

Instructions for Use

# IntelliVue Cableless Measurements

CL SpO2 Pod – CL NBP Pod – CL Respiration Pod Release D.00

**Patient Monitoring** 



# **Table of Contents**

1 Introduction and Basic Operation	5
Safety Information	6
Security Information	8
Introducing the IntelliVue Cableless Measurements	10
2 IntelliVue CL SpO2 Pod	13
General Operation of the SpO2 Pod	13
Connection with Host Systems	20
Monitoring SpO2	28
Alarms	34
Local Attended Monitoring	43
SpO2 Default Settings	49
Accessories	50
Maintenance and Troubleshooting	53
3 IntelliVue CL NBP Pod	55
General Operation of the NBP Pod	55
Monitoring NBP	62
Alarms	77
Local Attended Monitoring	86
NBP Default Settings	91
Integrated Battery Handling	92
Accessories	93
Maintenance and Troubleshooting	97
4 IntelliVue CL Respiration Pod	99
General Operation of the Respiration Pod	99
Connection with Host Systems	100
Monitoring Respiration	104
Respiration Default Sottings	108
Integrated Battery Handling	109
Accessories	110
Maintenance and Troubleshooting	112
5 Cableless Measurement Auxiliary Devices	113
Latellikus CL Transmitter and Latellikus CL Laterat	
IntelliVue CL Transmitter Base Station	113

IntelliVue CL Charging Station	118
	119
6 Care and Cleaning	121
General Points	121
Cleaning and Disinfecting the IntelliVue Cableless Measurement Devices	122
Disposing of the IntelliVue Cableless Measurement Devices	123
7 Specifications	125
Indications for Use	125
Compatible Medical Devices	127
Symbols	127
Manufacturer's Information	129
Regulatory and Safety Specifications	129
EMC and Radio Regulatory Compliance	130
Safety and Performance Tests	132
Electromagnetic Compatibility (EMC)	132
Accessories Compliant with EMC Standards	133
Electrosurgery Interference/Defibrillation	133
IntelliVue CL SpO2 Pod Specifications	133
IntelliVue CL NBP Pod Specifications	135
IntelliVue CL Respiration Pod Specifications	138
Alarm Specifications for CL NBP, CL SpO2 and CL Resp Pod	140
Telemetry Device Battery Runtime Specifications	141
IntelliVue CL Transmitter Specifications	141
IntelliVue CL Transmitter Base Station Specifications	143
IntelliVue CL Hotspot Specifications	144
Index	147

# **Introduction and Basic Operation**

These Instructions for Use are for clinical professionals using the IntelliVue Cableless Measurements and their specified compatible accessories.

**IntelliVue Cableless Measurements** refers to the IntelliVue Cableless Measurements product family consisting of the IntelliVue CL SpO<sub>2</sub> Pod (865215), IntelliVue CL NBP Pod (865216) and IntelliVue CL Respiration Pod (865218) with their accessories. Also included are the auxiliary devices: the IntelliVue CL Charging Station (865220), IntelliVue CL Transmitter (865221), IntelliVue CL Transmitter Base Station (865237) and IntelliVue CL Hotspot (865222).

The IntelliVue Cableless Measurements are used for monitoring and recording arterial oxygen saturation, pulse rate, noninvasive blood pressure and respiration rate of adult and pediatric patients.

Familiarize yourself with all instructions including warnings and cautions, and attend one of the training courses, before starting to make measurements with patients. Read and keep the Instructions for Use that come with any accessories, as these contain important information about care and cleaning that is not repeated here.

When using the IntelliVue Cableless Measurements with an IntelliVue Patient Monitor, an Avalon Fetal Monitor, a telemetry system or IntelliVue GuardianSoftware, refer to and adhere to all warnings in the Instructions for Use of the respective device or software.

This guide may contain descriptions of functionality and features that are not implemented in the equipment currently shipped to Japan and/or of products that are not currently sold in Japan due to limitations and restrictions under the applicable local laws and regulations in Japan. Please contact your local sales representative and/or Philips Customer Support for details.

In these Instructions for Use:

- 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 user or patient.
- A caution alerts you to where special care is necessary for the safe and effective use of the product.
   Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

**Display** refers to the physical display of the Cableless Measurement Device. **Screen** refers to everything you see on the IntelliVue Cableless Measurement's display, such as measurement values, patient data and so forth.

IntelliVue CL Transmitter/WLAN functionality may not be available in all countries.

# **Safety Information**

#### **Use Environment**

#### WARNING

- If a patient being monitored by Cableless Measurement Devices moves out of range of the patient monitor, the measurements are not transmitted to the patient monitor or the Information Center. Keep the patient monitor with the patient during transport.
- Always make sure that the applied pod is assigned to the correct patient.

#### **Electrical Hazards**

#### WARNING

- Electrical shock hazard: Do not open the device housing. Refer all servicing to qualified service personnel.
- Always use the supplied power cord with the grounded mains plug to connect the charging station to a grounded AC mains socket. Never adapt the mains plug from the charging station to fit an ungrounded AC mains socket.
- Do not use AC mains extension cords or multiple portable socket outlets. If a multiple portable socket outlet without an approved isolation transformer is used, the interruption of its protective grounding may result in enclosure leakage currents equal to the sum of the individual ground leakage currents, so exceeding allowable limits.
- Do not connect any devices that are not supported as part of a system.

#### Radiofrequency Interference

#### WARNING

Short Range Radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n) and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a No Host Monitoring INOP on the NBP or SpO<sub>2</sub> Pods, or a cl NBP Disconnect, cl SpO<sub>2</sub> Disconnect or cl Resp Disconnect INOP at the host monitor. Correct channel configuration is important, refer to the Configuration Guide for details.

#### **Battery Handling**

#### WARNING

- Do not crush or puncture mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- Do not incinerate the devices or expose them to temperatures above 60°C (140°F).

#### Accessories

#### WARNING

- **Reuse:** Never reuse single-patient sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard, in particular with regard to cross-contamination.
- Philips' approval: Use only Philips-approved accessories. Using non-Philips-approved accessories may
  compromise device functionality and system performance and cause a potential hazard.
- Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the IntelliVue Cableless Measurement Devices.

#### Maintenance

#### WARNING

- Schedule: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Contact: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.
- If the IntelliVue Cableless Measurement Device is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient, contact your service personnel.

#### Care, Cleaning and Disposal

#### WARNING

- If you spill liquid on the equipment, or if the equipment is accidentally immersed in liquid, contact your service personnel or Philips service engineer. Do not operate the equipment before it has been tested and approved for further use.
- Do not use flammable agents for disinfecting the equipment in an oxygen-enriched environment, as this might lead to sudden ignition of vapors, resulting in injury to the patient or staff.
- To avoid contaminating or infecting personnel, the environment or other equipment, make sure you
  disinfect and decontaminate the IntelliVue Cableless Measurement Devices appropriately before
  disposing of it in accordance with your country's laws for equipment containing electrical and electronic
  parts. For disposal of parts and accessories, where not otherwise specified, follow local regulations
  regarding disposal of hospital waste.

# **Security Information**

#### **Protecting Personal Information**

Protecting personal health information is a primary component of a security strategy. Each facility using the devices must provide the protective means necessary to safeguard personal information consistent with country laws and regulations, and consistent with the facility's policies for managing this information. Protection 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.

As per their intended use, the devices operate in the patient vicinity and contain personal and sensitive patient data. They also include controls to allow you to adapt the devices to the patient's care model.

To ensure the patient's safety and protect their personal health information you need a security concept that includes:

- Physical security access measures access to the devices must be limited to authorized users. It is
  essential that you consider physical security measures to ensure that unauthorized users cannot gain
  access.
- Operational security measures for example, ensuring that devices are powered off after monitoring in order to remove patient data from the device.
- **Procedural security measures** for example, assigning only staff with a specific role the right to use the devices.

In addition, any security concept must consider the requirements of local country laws and regulations.

Always consider data security aspects of the network topology and configuration when connecting devices to shared networks. Your medical facility is responsible for the security of the network, where sensitive patient data from the monitor may be transferred.

When a device is returned for repair, disposed of, or removed from your medical facility for other reasons, always ensure that all patient data is removed from the device by powering it off.

#### NOTE

Log files generated by the devices are used for system troubleshooting and do not contain protected health data.

#### About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, please visit: http://www.hhs.gov/ocr/privacy/

#### About the EU Directives

If applicable, your facility's security strategy should include the practices set forth in the Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995). In addition, your facility should also take into account any additional applicable regulation or statutory requirement.

#### **Philips Product Security Policy Statement**

Additional security and privacy information can be found on the Philips product security web site at: http://www.usa.philips.com/healthcare/about/customer-support/product-security

# Manufacturer Disclosure Statement for Medical Device Security – MDS2

You can view the Manufacturer Disclosure Statements for Medical Device Security ( $MDS^2$ ) for specific devices at:

http://www.usa.philips.com/healthcare/about/customer-support/product-security

# Introducing the IntelliVue Cableless Measurements

The IntelliVue Cableless Measurement Devices provide measurement values and communicate them to other system components using a wireless short range radio (SRR) interface.

#### Introduction

#### IntelliVue CL SpO<sub>2</sub> Pod

The IntelliVue CL SpO<sub>2</sub> Pod is a battery powered, cableless Pulse Oximetry measuring device.

#### IntelliVue CL NBP Pod

The IntelliVue CL NBP Pod is a battery powered, cableless, noninvasive blood pressure (NBP) measuring device.





#### IntelliVue CL Respiration Pod

The IntelliVue CL Respiration Pod is a battery powered, cableless device for measuring respiration rate and, optionally, pulse. It also provides basic information about patient posture and activity.



#### **Basic Operation**

#### IntelliVue CL SpO<sub>2</sub> Pod and IntelliVue CL NBP Pod

The IntelliVue CL SpO<sub>2</sub> Pod and the IntelliVue CL NBP Pod can be used together with IntelliVue Patient Monitors MP5/MP5SC/MP5T, MP2/X2, IntelliVue Telemetry System Transceivers TRx4841A/TRx4851A, MX40 wearable patient monitors, Avalon Fetal Monitors, and IntelliVue GuardianSoftware. Both devices have an LC display and three keys for basic operation:



- 1 Integrated monochrome LC display
- 2 Hardkeys
- 3 Measurement identifier

#### IntelliVue CL Respiration Pod

The IntelliVue CL Respiration Pod can be used together with IntelliVue Patient Monitors MP5/MP5SC/ MP5T, MP2/X2, or IntelliVue GuardianSoftware. The device has one multi-color LED for status display and one hardkey for basic operation, e.g. to start a measurement.



- 1 Multi-color LED
- 2 Measurement identifier
- 3 Hardkey
- 4 Indication for built-in RFID tag

# IntelliVue CL SpO2 Pod

The IntelliVue CL SpO<sub>2</sub> Pod is a wrist-worn device; you need a Mobile CL SpO<sub>2</sub> Cradle to hold the sensor connector in place and a wristband to fix the cradle to a patient's arm.



Specialized single-patient SpO<sub>2</sub> sensors are available for use with the IntelliVue CL SpO<sub>2</sub> Pod. For details regarding the complete set of single-patient supplies, cradle, wristband and sensors, refer to "IntelliVue CL SpO2 Pod Accessories" on page 52.

# General Operation of the SpO2 Pod

The following sections describe operation on the  $SpO_2$  Pod itself. For operation from a patient monitor, see "Controls Available with a Patient Monitor" on page 25. For operation from an Information Center via a telemetry system, see "Controls Available with a Telemetry Device" on page 26. For operation with IntelliVue GuardianSoftware, see "Controls Available with GuardianSoftware" on page 27.

The  $\text{SpO}_2$  Pod has three hardkeys for basic operation and a set of configurable SmartKeys which appear on the screen. These are used to activate and navigate through the on-screen menus and to select individual items. The typical operator's position is such that everything on the device's display can be read clearly and easily.

#### Switching the Device On

The first time an  $SpO_2$  Pod is used, or after the device has been powered off for storage, place it on the IntelliVue CL Charging Station. This will automatically switch the device on.

If the  $\text{SpO}_2$  Pod has only been switched off temporarily (see "Switching the Device Off" on page 17), press any hardkey to turn the device on again.

When an SpO<sub>2</sub> Pod is not operated, it will automatically switch off the screen lighting after a short time. A little later the low-activity screen will be displayed.

#### Screen Layout

There are three variations of the Main Screen layout depending on the Alarm status and the general activity level.

#### **Standard Layout**





- 1 Connection status indicator
- 2 Indicator that alarming capability has been transferred to the host (to the monitor or, for the telemetry device, to the Information Center). No patient alarms will be announced on the Cableless Measurement Device.
- 3 Battery indicator
- 4 Measurement values
- 5 Measurement-related symbols (see the "Monitoring SpO2" section for details)
- 6 Patient identification

When not assigned to a monitor or telemetry device:



- 1 Connection status indicator
- 2 Battery indicator
- 3 Measurement values
- 4 Measurement-related symbols (see the "Monitoring SpO2" section for details). The Alarms Off symbols indicate that no physiological alarms are available from the Cableless Measurement Devices when not assigned to a host.
- 5 Cableless Measurement Device equipment label

#### **Alarm Layout**

If an alarm occurs the full alarm message appears at the top of the screen. After the alarm message has been silenced the alarm indicator is shown as a symbol on the right side of the screen.



#### Low-Activity Screen

If the Cableless Measurement Device has not been operated for a while, the screen lighting will switch itself off and a little later the screen will switch to a pre-configured "low-activity" screen.

16:32 ! Am Doe, Jonathan

#### When a Cableless Measurement Device Cannot be Activated

If you cannot activate a device by pressing a key, place it on the IntelliVue CL Charging Station. The device becomes active. Check the battery status. If necessary, leave the device on the charger until the battery is fully charged.

#### **Using the Hardkeys**

The IntelliVue Cableless Measurement Devices have three hardkeys:  $\blacktriangleleft, \checkmark, \triangleright$ .

Use  $\blacktriangleleft$  and  $\blacktriangleright$  to navigate through SmartKeys and menus and  $\checkmark$  to select items or to silence alarms.

The three hardkeys also have an additional function when the key is held down for a couple of seconds:

- opens the Add To screen to assign a device (or to unassign it when it is already assigned)
- ✓ opens the SmartKeys menu
- returns to the Main Screen. If already on the Main Screen, it locks the keys and a lock symbol appears on the screen above the battery symbol. If keys are already locked, it unlocks the keys and the lock symbol disappears

#### Using the SmartKeys

A SmartKey is a graphical key which appears on the screen and gives you fast access to functions.

#### SmartKeys Menu

Press the ✓ hardkey (without any screen element highlighted) to get to the SmartKeys menu.



Use the  $\blacktriangleleft$  and  $\triangleright$  hardkeys to move along the row of SmartKeys. The highlighted SmartKey is displayed in full above the row of SmartKeys. When you use the  $\blacktriangleleft$  or  $\triangleright$  hardkey at the end of the row, an **Exit** screen appears and then with further presses you move on to the next page of SmartKeys. To leave the SmartKeys menu you can use the **Exit** screen or press the  $\triangleright$  hardkey for a couple of seconds to return to the Main Screen.

When the required SmartKey is highlighted, press the  $\checkmark$  key to activate the corresponding function.

To get to the next page of the SmartKeys menu, highlight the rightmost SmartKey then press the ▶ key.

# List of Available SmartKeys

SmartKey	Text Labels
	Main Setup
ſr <b>y</b> ∳	start an SpO <sub>2</sub> measurement
₽	set the SpO <sub>2</sub> mode
_ س	Add/Remove device
	enter Battery menu
	enter Profiles menu
ð	change Screen
Ċ	put device in standby mode (or power off when pressed for more than two seconds)
ş 🛉	enter Patient menu
$\triangle$	enters the <b>Alarms</b> menu to access: <b>Alarm Messages</b> , <b>Alarm Limits</b> , Alarms On/ Off/Pause, Alarm Volume.
1	Change alarm volume
<u> </u>	Change pulse tone volume

#### Using the Main Setup Menu

In addition to the hardkeys and SmartKeys for the most needed functions, the **Main Setup** menu gets you to all settings that can be adjusted for the respective device. Select the **Main Setup** SmartKey to get to the **Main Setup** menu.

Main Setup
SpO <sub>2</sub>
Pulse
Alarms
Patient
Equipment
User Interface
Standby
Profiles
Operating Modes
Date, Time
Battery
Revisions

#### Switching the Device Off

To put the device in standby mode, select the Standby SmartKey, then Confirm.

If you keep Standby pressed for more than two seconds, you can choose between Standby or Power Off.

- **Standby** means that the display is switched off and the measurements are disabled. Use this option if your device is not used temporarily. Press any hardkey to turn the device on again.
- **Power Off** means that the device is switched off completely and can only be switched on again by putting it on a charger. Use this option when the device is not used for a longer time or prepared for storage or shipping.

#### Auto Standby and Auto Power Off

The device can be configured to automatically go into standby mode after a configurable time span of inactivity. When in standby mode, the device can be automatically powered off after a configurable time span. See the IntelliVue Cableless Measurements Configuration Guide for details on how to configure these settings.

#### **Operating Modes**

Your device has four operating modes. Some are passcode protected.

- Monitoring Mode: This is the normal, every day working mode that you use for making measurements. You can change elements such as measurement modes, patient category and so forth. When you remove the patient from the device, these elements return to their default values. Changes can be stored permanently only in Configuration Mode. You may see items, such as some menu options, that are visible but 'grayed out' so that you can neither select nor change them. These are present for your information only and can be changed only in Configuration Mode.
- **Demonstration Mode**: Passcode protected, this is for demonstration purposes only. You must not change into Demonstration Mode during monitoring.
- **Configuration Mode**: Passcode protected, this mode is for personnel trained in configuration tasks. These tasks are described in the Configuration Guide. During installation the Cableless Measurement Device is configured for use in your environment. This configuration defines the default settings you work with when you switch on.

• Service Mode: Passcode protected, this is for trained service personnel.

When you switch the device on, it starts up in monitoring mode. To change to a different mode:

- 1 Use the Main Setup SmartKey to get to the Main Setup menu.
- 2 Select **Operating Modes** and choose the mode you require.

#### Using the Patient Menu

The **Patient** menu allows you to see patient demographics information and to remove a patient from a device. Patient Demographic information is only displayed if the Cableless Measurement Device is assigned to a patient monitor or GuardianSoftware. **Patient Category** is the only item of patient data which can be changed at the Cableless Measurement Device, but only when the device is not assigned to a patient monitor or telemetry device.

#### **Displaying the Patient Menu**

To display the Patient menu,

- select the Patient SmartKey, or
- select the Main Setup SmartKey followed by Patient.

#### Stop Using a Device for a Patient

To remove a patient from the Cableless Measurement Device,

#### in the Patient menu select Free Device.

All patient data is cleared, settings are reset to the defaults and the device is removed from the monitor or telemetry device.

#### NOTE

Depending on your configuration, when the device is put on the charger, patient data will also be cleared and the device will be free for another patient.

#### Using the Device for a New Patient

To use a device for a new patient,

in the Patient menu, select New Patient.

If the device was not free, the existing data will be deleted and the profile set to the default.

#### Using Profiles

A profile is a set of measurement and general settings which have been customized for a particular purpose. The Cableless Measurement Devices can have four different profiles configured to your requirements. The default profile is marked with a symbol.

To select a different profile,

- 1 Select the **Profiles** SmartKey or the **Main Setup** SmartKey followed by **Profiles**.
- 2 Select the required profile from the list.

Selecting New Patient or Free Device will always reset the profile to the default.

#### Setting the Date and Time

If the Cableless Measurement Device is assigned to a patient monitor, telemetry device or GuardianSoftware, the date and time will be taken from the host. If this is not the case, you can set the date and time on the Cableless Measurement Device,

- 1 Select the Main Setup SmartKey and then Date, Time.
- 2 Enter the data for date and time one after another.
- 3 Select Store Date, Time.

If the time has not been set, --:-- will display on the device.

#### **Battery Status**

The IntelliVue CL  $\text{SpO}_2$  Pods show their battery status on their display both in operating and charging condition. The battery status indicator is located in the lower right corner of the screen during operation and in the middle of the screen during charging.

#### **Battery Status Menu**

Select the **Battery** SmartKey or **Main Setup** followed by **Battery** using the  $\triangleleft$  and  $\triangleright$  keys, then press the  $\checkmark$  key to open the **Battery** menu. The **Battery** menu provides the following information: full-charge and remaining capacity, voltage, current and temperature.

## **Connection with Host Systems**

The following sections describe how the IntelliVue Cableless Measurement Devices work together with host systems (Patient Monitors, Fetal Monitors, Telemetry Devices / Information Center or GuardianSoftware).

#### IntelliVue Cableless Measurements Use Models

With these patient-worn measurement devices you can measure and transmit a patient's vitals regularly or on an intermittent data collection basis. There are four typical use models:

#### With a Patient Monitor

The IntelliVue Cableless Measurement Devices can be used together with an MP5/MP5SC/MP5T, MP2 or X2 patient monitor (with an SRR interface). They can communicate their measurement values via short range radio to the monitor. The monitor may be assigned to a patient sector at the IntelliVue Information Center (IIC). When assigned to the Information Center, certain actions can be performed at both the patient monitor and the Information Center. See the table "Controls Available with a Patient Monitor" on page 25.

In situations where patients are becoming more mobile (for example, in step-down/intermediate care units) the lightweight Cableless Measurement Devices allow increased mobility within the short range radio range, without giving up vital signs monitoring.

When assigned to a patient monitor, the Cableless Measurement Device can be selected for use in patient transport at the patient monitor (for details see the Patient Monitor Instructions for Use). In this case, the Cableless Measurement Device will perform **local attended monitoring**. The patient must be attended by a caregiver during transport, to ensure that alarms on the Cableless Measurement Device are recognized. In local attended monitoring mode, an alarm message text appears in the alarm status area at the top of the screen indicating the source of the alarm and an alarm tone is issued. See "Alarms" on page 34 for details.

A telemetry device can be assigned to a patient monitor equipped with short range radio at the same time as any Cableless Measurement Devices are also assigned to this monitor.

When assigned to a patient monitor, the admitted patient name is displayed on the  $SpO_2$  Pod.

If the connection between the monitor and the Cableless Measurement Device is lost, an INOP will be displayed at the monitor: **cl SpO<sub>2</sub> Disconnect**. A **No Host Monitoring** INOP will be displayed on the SpO<sub>2</sub> Pod, and an INOP tone will sound. In this case, visual and audible alarms are still available at the SpO<sub>2</sub> Pod, but it is not possible to change the alarm settings.

#### With a Fetal Monitor

In combination with an Avalon CL Transducer System, the IntelliVue CL  $\text{SpO}_2$  Pod can be used together with an Avalon FM 20-50 Fetal Monitor. The  $\text{SpO}_2$  Pods are assigned to the fetal monitor by docking them at the Avalon CL Base Station. For information about Avalon Fetal Monitors, the Avalon CL Transducer System and the Avalon CL Base Station, please refer to the Avalon Fetal Monitor Instructions for Use.

#### With a Telemetry Device

The Cableless Measurement Devices can be assigned to a patient with the telemetry device TRx4841A/ TRx4851A or an MX40 wearable patient monitor. They can communicate their measurement values via short range radio to the telemetry device which communicates them to an IntelliVue Information Center to provide a consolidated set of patient values.

Some of the measurement tasks can be performed remotely from the Information Center. See the table "Controls Available with a Telemetry Device" on page 26.

If the patient name is available at the Information Center, it will be also displayed on the SpO<sub>2</sub> Pod.

When a Cableless Measurement Device is assigned to a telemetry device, it is not possible for the telemetry device to be wirelessly assigned or directly connected to a patient monitor.

If the connection between the telemetry device and the Cableless Measurement Device is lost, an INOP will be displayed at the Information Center: **cl SpO<sub>2</sub> Disconnect**. A **No System Monitor.** INOP will be displayed on the SpO<sub>2</sub> Pod, and an INOP tone will sound.

#### With IntelliVue GuardianSoftware

The Cableless Measurement Devices can be used together with IntelliVue GuardianSoftware. GuardianSoftware collects non-continuous vital signs data that are transmitted via a Transmitter, Hotspot or MP5 from the Cableless Measurement Devices. Using the collected data, it provides trending, review, reporting and notification. The Guardian Early Warning Scoring (Guardian EWS) application provides basic assessment guidance, helping you to recognize the early signs of deterioration in your patients. GuardianSoftware is not intended for monitoring in combination with Cableless Measurement Devices.

Some of the measurement tasks can be performed remotely from GuardianSoftware. See the table "Controls Available with GuardianSoftware" on page 27. GuardianSoftware also manages the patient data.

If the connection between GuardianSoftware and the Cableless Measurement Device is lost, the connection symbol will be displayed gray at GuardianSoftware. A **No System** INOP will be displayed on the SpO<sub>2</sub> Pod (no alarm sound).

If a patient name is available at GuardianSoftware, it will be also displayed on the Pod. Any update of patient data will be synchronized between the Pods and GuardianSoftware. The only patient management action available directly at the Pod is **Free Device**. Selecting **Free Device** removes the current patient from the Pod and resets the Pod to the default profile. The Pod is unassigned.

#### **Device Compatibility**

The IntelliVue CL SpO<sub>2</sub> Pods require the following software levels in the associated equipment:

- IntelliVue Patient Monitor Release H.0 or above
- