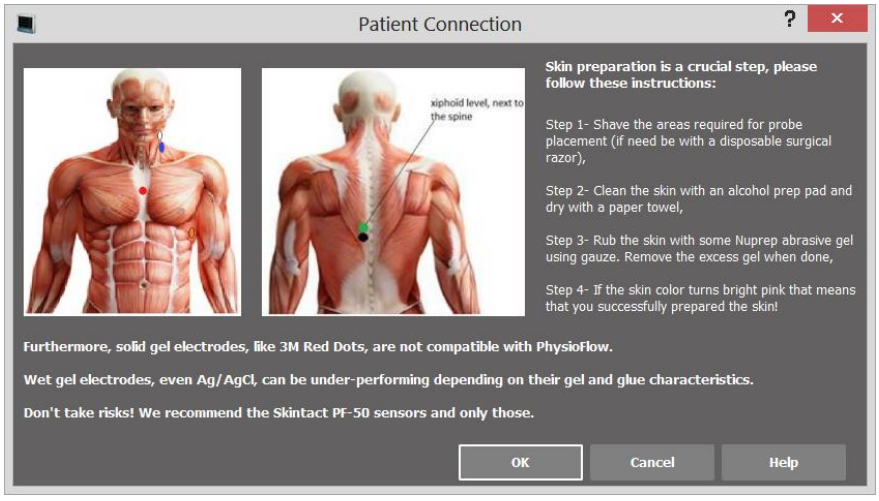
d) Measurement mode is very important please choose accordingly to measurement condition

e) Number of cycle for calibration set to 30 heart cycles by default (recommended value)

Measurement tips

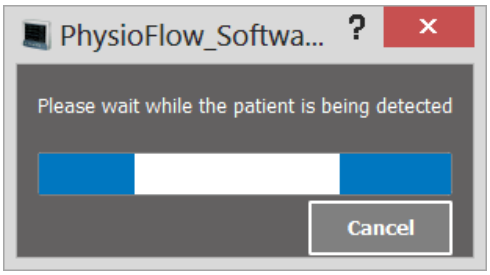
This window is displayed before starting calibration as a reminder for patient skin preparation and electrodes positions. It is very important to make sure that all the recommendations have been applied by users to obtain relevant results with good signal quality.

Note: The “help” button display a document: **Instructions for Attaching Leads**

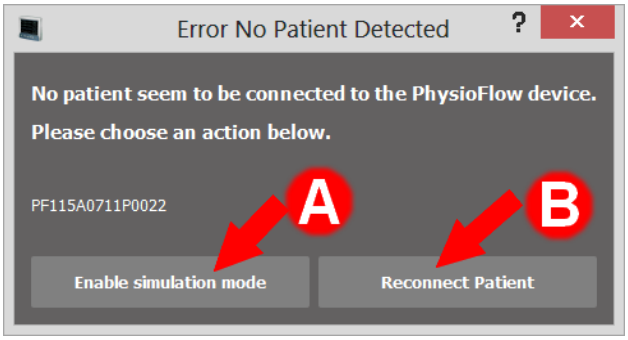


⚠	*Note: The images of the tool tip window change accordingly to the measurements parameters chosen previously. Users must read them carefully at least once.*

Patient detection window



For Enduro and Q-Link, after clicking the "Ok" button the system checks if a patient is connected or not. If not the following window is displayed:



A. Launch the simulation mode. This can be used for demonstration/training purposes. The system can be used without any patient connected.

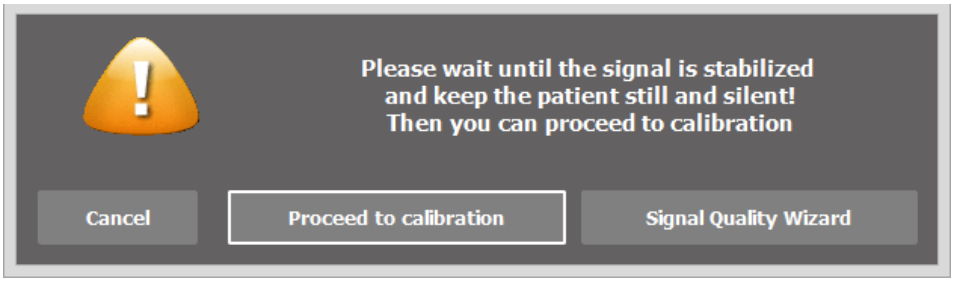
B. If a patient is supposed to be connected then click on the "Reconnect Patient" button. Patient connection window with recommendations is then displayed one more time to provide assistance (See "Measurement tips" section). Once all verifications are done please press "Ok"

⚠	For lab1 device such patient detection does not exist users must pay attention to the signal quality gauge during monitoring to detect a bad contact with the electrodes, bad patient skin preparation or cable failure.

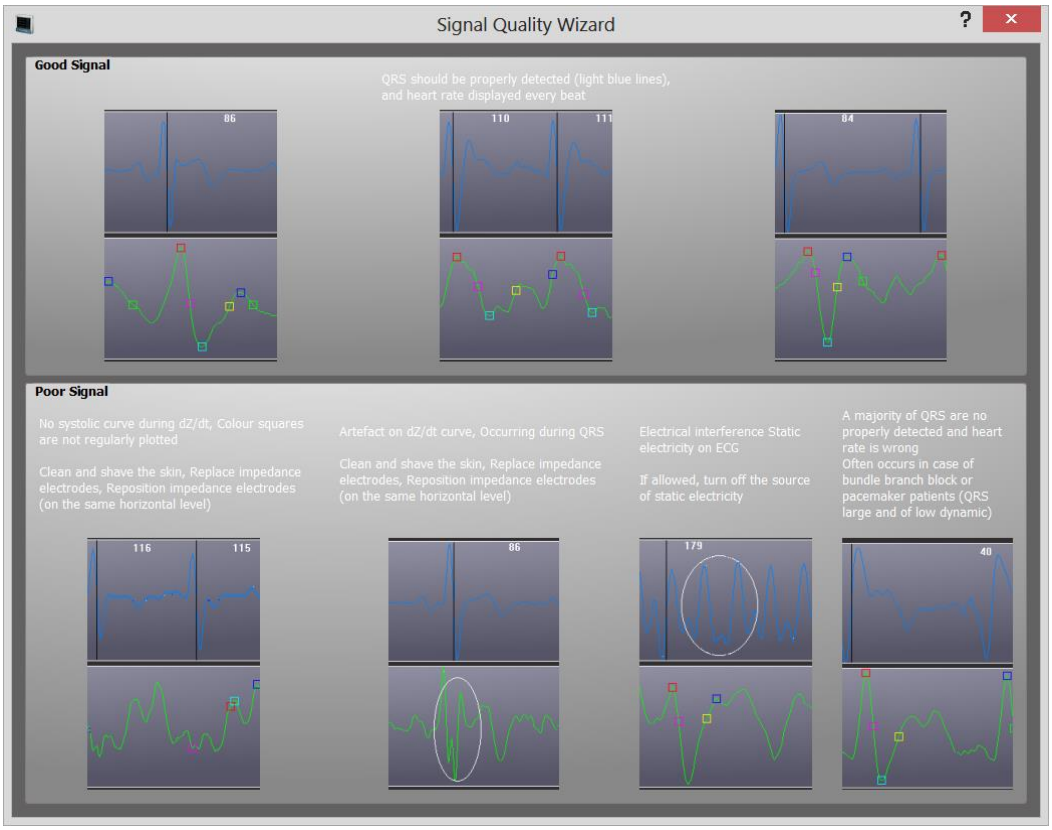
Calibration

Preview and signal quality

Please read carefully the calibration instructions on the Calibration Wizard screen before clicking on “Proceed to Calibration”. Calibration is critical. The accuracy and reproducibility of the patient measurement depends on the calibration. In order to have an accurate measurement, a strong signal stability and reproducibility must be obtained.



If users are not familiar with bioimpedance signal, the button “Signal Quality Wizard” provides help and illustrates the difference between good and bad signal:



Important: The operator should check that heart cycles are detected (black lines slicing on a beat by beat basis the ECG waveform (red)). Similarly, please verify that fiducial points of the Z time

derivative (green) signal are correctly detected (the presence of yellow, green, black and pink squares on the signal are necessary). The yellow square must not appear at the end of the heart cycle.

If the signal analysis and quality are questionable, the operator should try another derivation for the ECG (red electrode on the right shoulder and orange electrode on the left hip, for example), and for the impedance (horizontally move the pair of electrodes situated at the base of the thorax (green and black)

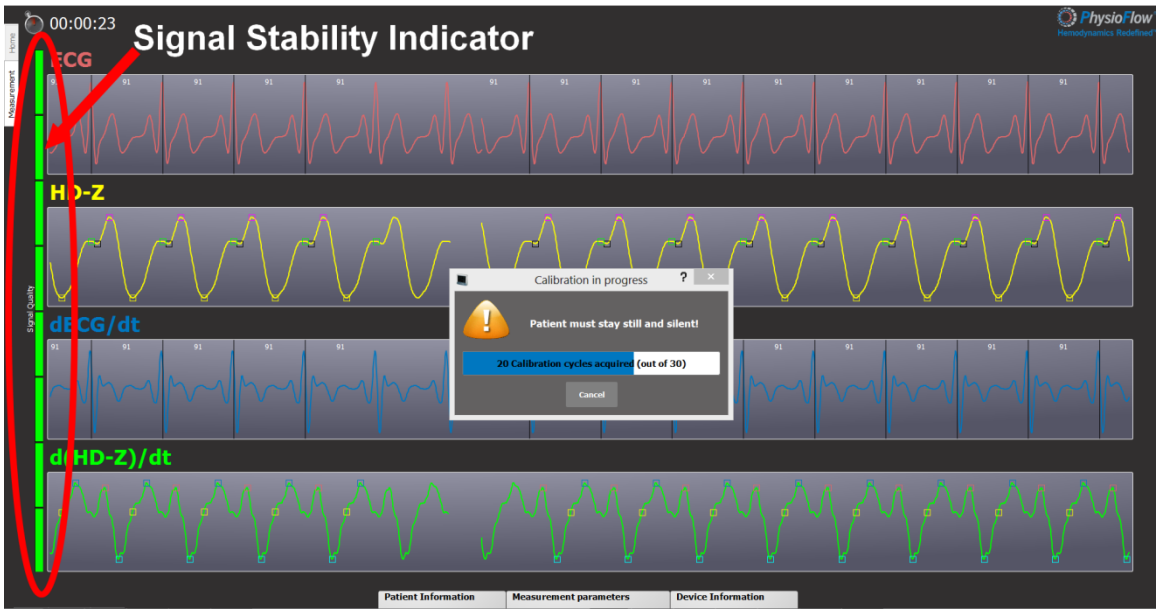
⚠	*IMPORTANT: It is essential that the operator understands the difference between acceptable and unacceptable signals!*

⚠	*ECG and impedance signals are displayed on the screen during this phase. Before proceeding to calibration, make sure that signals are reproducible, stable, and display no artefacts or interference.*

A signal stability indicator is shown during calibration and monitoring, and is associated to Ecg and Z plot graph (right side).

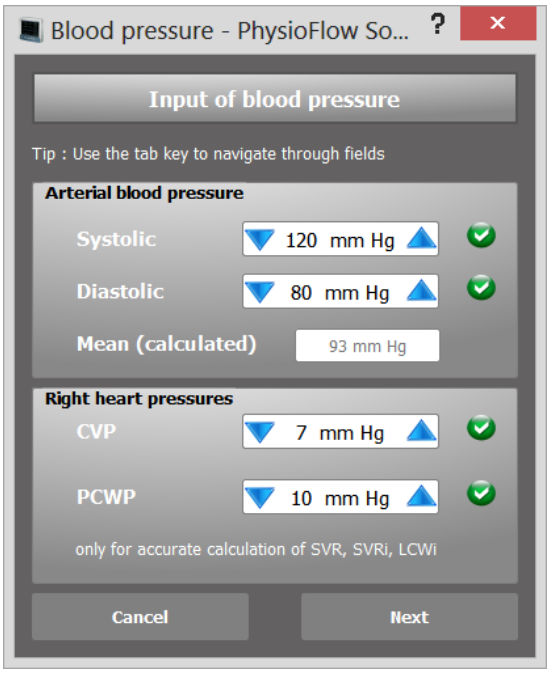
Please refer to Signal stability indicator and Signal switch or artifacts warning section in the tool chapter for more details about how to read the signal stability gauge.

When signal is acceptable, then click “Proceed to Calibration”.



Blood Pressures Input

It is necessary to proceed to simultaneous blood pressure measurement, in order to obtain blood pressure reference values (they are used for the reference cardiac output computation and for blood pressure profile calculation during exercise). Wait until calibration is finished (30 heartbeats) and then type in systolic and diastolic blood pressure when prompted by the software.



Default CVP (central venous pressure) and WP (Wedge Pressure) parameters can be updated (only for a more accurate computation of SVRi, and LCWi).

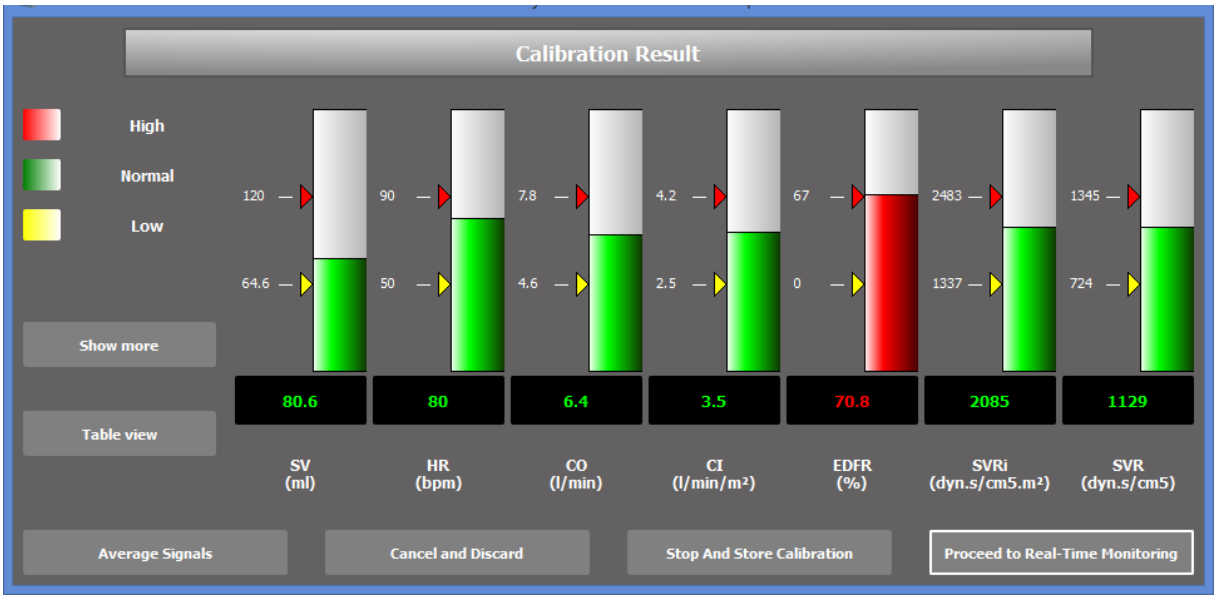
If necessary user may adjust values quickly after keyboard input thanks to the up and down arrow.

Then click on “Next” for calibration results

⚠	*IT IS ESSENTIAL THAT BLOOD PRESSURE READINGS ARE TAKEN ACCURATELY AND SYNCHRONIZED WITH THE CALIBRATION PHASE AS FAR AS POSSIBLE.*

Calibration results

Computed parameters are then displayed with a color code:



If the calibration results are satisfying click on the “Proceed to Real-Time monitoring” button to start acquisition. If no monitoring is necessary, but calibration must be saved for later review, click on “Stop and Store Calibration”. If monitoring is not necessary, and the calibration results do not have to be saved, click on “Cancel and Discard.

For more details about calibration results please refer to Calibration results section in the “PhysioFlow tools” chapter.

7. Real time monitoring measurement

Main screen presentation

This chapter list available functions during monitoring. Detailed descriptions of all functions are given in the "PhysioFlow Tools" chapter.

When acquisition begins, the monitoring screen appears. The four parameters shown by default are: HR= Heart Rate, SV= Stroke Volume, CO/CI= Cardiac Output/Index (cardiac index is cardiac output divided by the body surface area).

1. Main menu for real time monitoring measurement

Functions :

- Addition of markers
- Pressure update
- Stop the real time monitoring
- Analysis menu button:
  - Measurement data table display
  - Full report
  - Compact report

  - Calibration results
  - HemoDynamic Cross
  - HemoDynamic performance graph
- Export:
  - Export to CSV format
  - Export to Excel format
  - Export to PhysioFlow software
  - Measurement archiving
  - Select Archive Location
- Measurment comments

2. Measurement timestamp

It displays the time corresponding to the selected point.

Functions :

- Measurement chronometer
- Switch between absolute and relative time axis display

Please refer to Measurement timestamp section in the tool chapter for more details.

3. Signal stability indicator

This indicator is very important for consistent physiological results

Please refer to Signal stability indicator and Signal switch or artifacts warning section in the tool chapter for more details.

4. Measurement information slide menu

Please refer to Measurement information section in the tool chapter for more details.

5. Measurement configuration slide menu

Functions :

- Selection of parameters to display
- Trend Action Tool
  - Point selection on the curve
  - Linear regression (slope of the curve)

6. Battery level indicator (Only for Enduro device)

Please refer to Battery level indicator section in the tool chapter for more details.

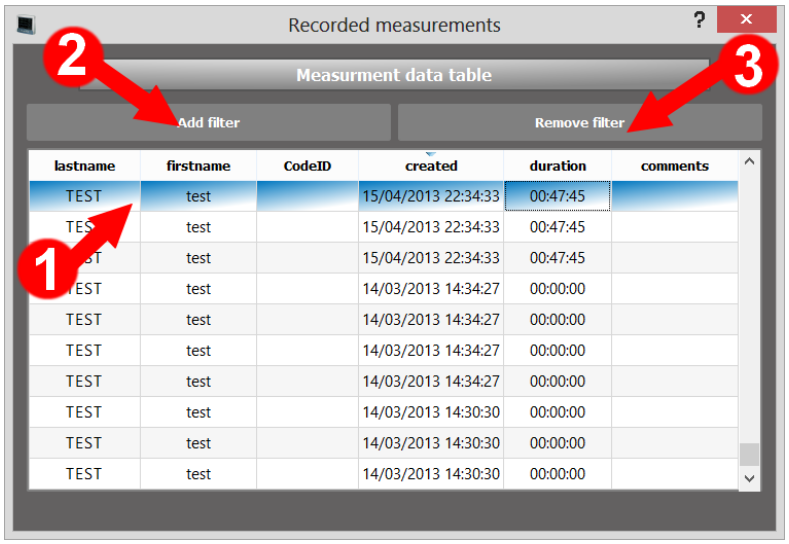
7. Handle for resize

Click and drag this handle to change the relative sizes of the graphs above and below.

