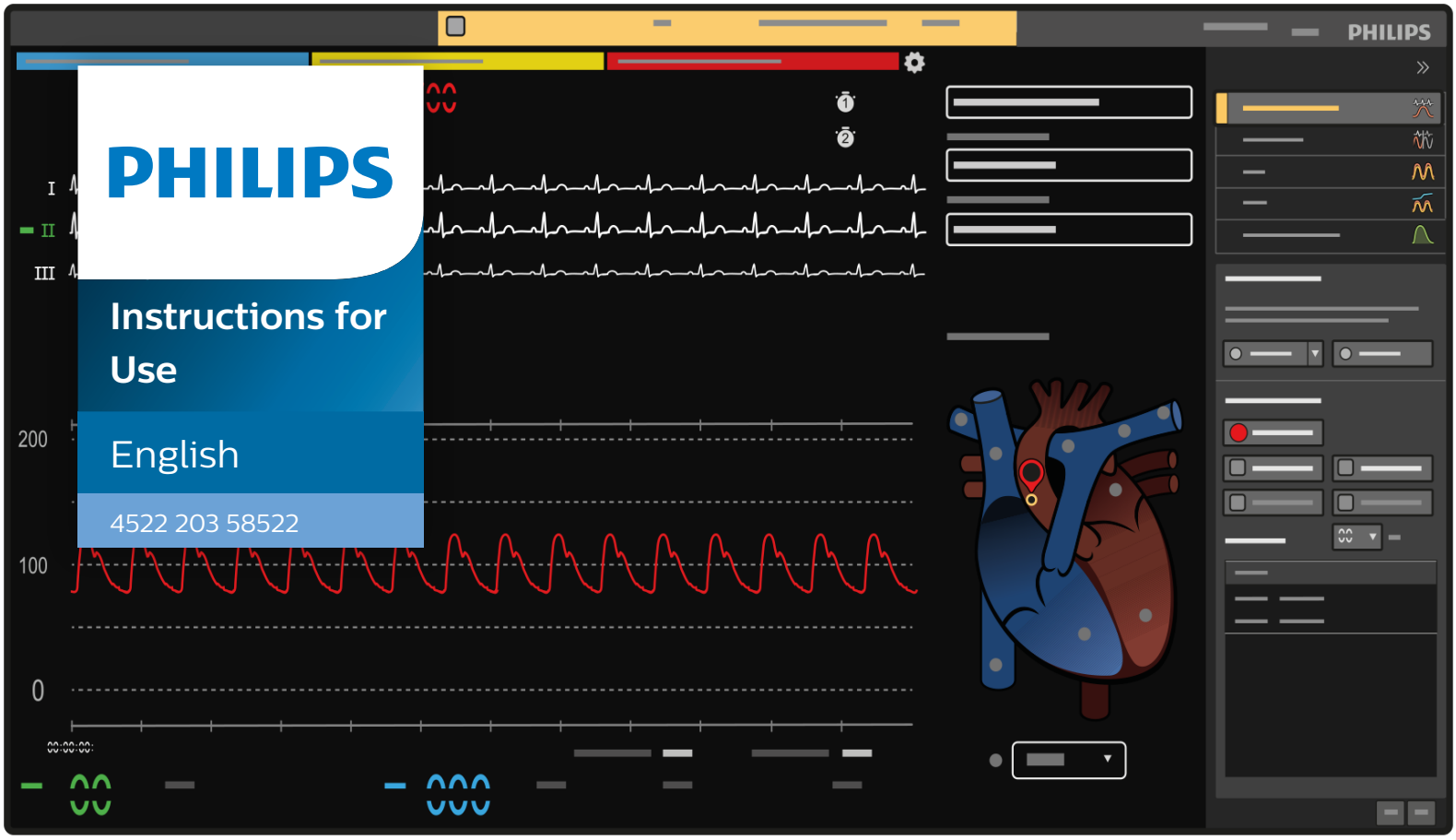

Philips Hemodynamic Application

Release 1.0

Contents

1 Introduction

Before attempting to operate the product, you must read these Instructions for Use.

1.1 About Philips Hemodynamic Application

The Philips Hemodynamic Application is medical device software that enables invasive investigation of cardiac and vascular disease.

When installed on a host computer with compatible Xper Information Management software and the host computer is connected to a compatible patient monitoring device, the combination provides full patient monitoring and hemodynamic analyses functionality. This combination is known as the Philips Interventional Hemodynamic System.

The Philips Hemodynamic Application provides the following functionality:

- Visualizing and analyzing surface electrocardiogram, respiration, invasive pressure, pulse oximetry (SpO_2), end tidal carbon dioxide (CO_2), non-invasive blood pressure, and body surface temperature
- Calculating valve area, valve gradient, thermal cardiac output, and physiological measurements (FFR/iFR)
- Interfacing with a compatible patient monitoring device for controlling and receiving the physiological signals and alarms from the patient monitoring device
- Interfacing to a compatible Xper Information Management version to provide data for:
  - Patient administration and data management such as charting, data analysis, or registration
  - Printing and archiving
  - Additional hemodynamic calculations

Users of the Philips Hemodynamic Application, as defined in the Intended Use, are responsible for interpreting the data made available. The data is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, and other clinical findings.

The software is intended for use on standard computer systems and does not require proprietary hardware.

1.2 About these Instructions for Use

These Instructions for Use are intended to assist operators in the safe and effective operation of the product described. The "responsible organization" is considered to be the body with authority over the product and "operators" are those persons who actually use the product.

To identify the Instructions for Use and the software tool for which they are intended to be used, the product can be identified using the **About** box of the related software tool. The **About** box indicates the following:

- Name of the software tool
- Release number of the software tool

All Instructions for Use supplied with the software tool are identified using the name and release number (first two digits) of the software tool, as indicated in the footer of the document or on the **Home** page of the electronic Instructions for Use. Before using these Instructions for Use with your system, ensure that it corresponds with the software tool installed.

The Philips Interventional Hemodynamic System is a hemodynamic monitoring system consisting of a patient monitoring device and a host PC on which applicable Xper Information Management software modules and the Philips Hemodynamic Application software are installed. These Instructions for Use

only describe the use of the Philips Hemodynamic Application software. Both Xper Information Management and the patient monitoring device have separate Instructions for Use.

Specific information about the patient monitoring device like hardware description, connection of catheters, warnings, alarms, boundary conditions, and cleaning can be found in the Instructions for Use for the Xper Flex Cardio Physiomonitoring System.

Specific information about patient administration, data management, printing and archiving, and additional hemodynamic calculations can be found in the Instructions for Use for Xper Information Management.

This manual may describe some products or features that are not available in all countries. Please contact your local sales representative for the availability of products and features in your region.

Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all **WARNING** and **CAUTION** notices.

Pay special attention to all the information given and procedures described in the Safety section.

WARNING
A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.

CAUTION
A caution alerts you when special care is necessary for the safe and effective use of the system. Failure to observe a caution may result in moderate personal injury or damage to the equipment, and presents a remote risk of more serious injury or environmental pollution.

NOTE ***A note highlights unusual points to assist you when using the system.***

1.3 Electronic Instructions for Use

These Instructions for Use are available to view on the screen.

- To open the electronic Instructions for Use, do one of the following:
  - Press F1 on your keyboard.
  - Click **Help** in the top bar menu, followed by **Show Help**.
- To move the window containing the electronic Instructions for Use, drag the header bar to the desired location on the screen.
- To browse topic headings, use the table of contents in the left pane of the viewing window.
- To expand and close topic headings, click the arrow next to the heading. If a heading does not have an arrow next to it, it cannot be expanded further.
- To go directly to a topic, click the corresponding heading in the table of contents. The topic is displayed in the right pane of the viewing window.
- To move sequentially between topics, click **Back** or **Forward**.
- To close the electronic Instructions for Use, click **Close**.

1.3.1 Searching the Electronic Instructions for Use

You can search the electronic Instructions for Use using keywords to help you find what you are looking for more quickly.

1 Click inside the search box and enter the keywords that you want to search for.

2 Click **Search** or press Enter to display the search results in the search window.

3 To view a topic, click it in the search results.

1.4 Intended Use

This Philips Medical Systems product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in these Instructions for Use for the purposes for which it was designed. The purposes for which the product is intended is given below. However, nothing stated in these Instructions for Use reduces operators' responsibilities for sound clinical judgment and best clinical procedure.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is being used. Operators must only operate the product in such a way as to not conflict with applicable laws, or regulations that have the force of law.

Uses of the product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or the manufacturer's agent) from all or some responsibility for resultant non-compliance, damage or injury.

CAUTION
In the United States, Federal law restricts this device to sale, distribution, and use by, or on the order of, a physician.

1.4.1 Intended Use of Philips Hemodynamic Application

Product Description
The Philips Hemodynamic Application is medical device software that enables invasive investigation of cardiac and vascular disease.

When installed on a host PC with compatible Xper Information Management software and the host PC is connected to a compatible patient monitoring device, the combination provides full patient monitoring and hemodynamic analyses functionality. This combination is known as the Philips Interventional Hemodynamic System.

The Philips Hemodynamic Application provides the following functionality:

- Visualize and analyse surface ECG (Electrocardiogram), respiration, invasive pressure, SpO_2 (Pulse Oximetry), end tidal CO_2 (Carbon dioxide), non-invasive blood pressure and body surface temperature
- Hemodynamic calculations such as calculating valve area, valve gradient, thermal cardiac output, and physiological measurements (FFR/iFR)
- Interfaces to a compatible patient monitoring device for controlling and receiving
  - the physiological signals
  - alarms (set upper and lower limits, suspend the audible alarms on the patient monitoring device, acknowledge the audible alarms on the patient monitoring device, display the patient monitoring alarms on the host PC)
- Interfaces to a compatible Xper Information Management version to exchange data for:
  - Patient administration/data management (e.g. charting, reporting, data analysis, registration)
  - Printing and archiving
  - Additional hemodynamic calculations

Users of the Philips Hemodynamic Application as defined in the intended use are responsible for interpreting the data made available. The data is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination and other clinical findings.

The software is intended for use on standard computer systems and does not require proprietary hardware.

Indications for Use/Medical Purpose

The Philips Hemodynamic Application is intended for use by professional healthcare providers for physiologic/hemodynamic monitoring, medical data processing and analytical assessment.

The software may be used to display and/or analyze surface Electrocardiogram (ECG), Respiration, Invasive Blood Pressure (IBP), Pulse Oximetry (SPO2), End Tidal CO2 (ETCO2), Fractional Flow Reserve (FFR), Instant Wave-Free Ratio (iFR), Non-Invasive Blood Pressure (NIBP), surface body Temperature and thermal Cardiac Output.

The software is intended for use with other devices, such as physiological monitoring systems, information management systems, image acquisition and other medical devices.

Use of the software in combination with physiological monitoring system is not intended to be used where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The software in combination with an information management system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet.

The software is indicated for use in the following areas: (interventional) cardiology, electrophysiology and radiology.

The Philips Hemodynamic Application is indicated for use for all human patients of all ages.

Intended Operator Profile

The user is a healthcare practitioner, such as an Interventional Cardiologist who is skilled and qualified to perform the invasive procedures and responsible for the sound clinical judgment to apply the best clinical procedure. The user may also be a nurse or technologist assisting the Interventional Cardiologist. Philips Hemodynamic Application is to be operated by adequately trained healthcare practitioner, who have understanding of the safety information and emergency procedures as defined by its organization and regulatory agencies (local, state, federal) and staff.

Clinical Environment

The Philips Hemodynamic Application is intended to be used in both sterile and non-sterile clinical environments, in accordance with regulatory agencies (local, state, federal) ruling and regulations.

General Safety and Effectiveness

To enable safe and effective operation of the Philips Hemodynamic Application by a trained healthcare professional, instructions for use are provided as part of the device labeling, as well as training prior to Philips Hemodynamic Application handover.

Installation, use and operation of this Philips Hemodynamic Application are subjected to all applicable local, state and federal laws and regulations.

Contraindications

No contraindications apply for this product.

Operating Principle

The Philips Hemodynamic Application can be operated using a keyboard and mouse in the control room and/or exam room and at the X-ray modality table side via a Touch Screen Module (TSM).

Contact with Body Parts/Tissue Type
The Philips Hemodynamic Application is a software medical device and does not come into contact with the patient.

1.5 Compatibility

Philips Hemodynamic Application is compatible with Xper Information Management and the Xper Flex Cardio Physiomonitoring System. For information about compatible systems, contact the manufacturer.

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips Medical Systems. A list of such products and components is available from the manufacturer.

Changes or additions to the product should only be carried out by Philips Medical Systems or by third parties expressly authorized by Philips Medical Systems to do so. Such changes or additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and with best engineering practice.

Philips Hemodynamic Application is only intended to be used with the PC hardware configuration on which it is initially installed by the manufacturer. Philips Hemodynamic Application may only be installed or reinstalled by authorized service personnel.

1.6 Training

Operators of this product must have received adequate training on its safe and effective use before attempting to operate the product described in this Instructions for Use. Training requirements for this type of device will vary from country to country. Operators must make sure they receive adequate training in accordance with local laws or regulations. As a minimum level of training, operators should read and understand these Instructions for Use.

If you require further information about training in the use of this product, please contact your local Philips Medical Systems representative. Alternatively, contact the manufacturer.

1.7 Contacting the Manufacturer

You can contact the manufacturer by post or by email.

Manufacturer's Address	
Postal address	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands
Email address	healthcare@philips.com

1.8 System Version

You can find system version details in the product information screen.

1 On the **System** menu, click **About...**.

The product information screen is displayed.

