

PHILIPS

Xper Flex Cardio



Flexibility and clinical
decision support

Xper Flex Cardio with Xper Information Management





1. Introduction

Philips provides patient care and clinical informatics solutions that improve the clinical practice and simplify the workflow. The Xper Flex Cardio Physiomonitring system applies these values, putting clinical IT to work through a space-saving design, Fractional Flow Reserve (FFR) support, advanced electrocardiogram (ECG) analysis tools, and a host of other features that deliver high quality physiomonitring – before, during, and after interventional procedures.

This product specifications document contains a complete description of Xper Flex Cardio Physiomonitring and the enhanced Xper Information Management (Xper IM) software.

Xper Flex Cardio Physiomonitring system

Xper Flex Cardio Physiomonitring system is a hemodynamic monitoring solution for cardiac monitoring in hospitals and clinics where interventional procedures are performed in cardiac catheterization and electrophysiology (EP) labs, as well as interventional radiology. Xper Flex Cardio brings workflow-enhancing features as well as advanced clinical decision support tools to the interventional workspace. The small, space-saving design provides flexible workflow inside the lab while offering scalability to meet ever-evolving clinical needs.

Key advantages

- Comprehensive hemodynamic analysis package and connected with Xper IM
- Streamlined FFR workflow makes it easy to perform FFR measurements, from acquisition to automatic data entry onto reports
- Patented DXL Algorithm facilitates Culprit Artery Detection, ST Maps and Critical Values
- Patient data connection with Philips image guided therapy systems such as Azurion
- Philips harmonized patient cables allows for reuse of cables from IntelliVue monitors
- Space-saving design delivers mounting and positioning flexibility



2. Intended use

Xper Flex Cardio Physiomonitring system

The physiomonitring system is intended for use by professional healthcare providers for complete physiologic and hemodynamic monitoring. The system may be used to display and analyze surface ECG, respiration, invasive pressure, pulse oximetry (SpO₂), end tidal CO₂ (ETCO₂), FFR, non-invasive blood pressure (NIBP), surface body temperature, and thermal cardiac output. The system also provides for clinical data acquisition, medical image and data processing, and analytical assessment. The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where cardiac monitoring may be required. The system is not intended to be used in the proximity of magnetic resonance imaging. The data may also be acquired from and sent to other devices, such as physiological monitoring systems, information management systems, image acquisition and storage devices, and other medical devices.

User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences to facilitate timely responses. Use of the system is not intended where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

Xper Information Management

The information management system is intended for use under the direct supervision of a healthcare practitioner for acquiring, displaying, trending, storing, and transmitting various types of data, such as physiologic/hemodynamic, clinical, medical image, and other related data. The system is capable of processing/analyzing information, such as multi-channel ECG signals, and performing other data management functions, such as creating reports. Data may be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.

The system is indicated for use in the following areas: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and surrounding areas where access to the information is needed.

The system consists of modules and may be entirely a software offering or a hardware/software offering. It is intended for use on standard computer systems and does not require proprietary hardware. The solution is available as a single module or combination of modules, or may function as a standalone system.

The system is capable of receiving and displaying user-adjustable alarms (both visual and audible) available in the system, which alert the operator to anomalous occurrences and facilitate timely responses. Use of the system is not intended where unattended patient monitoring is desired, or in situations where arrhythmia detection is required.

The system provides the ability to transmit patient data files for storage, viewing and analysis at distributed locations via the intranet or internet, or may function as a stand-alone device.

3. Monitoring parameters

Standard

- 12-lead ECG capability
- 4 invasive blood pressure channels
- Non-invasive blood pressure (NIBP)
- Pulse oximetry (SpO₂)
- Respiration rate
- Body surface temperature
- Thermodilution cardiac output

Optional

- Philips DXL Algorithm (ECG analysis, STEMI-CA, ST Maps and Critical Values)
- FFR – with approved third-party vendors
- End tidal CO₂ (capnography) mainstream and sidestream

4. Environmental and usability enhancements

- Philips has designed a small form factor physiomonitring system that enables flexible and easy positioning within the interventional lab environment or outside the lab where cardiac monitoring is needed
- The Xper Flex Cardio signal acquisition device is one-sixth the size (14.6%) and one-quarter the weight (22%) of the Xper Physiomonitring 5 device
- Xper Flex Cardio has a VESA (Video Electronics Standards Association) mounting capability, an industry-wide standard that enables a variety of positioning options
- Compatibility with the VESA standard allows for mounting in multiple locations, such as on an X-ray table rail inside a cath lab, an articulating arm, a roll cart that can be used in multiple cath labs, or flush against a wall by the bedside in a patient monitoring area
- Keeping the signal acquisition device off the floor increases available floor space within the procedure room
- Smart design enables users to simply swap the device in case maintenance is required, allowing them to quickly and easily continue their work without major disruption to workflow
- Simplified hemodynamic recording control via intuitive graphical user interface

5. Harmonious Philips connectivity

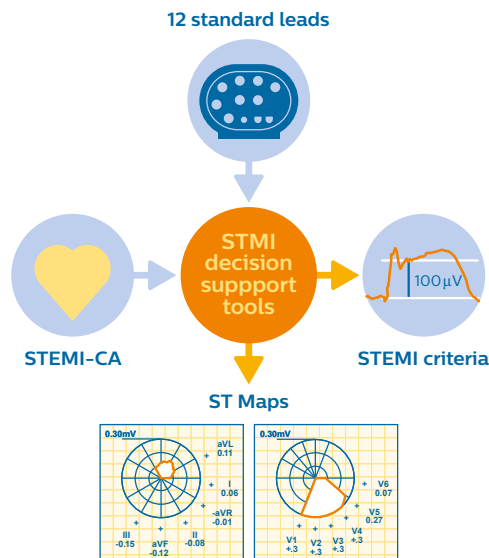
Xper Flex Cardio is compatible with a range of Philips cables and accessories that are currently used on the Philips IntelliVue patient monitoring systems. This helps streamline clinician workflow so the focus can be on patient care.



6. Exclusive functionality

Xper Flex Cardio brings the power of 12-lead ECGs to interventional environments. Using 12 leads for post-procedure ECGs enables rapid and confident assessment of cardiac symptoms. Xper Flex Cardio also supports standard 12-lead ECG monitoring, recording, and analysis.

In conjunction, Philips-exclusive DXL Algorithm incorporates tools that provide quantitative information for evaluation of ST Elevation Myocardial Infarction (STEMI). The integration of the DXL Algorithm into Xper Flex Cardio extracts quantitative criteria for Culprit Artery identification and displays the spatial orientation of the ST-segment abnormalities in 3D polar maps, which can help improve patient care in the cath lab.



7. ECG waveform analysis (DXL Algorithm)

The Philips DXL ECG Algorithm, developed by the Advanced Algorithm Research Center, uses sophisticated analytical methods for interpreting resting ECG. The DXL Algorithm analyzes up to 12 leads of simultaneously acquired ECG waveforms to provide an interpretation of rhythm and morphology for a wide variety of patient populations. The algorithm reflects new recommendations, such as the 2007 AHA/ACCF/HRS Recommendations, Part II¹ and the 2009 AHA/ACCF/HRS Recommendations, Part VI² for the Standardization and Interpretation of the ECG.

The ECG Analysis Module provides an analysis of the amplitudes, durations, electrical axis, ST Mapping, and morphologies of the ECG waveforms and associated rhythms. ECG waveform analysis is based on standard criteria for interpretation of these parameters. The ECG analysis is a tool to assist the physician in making a clinical diagnosis in conjunction with the physician's knowledge of the patient, the results of the physical examination, and other findings, and is not intended to be a substitute for interpretation by a qualified physician.

Expanded diagnostic capabilities

The Philips DXL ECG Algorithm goes beyond traditional 12-lead interpretation of the resting ECG. It also provides for incremental diagnostic capabilities not associated with analysis programs of the past:

- ST Maps that provide a visual representation of ST deviations in frontal and transverse planes, responding to the 2009 AHA/ACCF/HRS Recommendations, Part VI² for the Standardization and Interpretation of the ECG
- Updated criteria based upon the latest clinical research. Examples include the addition of “acute global ischemia” and incorporation of updated gender-specific STEMI criteria, as documented in the 2009 AHA/ACCF/HRS Recommendations
- STEMI-CA (Culprit Artery) criteria that suggests the probable site of an occlusion, consistent with the 2009 AHA/ACCF/HRS Recommendations
- Critical Values that highlight conditions requiring immediate clinical attention
- LeadCheck program that identifies 19 possible lead reversal and placement errors during ECG acquisition
- Updated statements that reflect the 2007 AHA/ACCF/HRS Recommendations

Gender-specific ECG interpretation

As cardiovascular medicine continues to advance, there has been continued learning regarding the physiological differences between men and women. Gender-specific criteria are not new to Philips. They have been incorporated into the multi-lead algorithms since 1987 and have been enhanced continually based upon the latest research and guidelines. For example, the DXL Algorithm applies gender, lead, and age limits to aid in the detection of acute MI. Based upon the 2009 recommendations, STEMI criteria are subject to reduced ST thresholds in women. The algorithm also uses gender-specific axis deviation and MI criteria, Cornell gender-specific criteria for detection of left ventricular hypertrophies, and Rochester and Rautaharju criteria for the detection of prolonged QT.