8. Reviewing acquisition

The acquisition review can be performed in two stages: immediately after the monitoring is completed, or at any other time by clicking on the “Open Recorded Measurement” button:

By default all measurements are sorted by chronological order. This can be changed by left clicking on any column title. Columns can be added or removed by right clicking on any column title.

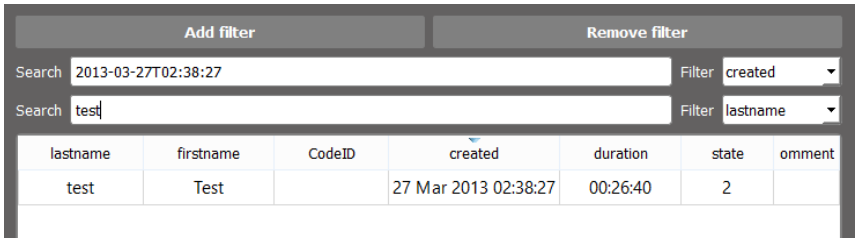


1. All stored measurements are displayed in this list. To select a measurement double click on line. The current selected measurement is highlighted in orange (one click action). Right click on a measurement gives access to delete function.

2. In case of important measurement database, filters can be added by clicking the “Add Filter” button. Several filters can be combined (Last names and creation date as shown in the example below).

3. Remove last added filter

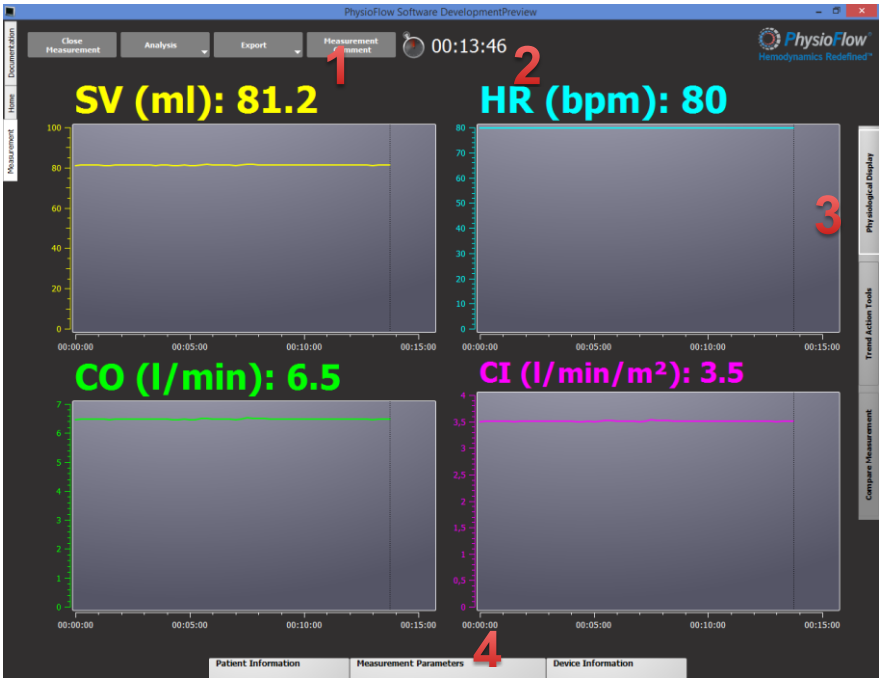
Filters examples



Note: Please notice that when filter by date/hours are used, the following format must be entered YYYY-MM-DDTHH:MM:SS

⚠	*It is not possible to store measurement or patient anywhere else than in the default PhysioFlow Software data base!* ***Only the PhysioFlow software has access to this database. It is not possible to manually access its data.***

Measurement reviewing main screen



1. Main menu for reviewing measurement mode

Functions :

- Close the measurement and return to the home screen menu
- Analysis menu button:
  - Measurement data table display
  - Full report
  - Compact report
  - Calibration results
  - HemoDynamic Cross
  - HemoDynamic performance graph
- Export:
  - Export to CSV format
  - Export to Excel format
  - Export to PhysioFlow software
  - Measurement archiving
  - Select Archive Location
- Measurment comments

2. Measurement timestamp

It displays the time corresponding to the selected point.

Functions :

- Measurement chronometer

- Switch between absolute and relative time axis display

Please refer to Measurement timestamp section in the tool chapter for more details.

3. Measurement information slide menu

Please refer to Measurement information section in the tool chapter for more details.

4. Measurement configuration slide menu

Functions :

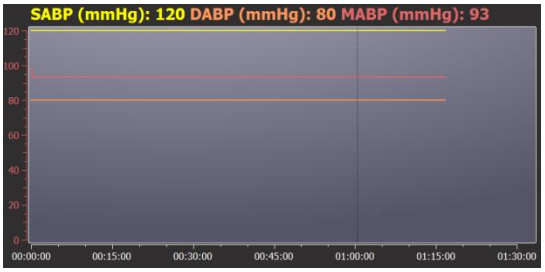
- Selection of parameters to display
- Trend Action Tool
  - Point selection on the curve
  - Zoom
  - Linear regression (slope of the curve)
- Measurement comparison

9. PhysioFlow tools

This chapter details the main actions possible while the measurement is running or opened for reviewing. However some functions are exclusive to real time monitoring or to measurement reviewing. This will be specified for every function in the availability note.

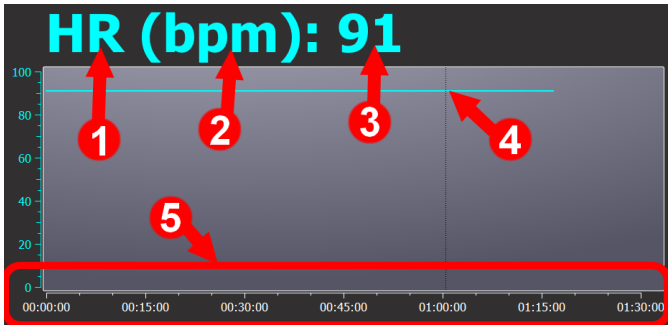
Plots

Availability: **for both real time monitoring and reviewing.**



Display trend curves of physiological data. The same plot can be used to display more than one physiological parameter. For instance the BP plots display all available blood pressures cf image above, or during comparison mode cf Compare Measurements section.

Overview



1- Name of the Physiological parameter

2- Unit of the physiological parameter

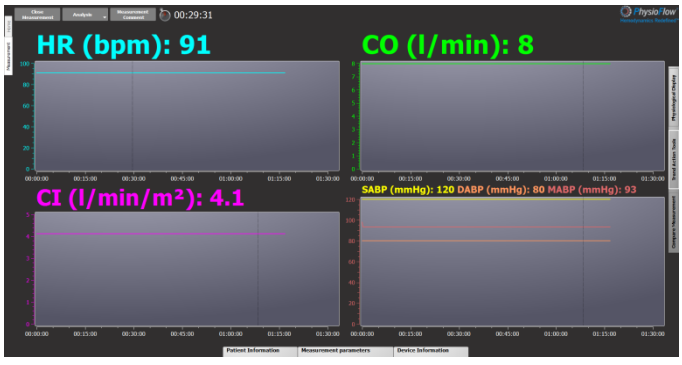
3- Display the value of the point highlighted by cursor (4)

4- Cursor : can be moved by clicking on any point of the curve to display its value (3)

5- Time axis: a double click on this axis allows switching from relative to absolute time display.

Note: A double click on the plot anywhere in the display zone switches from full screen to normal display mode. (In full screen mode only one parameter is displayed)

Normal display mode

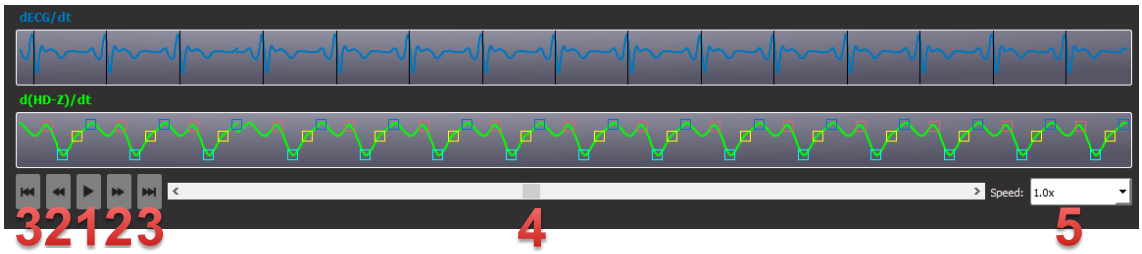


Full screen display of CO parameter

Raw Samples Review

Availability: **only for measurement reviewing mode.**

When raw samples are loaded (cf Physiological display), and any raw samples plot (ECG, HD-Z and their derivatives) is selected for display, graphical controls are added below graphs. They allow to review raw samples of a measurements after it is finished:



1- Start/stop the scrolling.

2- Step forward/backward 10 seconds

3- Jump to the end/beginning

4- Scroll bar representing the current position in the measurement. The position can be changed by dragging and dropping the scrollbar cursor, clicking in the area between the cursor and the arrows, or clicking on the arrows.

5- Speed selection drop-down list. “1.0x” makes the samples scroll at a speed identical to real time, “2.0x” makes the samples scroll twice faster etc.

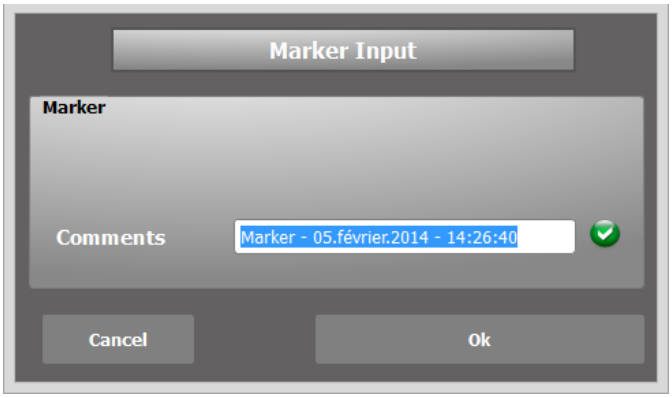
Pressing **1** makes the cursor of **4** move automatically, at the speed defined in **5**

The time of the samples on screen is displayed in the “Measurement timestamp” section at the top of the window.

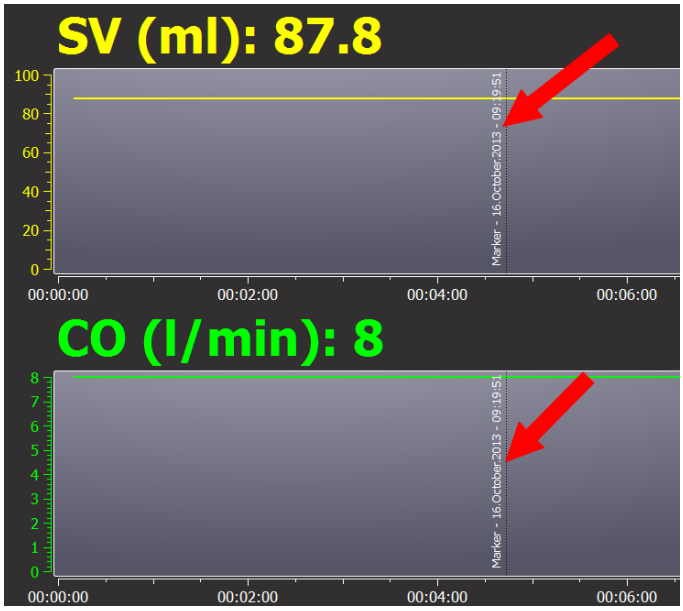
Markers

Availability: **only during real time monitoring mode.**

It allows users to add a note at a given timestamp. This function can be accessed through the "Add marker button" or hitting Space bar. When clicked, a new window is displayed with a comment set by default to the time and date. If there is nothing to add/replace just click on "Ok" or press "Enter" for final validation. This field is mandatory, so empty text prevent from pressing ok and validating the marker. The time of the marker matches the time users hit space bar or pressed the "Marker" button.



When the Ok button is cliked the marker and the associated comment are then added to every physiological trend.



Note: Once validated a marker cannot be edited/updated or deleted.

Blood pressure update

Availability: **only during real time monitoring mode.**

Users can type the new blood pressures and click ok. The new values are updated at the time new physiological parameters are computed.

Default CVP (central venous pressure) and WP (Wedge Pressure) parameters can be updated (only for a more accurate computation of SVRi, and LCWi).

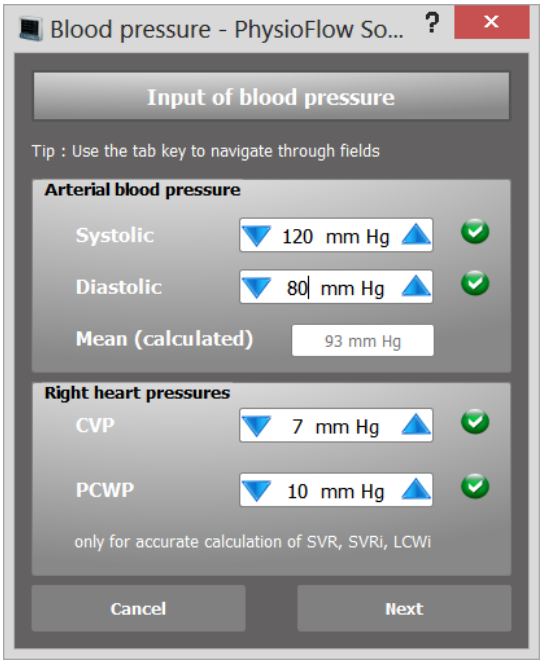


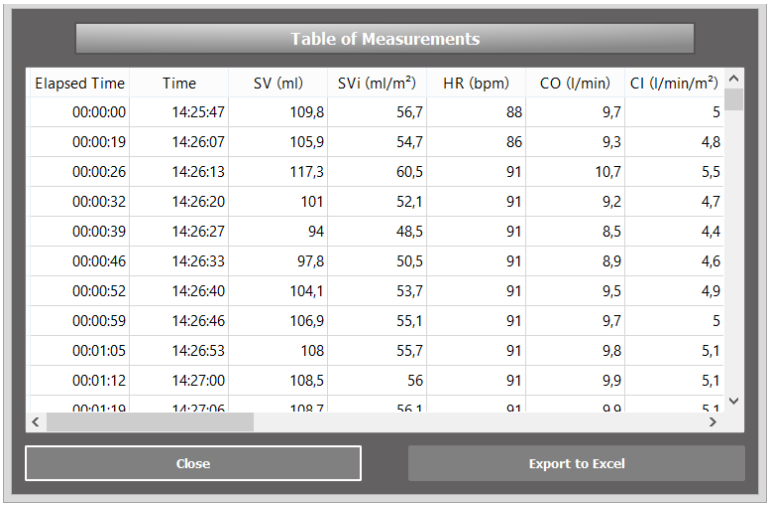
Table display mode

Availability: **for both real time monitoring and reviewing**

A table listing computed Physiological values with an option to export data to Excel (for details about Excel export please refer to Excel export section in this chapter).

Note: If Excel is not installed, an export to CSV format is performed.

Note: The table is not updated in real time with last computed value while the table is opened. The table must be closed and reopened to display newly computed value.

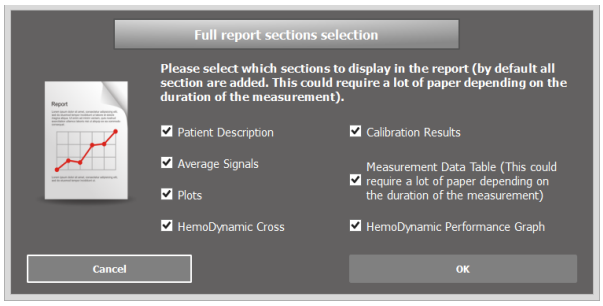


Elapsed Time	Time	SV (ml)	SVi (ml/m²)	HR (bpm)	CO (l/min)	CI (l/min/m²)
00:00:00	14:25:47	109,8	56,7	88	9,7	5
00:00:19	14:26:07	105,9	54,7	86	9,3	4,8
00:00:26	14:26:13	117,3	60,5	91	10,7	5,5
00:00:32	14:26:20	101	52,1	91	9,2	4,7
00:00:39	14:26:27	94	48,5	91	8,5	4,4
00:00:46	14:26:33	97,8	50,5	91	8,9	4,6
00:00:52	14:26:40	104,1	53,7	91	9,5	4,9
00:00:59	14:26:46	106,9	55,1	91	9,7	5
00:01:05	14:26:53	108	55,7	91	9,8	5,1
00:01:12	14:27:00	108,5	56	91	9,9	5,1
00:01:19	14:27:06	108,7	56,1	91	9,9	5,1

Full report

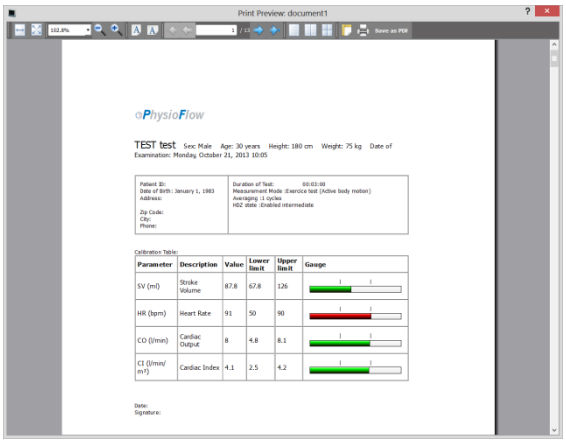
<u>Availability</u>: for both real time monitoring and reviewing

It displays the report of the measurement. It is launched by clicking on the print button or Ctrl+P keyboard combination.

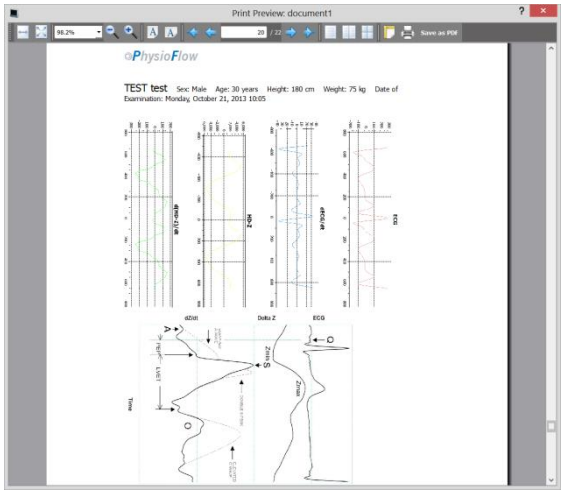


Before the creation of the report the user is asked to select which sections have to be included in the report (according to the measurement length and/or averaging value the measurements data table may consume a lot of paper and also make the digital copy of the report not very readable).

The first page of the report provides a summary of patient and measurement information/context. Calibration values are then displayed with lower/upper limits. Following pages print physiological parameters in a table, trend graphs, Hemodynamic cross and Hemodynamic Performance Graph.



Note: Physiological parameters in the report are the same as the ones displayed in the main measurement screen. To add/remove parameters, users have to add/remove parameters from the main screen. Refer to Physiological display in the configuration slide menu section.