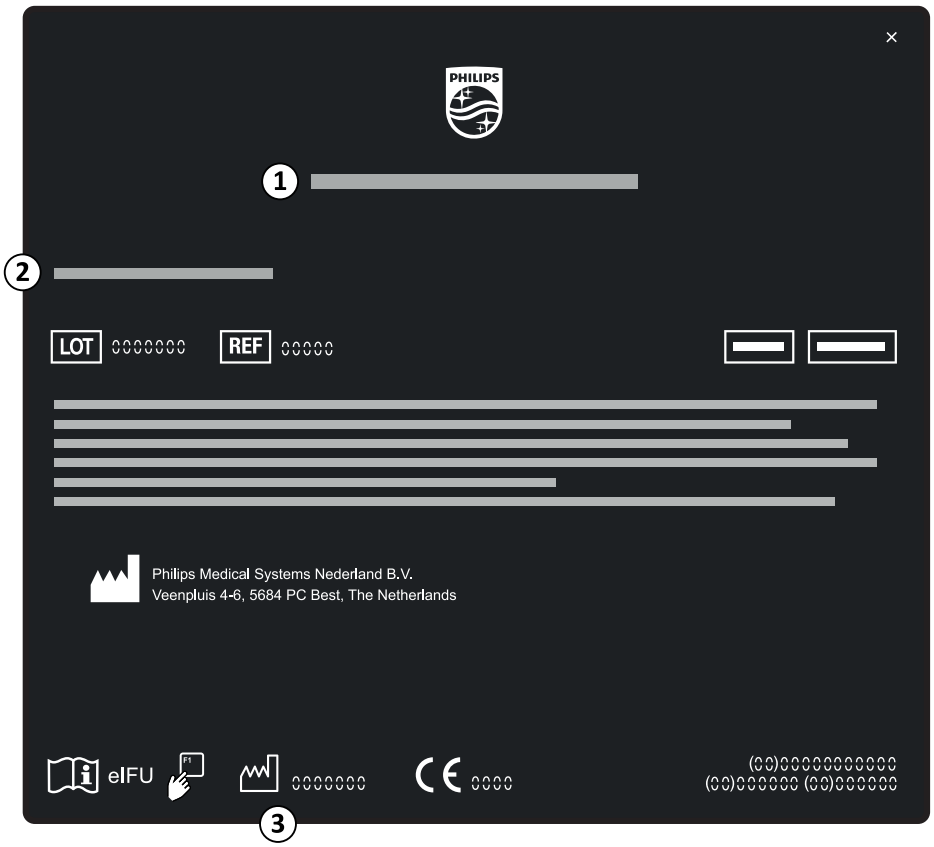

Figure 1 Product information screen

Legend	
1	Product name
2	Product release number
3	Date of manufacture

2 To close the screen, click in the upper-right corner.

1.9 Third Party Software

This product uses other software, including open source software, for which licenses and copyright notices can be found in the following location on the installation medium: thirdparty.txt.

2 Safety

Philips products are designed to meet stringent safety standards. To safeguard human safety all products require proper installation, use, and maintenance.

It is vital that you read, note, and where applicable, strictly observe all danger notices and safety markings on the equipment on which the product has been installed.

To help ensure the safety of both patients and users, it is vital that you strictly follow all directions under the heading Safety, and all warnings and cautions given throughout these Instructions for Use or displayed on the user interface.

Only qualified and authorized personnel may operate this product. "Qualified" means those legally permitted to operate this type of software medical device in the jurisdictions in which it is being used, and "authorized" means those authorized by the organization that is responsible for the equipment.

Personnel operating the product and personnel in the examination room must observe all laws and regulations that have the force of law within the jurisdictions concerned. If you are in doubt as to the laws and regulations that apply to this product, do not use it.

Product Symbols
For information about the symbols that are used with this product, refer to the following website:

www.symbols.philips.com

2.1 Operating Instructions

Philips Hemodynamic Application is part of the Philips Interventional Hemodynamic System, which utilizes equipment including, but not limited to patient monitoring devices, monitors, printers, and UPS/ line conditioners.

The operation of this equipment is not described within these Instructions for Use.

Operating instructions for such components are contained in the relevant documentation supplied by the equipment manufacturer when the system was installed. For information about using the equipment, refer to the accompanying documentation for the specific equipment.

2.2 Non-invasive Blood Pressure Monitoring

For information regarding the measurement of non-invasive blood pressure, and using and fitting cuffs, you should refer to the Instructions for Use supplied with your patient monitoring device.

CAUTION
Ensure the non-invasive blood pressure vital sign is set to neonatal mode when treating a neonatal patient.

2.3 Alternative Monitoring Source

The ACC/AHA Guidelines for Cardiac Catheterization Labs (JACC volume18, No. 5) emphasize the importance of patient monitoring during cardiac catheterization procedures.

CAUTION
You are strongly advised to ensure redundant monitoring capabilities are available. Philips Interventional Hemodynamic System should not be the sole means of monitoring patients during cardiac catheterization procedures.

2.4 Alarm Activation Responsibilities

Philips Hemodynamic Application monitors physiologic parameters and provides visual alarms in addition to alarms provided by the patient monitoring device.

CAUTION
It is your responsibility to ensure that alarm limits are appropriate for the patient being monitored prior to each procedure. If limits are set too high or low for the patient being monitored, failure of the alarm system may result.

NOTE ***The system is not designed for unattended use.***

You can pause audible alarms at your own discretion. It is your responsibility to configure the alarms for each patient, and to verify that alarm limits are appropriate for the patient being monitored. Inappropriate alarm limits, for example, alarms set too high or too low, may result in failure of the alarm system, or in harm to the patient.

NOTE ***A potential hazard can exist if different alarm settings are used for similar equipment in the examination room.***

3 System Overview

Philips Hemodynamic Application is used in the control room and the examination room.

These Instructions for Use provide information about the Philips Hemodynamic Application software only. The following system overview shows other parts of the Philips Interventional Hemodynamic System including hardware for information purposes only. For more details, refer to the Instructions for Use supplied with the relevant equipment.

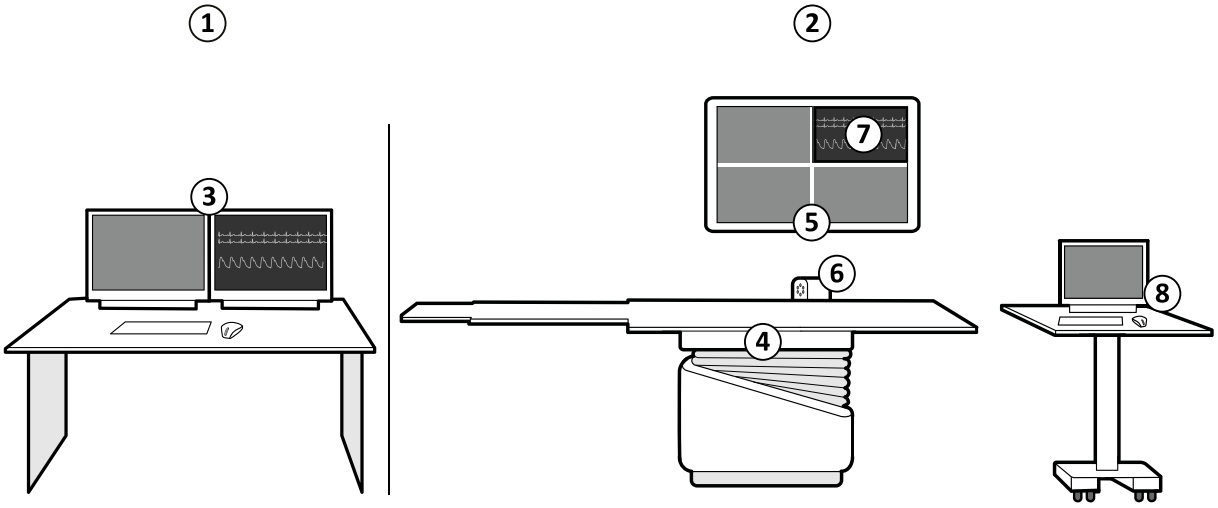

Figure 2 System overview

Legend			
1	Control room overview	5	Examination room monitor
2	Examination room overview	6	Patient monitoring device (location may vary)
3	Philips Hemodynamic Application workstation	7	Philips Hemodynamic Application display (location may vary)
4	Patient table	8	Nurse station (location may vary). For more information, see *Nurse Station (Option)* (page 19).

The main display screen is divided into several main areas.

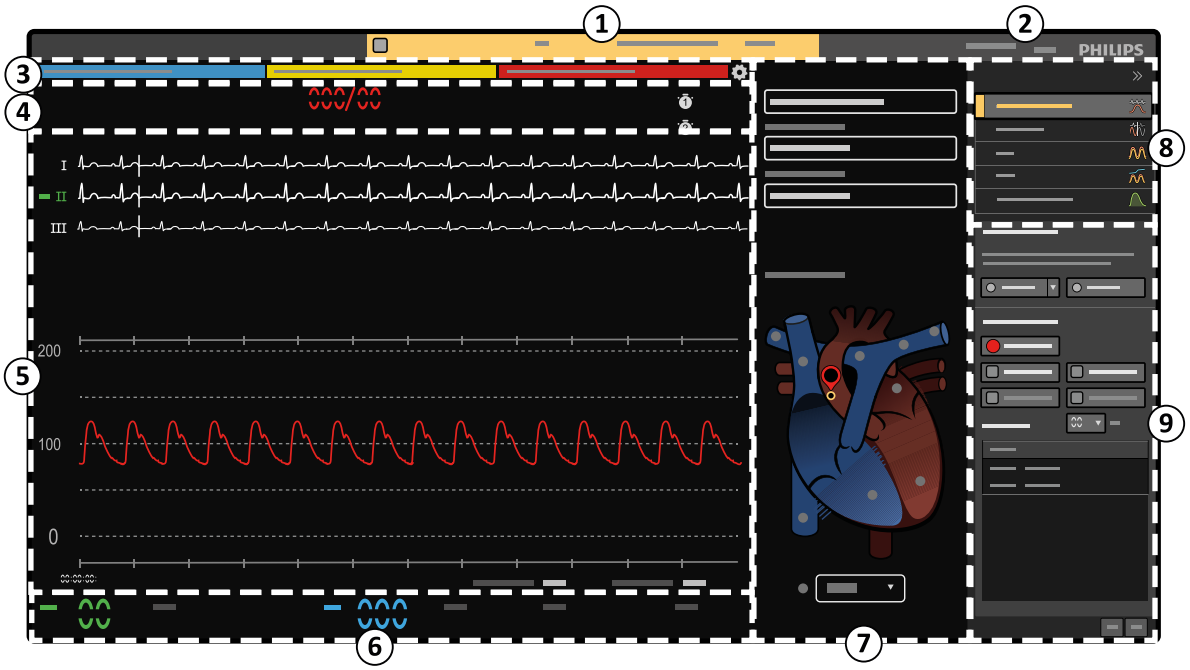

Figure 3 Main control room display screen

Legend			
1	Patient information area	6	Vital signs display area
2	Top bar menu	7	Procedure selection panel
3	Alarm message area	8	Task selection panel
4	Pressure value area	9	Control panel
5	Waveform display area		

Inputs from the patient monitoring device are displayed as waveforms with live readings.

Patient Information Area

Details of the current patient are displayed in the patient information area during the study. The information includes the patient's name, patient ID, date of birth and weight.

If the Philips Hemodynamic Application is displayed embedded in Xper Information Management, the information in this area is provided by Xper Information Management and so this area is not displayed in the Philips Hemodynamic Application.

Top Bar Menu

The top bar menu gives you access to additional functions to view the software version and access help functions. If the Philips Hemodynamic Application is displayed embedded in Xper Information Management, this menu is displayed in the bottom right corner of the embedded view.

Alarm Message Area

Visual alarm messages are displayed in the alarm message area and a visual alarm indication is also displayed around the numeric the alarm relates to.

Pressure Value Area

The value and label for each pressure channel is displayed in the pressure value area. Each pressure is color-coded so that the value is displayed in the same color as the waveform.

Waveform Display Area

The waveform display area contains the ECG and pressure traces. The upper section displays the ECG readings and the lower section displays pressure readings. Each pressure reading is displayed in a different color for visibility. The color of the pressure is determined by the label. You can customize the color associated with a label using Xper Information Management.

Vital Signs Display Area

Non-invasive vital signs are displayed including:

- Heart rate (**HR**)
- Non-invasive blood pressure (**NBP**)
- Pulse oximetry (**SpO2**)
- Respiration rate (**RR**)
- Skin temperature (**Tskin**)
- End tidal CO_2 level (**etCO2**)

Not all of these indications are displayed by default.

To display a vital sign, click on the vital sign in the vital signs display area. To hide a vital sign, click the relevant vital sign again. For more information, see *Setting Up Non-invasive Vital Signs* (page 27).

NOTE ***Heart rate is displayed at all times and cannot be hidden.***

Procedure Selection Panel

The procedure selection panel allows you to select the type of procedure being performed, as well as conditions and layouts for the procedure.

The panel also displays an interactive heart diagram allowing you to easily select catheter pressure locations.

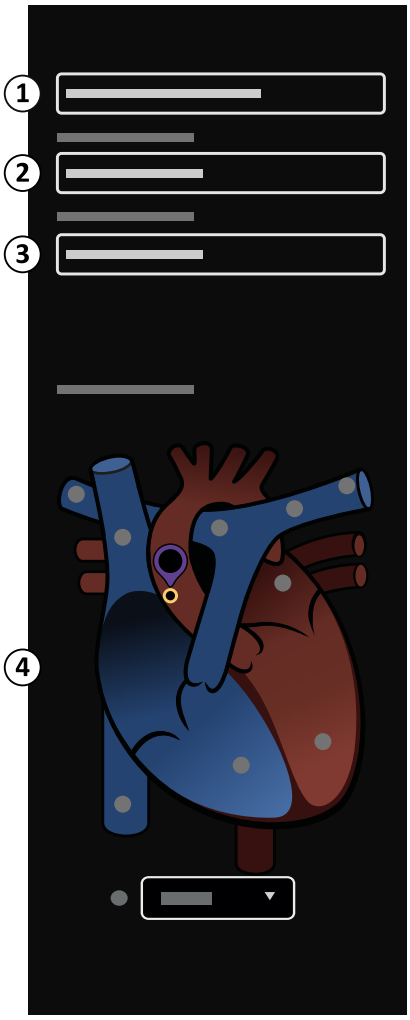

Figure 4 Procedure selection panel

Legend			
1	Procedure list	3	**Procedure Layout** list
2	**Condition** list	4	Heart diagram

You can select an alternative **Catheter Location** by clicking the desired location in the heart diagram.

Task Selection Panel

You can perform different tasks by selecting the desired task in the task selection panel. For more information about the tasks you can perform, see *Workflow Overview* (page 18).

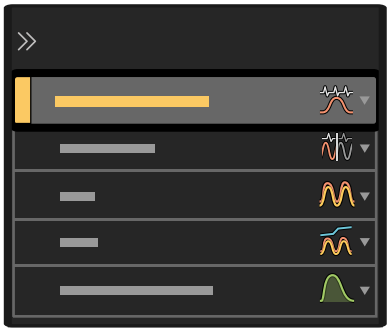

Figure 5 Task selection panel

Control Panel
Each task has different functions and controls associated with it. The control panel displays the controls available for the selected task.

3.1 Workflow Overview

Philips Hemodynamic Application allows you to perform several tasks.

Tasks are selected in the task selection panel.

Task	Icon	Description
Monitoring		Live monitoring of data from the patient monitoring device.
Review		Reviewing the full disclosure record or specific captured elements of patient monitoring data.
FFR		Performing Fractional Flow Reserve (FFR) measurements.
iFR		Performing instant wave-Free Ratio (iFR) measurements, with and without pullback.
Cardiac Output		Performing thermal cardiac output calculations.

You can also return to the monitoring task at any time by pressing Esc on the keyboard.

3.2 Patient Alarms

Philips Hemodynamic Application displays two levels of patient alarms: high priority, displayed in red, and medium priority, displayed in yellow.

A red alarm indicates a potentially life-threatening situation or irreversible injury, which requires immediate attention. Red warnings flash twice per second (2 Hz).

A yellow alarm indicates a less serious condition, but which still requires attention. Yellow warnings flash once every 2 seconds (0.5 Hz).

Audible alarms are generated by the patient monitoring device and are displayed on the Philips Hemodynamic Application monitors.

The system also displays technical alarms indicating potential error conditions involving the equipment, accessories or patient cables. Technical alarms are displayed in blue. For more information, see *Physiomonitoring Messages and Indications* (page 18) and *Error Messages and Troubleshooting* (page 60).

Alarms are indicated within 0.5 seconds of an alarm condition being received from the patient monitoring device. If one or more alarms are active, the parameters causing the alarms are highlighted in the appropriate color.

3.3 Physiomonitoring Messages and Indications

The system displays several physiomonitoring messages or technical alarms.

The Philips Hemodynamic Application displays technical alarms from the patient monitoring device, if the patient monitoring device detects a problem with the equipment, a patient cable, or an accessory. Technical alarms are displayed in blue in the alarm message area.

For more information about where alarms are displayed, see *System Overview* (page 14).

For more information about patient alarms, see *Patient Alarms* (page 18).

3.4 Full Disclosure

The full disclosure function records all waveform activity and vital signs for the current study during the procedure.

You can review all waveform activity, add samples, or print traces. If you miss a pullback, you can take the measurement later from the original recording, rather than reinserting the catheter to repeat the pullback. For more information, see *Reviewing Waveforms in the Full Disclosure Record* (page 47).

Recording starts automatically when you start a study. The entire study is recorded to a file which can be reviewed and used to record data you might have missed. The file is available at the station on which it was recorded for a period of time. In general, the full disclosure file for at least the last 20 cases performed remains on the local stations. Files are deleted as necessary to make room for new full disclosure files.

You can archive and retrieve data using the appropriate Xper Information Management version and configuration.

3.5 Nurse Station (Option)

You can operate Philips Hemodynamic Application remotely using an optional Nurse Station located in the examination room. This option is only available in North America.

The Nurse Station allows you to perform several functions:

- Monitor functions (such as non-invasive devices, invasive pressure channels, and ECG leads)
- View waveform activity
- Review the patient's samples and vital signs
- Record pressure samples
- Chart procedural notes
- Create transcription reports and arterial trees
- Print case reports

NOTE ***The Nurse Station is for single patient use only. It is possible to open a different study on the Nurse Station than the study that is active on the Philips Interventional Hemodynamic System workstation. If this occurs, the Nurse Station displays a notification that there is a mismatch between the study on the Philips Interventional Hemodynamic System workstation and the study on the Nurse Station. It is the operator's responsibility to ensure that the correct study is active on both workstations.***

The Nurse Station is not connected directly to Philips Interventional Hemodynamic System workstation. This may result in a delay between the monitoring display on the Philips Interventional Hemodynamic System workstation and the monitoring display on the Nurse Station. It is also possible that the Nurse Station may lose network communication with Philips Interventional Hemodynamic System. You should always use the Philips Interventional Hemodynamic System workstation as the primary monitoring source during procedures.

CAUTION
The Nurse Station should not be used as the primary source of monitoring or alarms.

4 Switching the System On and Off

Philips Hemodynamic Application starts automatically when the host PC is switched on.

4.1 Starting the Philips Hemodynamic Application

The Philips Hemodynamic Application is installed on a dedicated host computer and the software starts automatically when the computer is switched on.

If you need to start the computer individually, consult with your system administrator to ensure that the correct computer is identified in your installation configuration.

4.2 Shutting Down the Philips Hemodynamic Application

You can shut down the Philips Hemodynamic Application when not in use.

To shut down, click **System** and select **Shut Down**.

The host computer shuts down.

If the Philips Hemodynamic Application is displayed embedded in Xper Information Management, this menu is displayed in the bottom right corner of the embedded view.

This does not switch off the patient monitoring device. For information about switching off the patient monitoring device, refer to the relevant Instructions for Use supplied with the product.

5 Setting Up the Monitoring Environment

This section explains setting up the monitoring environment using the various controls and parameters.

You can also save combinations of settings as customized monitoring layouts.

5.1 Customizing Your Monitoring Layout

You can customize the monitoring layout you are using on screen and save the layout for future use.

Layouts allow you to save different sets of monitoring parameters and to recall them when you need them. You can change a number of different aspects of the layout of the screen:

- The ECG and pressure waveforms displayed
- The scales used on the waveforms
- Pressure waveform labels
- Sweep speed
- Waveform colors
- Mean waveform display
- Vital signs (except non-invasive blood pressure)

NOTE ***Changes to alarm settings are saved as part of your customized layout. For more information, see Setting Patient Alarms (page 35) and Saving, Recalling, and Deleting Layouts (page 34).***

The default layout is determined by the selected procedure. You can create as many additional layouts as desired. Your system may be optionally configured to require a username and password in order to save or delete layouts. For more information on configuring users and passwords, refer to the macro validation security information in the Xper Information Management Instructions for Use.

5.1.1 Selecting Waveforms to Display

You can choose which ECG or pressure waveforms to display in your screen layout.

ECG and pressure waveforms are displayed separately in the waveform display area. ECG waveforms are displayed in the upper part of the main display area, and pressure waveforms are displayed in the lower part.

You can display ECG waveforms over the entire waveform display area.

1 Do one of the following:

- Right-click in the waveform display area.
- Click **Live Setup** at the top of the waveform display area.

The **Live Setup** dialog box is displayed.

Tip: If you right-click on the upper part of the waveform display area on the existing ECG waveforms, the **ECG** tab is automatically selected when the **Live Setup** dialog box is displayed. Similarly, if you right-click on the lower part of the waveform display area on the existing pressure waveforms, the **Pressures** tab is automatically selected when the **Live Setup** dialog box is displayed.

2 To select ECG waveforms, do the following:

a Ensure the **ECG** tab is selected.

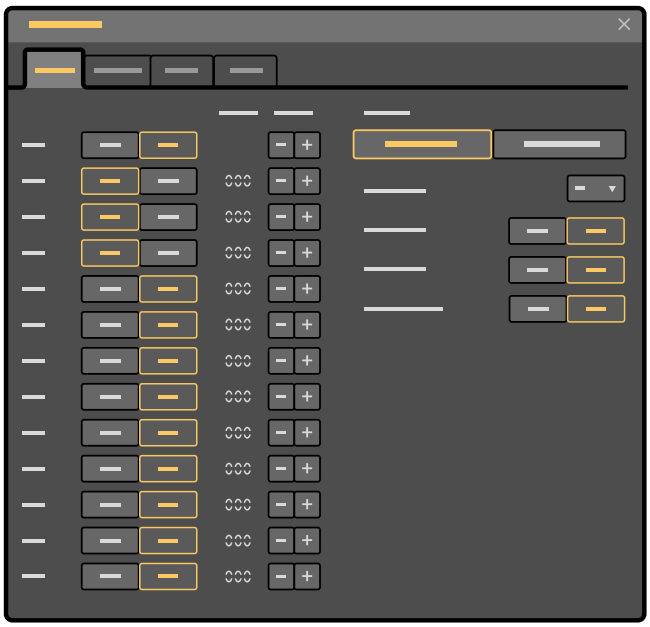

Figure 6 **ECG** tab in the **Live Setup** dialog box

The system supports up to 12 ECG channels.

b To display a desired waveform, click **On** for the desired waveform.

c To adjust the way a waveform is shown on the screen and the vertical scale used, adjust the **Gain** for the desired waveform by clicking **+** or **-**.

d To limit the amplitude of the heart rate (**HR**) waveform using clipping of the QRS complex, select the level of **Clipping** desired for each waveform.

e To change the order of ECG waveforms in the waveform display area, drag each ECG waveform to the desired position.

f To enable **Pacemaker Detection**, click **On**.

Pacing indications are displayed in red on the heart rate ECG waveform when pacemaker detection is active.

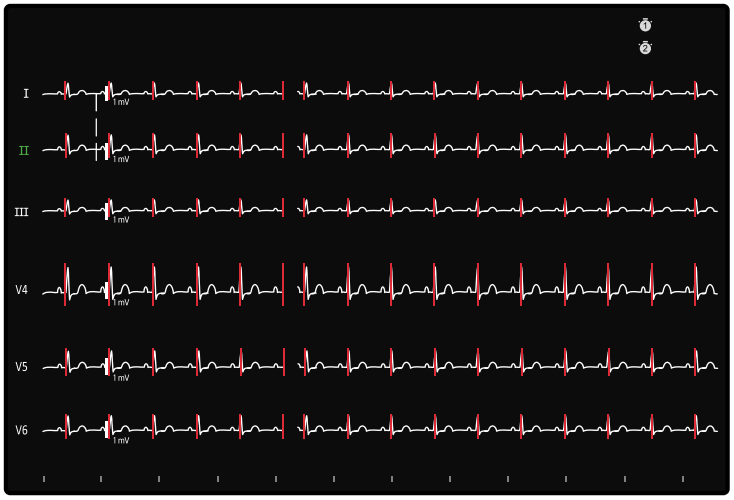

Figure 7 Pacing indications (red) on the ECG waveform

g To disable **Pacemaker Detection**, click **Off**.

Pacemaker rejection is always active.

3 To select pressure waveforms, do the following:

a Ensure the **Pressures** tab is selected.

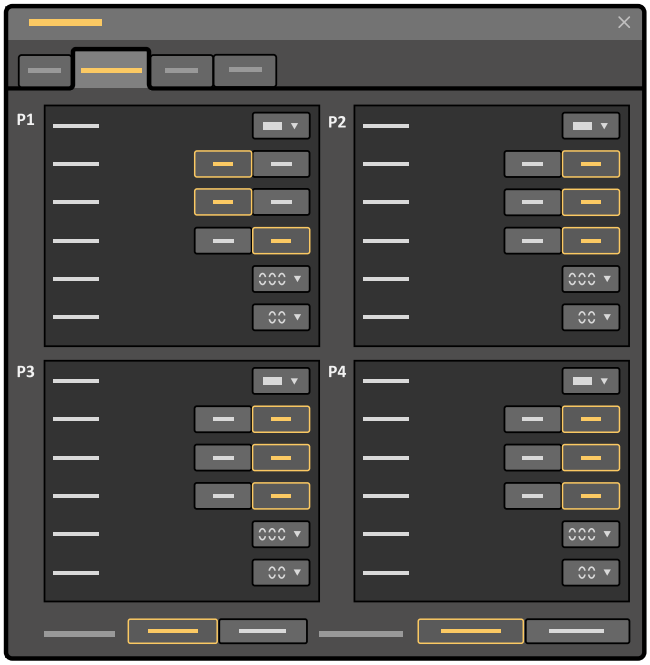

Figure 8 **Pressures** tab in the **Live Setup** dialog box

b To display a desired waveform, ensure that the **Enabled** control is set to **On** for the desired waveform, and the **Wave** control is set to **On**.

4 To close the dialog box, click **Close**, or click outside of the dialog box.

5.1.2 Changing Waveform Scales and Sizes

You can change the size of ECG waveforms and the scale used to display pressure waveforms.

Changing the scale or size allows you to see more detail in the waveform.

The displayed size of ECG waveforms is adjusted by changing the gain value of the signal. For pressure waveforms, you can change the scale used to display the waveform. These changes affect the vertical scales used in the waveform display.

Tip: If you right-click on the upper part of the waveform display area on the existing ECG waveforms, the **ECG** tab is automatically selected when the **Live Setup** dialog box is displayed. Similarly, if you right-click on the lower part of the waveform display area on the existing pressure waveforms, the **Pressures** tab is automatically selected when the **Live Setup** dialog box is displayed.

You can also change the sweep speed to make the waveform display more or less cycles.

Changing the sweep speed affects both ECG and pressure waveforms, and alters the horizontal scale used in the waveform display. The following sweep speeds are available: 5, 10, 25, 50, 100, 200, and 400 mm/s.

If you display a second pressure, each waveform is displayed with its own scale. You can display the waveforms with a single scale.

Moving average values are calculated over a 5 second period.

1 To change the ECG gain, do the following:

a Click **Live Setup** at the top of the waveform display area.

The **Live Setup** dialog box is displayed.

b Ensure the **ECG** tab is selected.

c Identify the ECG waveform to adjust, and click **+** and **-** to change the **Gain** for that waveform.

2 To change the pressure waveform scale, do the following:

a Click **Live Setup** at the top of the waveform display area.

The **Live Setup** dialog box is displayed.

b Ensure the **Pressures** tab is selected.

c Identify the pressure waveform to adjust, and select the desired **Scale Low** and **Scale High** settings for that waveform.

Tip: You can quickly make adjustments to the scale for all pressure waveforms by clicking on the upper and lower parts of the scales in the waveform display area.

3 To change the sweep speed, select the desired **Sweep Speed** from the list at the bottom of the waveform display.

4 To view the waveforms with a single scale, place the pointer on the scale area and click the scale button displayed.

The following icons indicate the current state and the new state you can select.