Application of these gender-specific criteria results in an ECG interpretation that helps clinicians assess the cardiac state of male and female patient.

STEMI-CA for identification of Culprit Artery

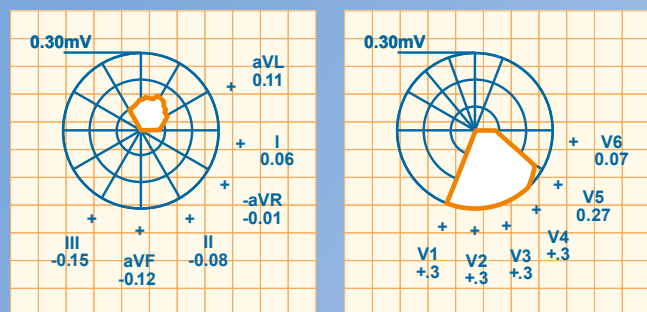
If STEMI criteria are met, the DXL Algorithm's STEMI-CA criteria helps you identify the likely Culprit Artery or probable anatomical site causing the functional ischemia. This may have prognostic significance as well as help to pinpoint the offending lesion when multiple obstructions are present, and can thus be used to enhance the treatment approach in the cath lab.

Specific anatomic sites can include the following coronary arteries:

- Left anterior descending artery (LAD)
- Right coronary artery (RCA)
- Left circumflex artery (LCx)
- Left main or multi-vessel disease (LM/MVD)

ST Maps

The 2009 AHA/ACCF/HRS document recommends the display of the spatial orientation of ST-segment deviations in both frontal and transverse planes. Xper Flex Cardio can display patented ST Maps in both planes to provide for rapid visual assessment of the degree of ST abnormalities (see Figure 1). The maps are plotted in "Cabrera sequence" to reflect the anatomical orientation. This presentation, previously available only on Philips IntelliVue patient monitors, provides distinct patterns for different anatomic sites of infarcts, global ischemia, pericarditis, and other conditions that are readily seen using such maps.



ST Maps provide rapid visualization of the degree of ST abnormalities

ST Maps draw attention to abnormalities

Early detection of STEMI shortens "discovery to treatment" times. The DXL Algorithm enables Philips patented ST Maps, a graphical indication of ST elevation or depression. Philips ST Maps meet the 2009 AHA/ACCF/HRS Recommendation that the spatial orientation of ST-segment deviations be displayed in both frontal and transverse planes. The maps provide distinct patterns for different anatomic sites of acute infarcts, region of ischemia, and other conditions, helping physicians assess a patient's condition before and during the procedure. After the intervention, ST Maps provide visual verification of the results, allowing assessment of the extent of the infarct and the success of the stent in alleviating the condition.

1 AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram, Part II: Electrocardiography Diagnostic Statement List. J Am Coll Cardiol. 2007;49:1128-135.

2 AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram, Part VI: Acute Ischemia/Infarction. Circulation. 2009;119:e262-e270.

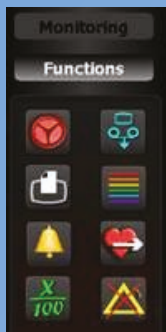
8. Supports FFR technology

FFR is a technique that has been shown to be beneficial in assessing ischemia and in determining if a physician should deploy a coronary stent as part of the patient's treatment. Xper Flex Cardio allows for interfacing with FFR devices, allowing users to perform integrated FFR measurements. FFR is a lesion-specific physiological index determining the hemodynamic severity of intracoronary lesions.

Within Xper Flex Cardio, a single click launches the FFR function which allows users to identify the appropriate anatomical site and capture FFR data, display the measured result in real time, and store the measurement as part of the hemodynamic record. These measurements can be used to automatically populate a physician's final report.

9. Enhanced hemodynamics and alarm controls

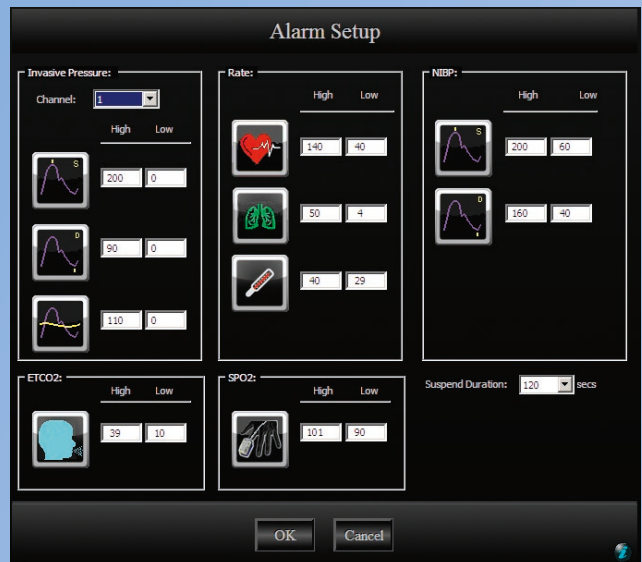
Intuitive icon-based controls for hemodynamic monitoring have been designed and implemented for simplified usability. Enhancements help users navigate to set-up screens to modify specific parameters and alarm settings. The icons that activate various functionality or commands also display a text bubble when a cursor is placed over them, helping users learn the functionality.



Hemodynamic functions and configurations



Xper Flex Cardio monitoring screen



The alarm capability in Xper Flex Cardio supports the IEC 60601-1-8 standard for alarms

10. Clinical and operations workflow modules

Xper IM offers a highly configurable cardiovascular workflow solution for the cath lab. This innovative software suite presents a variety of innovations for reporting, scheduling, inventory, and intelligent data management. With tools that enhance efficiency on multiple levels, the solution improves and simplifies workflow for cardiology professionals. It includes:

IntelliSpace Cardiovascular integration

Xper IM is integrated with Philips IntelliSpace Cardiovascular. This allows a user to access Xper IM directly from the Cardiology Timeline and Worklists applet and launch into study context as well as import images from IntelliSpace Cardiovascular into the Xper IM report for inclusion.

Charting

The Charting Module allows quick and easy procedure charting, where users can create custom menus to refine workflow. Procedural charting is integrally connected to transcription and statistical reports, as well as other modules throughout the application. In addition, entries and modifications to charting are tracked, so that users can perform audits if discrepancies arise.

Arterial trees

The Arterial Trees Module allows a physician to create a graphic representation of a patient's cardiac or peripheral arterial anatomy. The arterial trees allow users to indicate areas of disease, collaterals and bypass grafts, interventions performed, and other diagnostic data, such as anatomical aberrations. The data from the tree is automatically placed in the appropriate charting menu and can be included in a report or queried at a later time. Operators may use the provided templates or replace any or all of them with a preferred set.

Hemodynamic calculations

The Hemodynamic Calculations Module features a screen that contains the invasive pressure and cardiac output data that is collected during a procedure. The collected data is used to perform calculations, such as vascular resistance, intracardiac shunting, and valve stenosis. The calculations are performed automatically as samples are captured, and are recalculated when samples are edited using the waveform review screen. Users also enter oxygen saturation data into the hemodynamics screen. Hemodynamics screens correspond to monitoring conditions. When users record an initial pressure sample in a condition on the monitoring screen, a hemodynamics

screen is created to match that condition. Any data from subsequent samples taken in that condition is recorded on the corresponding hemodynamics screen.

Vitals capture

The Vitals Capture Module is an automatic function within Xper IM. The Vitals Capture Module can be set to collect and chart patient vital signs at intervals of 2 to 60 minutes. Once vitals have been captured, users can display the data elements in either a Vitals Record or a Sedation Flowsheet format. This module does not control setting the actual device parameters for vital signs capture, but merely the recording of the results. The actual parameters are set via the Hemodynamic Control Software. Additionally, an interface between Xper IM and PIIC iX allows automatic transfer of vital signs from IntelliVue monitoring units in the pre- and post-holding areas.

Scheduler

The Scheduler Module allows for the scheduling of patient studies for specific dates and times based on availability of staff and resources.

Inventory

The Inventory Module helps manage inventory. Existing inventory data can be imported from an Excel® spreadsheet and HL7 inventory master lists. The Inventory Module is tightly integrated with Charting, Billing, and Reporting modules. Inventory items are automatically deducted, modified, and updated in the background. Users can store data such as reference codes, barcodes, catalog numbers, pricing information, manufacturer, vendor, serial number and lot numbers (including compatibility with GS1-128 barcodes). The Inventory Module supports bi-directional interfaces to other third-party inventory systems. Bi-directional inventory interface provides real-time updates available via HL7 to import materials data. MFN-M16 record is our standard, but can be configured for any HL7. Another feature includes building and viewing orders. Built-in inventory reports can be run quickly to display items below par, item location, items approaching expiration, and aging reports.

Billing

Xper IM Billing module provides association of procedures with diagnostic codes, enabling compliance with regulations for meaningful use criteria and reimbursements. Xper IM provides a billing interface to send financial transactions from Xper IM. The billing interface sends collected charges to a billing system using HL7 or hospital-defined flat file (compatible with third-party systems such as Medi-Tech). Additionally, Xper IM supports (BAR-billing administration record) HL7 billing transactions.

Transcription

The Transcription Module offers report templates that can be edited, modified, and customized. With the Builder, users can reduce data redundancies by saving sections of a template that can be easily placed into another template report, saving valuable time. Users can also designate default reports based on the selected procedure. This module permits selection of coronary trees, images, and waveforms included in reports. For users of Nuance PowerScribe 360, Xper IM offers automatic integration and incorporation of text from dictation in Nuance Power Scribe 360 into the Xper IM transcription reports. All reports can contain electronic signatures and can be stored as a PDF when finalized.

Data analysis

The Data Analysis Module can query the database of information stored in the system. Data can be transformed into accessible and valuable information to create clinical and statistical reports. Users can build queries to filter, group, and sort data elements to create graphical bar graph, pie chart, matrix, and list displays. The queried information can be exported from the system. Users can also analyze the data of the Xper IM database using the Advanced Analytics tool in IntelliSpace Cardiovascular.

Registries

The Registries Module allows for the collection of data that is relevant for several purposes, including reporting to registry databases such as the American College of Cardiology National Cardiovascular Data Registry (CathPCI, ICD, etc.). Registry data can be exported to a third-party vendor for submission. The module also allows the capture and reporting of information for local, smaller registries, such as various state registries.

Custom forms

The Custom Forms Module allows users to capture data that is uniquely important to their institutions. Creating custom forms also allows users to organize the data concisely. The fields become part of the database, so scrapers* can be built to make data collection quick and easy. In addition, the data fields can be queried. Users can create as many forms as they need, and can create forms for different modalities.

Whiteboard Viewer

The Whiteboard Viewer Module is a utility module that displays patient status and location during procedures. Users can change status to pre-procedure, during-procedure and post-procedure. The module provides tools to enhance communication among family members, physicians, and staff.

IntelliBridge Enterprise**

IntelliBridge Enterprise is a single engine for enterprise interoperability; it allows two-way data exchange between cardiology informatics products (IntelliSpace Cardiovascular, Xper IM) and hospital's clinical and administrative systems; Embracing industry standards such as HL7, DICOM, and IHE, IntelliBridge Enterprise helps to reduce work required by your IT department.

IntelliBridge Enterprise for Xper IM supports interface installations with ADT, query ADT, billing, orders, outbound inventory, real time lab values, results, discreet clinical data, electronic medical record, DICOM worklists and MPPS.

Data center

Xper IM Data Center is the central server designed to give users with administrative rights access to system functions. From here, users can access:

- Software updates: Data Center manages and performs automatic database updates
- System auditing tools: users can review all auditing logs to verify that the system is performing optimally
- Client and server updates: this feature provides client and server automated data replication. If a user builds a menu in Xper IM and saves it, that menu will be distributed to all stations
- Security: Data Center provides the user with access to Xper IM's robust, innovative security features
- Administrative features: our convenient administrator toolset allows management of user rights and system configurations

* Data scrapers are powerful tools that enable users to collect data efficiently, and reduce duplication of work and errors in data entry. The functionality of the data scrapers has been expanded to allow data to be copied from one field to another, as well as to be copied from charting to related fields in the patient demographics screen, registry screens, and transcription reports.

**Xper Connect will be phased out as all interfaces become available with IntelliBridge Enterprise.

11. Technical specifications

General specifications Model FC2010 and FC2020

Dimensions	7.5" x 6.0" x 10.0" (19.05 cm x 15.24 cm x 25.4 cm)
Weight	4.4 lb (2 kg)
Operating System	embedded Windows 7
Component	Minimum specification
Processor	> 1.6 GHz
RAM	> 1 GB
Hard disk	> 16 GB SSD
Analog output channels	4
Analog output impedance	100 Ω
Output source, ECG Lead I	1 V \pm 0.2 V
Output source, ECG Lead II	1 V \pm 0.2 V
Invasive pressure	10 mV/mmHg
QRS	3 V pulse

Specification

Power consumption	< 75 W
Operating range	Temperature 0 – 35° C (32 – 95° F)
Storage temperature range	-20 – 60° C (-4 – 140° F)
Relative humidity range	15 – 95% non-condensing
Atmospheric pressure range	500 – 1600 hPa

ETCO₂ module – model: Philips M2741A Sidestream CO₂ sensor

Specification

Standard	ISO 21647
Measurement range	0 – 150 mmHg, 0 – 20 kPa (at 760 mmHg)
Accuracy	0 – 40 mmHg \pm 2 mmHg 41 – 70 mmHg \pm 5% of reading 71 – 100 mmHg \pm 8% of reading 101 – 150 mmHg \pm 10% of reading Note: All specifications are \pm 12% for respiration rates above 80 BPM
Sample flow rate	50 ml/min \pm 10 ml/min
Respiratory rate	Range 0 – 150 ipm Accuracy \pm 1 breath
Initialization time	Full specification within 2 minutes, waveform data in less than 20 seconds at ambient temperature of 25° C
Calibration	No routine user calibration required
Water resistance (sensor)	IPX4 Splash-proof
Operating temperature	0 – 40° C, 10 – 90% RH, non-condensing
Storage temperature	0 – 70° C, < 90% RH, non-condensing

ETCO₂ module – model: Philips M2501A Mainstream CO₂ sensor

Specification

Standard	ISO 21647
Measurement range	0 – 150 mmHg, 0 – 20 kPa (at 760 mmHg)
Accuracy	0 – 40 mmHg \pm 2 mmHg 41 – 70 mmHg \pm 5% of reading 71 – 100 mmHg \pm 8% of reading 101 – 150 mmHg \pm 10% of reading
Initialization time	Full specification within 2 minutes, waveform data in less than 20 seconds at ambient temperature of 25° C
Calibration	No routine user calibration required
Water resistance (sensor)	IPX4 Splash-proof
Operating temperature	0 – 40° C, 10 – 90% RH, non-condensing
Storage temperature	0 – 70° C, < 90% RH, non-condensing

NIBP module

Specification

Standard	IEC 60601-2-30
Measurement method	Oscillometric, employing stepwise pressure deflation
Modes	Manual or automatic
Manual: manometer	Accuracy check of NIBP pressure
Automatic	Host can select intervals of 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes
STAT	Typical measurement time in less than 20 seconds Five-second pause between measurements Runs in continuous STAT mode until user intervention
Blood pressure range (adult/pediatric)	Systolic: 35 – 255 mmHg Diastolic: 15 – 215 mmHg MAP: 20 – 235 mmHg Pulse: 30 – 240 BPM
Blood pressure range (neonatal/infant)	Systolic: 35 – 135 mmHg Diastolic: 15 – 105 mmHg MAP: 20 – 115 mmHg Pulse: 40 – 240 BPM
Pressure and pulse rate resolution	Pressure resolution: 1 mmHg Heart rate resolution: 1 BPM
Redundant hardware over pressure limits	Adult: 300 mmHg \pm 10% Neonatal: 150 mmHg \pm 10%
Pressure transducer accuracy	\pm 3 mmHg over the full range (0 – 270 mmHg) To maintain accuracy, it is recommended that the ND+ module be calibrated once a year
Pulse rate accuracy	\pm 2 BPM or \pm 2%, whichever is greater
Deflation method	Stepwise

SPO₂ module

Specification

Standard	EN ISO 9919:2005
Saturation range	0 – 100%
Resolution	1%
Pulse rate	30 – 300 BPM
Resolution	1 BPM
Accuracy	2% or 1 BPM
Arterial accuracy	With Philips sensor 70% -100%: M1196A – 3% M1131A – 3% M1132A – 2% M1133A – 3% neonatal, 2% adult/infant

Body temperature module

Specification

Standard	N/A
Measurement range	25 – 45° C
Probe type	Philips Reusable Skin Temperature Probe

Invasive blood pressure

Specification

Standard	IEC 60601-2-34
Channels	Four (4)
Transducer type	4-wire bridge
Excitation voltage	5 ± 0.1 V
Excitation current limit	20 mA min, 25 mA max (measured sensor short-circuited)
“No Probe” condition detection	Supported
Transfer function	25 µV/mmHg
Normal output resistance	300 Ω
Resolution	Better than 0.04 mmHg
Measurement range	0 – 300 mmHg
Frequency response	Selectable 1.5 Hz, 2.5 Hz, 0-8 Hz, 0-12 Hz, 0-20 Hz, 0-40 Hz, 0-80 Hz
Zero and span adjustment	Supported

Cardiac output

Specification

Standard	N/A
CO bath channel	
Injectate temperature range and accuracy	0.0 – 27° C ± 0.3° C
Injectate probe characteristic	2613 Ω @ 25° C
Injectate temperature resolution	0.1° C

Cardiac output (continued)

Specification

CO bath channel	
Injectate temperature “No Probe” condition detect	When measured temperature < -5° C or when probe circuit is open
Injectate temperature channel frequency response	DC to 2 Hz
CO distal	
Catheter	Edwards thermodilution catheters
System resolution	0.01° C
System accuracy	± 0.05° C
System temperature range	30 – 41° C

ECG

Specification

Standard	IEC-60601-2-27
Patient applied risk current (per IEC 60601-2-27)	10 µA normal condition, 50 µA single fault condition
Design creepage and clearances	Minimum 8 mm
Electrical isolation	7.5 kV peak, 6.0 kV rms (1 min.), no breakdown
ESU withstand	9 kV @ 0.5 – 4.0 MHz no damage
Defibrillator withstand	360 j (x5) with 100 Ω patient load no damage
Input impedance	> 20 MΩ shunted by < 500 pF
Input bias currents	< 0.05 µA
Frequency and impulse response IEC 60601-2-27	Selectable 0.01 – 100 Hz (diagnostic mode) or 0.5 – 40 Hz (monitor mode), -30% points
Notch filters	Selectable 50/60 Hz
Baseline reset after overload IEC 60601-2-27	Restore to usable in 3 seconds
Noise (per IEC 60601-2-27)	< 30 µV p-p referred to input
Loose patient lead behavior	Flatline and reported at clinical software module level

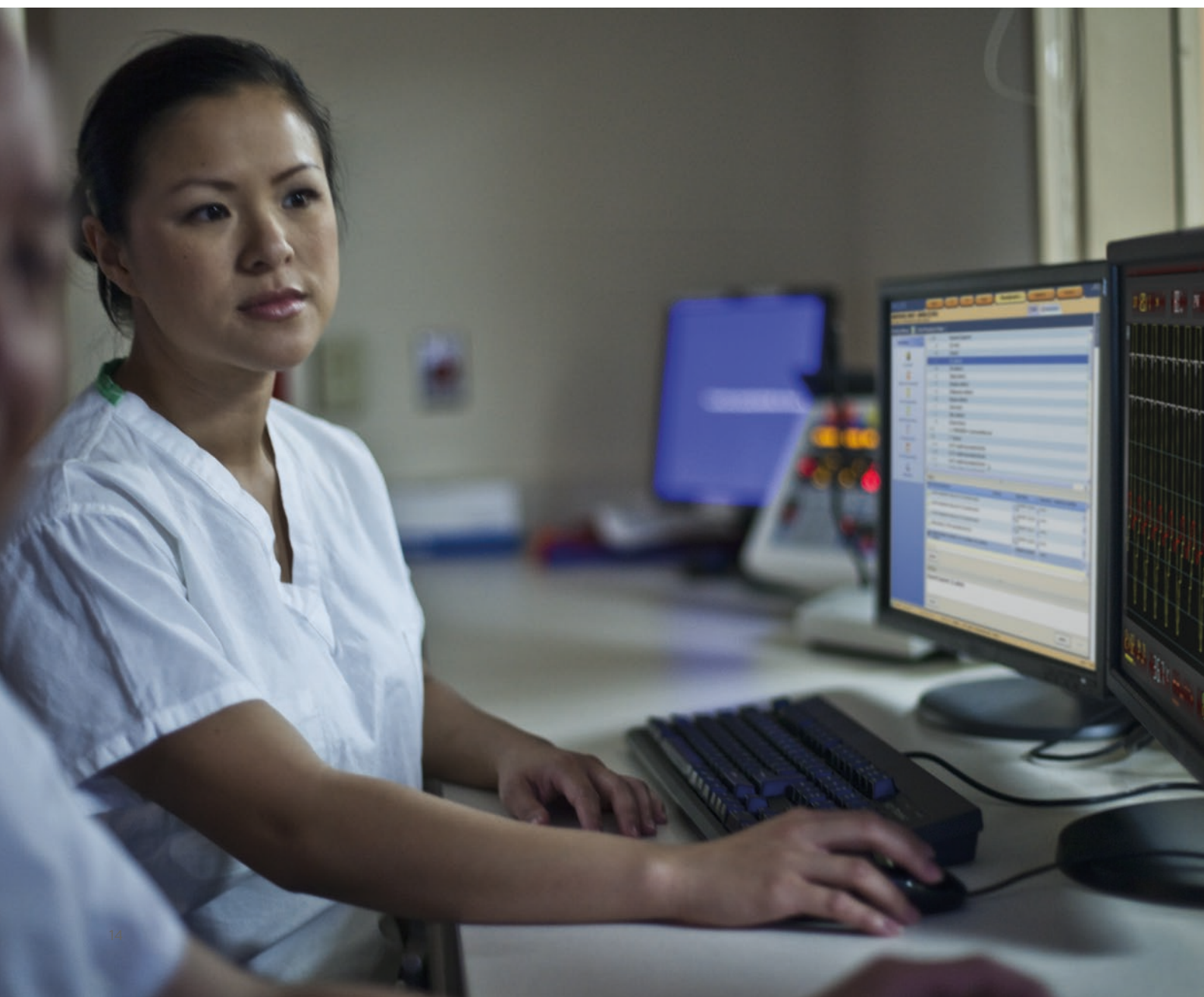
Respirations

Specification

Respiration range	4 – 150 ipm
Accuracy	± 3 ipm
Patient connection	RA, LL
Measurement method	Transimpedance, 60 kHz
Applied current @ 60 kHz	< 200 µA
Open circuit 60 kHz voltage	< 5 V p-p

Physiomonitoring alarms and alarm ranges

Value	Default	High range	Low range	Type	Silencing
Heart rate	140/40	270 to 35	265 to 30	Visual/tone	Configurable
BP systolic	200/0	360 to 10	295 to -40	Visual/tone	Configurable
BP diastolic	90/0	360 to 10	295 to -40	Visual/tone	Configurable
BP mean	110/0	360 to 10	295 to -40	Visual/tone	Configurable
NIBP systolic	200/60	260 to 25	220 to 10	Visual/tone	Configurable
NIBP diastolic	160/40	260 to 25	220 to 10	Visual/tone	Configurable
Temperature	40/29°	45 to 32°	42 to 29°	Visual/tone	Configurable
ETCO ₂	39/10	100 to 5	95 to 0	Visual/tone	Configurable
Respirations	50/10	150 to 9	145 to 4	Visual/tone	Configurable
SPO ₂	101/90	101 to 85	101 to 65	Visual/tone	Configurable



Patient care consumables

Item	Part number
ECG cables and leads	
CBL 5+5 ECG trunk cable, AAMI/IEC, 2.7 m	M1949A
CBL 5-lead ECG trunk, AAMI/IEC, 2.7 m	M1668A
CBL 5-lead set, grabber, chest, AAMI/ICU	M1976A
CBL 5-lead set, grabber, AAMI/ICU	M1968A
CBL 5-lead set, grabber, chest, IEC/ICU	M1978A
CBL 5-lead set, grabber, IEC/ICU	M1971A
CBL 3-lead set, grabber, AAMI/ICU	M1671A
CBL 3-lead set, grabber, IEC/ICU	M1672A
Radiolucent socket leadwires	M1649A
Trunk cable covers	989803148861
Combiner for 3-lead sets	M1501A
Combiner for 5-lead sets	M1502A
Bed sheet clip for trunk cables	M1509A
SpO₂ cables, sensors, and accessories	
CBL SpO ₂ 9-pin D-sub adapter 1.1 m (8-pin)	M1943A
Reusable clip, adult SpO ₂ sensor	M1196A
Disposable adult/pediatric SpO ₂ sensor	M1131A
Infant disposable SpO ₂ sensor	M1132A
Neo/infant/adult/disposable SpO ₂ sensor	M1133A
Wristband	M1627A
Non-invasive blood pressure supplies	
NIBP interconnect cable 3.0 m	M1599B
Reusable NIBP Comfort Cuff assortment	M1579A
Reusable NIBP Comfort Cuff/infant	M1571A
Reusable NIBP Comfort Cuff/pediatric	M1572A
Reusable NIBP Comfort Cuff/small adult	M1573A
Reusable NIBP Comfort Cuff/adult	M1574A
Reusable NIBP Comfort Cuff/large adult	M1575A
Reusable NIBP Comfort Cuff/thigh	M1576A
Reusable NIBP Comfort Cuff assortment	M1577A
Reusable NIBP Comfort Cuff assortment	M1578A

Item	Part number
Cardiac output supplies	
Ice bath temperature probe	23002A
Cardiac output cable, 4.8 m	M1643A
Temperature supplies	
Skin surface temperature probe	21078A
ETCO₂ accessories	
Mainstream sensor	M2501A
Single-patient use adult airway adapter	M2533A
Single-patient use infant airway adapter	M2536A
Gas cylinder regulator	M2505A
GAS verification gas	M2506A
Sidestream CO ₂ sensor	M2741A
CO ₂ nasal cannula – adult	M2744A
CO ₂ nasal cannula – pediatric	M2745A
CO ₂ nasal cannula – infant	M2746A
CO ₂ /O ₂ nasal cannula – adult	M2750A
CO ₂ /O ₂ nasal cannula – pediatric	M2751A
CO ₂ oral-nasal cannula – adult	M2756A
CO ₂ oral-nasal cannula – pediatric	M2757A
CO ₂ /O ₂ oral-nasal cannula – adult	M2760A
CO ₂ /O ₂ oral-nasal cannula – pediatric	M2761A
Airway adapter set – ET > 4.0 mm	M2768A
Airway adapter set H – ET > 4.0 mm	M2772A
Airway adapter set H – ET ≤ 4.0 mm	M2773A
Airway adapter set – ET ≤ 4.0 mm	989803144531
Miscellaneous accessories	
Patient cable organizer	M2281A