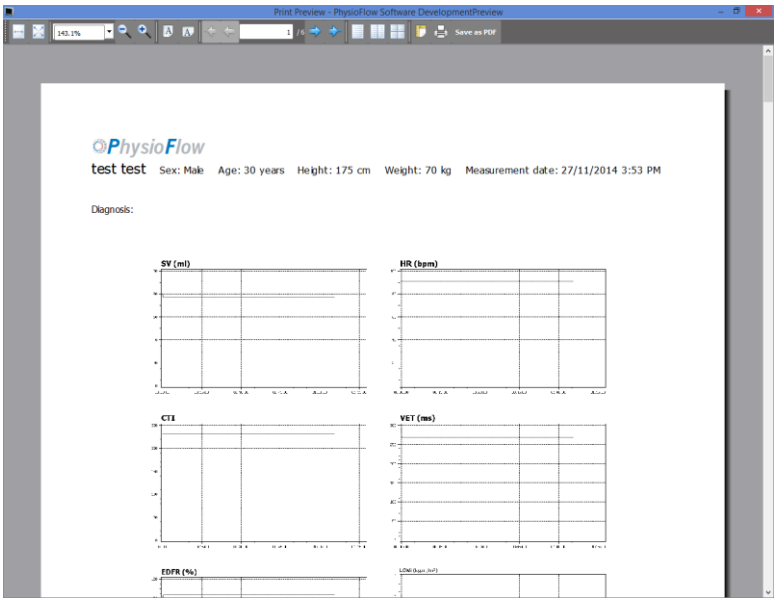


Compact report

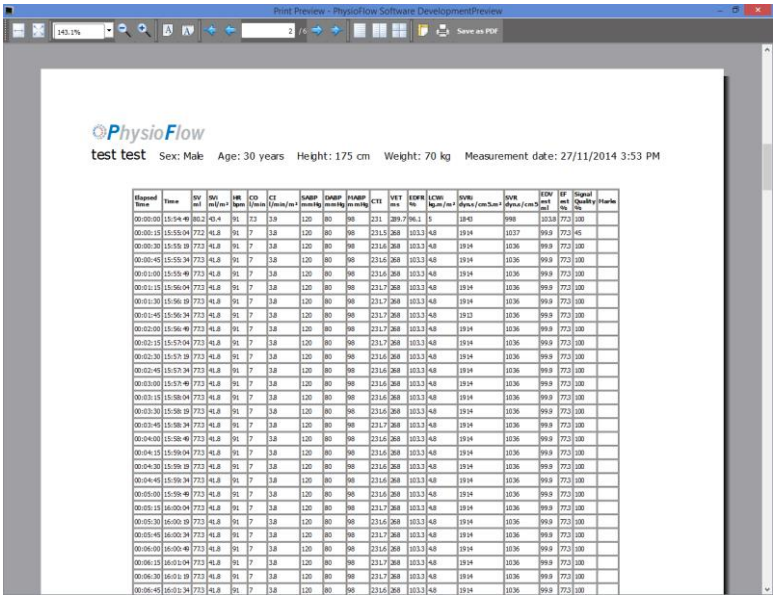
<u>Availability</u>: for both real time monitoring and reviewing

It displays the report of the measurement, in a more compact way.

The first page of the report provides a summary of patient and measurement information/context. Trend graphs are then displayed, with Hemodynamic cross and calibration average signals. Following pages print physiological parameters in a table.



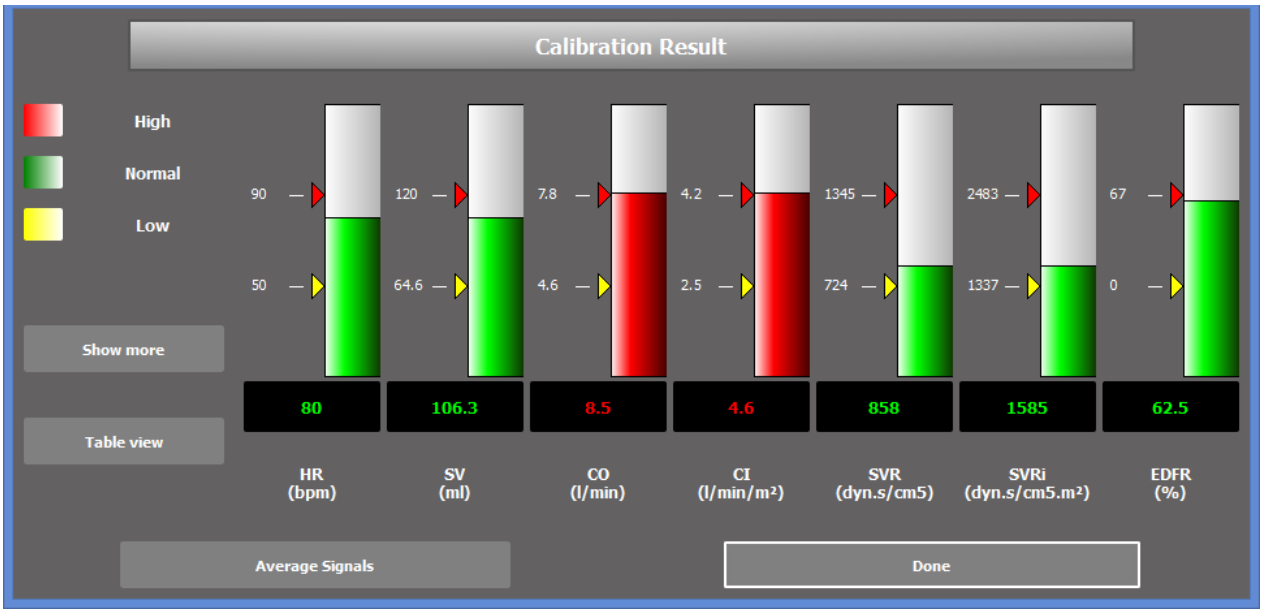
Note: Physiological parameters in the report are the same as the ones displayed in the main measurement screen. To add/remove parameters, users have to add/remove parameters from the main screen. Refer to Physiological display in the configuration slide menu section.



Calibration results

Availability: **for both real time monitoring and reviewing**

Calibration results are shown at the end of the calibration and then can be displayed at any time during the monitoring or review.



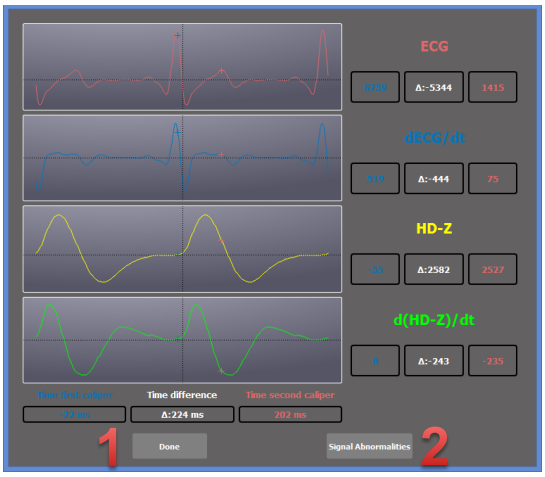
Note: Min and Max ranges are identified respectively by the yellow and red arrows.

Important: The basis of the upper/lower limits of the calibration parameters is derived from a normal healthy supine patient at rest. Parameters that exceed the standards will be shown in red; those within the limits will be shown in green and those that are lower than standards will be shown in yellow. If the calibration looks questionable (poor signal quality, aberrant values) please cancel the measurement and check the following points before restarting the procedure:

- Patient skin preparation
- Electrodes (reference, expiration date and position)

A. At the end of the calibration procedure the button “Done” is called “proceed to monitoring” to finish the calibration phase and start monitoring the patient. During other phases like reviewing acquisition or to display calibration results during monitoring the button is called “Done” and allows closing the window and returning to trends display.

B. For further analysis of the calibration phase it is possible to display the average signals of calibration cycles. Pressing the button will show a new window.



To compare time difference and value of two different points on the curve: click on any trend and maintain the click to set the first point and then move the cursor to the second targeted point. Release the button to obtain value of each point and the difference between the two. Time difference is common to all signals and is displayed on the bottom of the window. This procedure can be repeated as many times as necessary.

On all average signals, the vertical black dotted line shows t = 0.

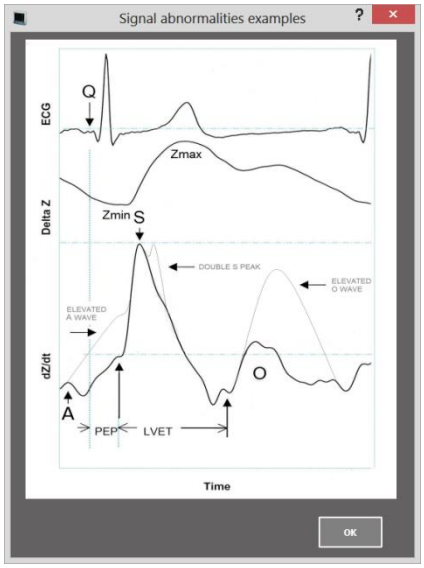
On ECG and HD-Z, the horizontal black dotted line shows the average value of the average signal.

On dECG/dt and d(HD-Z)/dt, the horizontal black dotted line shows the zero of the derivative.

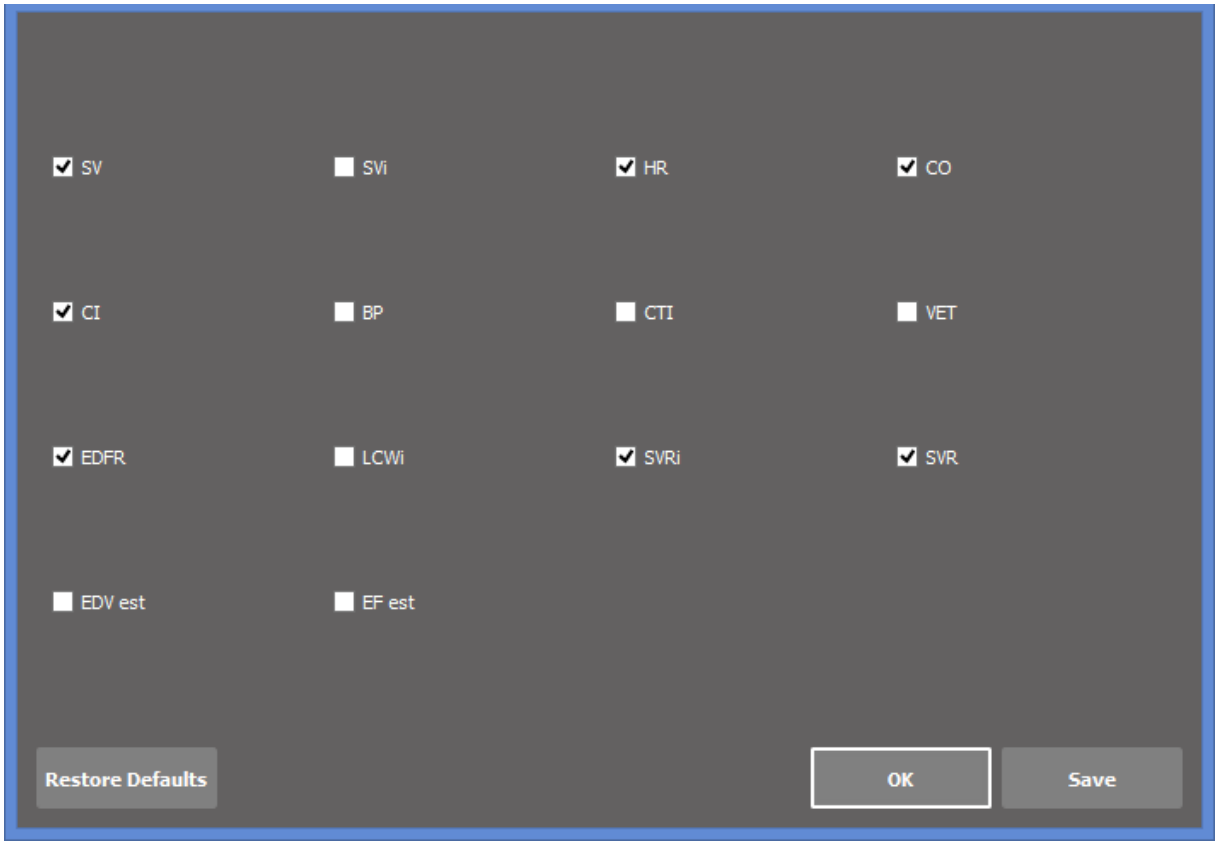
⚠	*The average signal is not available for measurement imported from previous software generation V1.0.7 generation. User may have an error messages for those measurements about average signal avaibility.*

1) To finish and return to the calibration result window press “Done”.

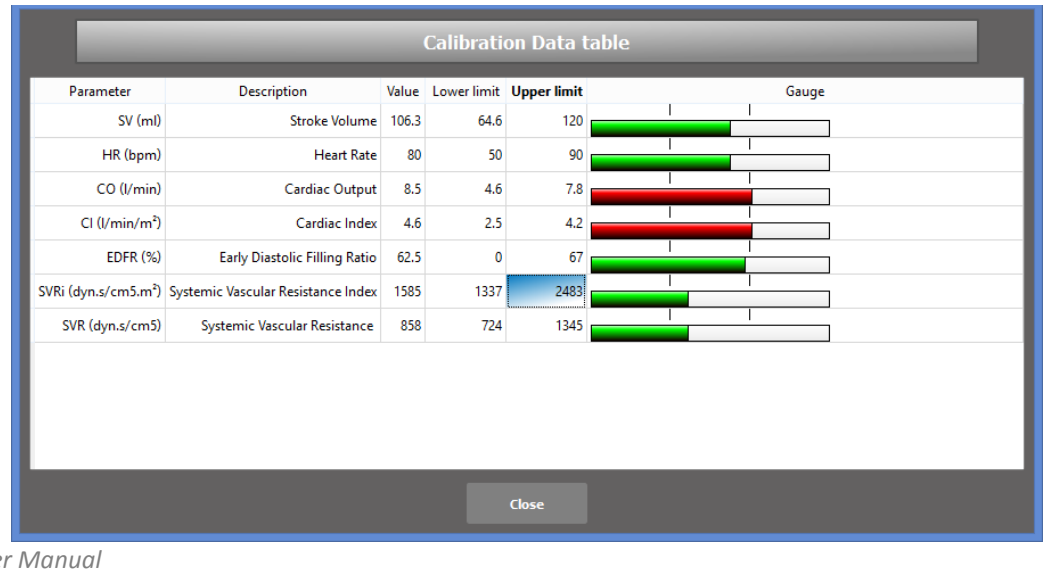
2) For help about average signal analysis and signal abnormalities :



C. For further analysis of the calibration phase it is possible to choose the physiological parameters displayed by clicking on the “Show more” button. Click on the checkbox of the needed parameters in the window shown below, and the corresponding gauges will be added in the calibration results window, and the corresponding lines will be added to the table view described in the next section.
Click on “OK” to go back to calibration results window. Click on “Save” to save the checked parameters as default for next calibration results windows displayed. Click on “Restore Defaults” to go back to the last configuration saved.



D. The “Table view” button allows to show calibration in a table:

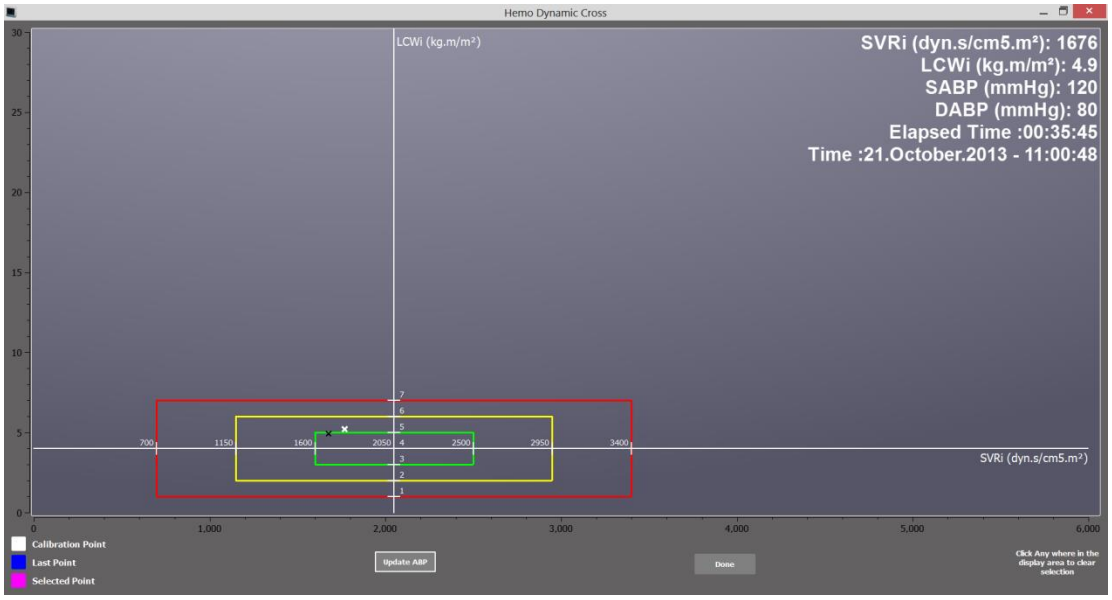


Hemodynamic Cross

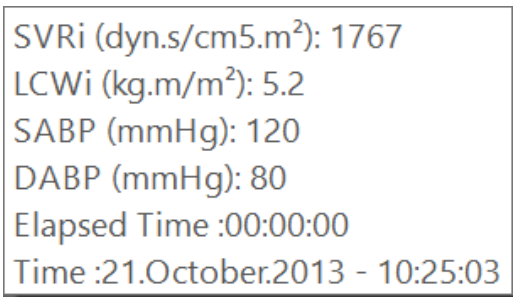
Availability: **for both real time monitoring and reviewing**

The Hemodynamic Cross is the graphic representation of the balance resistances vascular/cardiac work. It allows visualization of the hemodynamic status of the patient.

This two-dimensional diagram presents on the horizontal scale the systemic vascular resistance index (SVRi) and on vertical scale the left cardiac work index (LCWi), both normalized on a body surface area basis, so that the same diagram applies to all the patients, regardless of their morphological characteristics.



- **Only During real time monitoring** users can update blood pressures to increase results precision without leaving the Hemodynamic Cross window thanks to the "update ABP" button. See also "Blood pressure update" section. This button is not displayed in reviewing aquistion mode.
- **Only During reviewing measurment mode** users have acces to a replay button wich allows to highlight the evolution over time of the combination of physiologic value (SVRi and LCWi).
- When users move the mouse cursor over a point , a popup displays for a few seconds all the information about the point. Selected point is highlighted in Magenta



To clear selection just click on the plot.

All points are black colored however some particulars points are higlighted by other colors :

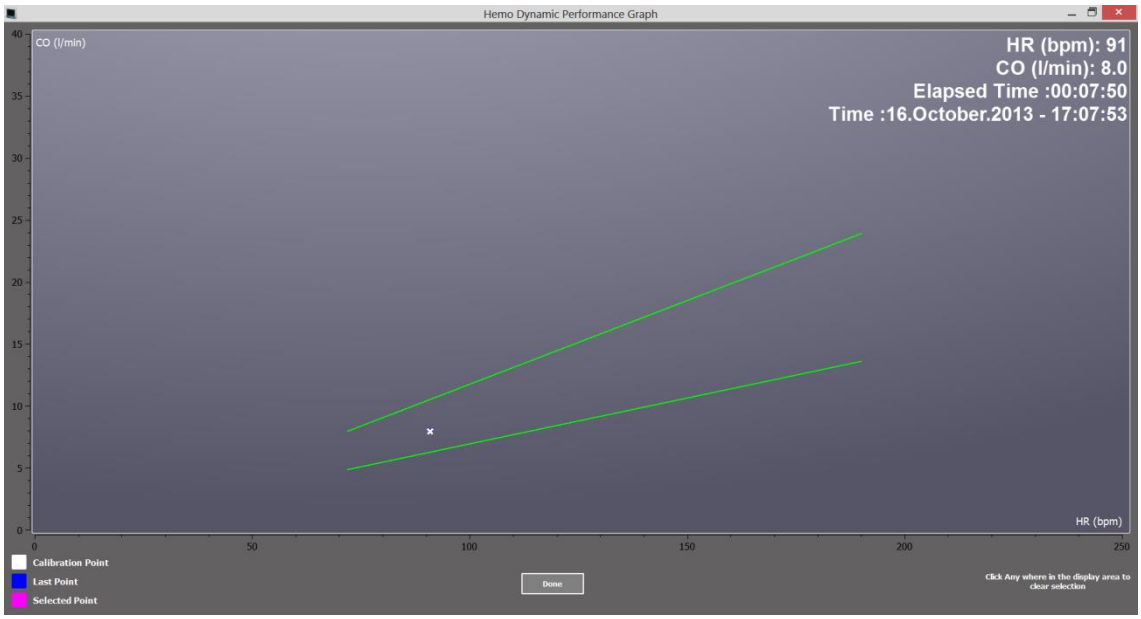
- Last point blinking in blue
- Calibration point in white
- Any selected point in magenta

Hemodynamic Performance Graph

Availability: **for both real time monitoring and reviewing**

The Hemodynamic performance graph is a two dimensional display of cardiac output against heart rate. It helps assess the performance of the heart during a stress or exercise test and see if cardiac output increases normally with the level of physical activity.

The two green lines show the upper limit (highly trained) and lower limit (borderline heart failure) of normal CO increase. The lines are computed in accordance with the scientific literature and normalized according to the body surface area of the subject/patient in order to provide clinically useful information regardless the size and weight.



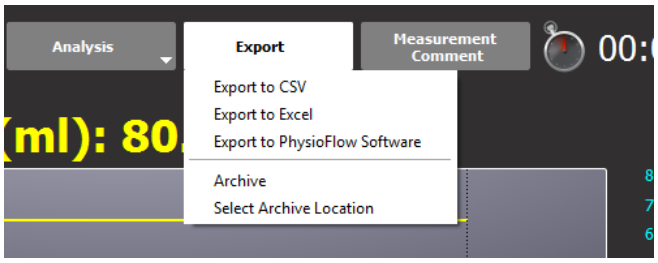
The selection procedure and the color code for point identifcation is the same as Hemo Dynamic Cross. Refer to Hemodynamic Cross section for details about point selection and color code for particular point identification.

Only During reviewing measurment mode users have acces to a replay button wich allows to highlight the evolution over time of the combination of physiologic value (HR and CO).

Data Export

Availability: **for both real time monitoring and reviewing**

This section is a submenu which offers various options for data export purpose.

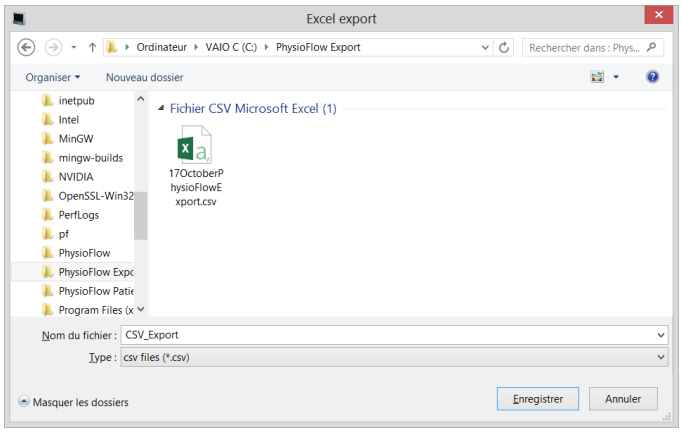


⚠	***For all export function please make sure to have enough disk space and all needed right privileges on user account to write data to target directory.***

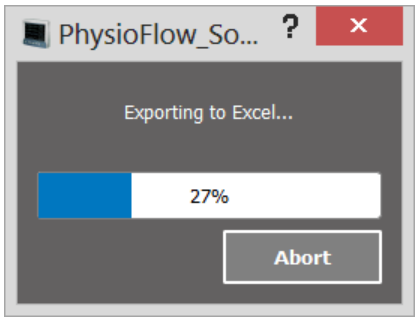
Export to CSV:

CSV (Comma-Separated Values) is a common, relatively simple file format widely supported and multi-platform. The CSV file format is supported by almost all spreadsheets programs.

Users must select target directory when prompted and enter the desired file name to store the exported data under CSV files format.



The software displays the data conversion progress during the procedure.

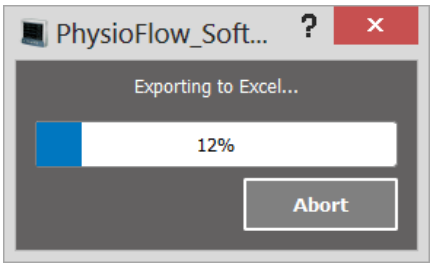


Export to Excel:

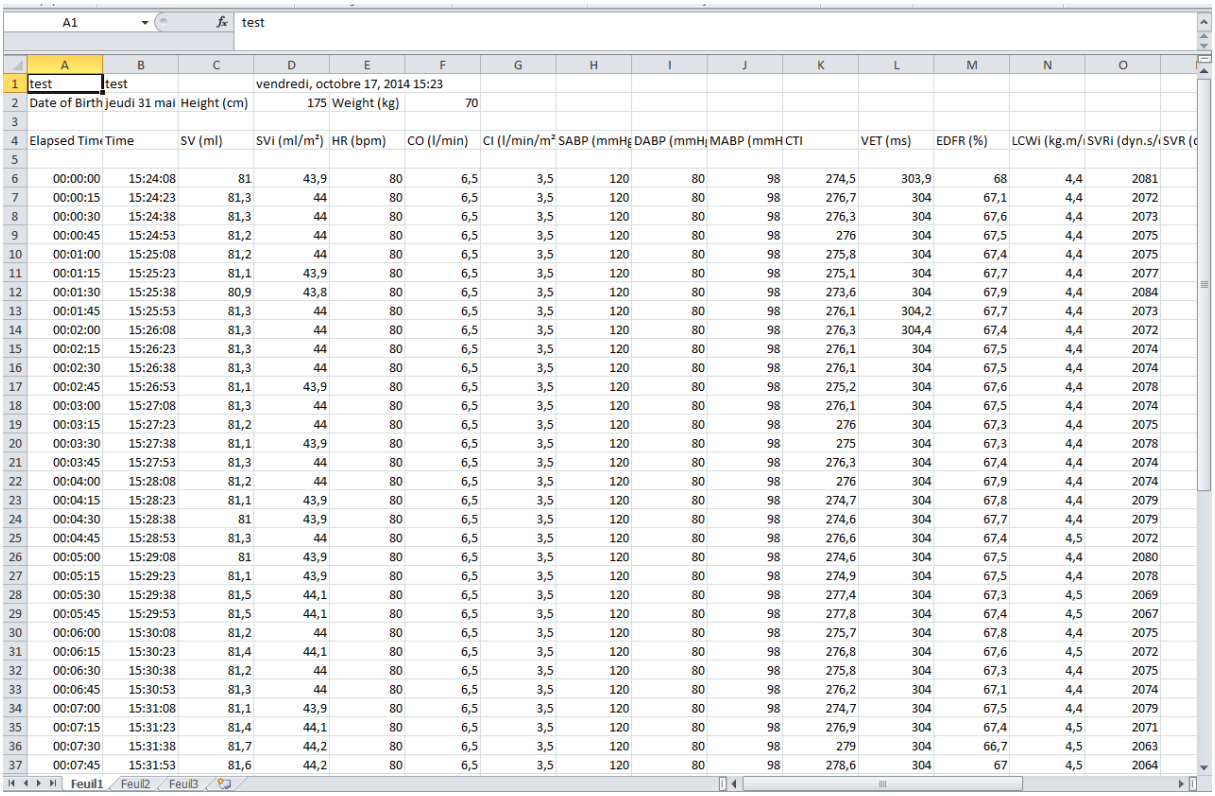
Excel is the most popular and available spreadsheets programs. Exporting data to this format allows users to benefit from all edition and formatting tools available under Excel (For reporting purpose for instance).

Note: CSV files are compatible with Excel.

The software displays the data conversion progress during the procedure.

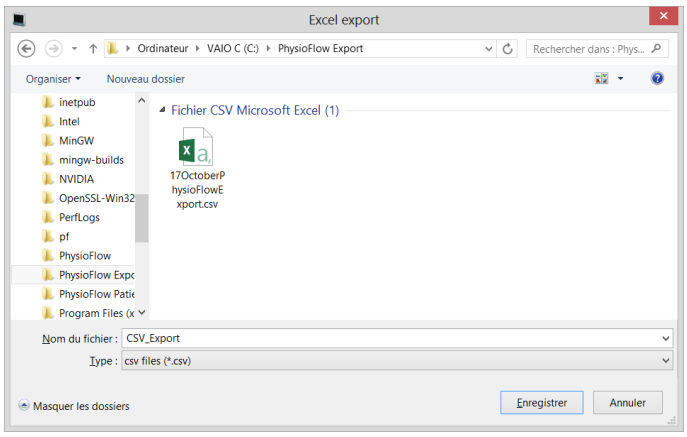


At the end of the procedure Excel is automatically opened with a spreadsheet containing the exported data and the summary of the measurement parameters and patient's information.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	test	test		vendredi, octobre 17, 2014 15:23											
2	Date of Birth	jeudi 31 mai	Height (cm)	175	Weight (kg)	70									
3															
4	Elapsed Time	Time	SV (ml)	SVi (ml/m²)	HR (bpm)	CO (l/min)	CI (l/min/m²	SABP (mmHg	DABP (mmHg	MABP (mmH	CTI	VET (ms)	EDFR (%)	LCWi (kg.m/i	SVRi (dyn.s/i	SVR (c
5															
6	00:00:00	15:24:08	81	43,9	80	6,5	3,5	120	80	98	274,5	303,9	68	4,4	2081	
7	00:00:15	15:24:23	81,3	44	80	6,5	3,5	120	80	98	276,7	304	67,1	4,4	2072	
8	00:00:30	15:24:38	81,3	44	80	6,5	3,5	120	80	98	276,3	304	67,6	4,4	2073	
9	00:00:45	15:24:53	81,2	44	80	6,5	3,5	120	80	98	276	304	67,5	4,4	2075	
10	00:01:00	15:25:08	81,2	44	80	6,5	3,5	120	80	98	275,8	304	67,4	4,4	2075	
11	00:01:15	15:25:23	81,1	43,9	80	6,5	3,5	120	80	98	275,1	304	67,7	4,4	2077	
12	00:01:30	15:25:38	80,9	43,8	80	6,5	3,5	120	80	98	273,6	304	67,9	4,4	2084	
13	00:01:45	15:25:53	81,3	44	80	6,5	3,5	120	80	98	276,1	304,2	67,7	4,4	2073	
14	00:02:00	15:26:08	81,3	44	80	6,5	3,5	120	80	98	276,3	304,4	67,4	4,4	2072	
15	00:02:15	15:26:23	81,3	44	80	6,5	3,5	120	80	98	276,1	304	67,5	4,4	2074	
16	00:02:30	15:26:38	81,3	44	80	6,5	3,5	120	80	98	276,1	304	67,5	4,4	2074	
17	00:02:45	15:26:53	81,1	43,9	80	6,5	3,5	120	80	98	275,2	304	67,6	4,4	2078	
18	00:03:00	15:27:08	81,3	44	80	6,5	3,5	120	80	98	276,1	304	67,5	4,4	2074	
19	00:03:15	15:27:23	81,2	44	80	6,5	3,5	120	80	98	276	304	67,3	4,4	2075	
20	00:03:30	15:27:38	81,1	43,9	80	6,5	3,5	120	80	98	275	304	67,3	4,4	2078	
21	00:03:45	15:27:53	81,3	44	80	6,5	3,5	120	80	98	276,3	304	67,4	4,4	2074	
22	00:04:00	15:28:08	81,2	44	80	6,5	3,5	120	80	98	276	304	67,9	4,4	2074	
23	00:04:15	15:28:23	81,1	43,9	80	6,5	3,5	120	80	98	274,7	304	67,8	4,4	2079	
24	00:04:30	15:28:38	81	43,9	80	6,5	3,5	120	80	98	274,6	304	67,7	4,4	2079	
25	00:04:45	15:28:53	81,3	44	80	6,5	3,5	120	80	98	276,6	304	67,4	4,5	2072	
26	00:05:00	15:29:08	81	43,9	80	6,5	3,5	120	80	98	274,6	304	67,5	4,4	2080	
27	00:05:15	15:29:23	81,1	43,9	80	6,5	3,5	120	80	98	274,9	304	67,5	4,4	2078	
28	00:05:30	15:29:38	81,5	44,1	80	6,5	3,5	120	80	98	277,4	304	67,3	4,5	2069	
29	00:05:45	15:29:53	81,5	44,1	80	6,5	3,5	120	80	98	277,8	304	67,4	4,5	2067	
30	00:06:00	15:30:08	81,2	44	80	6,5	3,5	120	80	98	275,7	304	67,8	4,4	2075	
31	00:06:15	15:30:23	81,4	44,1	80	6,5	3,5	120	80	98	276,8	304	67,6	4,5	2072	
32	00:06:30	15:30:38	81,2	44	80	6,5	3,5	120	80	98	275,8	304	67,3	4,4	2075	
33	00:06:45	15:30:53	81,3	44	80	6,5	3,5	120	80	98	276,2	304	67,1	4,4	2074	
34	00:07:00	15:31:08	81,1	43,9	80	6,5	3,5	120	80	98	274,7	304	67,5	4,4	2079	
35	00:07:15	15:31:23	81,4	44,1	80	6,5	3,5	120	80	98	276,9	304	67,4	4,5	2071	
36	00:07:30	15:31:38	81,7	44,2	80	6,5	3,5	120	80	98	279	304	66,7	4,5	2063	
37	00:07:45	15:31:53	81,6	44,2	80	6,5	3,5	120	80	98	278,6	304	67	4,5	2064	

When prompted, users must select target directory and enter the desired file name to store the exported data under Excel files format.



Export to PhysioFlow Software

This feature can be used in two different modes, depending of the target of the export.

According to data base size this procedure can take some time so the software displays the percentage progress and an estimation of the remaining time until the end of the procedure. At the end of the procedure the software displays a success message if everything is ok. User must wait for the success message before starting another procedure or considering the procedure finished.

New PhysioFlow Software 2.x.y

Users can export measurement to PhysioFlow Software 2.x.y with this option, starting with 2.6.0. They have to choose a folder and name for the exported file, which has a ".pfdz" extension. Contrary to the previous generation file format, all the data are stored in only one file: patient information, measurement parameters, raw signals, computed physiological values, markers, and measurement comments. What is more, this file contains data from the signal preview, the calibration and the monitoring phase.

This function can be useful in the following cases:

- Exchange data with other PhysioFlow users: these exported files can be imported into another software database, following the procedure in section Import data from PhysioFlow software.
- Send files for analysis by PhysioFlow technician for support purpose.

The extension format ".pfd" is also available: the content of pfd file is identical to pfdz files, but pfd files are not compressed so they require a lot more disk space. This extension format should be used only if the file has to be imported in PhysioFlow Software 2.6.0, 2.6.1, 2.6.2, 2.6.3 and 2.6.4, because these versions do not support pfdz extension format.

Export to PhysioFlow Software V107 (Previous generation):

Users of previous PhysioFlow software V1.X.X can use this function to export the data of the current software to the previous file format (PFP, PFS, PFM, PFC and PFK).

Users must select target directory containing the previous generation software patient database, usually C:\PhysioFlow Patients\

This function should be used only when the measurement has to be opened in the PhysioFlow Software v107, for example to compare newly acquired data to old measurements

Measurement archiving

Measurement archiving can be used when several measurements need to be exported to the same destination and format. Currently, only the CSV format is available, and is selected by default.

First, the archive location must be selecting by clicking “Select Archive Location”

- If the archive location is a folder on a local hard drive, which is directly connected to the computer, select the location type “Local Drive”. E.g. a folder on c:\, or a folder on a USB drive. Then select the folder in the next window
- If the archive location is a network location, select the location type “Network URI”. Then enter the URI in the standard format, according to IETF RFC 3986. E.g ftp://user:password@host:21/path/to/directory

The archive location is then tested, and an error message is displayed if there was a problem.

Once an archive location is properly set up, the user is asked at the end of each measurement if he wants to archive it. Click “yes” to archive the measurement at the location previously defined, otherwise click “no”. It is also possible to manually archive a measurement opened by clicking on the “Archive” button.

A message is then displayed to inform the user if the archive was successful or not.

Measurement comments

Availability: **for both real time monitoring and reviewing**

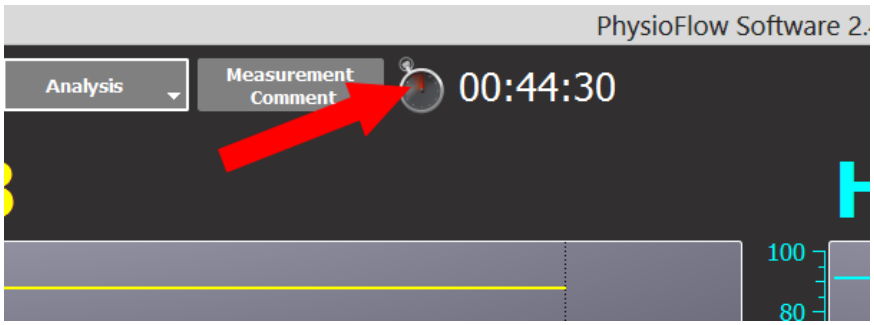
This window can be used to update/add comments related to the measurement. To prevent any error, users are asked for confirmation before any modification.

When this function is called all previous comments are loaded and displayed. Users can complete or modify any previous comments.

Measurement timestamp

Availability: **for both real time monitoring and reviewing**

It displays the relative or absolute time of the selected point on the physiological trends.



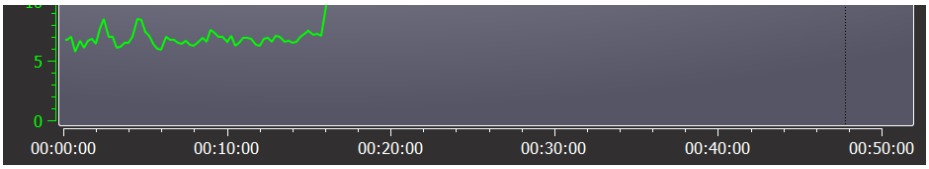
- By default the cursor is set to the last computed values and the time reflects the elapsed time since the beginning of the measurement.
- After clicking on a trend: The cursor is set accordingly to the click and the associated time is displayed. **During real time monitoring, the cursor returns automatically to the last value after 10 seconds**.
- By defaults the relative time is displayed. Double clicking on the chronometer image will switch all trends to absolute time (locale time of the computer).

  As a visual confirmation of the switch from relative time to absolute time the Icon image is changed to a clock.

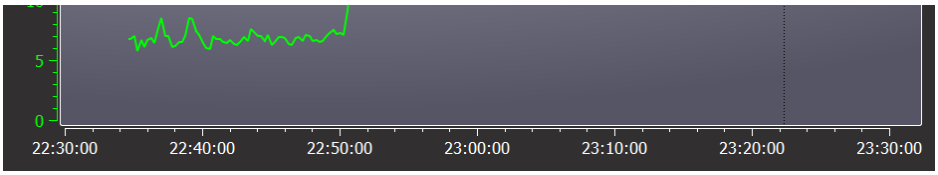
Another double-click switches back to relative timestamp display.

Note: A double-click on trends' time axis also switches the display from relative to absolute time and vice versa.

Relative time display on trend axis



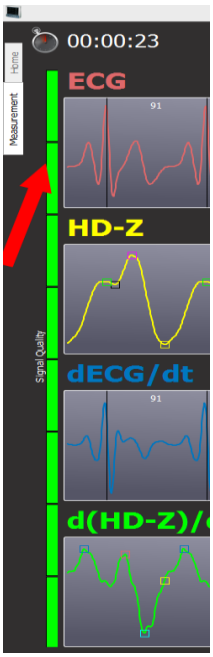
Absolute time display on trend axis

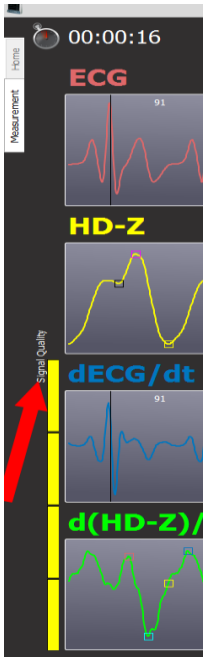


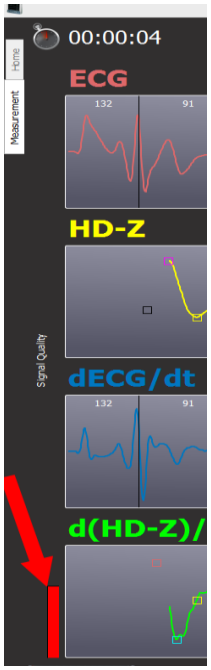
Signal stability indicator

Availability: **only during real time monitoring.**

Users must always pay attention to the signal quality indicator (it has to stay green during the measurement).







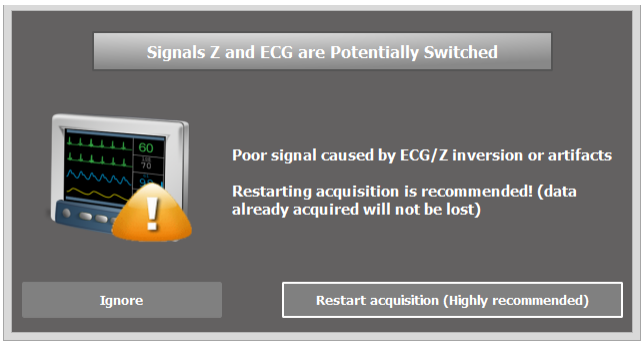
8 green squares:	Yellow squares:	Red squares:
Ideal quality of the signal	Low Stability	Poor / Incorrect Stability

If the signal quality looks questionable (artifacts, aberrant physiological values) the following points must be checked:

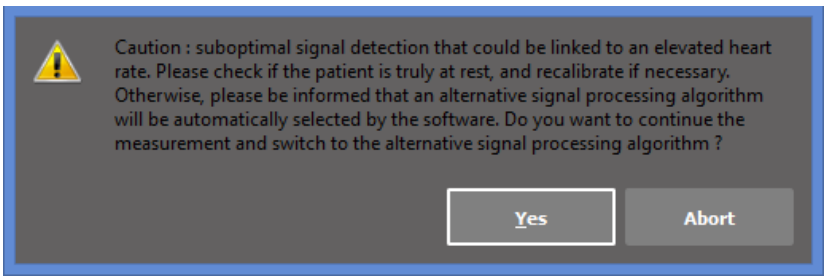
- Patient skin preparation
- Electrodes:
  - Recommended electrodes are used,
  - Expiration date has not passed
  - Positioning complies with recommendations

Signals switch or artificacts warning

For Lab1 devices, this message means that the ECG and Z signals are switched: ECG is displayed in the plot dedicated to the display of Z signal and vice versa. This message may be displayed for other devices if the signal quality is too bad or if it has too many artifacts. Those phenomena may be due to slow operating system because of an intrusive antivirus or something else).



Suboptimal signal detection warning

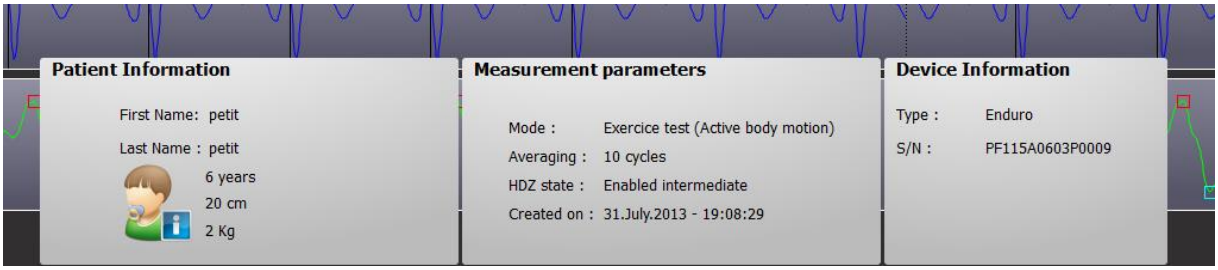


This message can be shown if the heart rate of the patient is relatively high, and if the measurement mode selected at the beginning of the procedure is “rest” or “heart surgery”. In this case please make sure that the appropriate measurement mode was selected. If not, click “Abort” and restart the measurement with the proper mode. Otherwise click “Yes”, an alternative signal processing algorithm adapted to the signals being measured will be automatically selected by the software.

Measurement information slide menu

Availability: **for both real time monitoring and reviewing**

Place the mouse cursor over the “Patient information” or “Measurement parameters” or “Device Information” title to display information related to the current measurement: patient information, measurement parameters summary and device used to acquire data. When the mouse is moved outside this information area, the menu slides back to its initial position.



Note: Device information and some measurement parameters like Averaging and HD-Z state are not available for imported measurement from PhysioFlow software v107 (previous generation)

Measurement configuration slide menu

This menu allows to access very quickly to most used feature of PhysioFlow software. The menu is divided in three sections:

- Physiological display.
- Trends Action Tools
  - Point selection
  - Zoom on trend
  - Linear regression
- Compare measurement

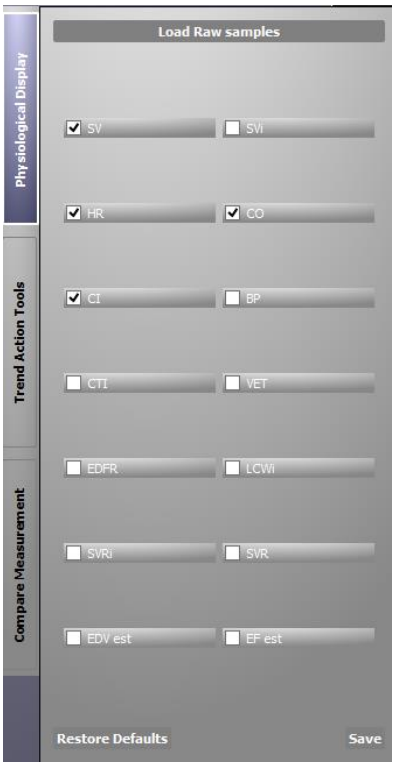
Place the mouse over any title of the configuration slide menu to display the corresponding menu.

When the mouse is moved outside of the menu, then the menu slides back to its initial position.

⚠	Users must pay attention to unwanted mouse. If the mouse cursor moves over another title menu, the other menu will be automatically displayed.

Physiological display

Availability: **for both real time monitoring and reviewing**



One parameter is added/removed to/from the main screen when ticking the associated check box.

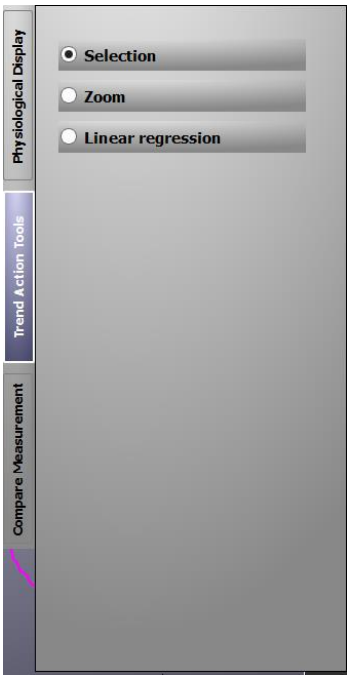
By default SV, HR, CO and Ci are displayed at the beginning of a measurement or when it is opened.

ECG, HDZ, dECG/dt and d(HDZ)/dt are directly available during monitoring. When reviewing a measurement, click on “Load raw samples” to add these graphs.

The BP checkbox display all blood pressures parameters: SABP, DABP and MABP.

Click on “Save” to save the currently checked parameters for next montoring or reviewing. Click on “Restore defaults” to go back to the last configuration saved.

Trend Action Tools



Availability: **for both real time monitoring and reviewing**

This menu allows selecting the action associated to mouse click on the trends.

Note: *Switching from a function to another on this menu will clear any previous action done with one of those tools.*

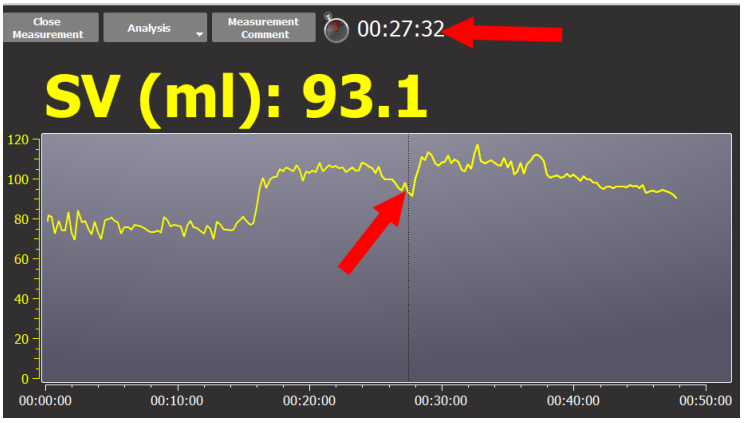
Selection

Availability: **for both real time monitoring and reviewing**

It allows displaying the value and timestamp of any point on the trends. Users just need to click on the desired point, and a marker is displayed to highlight the selected point. The selection is synchronized on all displayed trends.

Note: during real time monitoring the display lasts only 10 seconds before the cursor return to the last point in date.

Right-clicking on the plot clears the selection a removes the selection marker.



Zoom

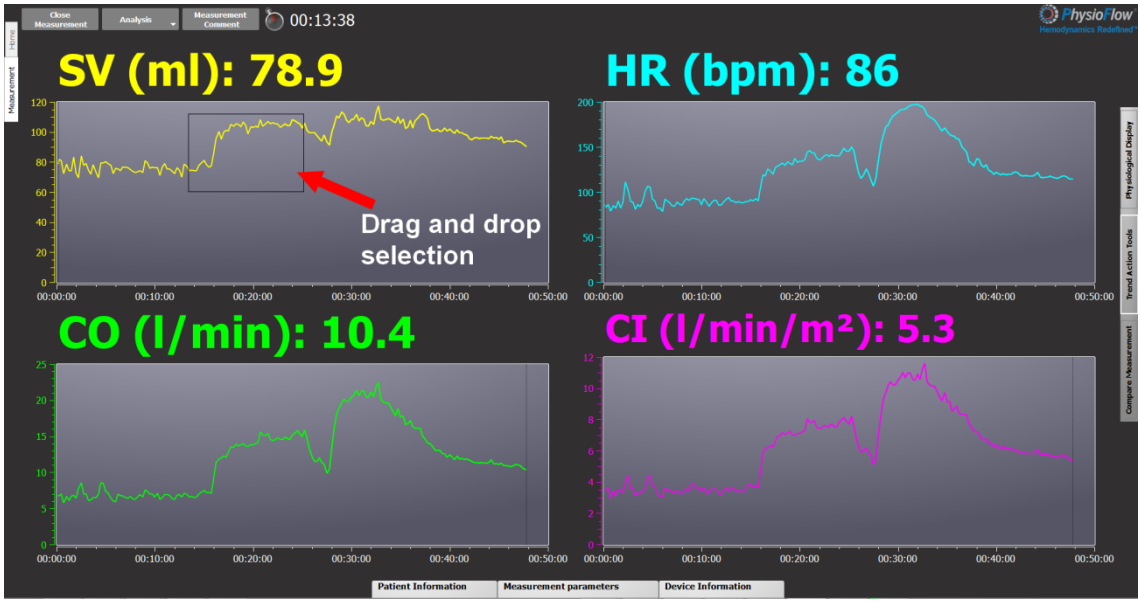
Availability: **only for measurement reviewing mode. During acquisition this option is visible but disabled.**

It allows selecting with a drag and dropping action any part of the curve of any trends to zoom on it.

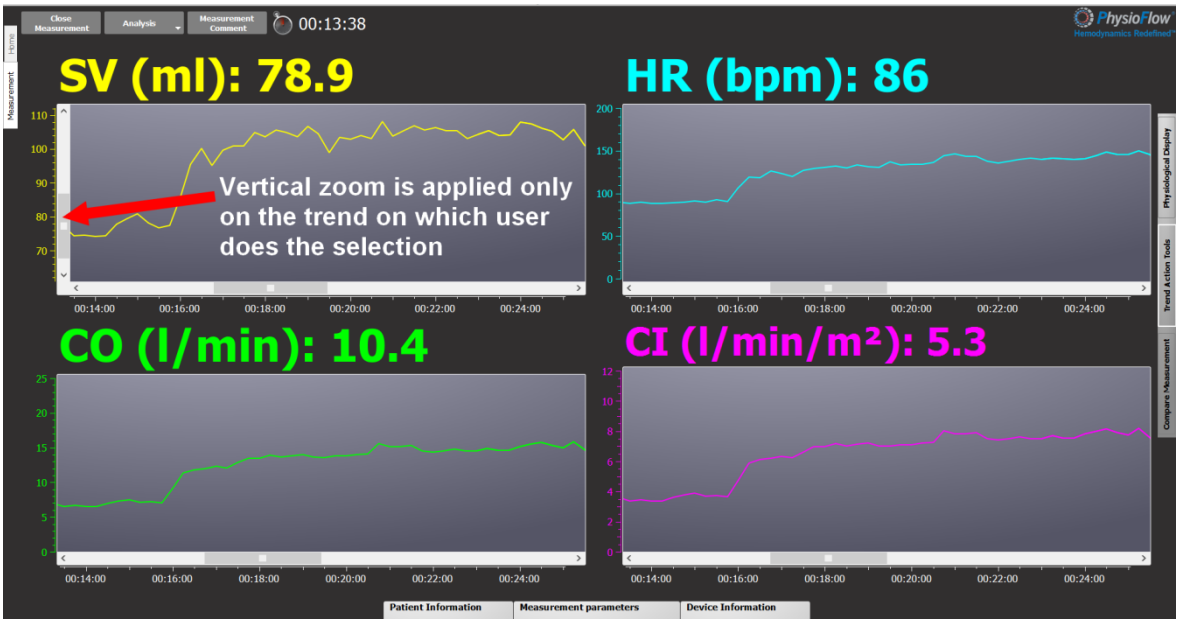
This procedure can be repeated to zoom on an already zoomed portion of the curve to enlarge details not visible with the first zoom action.

The zoom is synchronized on all displayed trends.

A right-click on any plot goes back to the original zoom.



After selection all trends are zoomed to selected zone : same beginning and ending timestamp. However the zoom is not applied on the vertical axis to all trends because physiological parameters have no compatible units.



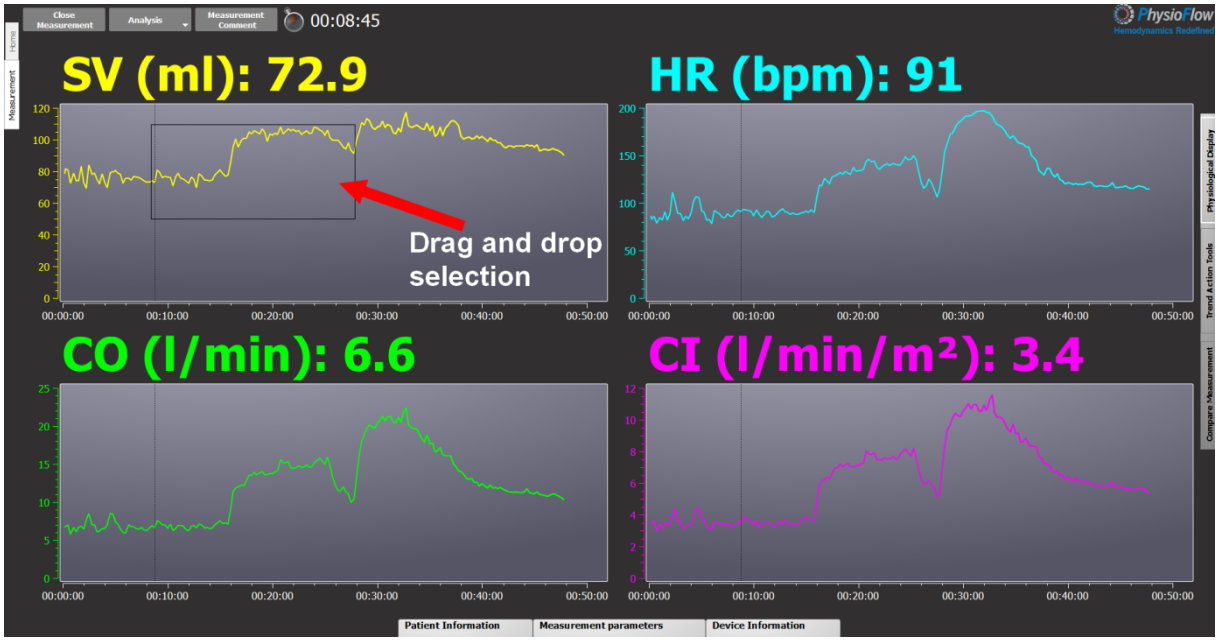
Linear regression

Availability: **only for measurement reviewing mode.**

It computes and displays the slope of the selected part of the curve, using the least square linear regression. The linear regression is synchronized on all displayed trends.

Note: linear regression is not applied nor displayed for time discreet parameters like BP.

Right-clicking on the plot hides all slope information and line.



Linear regression results are displayed in two forms:

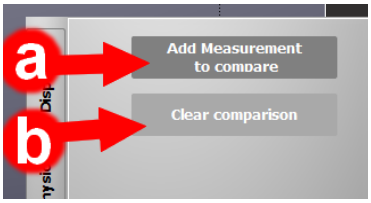
-numerical value for the average and slope on the lower part of the plot

-a line of the same color as the trend

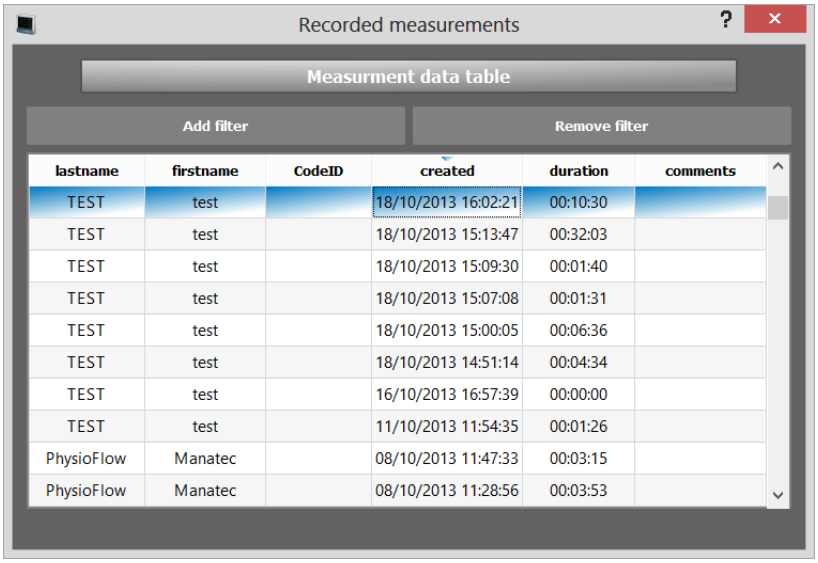
Compare measurement

Availability: **Only for reviewing measurement mode.**

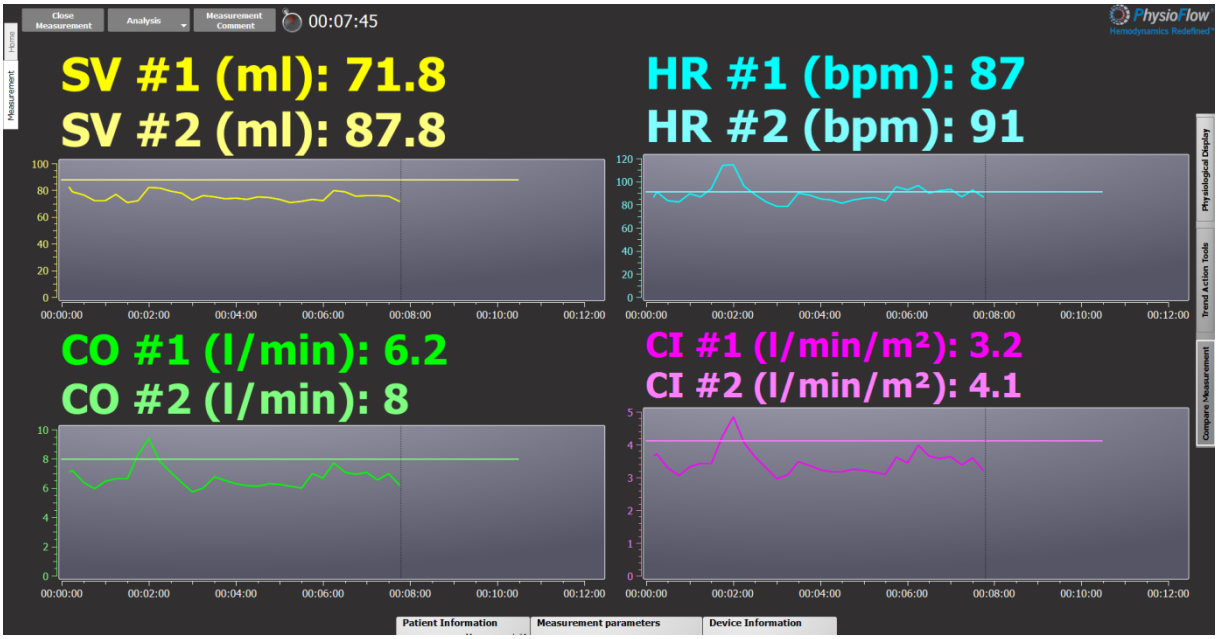
It allows choosing a second measurement to compare to the currently opened recording.



a) First step consists of selecting and opening the measurement to compare results with the currently opened recording.



After measurement selection the data is loaded and trends of both measurements are displayed



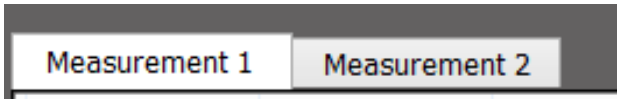
Values of both measurement are identified by index (the originaly opened measurement have index 1 and the measurement added for comparison have index 2).

⚠	*Measurement comments entered during this mode applies only to first measurement.*

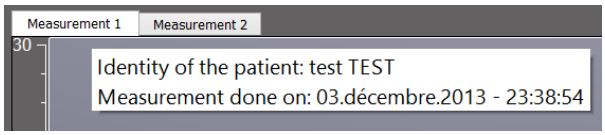
b) Once the comparison is finished, the « clear comparison » button will unload the second measurement and get back to the default display mode.

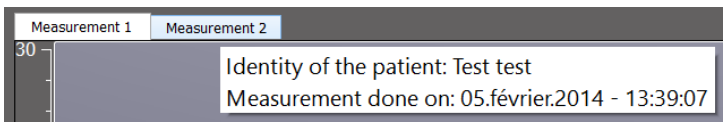
Some of the most popular feature or function are compatible with the measurement comparison mode however the data are not displayed simultanously on the same plot or table but they are displaied in separeted tab on the same window essentially for a matter of readability:

In the top of every window compatible with the comparison mode the tabs for each measurement are identified by index (the originaly opened measurement have index 1 and the measurement added for comparison have index 2).



When mouse cursor is mouved over one of those labels a popup window is displayed with the name of the patient and date of creation of the measurement (here an example with two measurments done on the same patient two months apart from one another) :





All compatible functions with the comparison mode are listed below:

Measurement information:

During measurements comparison a summary of both measurements information are available in the Measurement Information section (Patient Information, Measurement Parameters and Device Information).

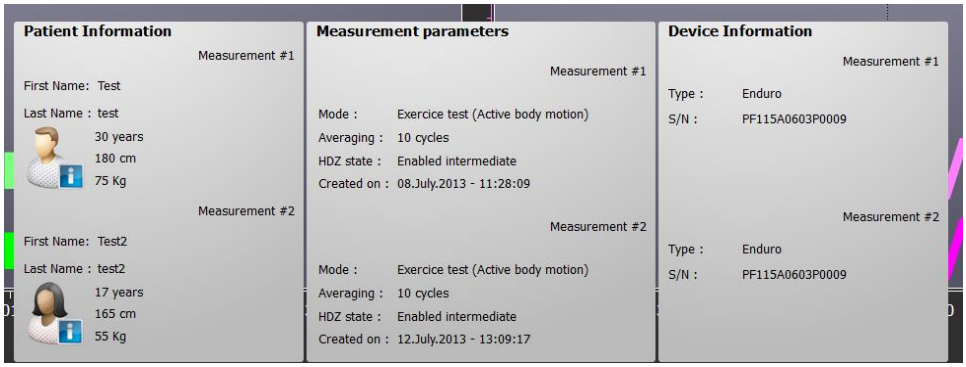
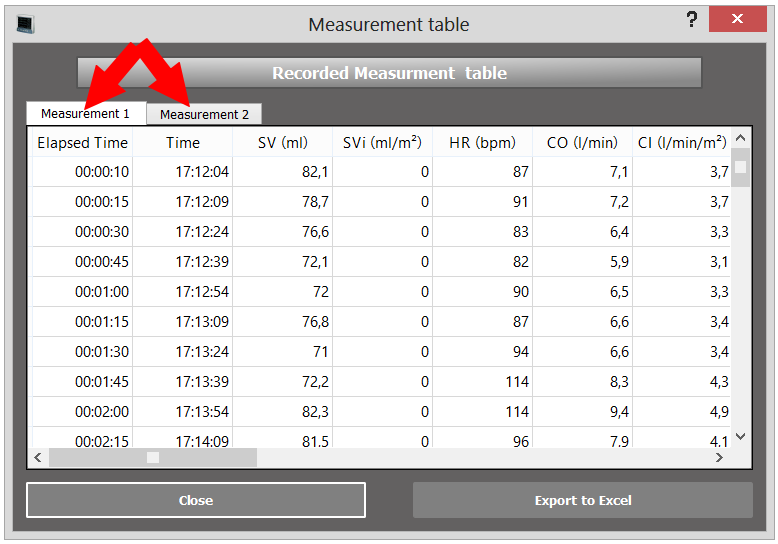


Table display mode:

The second measurement table is available via the tab menu showed below:

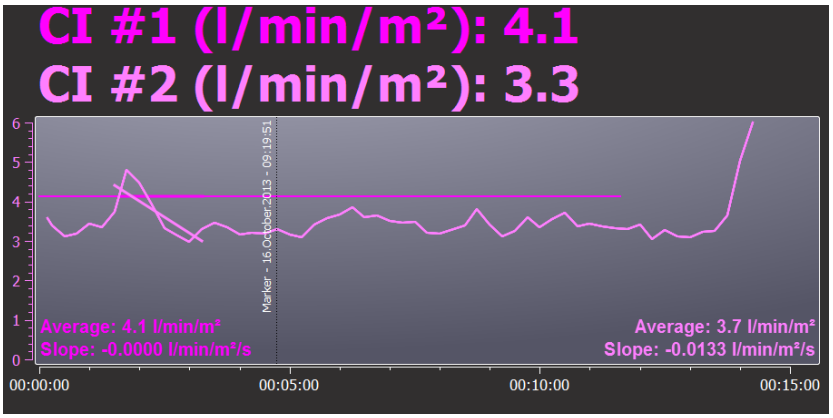


Elapsed Time	Time	SV (ml)	SVi (ml/m²)	HR (bpm)	CO (l/min)	CI (l/min/m²)
00:00:10	17:12:04	82,1	0	87	7,1	3,7
00:00:15	17:12:09	78,7	0	91	7,2	3,7
00:00:30	17:12:24	76,6	0	83	6,4	3,3
00:00:45	17:12:39	72,1	0	82	5,9	3,1
00:01:00	17:12:54	72	0	90	6,5	3,3
00:01:15	17:13:09	76,8	0	87	6,6	3,4
00:01:30	17:13:24	71	0	94	6,6	3,4
00:01:45	17:13:39	72,2	0	114	8,3	4,3
00:02:00	17:13:54	82,3	0	114	9,4	4,9
00:02:15	17:14:09	81,5	0	96	7,9	4,1

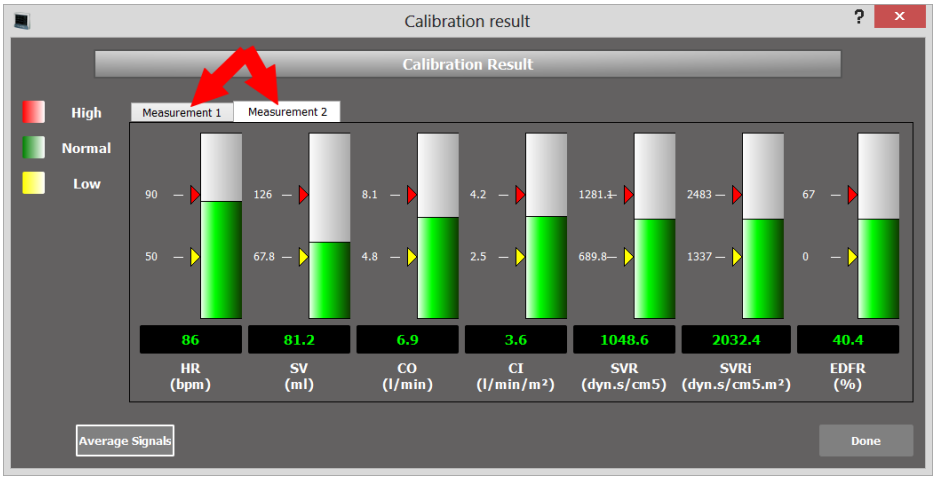
Note : Same thing for Excel export, two spreadsheet will be exported.

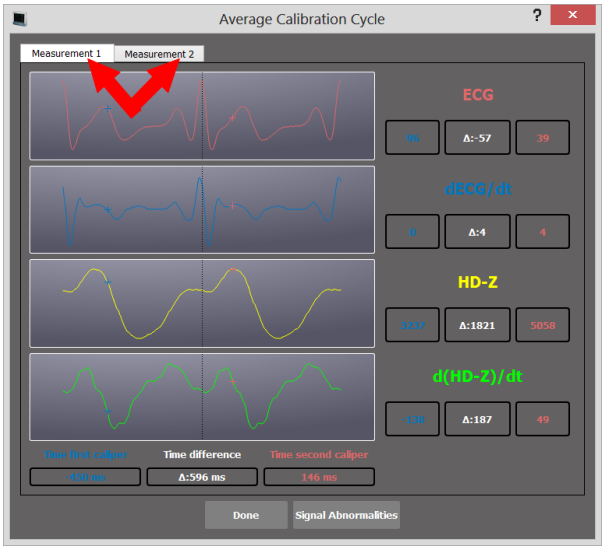
Selection, Zoom and linear regression:

When any of the Trend action tool feature is used, it applies to both measurements. The example below shows a linear regression where the values on the bottom left are for the original measurement and values on the bottom right are for the measurement added for comparison.

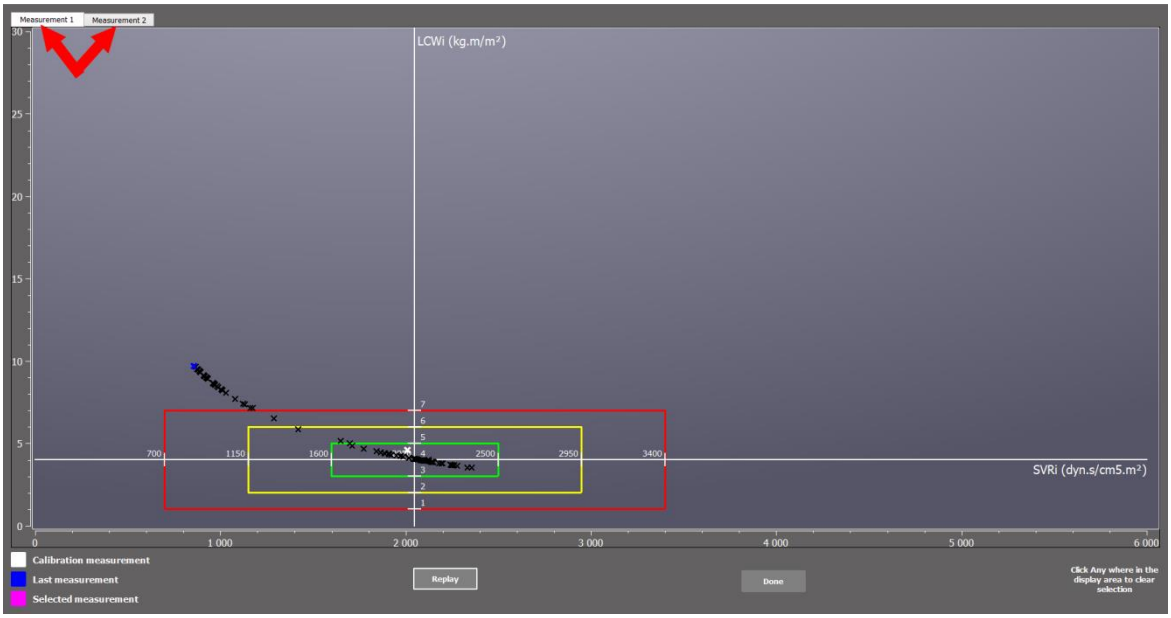


Calibration results:

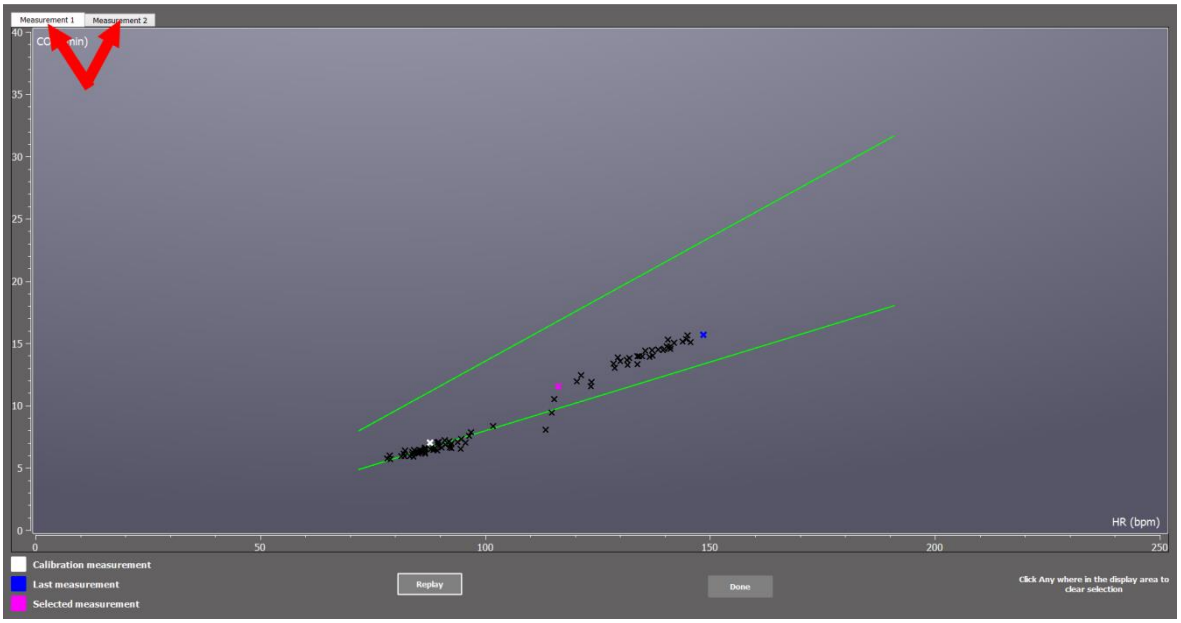




Hemodynamic Cross:



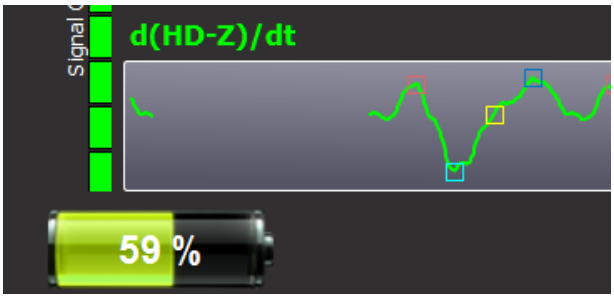
HemoDynamic performance graph:



Battery level indicator (For Enduro devices only)

Availability: **only for real time monitoring mode when an Enduro device is used.**

The battery level indicator change color accordingly to battery level to help users identify quickly batteries state. The battery level is an approximation of the battery state and loses precision if the batteries have done too much charging cycles.



. If some reason batteries state can be retrieved or are obviously aberrant this image is displayed.

⚠	*Battery level indicator is specifically designed to predict state of rechargeable batteries. For high level performance batteries like Energizer Ultimate Lithium this indicator is not completely reliable so users should rather not take it into account in this case and keep in mind that Energizer Ultimate Lithium last about 8 hours of measurement.*

Disk space warning message

Availability: **This window can be displayed at software launch or during a real time monitoring measurement.**

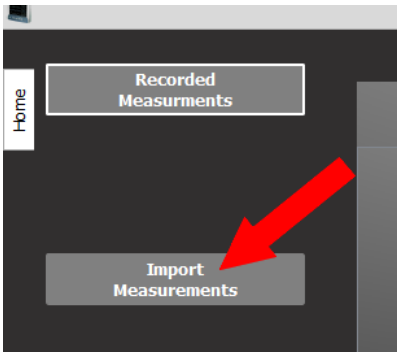
The PhysioFlow software records locally on the hard drive all the data gathered by the device and so needs a certain amount of disk space to work properly and to store data. The minimum recommended level of free disk space is 10 Gigabytes. If the PC reaches an amount of free disk space inferior to that limit a message is displayed to user asking to make some available disk space. At this stage the software is still enable to acquire data but it's strongly recommend to follow instructions and freeing disk space.

If the disk space is lower than 250 Megabytes the software may lose data of the measurement in progress and subject to unexpected behavior and crashes. Also available device are no more detectable. A message is displayed explaining that freeing disk space is now mandatory to continue acquiring data with the currently running measurement or for any PhysioFlow software activity.

Import data from PhysioFlow software

<u>Availability</u>: on the software home screen.

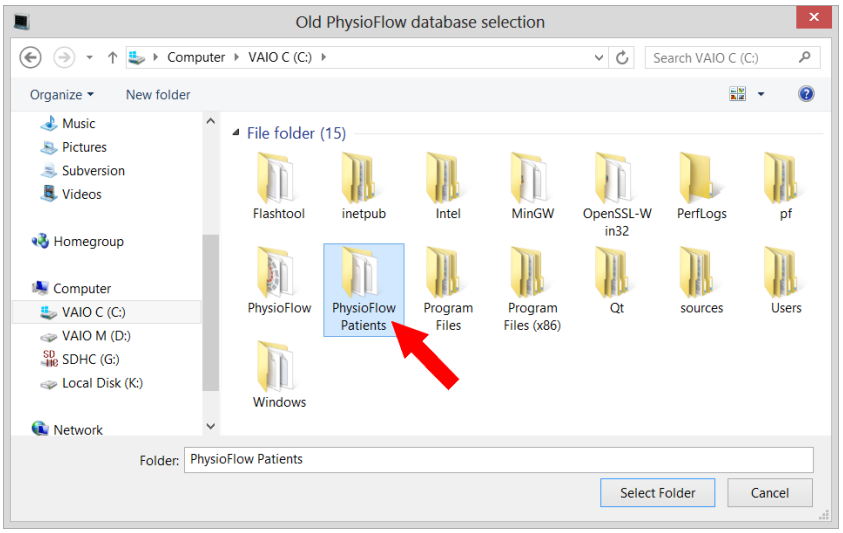
This function allows retrieving PhysioFlow data from source directory and storing it in the software data base.



Users who want to import data exported by any other users also using PhysioFlow software 2.x.x can choose the source “New PhysioFlow Software 2.x.y”, and users of previous generation V10x PhysioFlow software can choose the source “PhysioFlow Software v107 (previous generation)”.

<u>Note:</u> Device information and some measurement parameters like Averaging and HD-Z state, and data from signals preview and calibration are not available for measurement imported from PhysioFlow software v107 (previous generation)

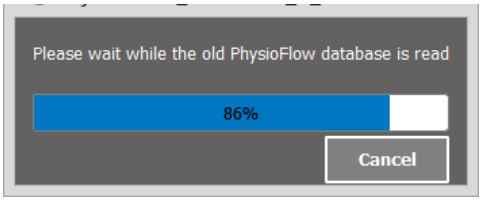
1. In case the source is PhysioFlow Software 2.x.y, select the pfdz or pfd file which has been exported. In case the source is PhisioFlow software v107, select the directory of the patient database of the previous generation PhysioFlow software. The click on the “Select folder” button.



⚠	*Users must select a folder, not a file. The folder must contain at least a .PFP file and a sub-folder with the same name containing at least one file for each of the following extensions: .PFS, .PFM and, .PFK*

⚠	Previous generation V1.x.x PhysioFlow software patient *data base is located by default in :* *C:\PhysioFlow Patients*

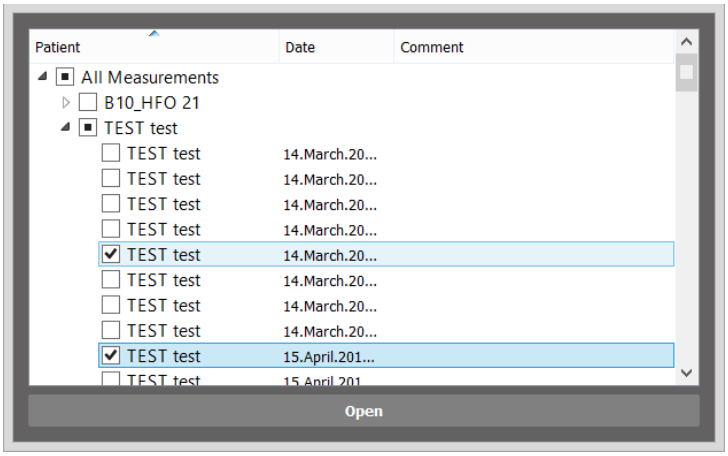
2. The software shows the progression of the folder analysis



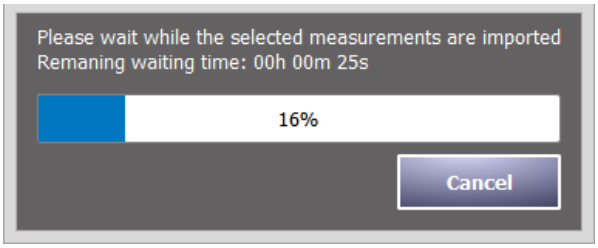
3. After the analysis the software shows a window with all patients in the data base and their associated measurement. This window allows selecting which measurements to import.

   The software allows selecting all or only some of the measurements contained in the previous software generation data base. The measurement can be sorted by their date of creation or by their comment.

   Users can all select the “All measurements” option and then import all data from all patients contained in the data base.

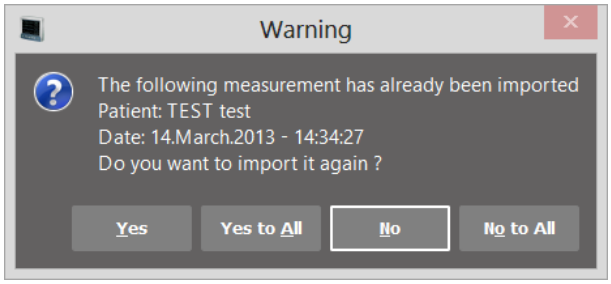


4. The software shows the progression of the data import

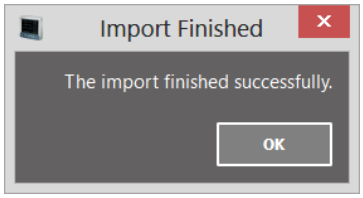


According to data base size this procedure can take some time so the software displays the progress percentage and an estimation of the remaining time until the end of the procedure.

If selected measurement are already in data base, the software will detect it and ask users what to do:



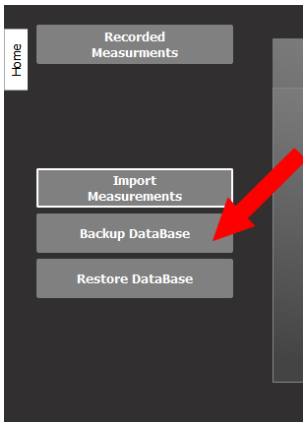
5. Once the import is done, the software shows a success message.



⚠	*Some informations and data are not available for imported measurements from previousPhysioFlow software generation v107:* ▪ *All Device information* ▪ *Averaging value* ▪ *HD-Z state*

Backup software data base

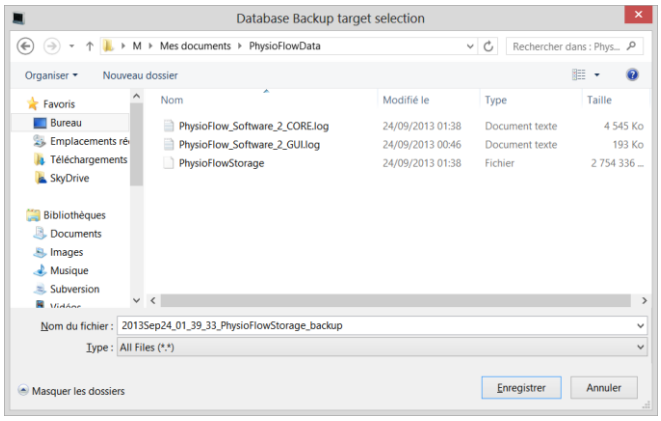
Availability: **on the software home screen.**



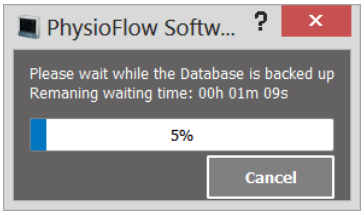
It is strongly recommended to back up the database regularly to prevent any data loss in case of PC crash or hard drive failure. The backup should be stored in an external drive when possible.

User may also select a specific directory for PhysioFlow backup as the backup files have no extension it may be difficult to find those files if mixed with other type of file.

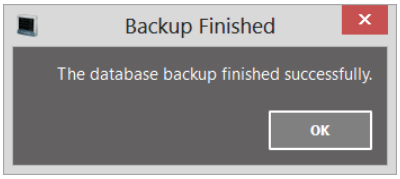
First step is to select the directory to store the backup file.



Backup process progress: according to data base size this procedure can take some time so the the software display an estimation of the remaining time to the end of the procedure in addition to the percentage of advancement.

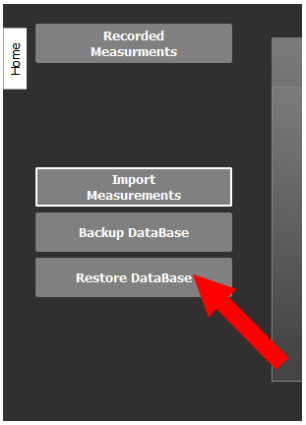


Success message at the end of the procedure



Restore software data base

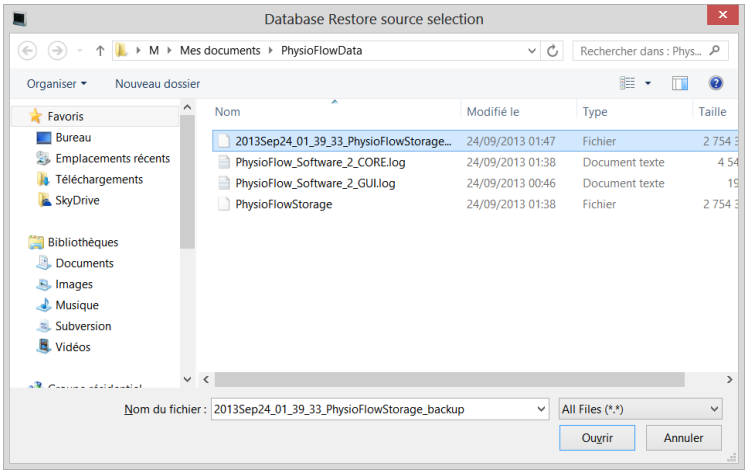
<u>Availability</u>: on the software home screen.



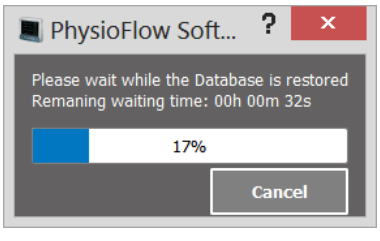
It allows restoring software data base from previous backup.

⚠	All the measurements recorded between the date of the backup and the date of the restore will be irremediably lost.

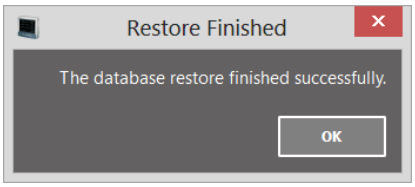
First step is to select the file containing a backup created with the procedure described in the <u>backup software data base</u> section.



Restore process progress: according to data base size this procedure can take some time so the the software display an estimation of the remaining time to the end of the procedure in addition to the percentage of advancement.



Success message at the end of the procedure.



10. Standalone measurement (For Enduro devices only)

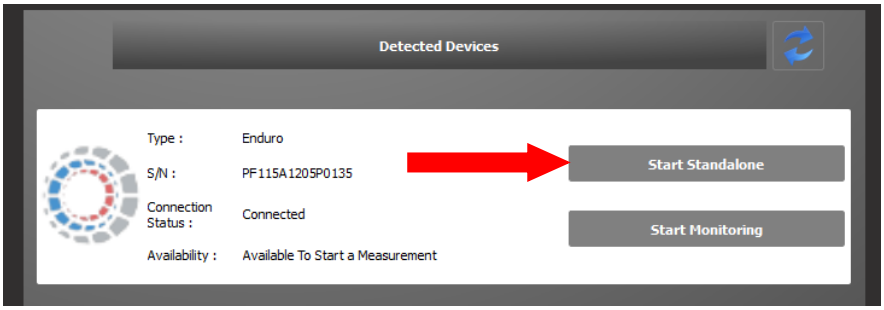
General information

Standalone acquisition provides a solution to users who cannot keep the patient and Enduro device within the Bluetooth transmission range. In this mode, measurement data is stored in the device's internal memory. When the measurement is finished, users have to run an additional download operation to retrieve data on the host PC data base and then review the recording. Downloading time depends on the acquisition duration.

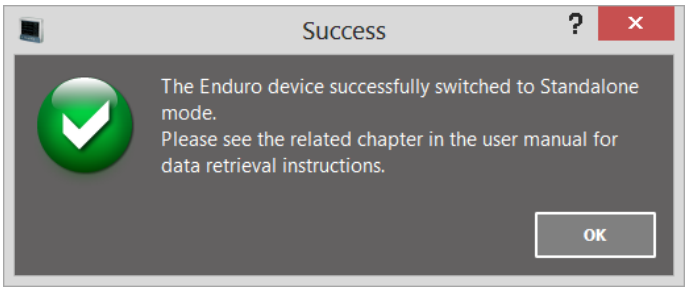
⚠	*The downloading time is roughly half the measurement duration time with Bluetooth and it can be slightly faster with a download through USB interface*

Start standalone measurement

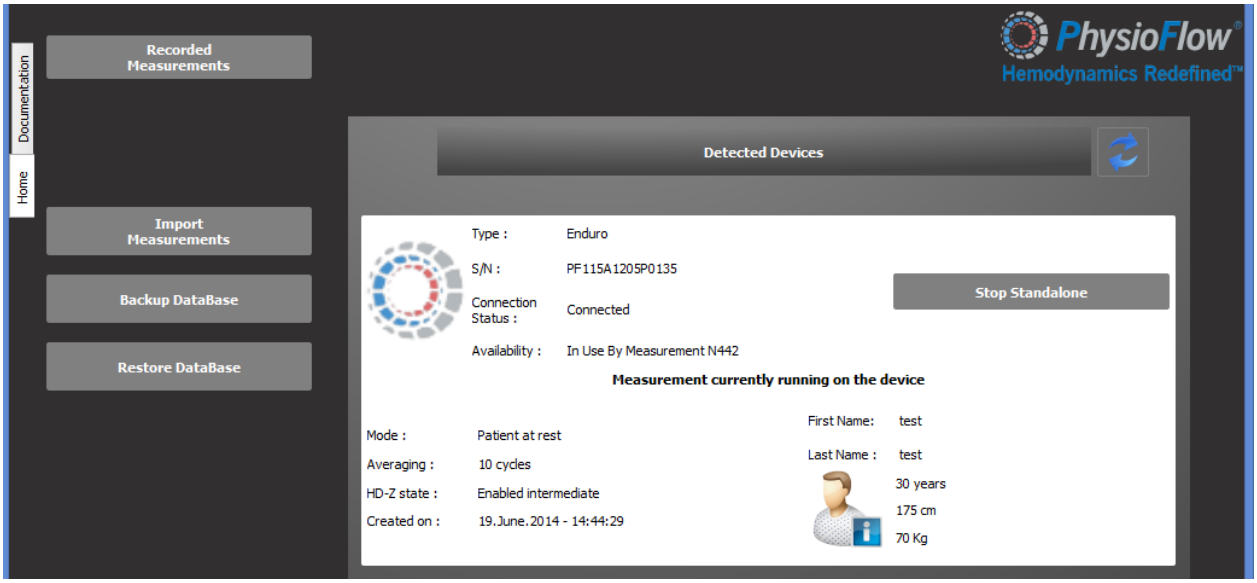
The measurement must be started with "Start Standalone" button.



After that, the procedure described in the start a measurement chapter applies also to start a standalone measurement. After calibration results the software displays a success message confirming the switch of the Enduro device to the standalone acquisition



When the Ok button is clicked then the main screen is displayed. The device's state in the device information section is updated. The only possible action is « Stop Standalone ». It is not possible to start any other operation while a standalone mode is running on a device.



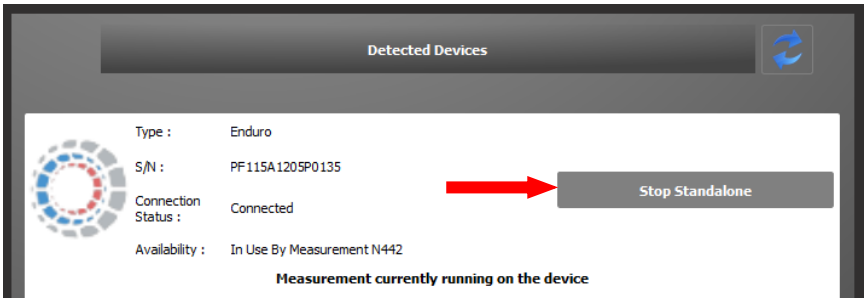
At this point users can either let the software running or close the application.

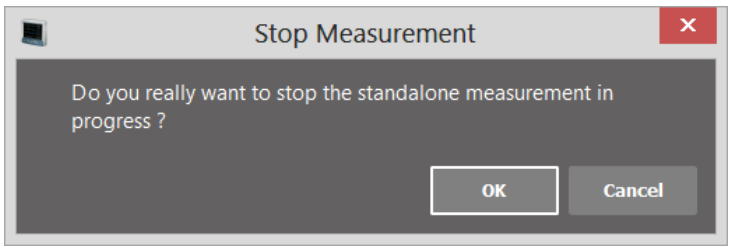
⚠	*If the software is restarted the patient and measurement information will no more be available neither displayed for the currently running standalone measurement. User will be able only to stop themeasurement.*

Stop Standalone measurement

At the end of the standalone session, to stop the on-going measurement:

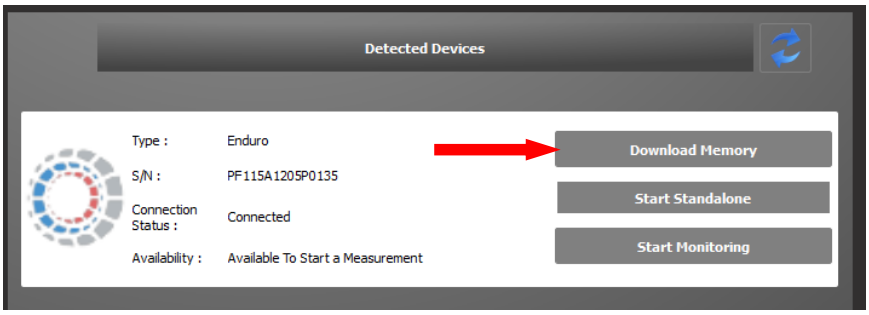
- Launch the software, wait for device detection and click on the "Stop Standalone" button. The button is only available if a standalone measurement is in progress.



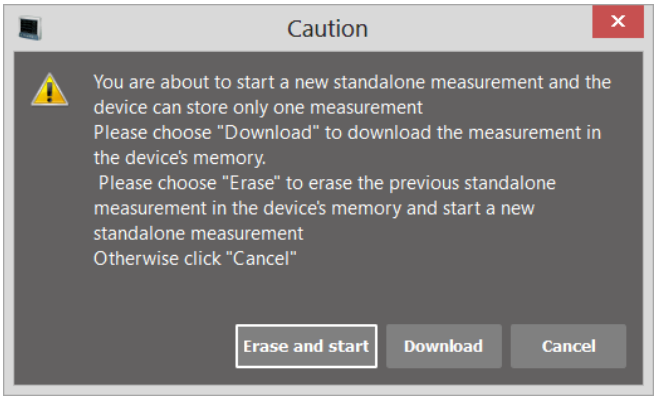

Stop Measurement
Do you really want to stop the standalone measurement in progress ?
OK
Cancel

Steps to retrieve Standalone measurement data

1. If needed Stop the standalone measurement (refer to “Stop Standalone ” section)
2. When a standalone measurement is stored in the Enduro’s internal memory, the following actions are displayed in the device information section.



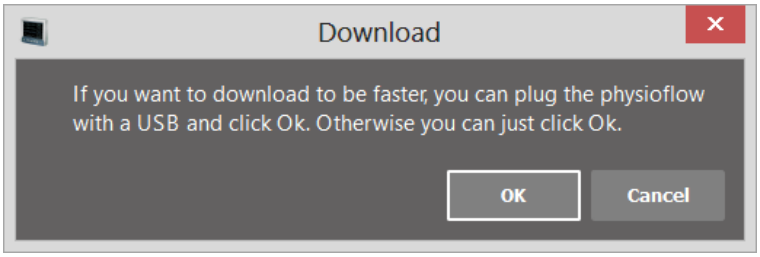
- **Start Monitoring**: It is possible to start a real time monitoring measurement without downloading the data. Recorded information in internal memory will not be erased or affected.
- **Start a standalone**: if internal memory is not empty a new window is displayed. The following options are available to users:



- **Erase and start**: Previous data are lost and a new Standalone procedure is launched.
- **Download**: Download memory procedure is launched. Standalone mode procedure is aborted.
- **Cancel**: Standalone mode procedure is aborted.

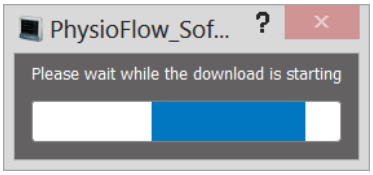
⚠	*Only one standalone measurement can be stored in the internal memory. To avoid data loss it is mandatory to download data before starting a new standalone measurement.*

- **Download memory**: When the button is clicked the following window is displayed:

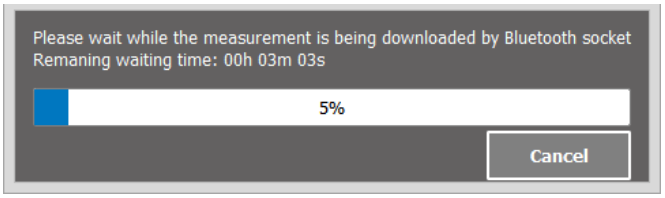


Bluetooth interface is selected by default to download the memory. To use USB interface, plug the USB cable before clicking the Ok button. Communication link selection is automatic and no configuration is required.

3. The measurement is downloaded.

⚠	It can take few minutes for a download to start so user has to be patient until the download begins. 

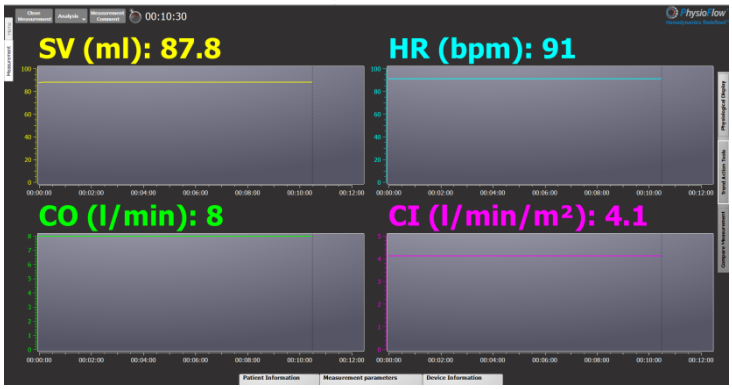
Download progress window : according measurement duration this procedure can take some time so the software display an estimation of the remaining time to the end of the procedure in addition to the percentage of advancement.



The software displays on which communication interface the file is downloaded.

If for any reason the download is interrupted (batteries removed, USB cable unplugged, software closed etc.), the next download will start from the point it stopped. It may however take slightly longer before the download actually starts.

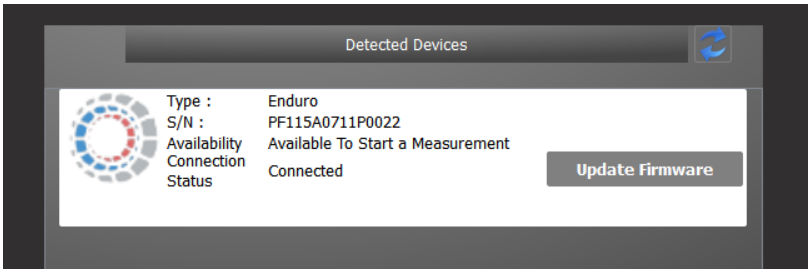
4. The measurement is stored in the database and opened automatically. It can be re-opened at any time. (Please refer to “Reviewing acquisition” section for more information).



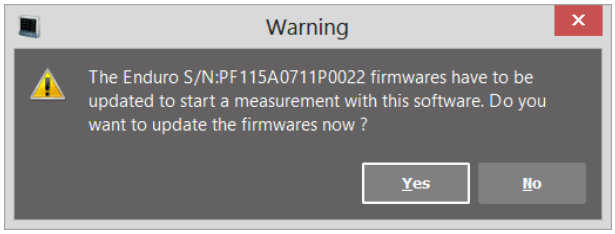
11. Enduro and Q-Link Firmware Update

The software detects automatically when the device needs a firmware update and displays the "Update Firmware" button instead of the usual "Start Monitoring" and "Start Standalone" buttons.

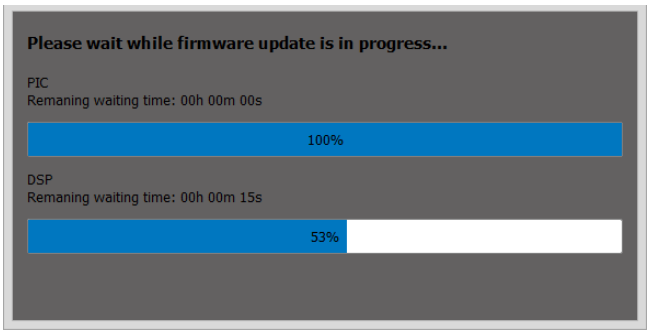
Note: The firmware for the new PhysioFlow software 2.x.x is not compatible with the previous generation v1xx software, so users have to make sure that the device is no more needed to operate with the PhysioFlow software V107. For more information regarding the relevance of updating a PhysioFlow device firmware or not please contact Physioflow technical service (support@physioflow.com).



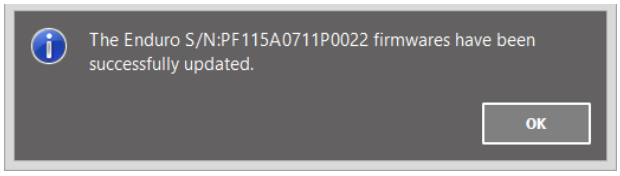
At the beginning of the procedure a message reminds that no other operation will be available for the device until the firmware update is completed.



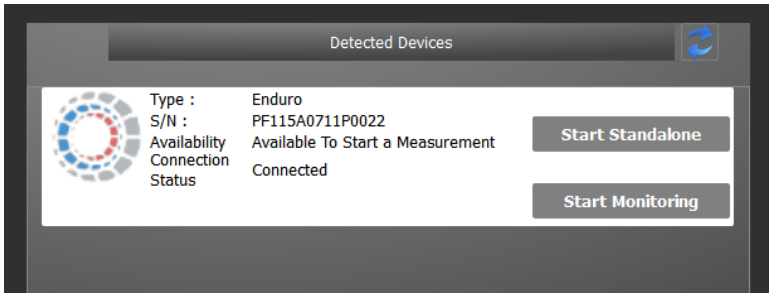
The update consists of uploding new firmware in two steps. Users must wait until the data are completely transfered for both PIC and DSP as follow (remaining time is displaied for every step) :



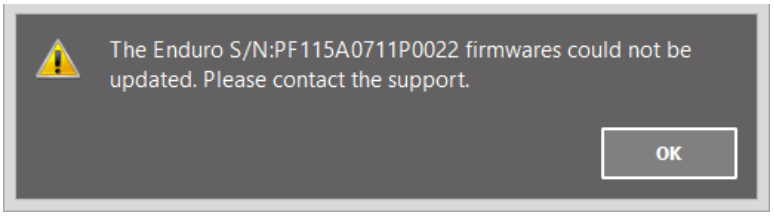
If the procedure succeeds a message is displayed at the end of the operation.



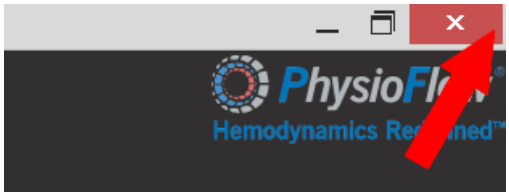
The device should now display availables procedures :



If for some reason the update fails, a message will invite users to contact Physioflow technical service (support@physioflow.com).

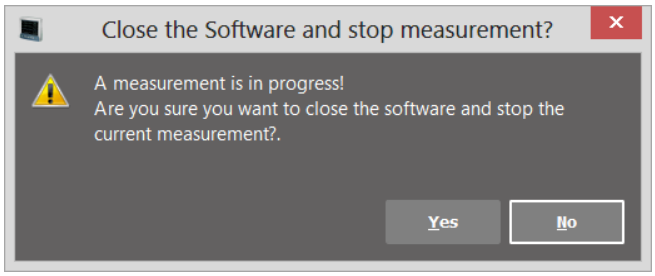


12. Exit the software

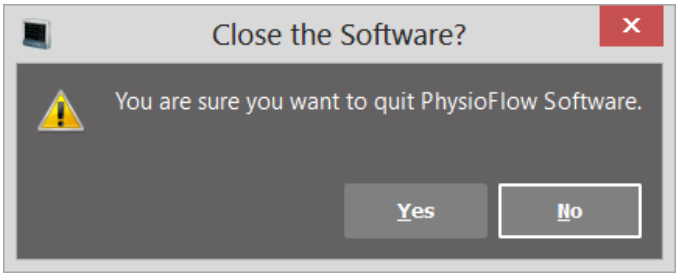


Software can be closed by clicking on the usual “close icon” (upper right side on Tool Bar).

- If a measurement is in progress: a message asks the operator to close the on-going monitoring before leaving the software. If the Yes button is clicked then the measurement is stopped and software is closed

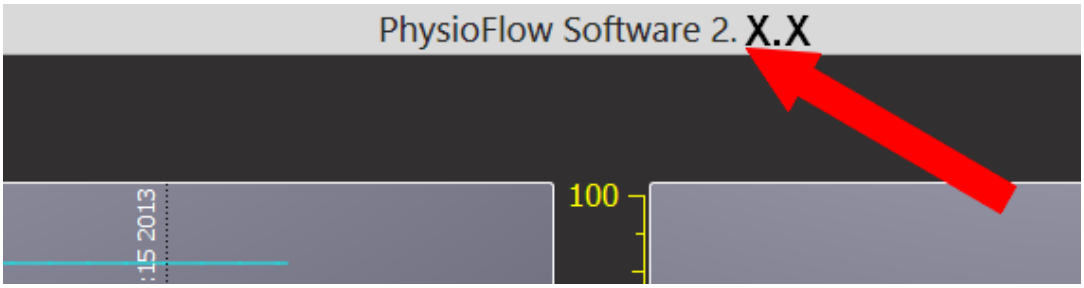


- If no measurement is running the following message is displayed before closing the software:



13. Identification of the PhysioFlow software V2

To know the version of the PhysioFlow software installed on the computer, launch the software by double clicking on the desktop shortcut "PhysioFlow Software". Once the software is launched the version can be read in the title bar as shown below:

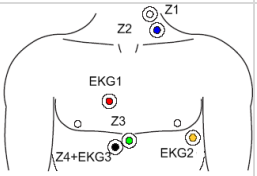


Note: For any further information, please contact PhysioFlow technical service (support@physioflow.com).

PhysioFlow V2 software update is made through an installer. The process is identical to the one described in the "*Software Installation*" section. The installation of a new version of the software replaces the previous one without affecting data recorded on the computer.

Appendix A: Patient Measurement Summary

This table summarizes the steps required for the proper measurement operations. The checkbox allows the operator to validate the current step to ensure that nothing has been neglected.

	Validation
1 – Shave the patient where electrodes are positioned *NB: For the stress tests, apply the black and green electrodes in the back (Cf Chapter 5 for position).* 	☐
2 – Clean the patient skin with alcohol (an additional cleaning with the abrasive gel Nuprep is highly recommended for more effective skin prep)	☐
3 – Clip the PhysioFlow PF50 electrodes onto the patient cable; avoid pressing the part with the gel.	☐
4 – Attach the electrodes to the chest according to the "chest example" above. (Position to adapt depending on the measurement: at rest or during a stress test).	☐
5 – Attach the patient cable to the PhysioFlow Device. **For Enduro devices:** Pass the device patient cable interface through the purse opening. Once Enduro and patient cable are connected, insert the system in the purse.	☐
6 – **For Enduro devices:** Plug recommended Bluetooth dongle to the PC and place fully charged batteries in the device. **For QLink devices:** Plug device USB cable to the PC. **For Lab1 devices:** Plug USB to Serial adapter to lab1 and then to the PC.	☐
7 – **For Enduro and Qlink devices:** Wait until the LED indicator is green. **For Lab1 devices:** Switch the device ON by pluging the power cable to the main supply and check that power button is ON. **Common to all device :** Launch PhysioFlow Software V2.x.x	☐
8 – From this moment until the end of the calibration, the patient should remain calm and not move.	☐
9 – Once the device is detected by the software press "Start Monitoring" button. **For Enduro devices:** "Start Standalone" button is also available	☐
10 – Select or create the patient	☐
11 – Select patient parameters.	☐
12 – Read and validate recommendations	☐

13 – Once signals are stable click “Proceed to calibration” button	☐
14 – Take patient’s blood and enter values and then click next.	☐
15 – Calibration results are then displayed. Measurement session can be started (real time monitoring or for Enduro devices only it can be a standalone measurement). For further analysis, it is strongly recommended that the patient stay calm during an additional minute.	☐

	DO NOT USE THE PHYSIOFLOW SYSTEM WHEN A DEFIBRILLATOR IS CONNECTED TO THE PATIENT. ***THE PATIENT CABLE, THE DEVICE AND THE USB CABLE MUST NEVER COME INTO CONTACT WITH THE PATIENT DURING DEFIBRILLATION****.*

Appendix B: Performances and limits of physiological parameters

The table below shows the limits applicable to a patient at rest in supine position

Parameter	Unity	Lower value	Average value	High Value	Precision
Heart rate (HR)	bpm	20	72	220	1%
Systolic Volume (Sv)	mL	0	85	220	3.7%
Cardiac Output (CO)	L/min	0	6.0	40	4.8%
Cardiac Index (CI)	L/min/m²	0	3.3	20	4.8%
Contractility Index (CTI)	None	4	120	3000	4.2%
Ventricular Ejection Time(VET)	ms	43	300	573	1%
Ejection Fraction (EF)	%	10	62	92	1%
End Diastolic Volume (EDV)	mL	0		300	3.8%
Systolic Arterial Pressure (SAP)	mmHg	20	120	330	The accuracy depends on the device used to monitor BP
Mean Arterial Pressure (MAP)	mmHg	20	144	330	
Diastolic Arterial Pressure (DAP)	mmHg	20	80	330	
Index (SVRi)	Dyn.s/cm^5.m²	0	2050	6000	
Systemic Vascular Resistance (SVR)	Dyn.s/cm^5	0	1135	3000	
Cardiac Work index (CWi)	kg.m/m²	0	4.0	30	
Stoke Volume Variation (SVV)	%	0	7	15	1%
Early Diastolic Filling Ratio (EDFR)	None	0	33	300	1%
Thoracic Fluid Index (TFi)[1]	Ohm	15		60	4.2%
Thoracic Fluid Content (TFC)[1]	/kOhm	16		66	4.2%
Thoracic Fluid Content index (TFCi)[1]	/kOhm/m²	8		33	4.2%

[1] These physiological parameters are not available on LAB1, and may not be available on Q-Link and Enduro depending on the device's hardware configuration. If you need to measure one of these parameters, please contact Physioflow (support@physioflow.com)