Icon	Description
	A single scale is currently displayed. Click the button to display multiple scales.
	Multiple scales are currently displayed. Click the button to display a single scale.

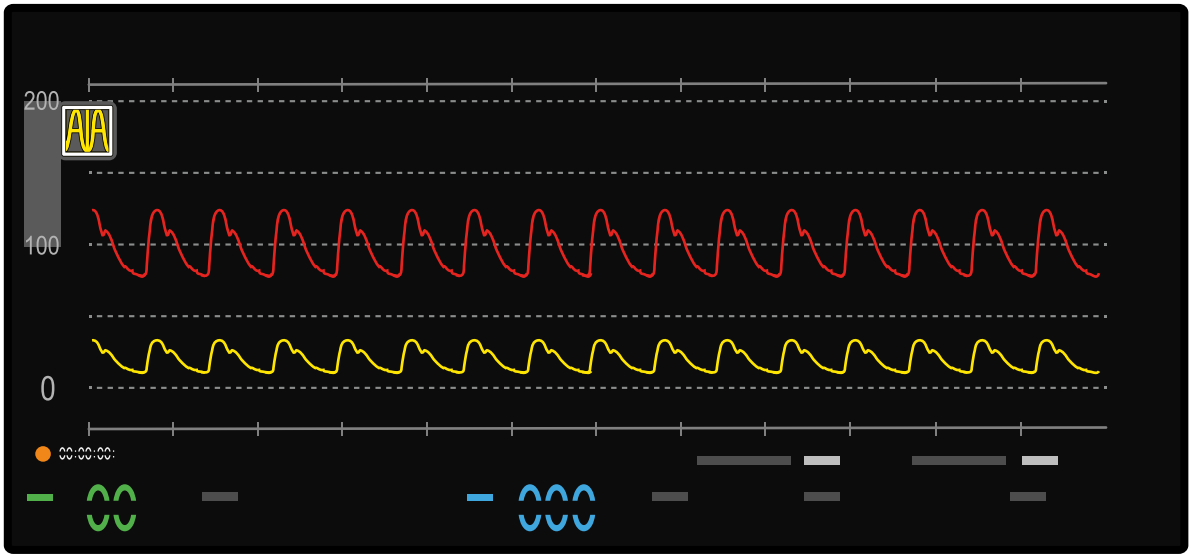

Figure 9 Single scale waveform display

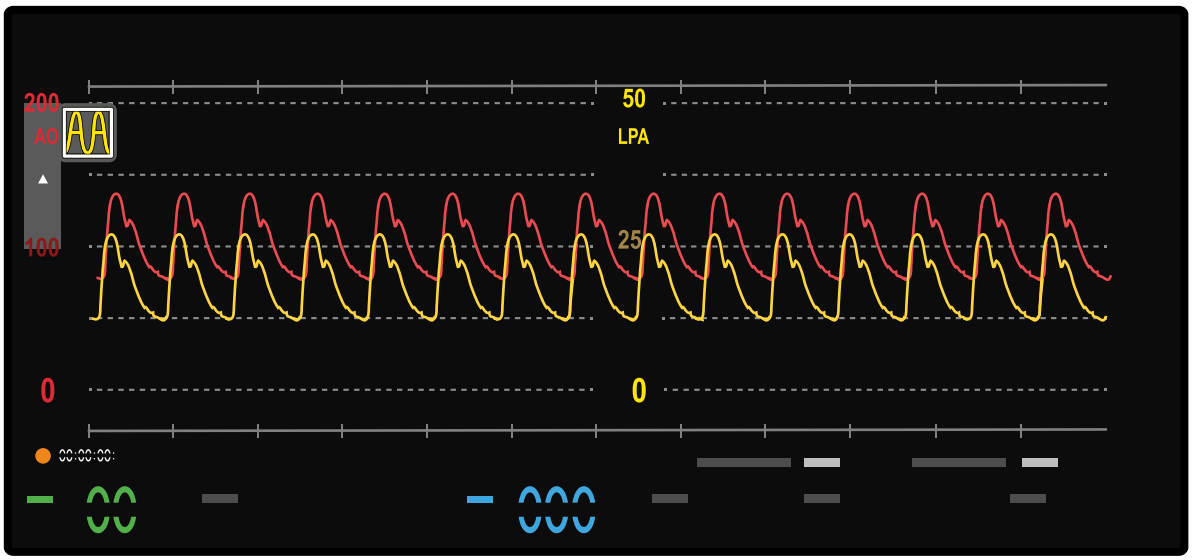

Figure 10 Multiple scale waveform display

5.1.3 Changing Pressure Waveform Labels

You can change the label associated with a pressure waveform.

This changes the label of the pressure input channel associated with the relevant pressure waveform, allowing you to ensure the correct label is applied for the waveform being displayed. The color of a waveform is automatically determined by the label selected. The catheter location on the interactive heart diagram in the procedure selection panel is also updated to reflect the selected label.

NOTE ***The values displayed depend on the type of waveform you are customizing.***

For arterial waveforms, systolic/diastolic (mean) values are displayed. For ventricular waveforms, systolic/diastolic and end diastolic values are displayed. For venous waveforms, only the mean value is displayed in the live view.

1 To change a pressure label using the **Live Setup** dialog box, do the following:

a Click **Live Setup** at the top of the waveform display area.

The **Live Setup** dialog box is displayed.

b Ensure the **Pressures** tab is selected.

c Identify the desired pressure waveform, and select the desired **Label**.

The waveform changes in the waveform display area and the selected waveform label and color is displayed at the top of the waveform display area.

2 To change a pressure label from the waveform display area, do the following:

a Identify the desired pressure to be changed at the top of the waveform display area.

b Right-click the desired pressure reading.

A dialog box for the selected pressure is displayed.

c Select the desired **Label**.

The waveform changes in the waveform display area and the selected waveform label and color is displayed at the top of the waveform display area.

3 To add a temporary pressure label to a waveform, do the following:

a Identify the desired pressure to be changed at the top of the waveform display area.

b Right-click the desired pressure reading.

A dialog box for the selected pressure is displayed.

c In the **Label** list, select **New**.

d Enter a name for the **Label**.

e Select the relevant label **Type**.

f Select the desired **Color**.

g To close the dialog box without adding a temporary pressure label, click **Cancel**.

h To add the temporary pressure label, click **OK**.

The new label is displayed. This temporary pressure label is not saved for future use. To customize permanent site labels, you should edit the relevant list of site labels using the Xper Information Management application. For more information, refer to the Instructions for Use for Xper Information Management.

5.1.4 Adjusting Pressure Waveform Filters

The system provides filtering on each of the four invasive pressure channels

The filters affect the sensitivity of the incoming signal. You can apply a different filter level to eliminate as much or as little interference as desired.

1 Right-click on the desired pressure reading at the top of the waveform display area.

A dialog box is displayed for the desired pressure channel.

2 Select an appropriate **Hz Filter** setting.

Selecting a higher value (e.g. 80 Hz) filters less interference than a lower value (e.g. 12 Hz). The default filter value is 20 Hz.

5.1.5 Setting Up Non-invasive Vital Signs

Non-invasive vital signs are displayed in the vital signs display area, below the waveforms.

You can set the devices to collect and chart patient vital signs at intervals of 2 to 60 minutes. Once vitals are captured, they are sent to Xper Information Management where they are used to populate information sheets. Only vital signs that are active are sent to Xper Information Management. You can choose which vital signs to display.

- Non-invasive blood pressure (**NBP**)
- Pulse oximetry (**SpO2**)
- Respiration rate (**RR**)
- Skin temperature (**Tskin**)
- End tidal CO_2 level (**etCO2**)

Non-invasive blood pressure display is not saved in a customized layout. You should manually display or not display the non-invasive blood pressure vital sign as appropriate when using the system.

Not all of these indications are displayed by default.

NOTE ***You cannot hide the patient's heart rate (HR). Heart rate is displayed at all times.***

In addition, you indicate whether Xper Information Management should record a Level of Consciousness indicator and a Level of Pain indicator.

If a non-invasive vital sign signal from the patient monitoring device is not being received or if the Philips Hemodynamic Application deems the received signal to be potentially incorrect for technical reasons, a question mark symbol (?) is displayed in the relevant non-invasive vital sign display.

You can adjust these settings using the **Vitals** tab in the **Live Setup** dialog box.

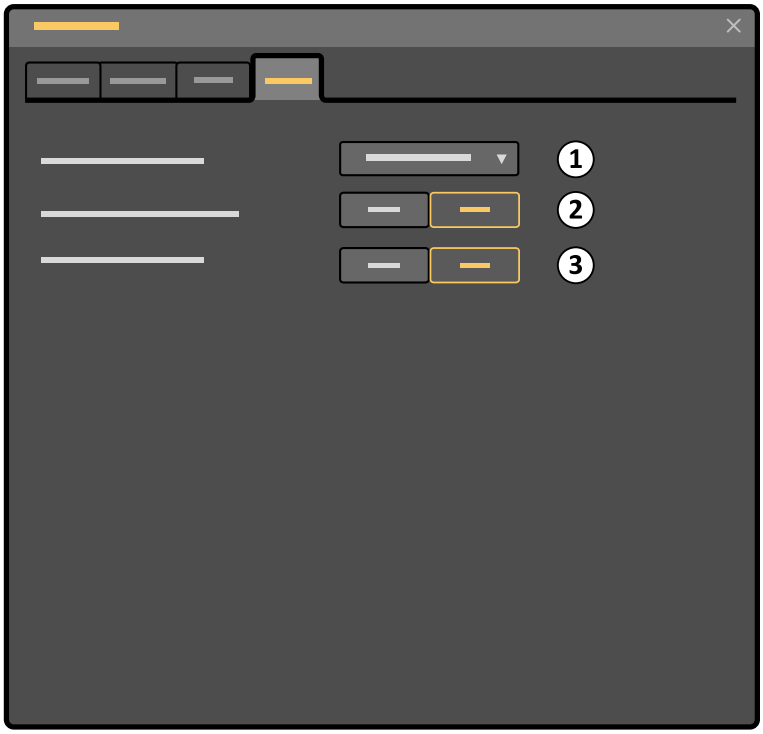

Figure 11 **Vitals** tab in the **Live Setup** dialog box

Legend	
1	**STAT vitals duration**
2	**Level of Consciousness prompting**
3	**Level of Pain prompting**

Enabling and Disabling the Heart Rate Monitoring Tone

You can enable or disable the heart rate audible monitoring tone.

1 Do one of the following:
- Right-click in the waveform display area.
- Click **Live Setup** at the top of the waveform display area.

Tip: If you right-click on the upper part of the waveform display area on the ECG waveforms, the **ECG** tab is automatically selected when the **Live Setup** dialog box is displayed.

The **Live Setup** dialog box is displayed.

2 Select the **ECG** tab.

3 In the **QRS** section of the dialog box, click **On** to turn the **Beep** on.

Setting Up the Non-invasive Blood Pressure (NBP)

You can display the patient's non-invasive blood pressure in the vital signs display area.

You can also set upper and lower alarm limits and display a virtual sphygmomanometer which is visible when blood pressure readings are taken.

1 If the patient's blood pressure is not displayed in the vital signs display area, click **NBP**.

The **NBP** value is displayed. The patient monitoring device starts inflating the cuff to allow a measurement to be taken. A reading may not be available immediately.

2 To display the **NBP** dialog box, right-click the **NBP** vital sign.

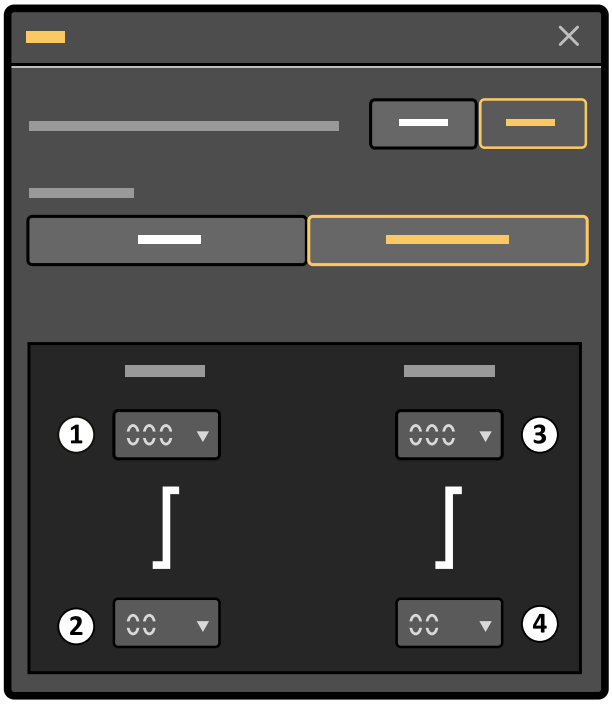

Figure 12 NBP dialog box

Legend			
1	**Systolic** upper alarm limit	3	**Diastolic** upper alarm limit
2	**Systolic** lower alarm limit	4	**Diastolic** lower alarm limit

3 To display the **Virtual Sphygmomanometer** , click **On**.

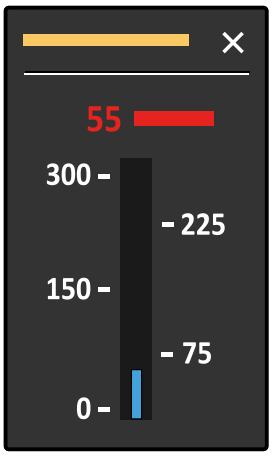

Figure 13 Virtual sphygmomanometer

The virtual sphygmomanometer displays the cuff pressure when the patient's blood pressure is being measured.

4 If the patient is a child less than 1 month old, ensure the **Mode** selected is **Neonatal**.

Neonatal is selected automatically when the patient's age is less than 1 month.

CAUTION
Ensure the non-invasive blood pressure vital sign is set to neonatal mode when treating a neonatal patient.

If **Neonatal** is selected, this is indicated in the vital sign display.

For pediatric patients aged from 1 month to 3 years, the default selection is a pediatric procedure with the associated alarm limits.

If **Neonatal** is selected and a change is made to the patient's date of birth indicating that the patient is older than 1 month, then you should change the **Mode** to **Adult**.

5 To set **Alarm Limits**, select the desired upper and lower **Systolic** and **Diastolic** limits.

Setting Up the Pulse Oximetry (SpO2)

You can display the patient's pulse oximetry (**SpO2**) measurement in the vital signs display area.

You can choose to use an audible tone for the vital sign, and set upper and lower alarm limits.

1 If **SpO2** is not displayed in the vital signs display area, click **SpO2**.

The **SpO2** vital sign is displayed.

2 To display the **SpO2** dialog box, right-click the **SpO2** vital sign.

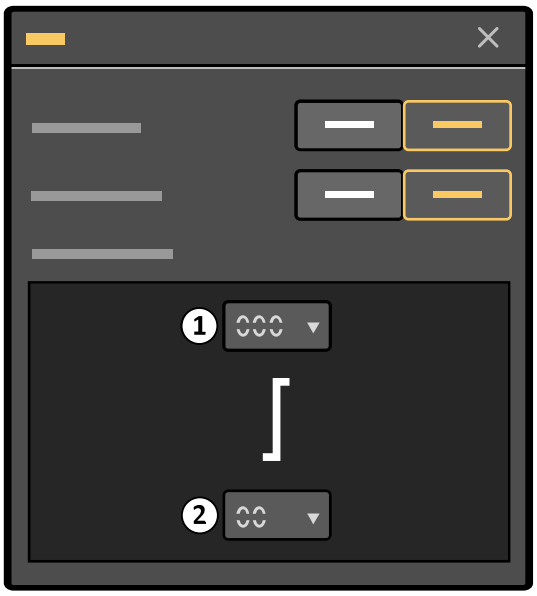

Figure 14 **SpO2** dialog box

Legend	
1	Upper alarm limit
2	Lower alarm limit

3 To display the waveform, click **On** at the **Wave** control.

4 To set an audible **SpO2 Tone**, click **On**.

The audible tone operates in sequence with the patient's heart rate. The pitch of the tone varies if the patient's pulse oximetry changes. For more information, refer to the Instructions for Use supplied with the patient monitoring device.

5 To set **Alarm Limits**, select the desired upper and lower limits.

Setting Up the Respiration Rate (RR)

You can display the patient's respiration rate in the vital signs display area.

You can also choose to display the respiration rate as a waveform, and set upper and lower alarm limits.

1 If the respiration rate is not displayed in the vital signs display area, click **RR**.

The **RR** vital sign is displayed.

2 To display the **RR** dialog box, right-click the **RR** vital sign.

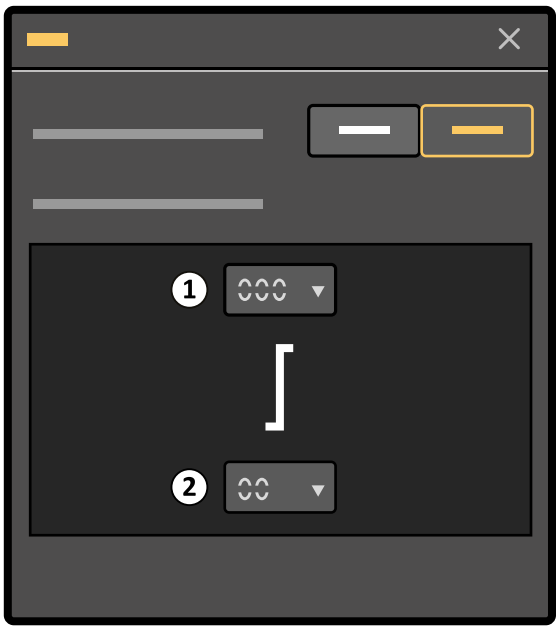

Figure 15 **RR** dialog box

Legend	
1	Upper alarm limit
2	Lower alarm limit

3 To display the waveform, click **On** at the **Wave** control.

4 To set **Alarm Limits**, select the desired upper and lower limits.

Setting Up the Skin Temperature (Tskin)

You can display the patient's skin temperature in the vital signs display area.

You can choose to display the patient's skin temperature as a waveform, and set upper and lower alarm limits.

1 If the skin temperature is not displayed in the vital signs display area, click **Tskin**.

The **Tskin** vital sign is displayed.

2 To display the **Tskin** dialog box, right-click the **Tskin** vital sign.

Figure 16 **Tskin** dialog box

Legend	
1	Upper alarm limit
2	Lower alarm limit

3 To set **Alarm Limits**, select the desired upper and lower limits.

Setting Up the End Tidal CO_2 (etCO2)

You can display the patient's end tidal CO_2 level in the vital signs display area.

You can also choose to display the end tidal CO_2 level as a waveform, reset the displayed values, and set upper and lower alarm limits.

1 If the respiration rate is not displayed in the vital signs display area, click **etCO2**.

The **etCO2** vital sign is displayed.

2 To display the **etCO2** dialog box, right-click the **etCO2** vital sign.

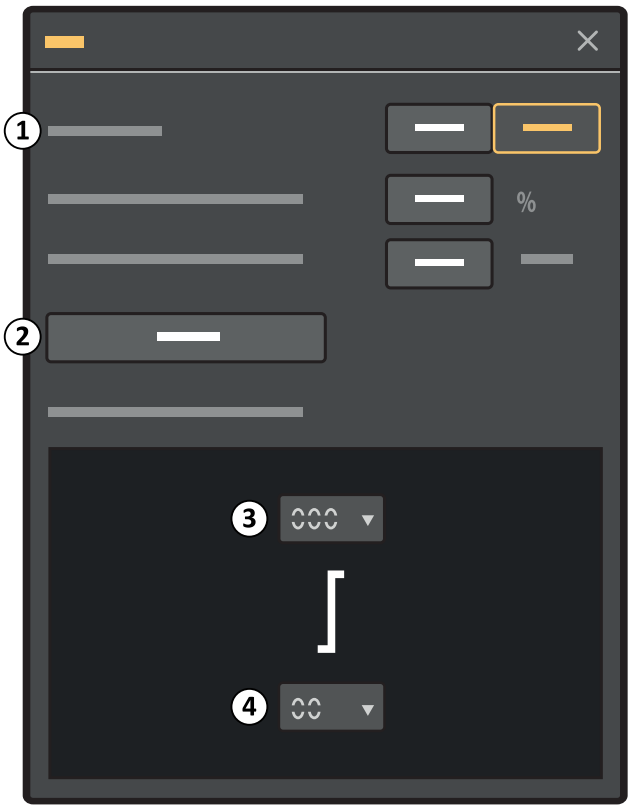

Figure 17 **etCO2** dialog box

Legend	
1	**Wave On/Off**
2	**Zero**
3	Upper alarm limit
4	Lower alarm limit

3 To display the waveform, click **On** at the **Wave** control.

4 Enter values for **O2 Compensation** (%) and **Barometric Pressure** (mmHg).

For more information, see *Barometric Pressures* (page 62).

5 To zero the $etCO_2$ module of the patient monitoring device, click **Zero**.

6 To set **Alarm Limits**, select the desired upper and lower limits.

5.2 Saving, Recalling, and Deleting Layouts

You can save and recall customized layouts for future use.

You can also save changes that you make to existing customized layouts during studies. These changes are available in that customized layout in the future.

NOTE ***Before changing or recalling a layout, you should ensure that the alarm limits associated with the saved layout are appropriate to use with the particular patient.***

1 To save a new customized layout, do the following:

a Set your preferred layout.

Any changes that you make to alarm settings are saved as part of your customized layout. For more information, see *Customizing Your Monitoring Layout* (page 22) and *Setting Patient Alarms* (page 35).

NOTE ***When storing alarm limits in a layout, the lower SpO2 limit cannot be lower than the lower SpO2 limit in the default layout for the procedure.***

b Select **Add New** in the **Procedure Layout** list.

A dialog box is displayed allowing you to enter a name for your customized layout.

c Enter a name for your customized layout.

d To close the dialog box without saving the new layout, click **Cancel**.

e To save the new customized layout, click **Save**.

2 To save changes to an existing customized layout, select **Save** in the **Procedure Layout** list.

3 To save a change to the default layout, do the following:

a Select the default **Procedure Layout** from the list.

b Customize the layout.

For more information, see *Customizing Your Monitoring Layout* (page 22).

c Select **Save** in the **Procedure Layout** list.

The default layout is changed to include the customized changes you made.

4 To recall a customized layout, select the desired layout in the **Procedure Layout** list.

The selected layout is applied to the screen for the current patient.

5 To delete a layout, do the following:

a Select the desired layout in the **Procedure Layout** list.

b To delete the layout, select **Delete Layout** in the **Procedure Layout** list.

A dialog box is displaying requesting confirmation.

c To close the dialog box without deleting the layout, click **Cancel**.

d To delete the layout, click **OK**

NOTE ***You cannot delete the default layout.***

5.3 Setting Patient Alarms

You can set patient alarms for all vital signs and invasive pressures using the **Live Setup** dialog box.

You can also set alarms using the individual vital signs dialog boxes.

The alarm limits you set determine the conditions that trigger high or medium priority patient alarms. It is important that you review your alarm settings at the beginning of each study and determine whether they are appropriate for the patient being monitored. Setting an alarm limit too high or too low for the patient being monitored can result in failure of the alarm system if an adverse condition occurs.

There are different default limits for adult and pediatric alarm settings. For more information, see *Default Settings* (page 60).

CAUTION
It is your responsibility to ensure that alarm limits are appropriate for the patient being monitored prior to each procedure. If limits are set too high or low for the patient being monitored, failure of the alarm system may result.

NOTE ***Changes made to alarm limits during a study are temporary. The alarm settings revert to the settings stored in the default layout when the next procedure is started. If power is interrupted, the default alarm settings are implemented when power is restored.***

To save the alarm settings, you can save the whole layout for future use. For more information, see *Customizing Your Monitoring Layout* (page 22) and *Saving, Recalling, and Deleting Layouts* (page 34).

NOTE ***If you are using a saved layout, the layout may have alarm limits associated with it that are not the default alarm limits. You should ensure that the alarm limits associated with the saved layout are appropriate to use with the particular patient.***

1 Click **Live Setup** at the top of the waveform display area.

The **Live Setup** dialog box is displayed.

2 Select the **Alarms** tab.

Legend			
1	**Invasive Pressures**	3	**NBP**
2	Pressure channel list	4	**Vitals**

3 To set alarm limits for an invasive pressure, do the following:

a In the **Invasive Pressures** section of the dialog box, select the desired pressure channel from the list.

b Select the desired upper and lower alarm limits for the **Systolic**, **Diastolic**, and **Mean** values.

You can set different limits for each channel or set them all to the same limits.

c To set alarm limits for another pressure, repeat steps 3a and 3b.

4 To set alarm limits for non-invasive blood pressure, select the desired upper and lower alarm limits for the **Systolic** and **Diastolic** measurements in the **NBP** section of the dialog box.

5 To set alarm limits for the remaining vital signs, select the desired upper and lower limits for each of the desired vital signs in the **Vitals** section of the dialog box:

- **HR**
- **SpO2**
- **RR**
- **Tskin**
- **etCO2**

6 To pause audible alarms, do the following:

a Select a time period to pause the audible alarms.

b Click **Pause Audible Alarms**.

The maximum audio pause time available can be customized by a qualified service engineer. The factory default alarm pause time for audible alarms is 2 minutes. This can be changed to a maximum of 4 hours by a qualified service engineer.

7 To restore the factory default alarm limits, click **Reset**.

5.4 Checking Patient Alarm Functions

To ensure that the patient alarm functions are operating as expected, you should check their function periodically.

You can check the function of patient alarms by adjusting the patient alarm settings to activate each alarm and check its function.

1 Ensure the patient monitoring device is connected to a source for measurements.

This could be by attaching the equipment to yourself or by using a suitable simulator. For more information about using a simulator with the patient monitoring device, refer to the Instructions for Use supplied with your patient monitoring device.

2 In the Philips Hemodynamic Application, select a non-invasive vital sign to test.

For more information, see *Setting Up Non-invasive Vital Signs* (page 27).

3 Adjust the upper and lower alarm limits for the selected non-invasive vital sign to activate the relevant patient alarm.

For more information, see *Setting Patient Alarms* (page 35).

4 Observe the alarm behavior.

Adjusting the upper and lower alarm limits beyond the upper and lower limits of the current measurements should result in alarm activation for the relevant vital sign.

5 Perform steps 2 to 4 for each non-invasive vital sign.

5.5 Changing the Primary Lead

You can manually change the primary lead used for the **HR** vital sign.

1 In the vital signs display area, right-click on the heart rate (**HR**) vital sign.

The **HR** dialog box is displayed.

Figure 18 HR dialog box

2 To change the heart rate (**HR**) waveform signal source, select the correct **Primary Lead** from the list.

3 To close the dialog box, click **Close**, or click outside of the dialog box.

The primary lead is always displayed and cannot be switched off.

6 Performing Procedures

You can capture sample data and perform measurements using the tasks in the task selection panel.

When you select a task, the controls for the task are displayed in the control panel.

Patient admission is done via Xper Information Management. After closing a patient, if the case is re-opened within 8 hours the Philips Hemodynamic Application opens in live mode. After more than 8 hours the Philips Hemodynamic Application opens in review mode.

6.1 Recording Pressure and ECG Samples

Prior to sampling pressure data, zero your transducers. If you wish to calibrate the pressure channels, you may do so; however, since the signal drift is almost nil, calibration of the transducers is necessary only under special circumstances, such as changing transducer brands or cabling.

You may record physiologic data in two ways—retroactively and proactively. The length of the sample depends on the setting you select in the control panel. You can also print your sample. For more information, see *Printing a Sample* (page 52).

If you should miss recording a sample or would like to capture additional samples and/or vitals data, you can review the full disclosure file and capture additional pressure samples or vitals data that you might have missed during the case. For more information, see *Reviewing Waveforms in the Full Disclosure Record* (page 47).

6.1.1 Balancing the Pressure Transducers

Before balancing the pressure transducers, ensure that all transducers are set up in accordance with the manufacturer's instructions.

You should zero the pressure transducer channels after you admit a patient. The system indicates when this is necessary.

1 Open the transducer to room air and click **Zero**. The pressure trace will move to the 0 mm line in the display window.

2 To zero all active transducer channels simultaneously, ensure that they are open to room air and click **Zero All**.

6.1.2 Snap (Retroactive Sampling)

As waveforms move across the waveform display area, they are stored in memory. When you sample retroactively, you are sampling the waveform backward from the point in time at which you capture the sample. This is called retroactive sampling.

1 Click **Snap** in the control panel.

2 To capture a sample using the keyboard, press S on your keyboard.

The system analyzes the waveform, captures a retrograde sample and automatically posts it to the hemodynamic page in Xper Information Management and the sample list. The sample length is determined by the selected **Sample Length** setting.

Retroactive sampling gives you control over your samples because you are capturing what you see on the screen.

6.1.3 Record (Proactive Sampling)

Acquiring data samples in real-time is called proactive sampling.

1 To capture a proactive sample, click **Record**.

A progress bar is displayed showing capture progress

2 If you wish to terminate the recording prior to the end of the selected sample length duration, click **Stop**.

After the indicator bar has cleared, the system analyzes the sample and automatically posts it to the hemodynamic page in Xper Information Management and the sample list.

6.2 EDP Recording

The EDP sampling routine automatically configures the live monitoring screen for a 50 mmHg pressure scale and a 50 mm/sec sweep speed. It then records a pressure sample and returns the screen to its previous settings.

1 Click **EDP**.

The scale and sweep speed will change to 50, the sample will be recorded, and the scale and sweep speed will revert to their previous settings.

Data is posted to both the hemodynamic page in Xper Information Management and the sample list.

6.3 Recording Pullback Data Across Valves

Pullback recording retroactively samples from the first chamber, captures the actual pullback, then proactively samples from the second chamber.

The pullback routine works automatically on any valve or chamber in the heart.

1 Set the label of the pressure channel to the correct site.

If more than one channel is activated, the pullback occurs in the order P1 to P4, on the first channel that allows a pullback.

2 When you see the waveform change from one chamber to the next, click **Pullback** or **Pull** on the interactive heart.

Once the pullback has completed, the data is posted to both the hemodynamic page in Xper Information Management and the sample list.

6.4 Calculating Valve Gradients

You can calculate valve gradients after capturing pullback or simultaneous pressure samples with which to generate valve data (LV/AO, LV/PW, RV/RA, etc.).

1 Select the desired pullback sample from within the sample list.

You can also link two separate samples if you do not have a pullback sample in the sample list. For more information, see *Linking Samples* (page 50).

2 To adjust the sweep speed, click the **Sweep Speed** and select a new speed.

3 To adjust the beginning and end times of the sample, edit the sample.

For more information, see *Managing Samples* (page 49).

4 Click **Valve**.

The screen switches to the valve gradient view screen, where the waveform is automatically analyzed and gradient data is recorded to the hemodynamic page in Xper Information Management and the sample list. For more information, see *Reviewing Waveforms in the Full Disclosure Record* (page 47).

If cardiac output data is available, a valve area is also calculated. For more information, see *Valve Area* (page 56).

You can choose which cardiac output method is used to calculate valve area. This is selected in the hemodynamic page in Xper Information Management.

5 To realign waveforms, drag the desired waveform to the desired position.

The values update automatically.

6 Click **Monitoring** to return to live monitoring.

6.5 Cardiac Output Measurement

You can capture and analyze thermal dilution cardiac output data directly from the patient monitoring device.

The catheters connect directly to the patient monitoring device, so there is no need for standalone cardiac output computers.

1 Select the **Cardiac Output** task.

The control panel displays the **Cardiac Output** task controls.

2 In the **Select Condition** step in the control panel, select the appropriate patient condition.

3 In the **Setup** step, select the **Catheter** to be used in the procedure.

The catheter information is automatically populated.

If the catheter you are using is not displayed in the list, you can enter the name and catheter information manually. Manually entered catheter information are not saved when the procedure is closed.

4 To acquire a cardiac output reading, click **Record**.

A progress bar is displayed, indicating that recording is in progress. Guidance is displayed at the bottom of the screen.

To stop the capture, click **Stop**.

5 Inject the bolus.

As the injectate is pushed, the injection is automatically detected and analyzed to calculate the cardiac output and cardiac index. The data is displayed as a graph in the cardiac output view, listed in the sample list, and sent to the hemodynamic page in Xper Information Management.

Average values are displayed in the sample list. Each graph is known as a trial and up to 5 trials can usually be performed. The average is automatically calculated.

6 To capture additional trials, repeat step 5.

Ensure the graph returns to the baseline between each injection.

You can capture up to 5 trials. When you capture a sixth trial, the first trial captured, or any excluded trial, is overwritten. The system displays a real-time average of all the captured trials. The average value is displayed in the sample list and in the trials display window below the trial results.

If you select a trial, it is displayed in the cardiac output view, with the relevant associated values.

7 To exclude a trial from the average calculation, select the checkbox under the desired trial area.

Excluded trials are displayed in red.

8 To return to the live **Cardiac Output** task, click **CO Live**.

9 To close the **Cardiac Output** task, select the **Monitoring** task.

6.6 Functional Measurements

This section provides information about functional measurement methods including Fractional Flow Reserve (FFR) and Instant Wave-Free Ratio (iFR)

Refer to the Instructions for Use for the relevant pressure wire for instructions about preparing the pressure wire system.

CAUTION
Normalization adjusts the distal pressure (Pd) measurement from the pressure wire to match the aortic pressure (Pa) reading. It also adjusts the time delay between the Pd and Pa signals to synchronize their display. If the Pd and Pa waveforms do not overlap, repeat the normalization step.

CAUTION
If normalization fails to establish a Pd/Pa ratio of 1.0 after multiple attempts, stop using the system.

CAUTION
If you zero the Pa after the guide wire pressure (Pd) has been normalized, you should move the guide wire pressure sensor to the normalization location and repeat normalization to ensure measurement accuracy.

CAUTION
After performing an FFR or IFR measurement, position the Pa and Pd catheters at the same position to check that no drift in the pressure values has occurred. If pressures have drifted, repeat both normalization and the measurement.

6.6.1 Fractional Flow Reserve (FFR)

NOTE ***The lowest FFR value may be at a location other than maximum hyperemia due to abnormal heart beats or artifacts in the Pa from flushing the guide catheter or manipulating the manifold. You should confirm that the lowest FFR is located at a valid location for FFR measurement.***

There are several procedural activities that can result in artifacts leading to an incorrectly recorded FFR value. These include:

- Manipulating the manifold during the recording
- Injecting the hyperemic agent while recording
- Flushing the guide catheter with saline while recording
- Withdrawing the guide wire from the measurement location while recording
- The patient coughing or an irregular heartbeat during the recording

When an artifact is detected, you should review the case to determine the correct FFR location, which should be in the area of maximum hyperemia.

You should also perform a normalization check after obtaining the FFR value by pulling the pressure wire back to the tip of the guide catheter, verifying that there is no drift and that Pa is still equal to Pd. Repeat the measurements as necessary.

Recording FFR requires that 2 pressure channels are active and that one is labeled AO.

1 Select the **FFR** task.

The screen is split to display live waveforms on the left and the live FFR data on the right.

Only one ECG waveform is displayed, to allow space for the FFR data. Two pressure channels are displayed: Pa and Pd. Pa is AO pressure and Pd is the second pressure in live monitoring.

CAUTION
The wire should be auto-zeroed before normalization, FFR, iFR Spot or iFR Pullback is performed. While the wire is being auto-zeroed, the wire should be outside of the patient's body.

2 If prompted, select the Pd pressure channel.

If you are using a patient interface module, this is automatically selected as the Pd pressure transducer, and a request to select the Pd pressure channel is not displayed.

3 To normalize the Pa and Pd pressure waveforms, click **Normalize**.

The Pa and Pd pressure waveforms align.

4 In the **Select Site Label** list, select the appropriate location of the measurement.

5 To record a sample, click **Record** and start injecting adenosine.

The FFR value is displayed dynamically while the sample is captured.

NOTE ***The capture time is independent of the selected sample length setting. Data is captured for a maximum of 10 minutes. If you wish to stop capturing before the time limit is reached, click Stop.***

6 To stop capturing, click **Stop**.

The sample is added to the sample list and displayed for review.

When reviewing a sample, a caliper line is automatically displayed at the point where the value was taken.

You can capture as many samples as desired.

7 To update the value, drag the caliper to a different part of the waveform.

The values at the part of the waveform associated with the caliper are displayed.

To update the value, click **Update FFR**. The value and main caliper updates to this point.

If you drag the caliper and release it, the waveform repositions, displaying the caliper in the center of the screen.

8 Pull the pressure wire back to the tip of the guide catheter to check for drift in the pressure values.

Verify that Pa is still equal to Pd.

If Pa and Pd are not equal, repeat the measurements as necessary.

9 To return to the live **FFR** task, click **FFR Live**.

10 To close the **FFR** task, select the **Monitoring** task.

6.6.2 Instant Wave-Free Ratio (IFR)

Recording an Instant Wave-Free Ratio requires two pressure channels to be active and one channel should be labeled **AO**.

CAUTION
You cannot use the iFR Pullback Assessment display to determine stenosis length because the pullback speed is operator-dependent and cannot be controlled.

iFR measurements are intended to be performed without administering a hyperemic agent.

Cardiac cycles that are shorter than 0.4 seconds (heart rate greater than 150 beats per minute) or longer than 2 seconds (heart rate lower than 30 beats per minute) are not recognized by the system consistently and are excluded from the iFR calculation.

An iFR cut-point of 0.89 matches best with an FFR ischemic cut-point of 0.80 with a specificity of 87.8% (95% CI, [84.4%, 90.7%]) and sensitivity of 73.0% (95% CI, [67.0%, 78.4%]) [1] [2] [3].

NOTE ***Patient variables may impact pressure measurement accuracy and the resulting iFR value.***

The amount of data collected during an iFR Pullback Assessment, and the measurement resolution, depends upon the pullback rate. The iFR Pullback Assessment display draws one single-cycle iFR data point for each cardiac cycle. A fast pullback results in fewer data points, making interpretation of the recorded data difficult.

NOTE ***The relative scales for FFR and iFR measurements are different. An iFR value of 0.80 must not be compared directly to an FFR value of 0.80.***

[1] Escaned J, et al. Prospective Assessment of the Diagnostic Accuracy of Instantaneous Wave-Free Ratio to Assess Coronary Stenosis Relevance. JACC: Cardiovascular Interventions 2015; 8 (6):824-833.

[2] Van de Hoef T, et al. Fractional flow reserve as a surrogate for inducible myocardial ischaemia. Nat Rev Cardiol 2013; 10(8):439-52

[3] Petraco R, et al. Baseline coronary pressures, instant wave-free ratio (iFR) and Pd/Pa: making the most of available information. EuroIntervention 2013; 9(1):170-23

1 Select the **iFR** task.

The screen is split to display live waveforms on the left and the live Instant Wave-Free Ratio on the right.

CAUTION
The wire should be auto-zeroed before normalization, FFR, iFR Spot or iFR Pullback is performed. While the wire is being auto-zeroed, the wire should be outside of the patient's body.

2 To normalize the Pa and Pd pressures, click **Normalize**.

The pressures are normalized and a sample of the normalized pressures is added to the sample list.

3 In the **Select Site Label** list, select the appropriate location of the measurement.

4 To capture the Instant Wave-Free Ratio value, click **Record**.

The sample is captured over several cardiac cycles until the Instant Wave-Free Ratio is calculated. The sample is added to the sample list and displayed for review.

5 To return to the live **iFR** task, click **iFR Live**.

The review window is closed and the live **iFR** task is displayed.

6 To capture a pullback measurement, do the following:

a Click **Pullback**.

The system starts to capture a sample. A progress bar is displayed indicating that the capture process is underway.

b Perform the pullback.

The Instant Wave-Free Ratio trend and raw values, and the wave-free period are displayed.

c Once the pullback is complete, stop the capture process by clicking **Stop**.

d To return to the live **iFR** task, click **iFR Live**.

7 Pull the pressure wire back to the tip of the guide catheter to check for drift in the pressure values.

Verify that Pa is still equal to Pd.

If Pa and Pd are not equal, repeat the measurements as necessary.

8 To close the **iFR** task, select the **Monitoring** task.

9 To inspect a trend and raw line, drag the caliper to a different part of the waveform.

The values at the part of the waveform associated with the caliper are displayed.

If you drag the caliper and release it, the waveform repositions, displaying the caliper in the center of the screen.

6.7 Acknowledging and Pausing Audible Alarms

The system allows you to acknowledge and pause audible alarms.

Visual alarms display at all times if an alarm condition exists.

You can acknowledge an individual audible alarm by clicking **Acknowledge alarm**.

Audible alarms are generated by the patient monitoring device.

If a second or subsequent alarm condition arises, the new alarm is still audible.

You can pause all audible alarms by clicking **Pause**.

Pausing audible alarms suspends audible tones for the duration interval you have selected. The visual indication continues to be displayed while an alarm condition exists. After the pause interval has elapsed, audible alarms sound again. You can continue to pause audible alarms while an alarm condition persists.

You can find the **Pause** control in the **Alarms** tab of the **Live Setup** dialog box, and in a drop-down control in the lower right corner of the control panel.

A timer is displayed under the stopwatch timers in the main pressure value area of the main display. The timer shows the time remaining until alarms are audible again. If you resume audible alarms, the timer is no longer displayed and the audible alarm sounds.

NOTE ***Do not rely exclusively on audible alarms for patient monitoring. Pausing alarms during monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with the correct operation of the monitoring equipment.***

You cannot adjust the maximum pause time. This can only be customized by a qualified service engineer or by a hospital system administrator. For more information, see *System Management* (page 59) and *Changing the Alarm Pause Settings* (page 59).

6.8 Using the Stopwatch Timers

Two stopwatch timers are available to use during procedures.

The timers are displayed in the main pressure value area of the main display and operate independently of each other.

1 To start a timer, click the desired timer.

2 To pause a timer, click the desired timer while it is running.

The timer pauses and a pause symbol is displayed.

3 To resume the timer, click the desired timer again.

4 To reset a timer to zero, double-click the desired timer.

The timer is also switched off.

7 Reviewing and Managing Data

Several review options are available during or after a study.

You can review samples during a study or after a study, using the **Review** task. You can also review the **Full Disclosure** record and create samples after capturing data.

The **Review** task also allows you to edit and delete samples.

When reviewing samples, you can modify scales, and select ECG signals or pressure waveforms to display.

To do this, click **Review Setup** at the top of the review display area. The **Review Setup** dialog box is displayed. The controls are similar to the **Live Setup** dialog box.

After closing a patient, if the case is re-opened within 8 hours the Philips Hemodynamic Application opens in live mode. After more than 8 hours the Philips Hemodynamic Application opens in review mode. In review mode no signals are recorded. The full disclosure and samples can be accessed for reviewing.

7.1 Reviewing Waveforms in the Full Disclosure Record

Full Disclosure records all waveform activity and vitals for the current study during the procedure, giving you the ability to review the hemodynamic data and capture missed or additional samples.

You can review samples and the full disclosure record, using the **Review** task, during a study or after a study is closed.

You can review data and capture new samples from within the full disclosure data, and apply conditions to time periods in the data set.

Full disclosure is the “as acquired” data and you are unable to manipulate it, however, you can change, add, or delete a condition marker. To manipulate the data, you must first add a sample.

NOTE ***Thermodilution cardiac outputs, FFR and iFR, cannot be recaptured from Full Disclosure.***

1 To review data during a study, select the **Review** task.

The screen is split to display live waveforms on the left and the **Full Disclosure** window on the right. The **Full Disclosure** window displays the full disclosure record.

2 To review data after a study is closed, open the study for review in Xper Information Management.

The **Review** task is automatically selected and the screen is split to display live waveforms on the left and the **Full Disclosure** window on the right. The **Full Disclosure** window displays the full disclosure record.

If the full disclosure record has been purged in Xper Information Management, only the captured waveforms are available.

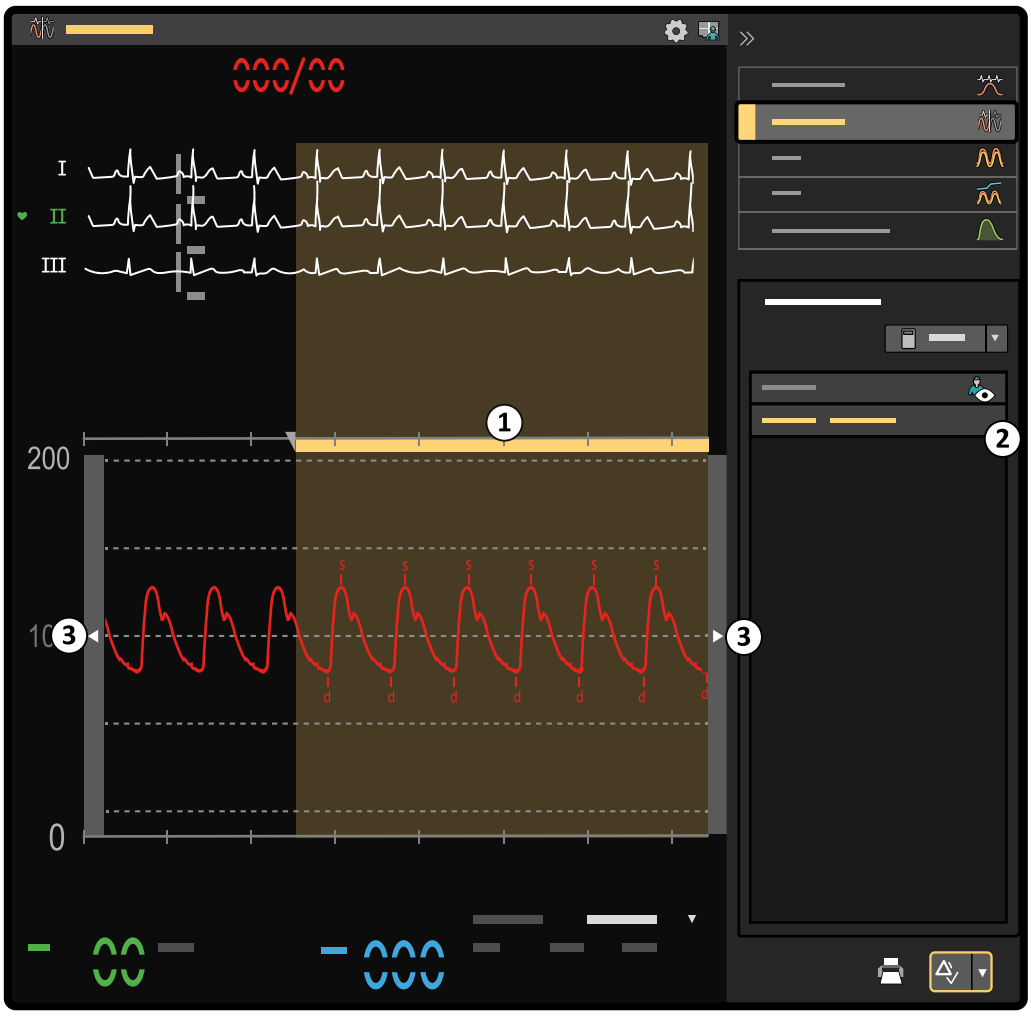

Figure 19 Review task

Legend	
1	Selected sample in the full disclosure record
2	Sample list
3	Scroll arrows

3 To scroll the **Full Disclosure** window, do one of the following:
- Rotate the wheel button on the mouse.
- Move the pointer over the left or right end of the waveform display and click the arrow.
- Drag the slider to the desired position.

4 To display a vital sign, click on the vital sign in the lower part of the review window.

5 To adjust the sweep speed, click the **Sweep Speed** and select a new speed.

6 To create a new sample from a time period within the full disclosure record, do the following:

a Scroll the waveform to desired location and select **New Sample** in the **Manage Sample List**.

A new sample is created in the selected section of the waveform. The sample is added to the sample list in the control panel.

b Adjust the start and end positions of the sample as desired by dragging the boundary lines.

7 To create a pullback sample from a time period within the full disclosure record, scroll the waveform to the desired location and select **Pullback** in the **Manage Sample List**.

The sample is added to the sample list in the control panel.

8 To create a baseline sample from a time period within the full disclosure record, scroll the waveform to the desired location and select **Baseline** in the **Manage Sample List**.

The sample is added to the sample list in the control panel.

9 To assign a hemodynamic condition, do the following:

a Scroll the waveform to the desired location.

b Right-click on the desired location within the full disclosure record, move the pointer over **Add condition** and select the desired condition label.

A section is created in the sample list and all samples taken after the time that this condition relates to, appear under the new section, to indicate that the samples occurred after the condition.

c To change a condition label, right-click on the condition label, move the pointer over **Rename condition** and select the desired condition label.

d To delete a condition, right click on the condition label, and select **Remove condition**.

10 To close the **Review** and return to live monitoring, select the **Monitoring** task.

7.2 Managing Samples

You can edit and delete samples in the sample list.

You can also add, move, and delete markers within the sample.

Markers are points on a waveform that are used to calculate values related to a particular waveform. Different markers are displayed dependant on the type of waveform that is configured in Xper Information Management.

For arterial waveforms, s (systolic) and d (diastolic) markers are displayed. For ventricular waveforms, s, d, and e (end diastolic) markers are displayed. For venous waveforms, a, v, and c markers are present. You can also edit R and T markers on the ECG.

1 Select the **Review** task.

2 Select the desired sample in sample list.

3 To adjust the beginning and end times of a sample, drag the vertical bars at the beginning and end of the sample to new positions.

4 To move a marker, drag the marker to a new position.

Markers are not displayed on FFR and iFR samples.

You can also move all markers of the same type by pressing and holding Ctrl on the keyboard and dragging the markers.

5 To delete a marker, right-click on the marker and select **Delete marker**.

6 To add a marker, right click on the waveform and select **Insert systolic marker** or **Insert diastolic marker** as appropriate.

The type of markers that are available changes depending on the type of waveform.

7 To adjust the pullback moment in a pullback sample, drag the vertical bar in the center of the sample to a new position.

8 To calculate dP/dT, select **dP/dT** in the **Manage Sample List**.

The calculation is displayed and added to the sample list.

9 To undo the changes you have made to the sample, click **Reset** in the **Manage Sample List**.

10 To delete a sample, right-click on the sample an select **Delete**.

The sample is deleted from the sample list.

You can delete samples in any task.

7.3 Linking Samples

You can link samples captured at different time periods in the same full disclosure record and use them to perform calculations.

1 Select the **Review** task.

2 Select the first desired sample in the sample list.

If the sample is not yet created, you can create it. For more information, see *Reviewing Waveforms in the Full Disclosure Record* (page 47).

3 Click **Link To**.

4 Select the sample to link to.

The samples are linked and this is indicated in the sample list.

5 To calculate valve gradient based on the linked samples, select **Valve** in the **Manage Sample List**.

The calculation is displayed and added to the sample list.

6 To unlink the samples, select the sample link in the sample list and click **Unlink** in the **Manage Sample List**.

7.4 Displaying Data in the Examination Room

When working in the control room, you can display review data for the physician in the examination room for the **Review**, **FFR**, **iFR**, and **Cardiac Output** tasks.

Data is shown in the examination room by default for the **FFR**, **iFR**, and **Cardiac Output** tasks, but you can stop displaying the data for each of these tasks. Live monitoring data is always displayed in the examination room.

When using the **FFR**, **iFR**, and **Cardiac Output** tasks, you can also show or hide the sample list in the examination room to provide more viewing space on the screen.

1 To display review and calculation task data in the examination room, click **Click to show the review panel to physician**.

2 To stop displaying review and calculation task data in the examination room, click **Click to hide the review panel from physician**.

3 To hide the sample list in the examination room, click **Click to hide the sample list from the physician** in the control panel.

4 To show the sample list in the examination room again, click **Click to show the sample list to the physician** in the control panel.

8 Exporting and Printing

You can print individual samples to your default printer.

All other printing and exporting tasks are performed using Xper Information Management. For more information, refer to the Instructions for Use for Xper Information Management.

NOTE ***When handling personal data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.***

8.1 Printing a Sample

You can select and print individual samples.

1 Select the **Review** task.

2 In the sample list, select the sample you want to print.

3 Edit the sample as desired.

4 In the **Manage Sample List**, select **Print**.

The sample is sent to the default printer.

If the sample requires more than one page when printed, the system prompts you to confirm that you want to print the pages.

9 Maintenance and Security

This section outlines your responsibilities regarding the maintenance and security of the product.

9.1 Maintenance

Due to the nature of this product, there are no maintenance tasks.

9.2 Customer Role in the Product Security Partnership

Philips Medical Systems recognizes that the security of its products is an important part of your facility's in-depth security strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, authentication technologies. As with any computer-based system, protection must be provided such that firewalls or other security devices are in place between the medical system and any externally accessible systems. The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

The latest information on security and privacy, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

NOTE ***You should check the system's published cyber security status regularly on this website.***

9.3 Malware Protection

This equipment incorporates protection mechanisms against the intrusion of malware. Without proper cyber security maintenance, the effectiveness of these provisions may degrade over time, since malware is continuously altered to target newly discovered vulnerabilities. Philips Medical Systems systematically analyzes sources of information related to cyber security vulnerabilities to assess the cyber security risk to its systems. To ensure the proper functioning of the system, Philips Medical Systems may recommend specific customer or service actions, or issue service recommendations to update, alter, or replace system protection mechanisms.

Despite preventive measures already implemented, a remote possibility remains that the system may become infected with malware. When malware is detected, or when you notice that unfamiliar behavior or degraded performance occurs repeatedly, including after being switched off and on again, you should call technical support for an inspection. When the inspection confirms the infection, be sure to take measures to contain and remove the source of infection. Technical support will reinstall the system software to bring the system back into specification. Technical support can also assist in accessing the system's event log, which may provide information useful for the investigation.

10 Appendices

This section provides additional information related to the use of Philips Hemodynamic Application.

10.1 Hemodynamic Abbreviations

Abbreviation	Definition
AAO	Ascending aortic artery
AO	Aortic artery
AOm	Aortic artery monitoring
AOp	Aortic artery pullback pressure
AOpo	Aortic artery pullback outflow
AoRt	Aortic root
Art	Arterial pressure
Atrm	Atrium
Azyg	Azygous vein
BLAL	Blalock, Taussig
C/S	Coronary sinus
ComV	Common venous
Cond	Conduit
Cuff	NIBP Cuff pressure
DAO	Descending aortic artery
DLPA	Descending left pulmonary artery
DMPA	Descending mid pulmonary artery
DRPA	Descending right pulmonary artery
FA	Femoral artery
FAC	Femoral artery compensation
FV	Femoral
GLEN	Glenenatimosis
HepV	Hepatic vein
HIVC	High inferior vena cava
HLA	High left atrium
HRA	High right atrium
HRV	High right ventricle
HSVC	High superior vena cava
InnV	Innominate vein
IVC	Inferior vena cava
LA	Left atrium
LAxA	Left axillary artery
LBA	Left brachial artery
LCA	Left coronary artery
LCCA	Left common carotid artery
LCIA	Left common iliac artery
LEIA	Left internal iliac artery
LFA	Left femoral artery
LFV	Left femoral vein

Abbreviation	Definition
LIJV	Left internal jugular vein
LIVC	Lower inferior vena cava
LLA	Lower left atrium
LLPA	Lower left pulmonary artery
LLPV	Lower left pulmonary vein
LPA	Left pulmonary artery
LPOP	Left popliteal artery
LPV	Left pulmonary vein
LPW	Left pulmonary wedge
LRA	Lower right atrium
LRNA	Left renal artery
LRV	Lower right ventricle
LSCA	Left subclavian artery
LSVC	Lower superior vena cava
LUPA	Left upper pulmonary artery
LUPV	Left upper pulmonary vein
LV	Left ventricle
LVA	Left ventricular apex
LVO	Left ventricular outflow
LVp	Left ventricular pullback pressure
LVpo	Left ventricular pullback outflow
MIVC	Mid inferior vena cava
MPA	Mid pulmonary artery
MPV	Main portal vein
MRA	Mid right atrium
MSVC	Mid superior vena cava
PA	Pulmonary artery
PAp	Pulmonary artery pullback pressure
PLPA	Proximal left pulmonary artery
PMPA	Proximal mid pulmonary artery
PRPA	Proximal right pulmonary artery
PT	Pulmonary track
PV	Pulmonary vein
PVW	Pulmonary venous wedge
PW	Pulmonary wedge
PWp	Pulmonary wedge pullback pressure
RA	Right atrium
RAp	Right atrial pullback pressure
RArt	Right arterial
RAxA	Right axillary artery
RBA	Right brachial artery
RCA	Right coronary artery
RCCA	Right common carotid artery
RCIA	Right common iliac artery
REIA	Right external iliac artery
RFA	Right femoral artery

Abbreviation	Definition
RFV	RIght femoral vein
RHV	Right hepatic vein
RICA	Right internal carotid artery
RIJ	Right internal jugular
RIJV	Right internal jugular vein
RLPA	Right lower pulmonary artery
RLPV	Right lower pulmonary vein
RPA	Right pulmonary artery
RPOP	Right popliteal artery
RPV	Right pulmonary vein
RPW	Right pulmonary wedge
RRNA	Right renal artery
RSCA	Right subclavian artery
RSVC	Right superior vena cava
RUPA	Right upper pulmonary artery
RUPV	Right upper pulmonary vein
RV	Right ventricle
RVOT	Right ventricular outflow tract
RVp	Right ventricular pullback pressure
SMV	Superior mesenteric vein
SpO2	Pulse oximetry site
SPV	Splenic vein
SubC	Subcutaneous
SVC	Superior vena cava
SysV	Systemic venous
UA	Umbilical artery
UV	Umbilical vein
Ven	Venous
Vent	Ventricular
VenV	Ventricular venous
VV	Venous ventricle

10.2 Hemodynamic Calculations

Cardiac Index

The cardiac index is calculated using the following equation:

CI = CO / BSA

where CI (l/(min m^2)) is the cardiac index, CO (l/min) the cardiac output and BSA (m^2) is the body surface area.

Body Surface Area is calculated using the Dubois formula [1]:

BSA = 0.20247 x $h^{0.725}$ [m] x $w^{0.425}$ [kg].

Valve Area

Valve area is calculated using the Gorlin Formula [2]

Area [cm^2] = flow [ml/s] / (K x C x $\sqrt{}$(MVG) [mmHg]) ,

where MVG is the mean valvular gradient, K = 44.3 (a derived constant by Gorlin and Gorlin), and C is an empirical constant that is 1 for semilunar valves (aortic, pulmonary, 3 leaflets) and 0.85 for the mitral valve (2 leaflets).

For the mitral valve and the tricuspid valve:

flow = CO [ml/min] / ((diastolic filling period) [sec/beat] x (HR) [bpm])

for the aortic valve and the pulmonary valve:

flow = CO [ml/min] / ((systolic ejection period) [sec/beat] x (HR) [bpm])

where CO is the cardiac output.

Thermal Cardiac Output

The temperature is analyzed to calculate the cardiac output (CO). In the method, a cold bolus of temperature T_I is injected into the vena cava while the temperature of the blood T_B is measured in the pulmonary artery (PA).

The speed at which the cold bolus passes the PA is indicative of the cardiac output [3]:

$CO = (V_I \times (T_B - T_I) \times C)/(\int \Delta T_B(t)dt)$

where V_I is the injection volume (ml), and C is a constant, which is given by the manufacturer of the catheter.

A thermodilution curve is characterized by a rapid upslope to a peak, a gradual downslope, and an exponential decay of the thermal signals. The integration of the area under the thermodilution curve starts at the instant of injection and terminates integration when the exponential decay reaches a value of approximately 30%. The part of the dilation curve between 80% and 30% is used to extrapolate the exponential decay of the remaining part. In this way, any artifact introduced by recirculation of indicator is minimized [4].

FFR

FFR is defined as the ratio of hyperemic flow in the distal (stenotic) coronary artery to hyperemic flow in the same artery if it were normal. A vasodilator, such as adenosine, is used to induce hyperemia and override the heart's autoregulatory flow mechanisms.

The FFR value is calculated using the following formula [5].

(Pd/Pa) = (MDP - VP) / (MAP - VP)

where MDP is the mean distal pressure during maximum hyperemia, MAP is the mean aortic pressure during maximum hyperemia, and VP is the venous pressure.

- FFR > 0.80 means that a lesion is not hemodynamically significant [6][7].
- FFR $\leq$ 0.80 means that a lesion is hemodynamically significant [6][7].

NOTE ***In the Philips Hemodynamic Application the venous pressure is assumed to be zero.***

iFR

iFR modality is a vasodilator-free measurement that is able to take a pressure measurement similar to the FFR Modality. iFR modality is a Philips Volcano proprietary software algorithm. The iFR modality includes iFR spot measurement and iFR Scout Pullback measurement capabilities. The iFR values are calculated over a portion of the cardiac cycle called the wave-free period where microvascular resistance is naturally constant and minimized and where intracoronary flow is maximized. Pressure tracings with both baseline (i.e. resting) measurement and vasodilator-based (i.e. hyperemic)

measurement were used for algorithm development and were used for validation of values. This results in the ability to measure pressure without administration of a hyperemic agent with the iFR modality.

The iFR Spot measurement provides a single location measurement while the iFR Scout Pullback measurement provides the option to analyze multiple lesions within a single vessel in one measurement composed of a series of single-cycle iFR values made along the length of the vessel. iFR scout constitutes a Pullback feature and a live iFR display representing the iFR value over a single cardiac cycle. The iFR Scout feature allows you to assess a length of lesion by placing the pressure sensor distally initiating an iFR Pullback recording, and pulling the sensor back through the vessel to a proximal position where the recording is stopped. This generates a graph of the iFR values along the vessel and a distal iFR value that represents the condition of the vessel at the most distal point of the recording. The user can review this trend plot to determine which lesion is most significant. Once the most significant lesion is determined, the established current iFR workflow is followed to establish specific lesion severity and to plan treatment.

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10.3 Patient Alarm Adjustment Ranges and Resolutions

The patient alarms have the following adjustment ranges and resolutions.

Vital sign	Lower limit range	Upper limit range	Resolution
Heart rate (bpm)	30 - 295	35 - 300	1 (values <40) 5 (values >40)
Respiration rate (rpm)	4 - 145	9 - 150	1 (values <20) 5 (values >20)
Skin temperature (°C)	25 - 42	32 - 45	1
Skin temperature (°F)	77 - 107	90 - 113	1
Pulse oximetry (%)	70 - 95	85 - 100	1
End tidal CO_2 (mmHg)	0 - 95	5 - 150	1
Non-invasive blood pressure (systolic) (mmHg)	35 - 250 (adult mode) 35 - 130 (neonatal mode)	40 - 255 (adult mode) 45 - 135 (neonatal mode)	2 (values <50) 5 (values >50)
Non-invasive blood pressure (diastolic) (mmHg)	15 - 210 (adult mode) 15 - 100 (neonatal mode)	25 - 215 (adult mode) 25 - 105 (neonatal mode)	2 (values <50) 5 (values >50)
Invasive blood pressure (systolic) (mmHg)	-30 - 295	10 - 300	2 (values <50) 5 (values >50)

Vital sign	Lower limit range	Upper limit range	Resolution
Invasive blood pressure (diastolic) (mmHg)	-30 - 295	10 - 300	2 (values <50) 5 (values >50)
Invasive blood pressure (mean) (mmHg)	-30 - 295	10 - 300	2 (values <50) 5 (values >50)

10.4 System Management

Some system settings are password protected.

NBP Verification Mode

Verification of the non-invasive blood pressure (NBP) can only be performed when no patient is selected. To perform this function, you must log in as a hospital system administrator. This will allow the patient monitor to enter a state where it is able to display the pressure that is applied to the NBP port.

Service Application

Some items in the service application are available to hospital system administrators. After starting the service application the following items are available:

- Enable and disable licenses.
- View and load a license file.
- Change the maximum audio pause time.
- Enable or disable the audio pause reminder tone.
- Show disk space used.
- Select country-specific keyboards.
- Select regional settings for displaying time and numbers.
- Select and configure displays.
- View and export a log.
- Adjust the date and time.
- Add a new printer.
- Select the default printer.
- Adjust printer settings.

NOTE ***Do not use date formats containing letters.***

NOTE ***Print scaling should always be turned off.***

NOTE ***The system only supports printers that are compatible with Windows.***

10.4.1 Changing the Alarm Pause Settings

To change the alarm pause settings, you must be logged in as a hospital system administrator.

1 Click **System** and select **Service**, followed by **Service application**.

A dialog box is displayed. You must confirm that you want to start the service application.

2 Click **OK** to start the service application.

A dialog box is displayed allowing you to log in. You must log in as a hospital system administrator.

3 Enter your **User** name and **Password**.

4 Click **Log In**.

The service application is displayed.

5 Click **Hemo Configuration** and select the **Alarms** tab.

6 In the **Alarm Pause Settings** section, select the desired settings for the **Maximum pause duration** and the **Pause reminder tone**.

The new settings are saved automatically.

The interval between reminder tones is 1 minute.

The default maximum alarm pause duration is 2 minutes. This can be increased to a maximum of 4 hours by a qualified service engineer or by a hospital system administrator.

7 To close the service application, click in the upper right corner.

10.5 Error Messages and Troubleshooting

The following ECG-related messages can be displayed by the Philips Hemodynamic Application.

Symptom/Error message	Possible problem	Possible solution
xx lead off	The indicated lead is disconnected. Where xx is the name of the disconnected lead.	Check the indicated ECG lead and connections, and connect the lead securely.
ECG leads off	All limb leads are disconnected.	Check the limb lead and connections, and connect the leads securely.

For information regarding error messages concerning accessories connected to the Xper Flex Cardio Physiomonitoring System, refer to the relevant chapter in the Instructions for Use for the Xper Flex Cardio Physiomonitoring System.

For information regarding error messages for the IGT-D wire, refer to the relevant Instructions for Use.

10.6 Default Layout Settings

The following table indicates the default layout settings for each type of procedure.

Procedure	Macros	Waveforms	Vital signs
Left Heart Cath	1 pressure (P1)	3 ECG leads (I, II, III) with HR from II 1 pressure channel (AO)	SpO_2
Right Heart Cath	1 pressure (P1)	3 ECG leads (I, II, III) with HR from II 1 pressure channel (PW)	SpO_2
Full Heart Cath	1 pressure (P1)	3 ECG leads (I, II, III) with HR from II 1 pressure channel (AO)	SpO_2
Structural	2 pressures (P1, P2)	3 ECG leads (I, II, III) with HR from II 2 pressure channels (LV, PW)	SpO_2
Pediatric	1 pressure (P1) SpO_2	3 ECG leads (I, II, III) with HR from II 1 pressure channel (AO)	SpO_2

10.7 Default Settings

The tables below detail the default settings for the Philips Hemodynamic Application.

ECG			
	Adult	Pediatric	Neonatal
Upper alarm limit (bpm)	120	160	200
Lower alarm limit (bpm)	50	75	100
Primary Lead	II	II	II
Filter	Monitoring	Monitoring	Monitoring

SpO_2 Alarms			
	Adult	Pediatric	Neonatal
Upper alarm limit (%)	100	100	95
Lower alarm limit (%)	90	90	85

SpO_2 Pulse			
	Adult	Pediatric	Neonatal
Upper alarm limit (bpm)	120	160	200
Lower alarm limit (bpm)	50	75	100

Respiration Rate			
	Adult	Pediatric	Neonatal
Upper alarm limit (rpm)	30	30	100
Lower alarm limit (rpm)	8	8	30

Non-invasive Blood Pressure			
	Adult	Pediatric	Neonatal
Upper alarm limit (mmHg)	160/90 (110)	120/70 (90)	90/60 (70)
Lower alarm limit (mmHg)	90/50 (60)	70/40 (50)	40/20 (24)

Invasive Blood Pressure			
	Adult	Pediatric	Neonatal
Upper alarm limit (mmHg)	160/90 (110)	120/70 (90)	90/60 (70)
Lower alarm limit (mmHg)	90/50 (70)	70/40 (50)	55/20 (36)
Filter (Hz)	12	12	12

Temperature			
	Adult	Pediatric	Neonatal
Upper alarm limit (°C)	39	39	39
Lower alarm limit (°C)	36	36	36

Cardiac Output			
	Adult	Pediatric	Neonatal
Tblood upper alarm limit (°C)	39	39	39
Tblood lower alarm limit (°C)	36	36	36

$etCO_2$			
	Adult	Pediatric	Neonatal
Upper alarm limit (mmHg)	60	60	60
Lower alarm limit (mmHg)	25	25	25

10.8 Barometric Pressures

This section provides standard air pressure for elevations below and above sea level.

To ensure accurate end tidal CO_2 (**etCO2**) vital sign measurements, you should enter the correct barometric pressure (mmHg) for your location. For more information, see *Setting Up the End Tidal CO2 (etCO2)* (page 33).

Altitude above sea level		Absolute barometric pressure
Feet	Meters	mmHg
0	0	765
500	152	751
1000	305	738
1500	457	724
2000	610	711
2500	762	698
3000	914	686
3500	1067	673
4000	1219	661
4500	1372	649
5000	1524	637
6000	1829	613
7000	2134	590
8000	2438	568
9000	2743	547
10000	3048	526

10.9 X-ray System Touch Screen Module (TSM)

If a touch screen module is installed with the Philips Interventional X-ray system, you can operate selected Philips Hemodynamic Application functions from the X-ray table using the touch screen interface.

You can operate the Philips Hemodynamic Application using the touch screen module, located on the tableside in the examination room. The TSM allows you to perform most of the monitoring functionality that is offered on the Philips Hemodynamic Application, including:

- Monitor functions (such as non-invasive devices, invasive pressure channels, and ECG leads)
- View waveform activity
- Record pressure samples
- Review the patient's samples and vital signs

NOTE ***Before using the touch screen module, admit the patient on the Philips Interventional Hemodynamic System.***

The touch screen module is not connected directly to Philips Interventional Hemodynamic System workstation. This may result in a delay between actions on the touch screen module and results on the Philips Hemodynamic Application. The Philips Interventional Hemodynamic System workstation is always the primary control during procedures.

The upper area of the touch screen module contains the main level menu where tasks and the most frequently used functions appear. When you select a main level function, a sub-menu is displayed in the lower area, associated with the main level selection.

The controls displayed in the sub-menu depend upon the task you are performing.

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This Medical Device meets the provisions of the transposition of the Medical Device Directive 93/42/EEC within the country of origin of the Notified Body concerned with the device.

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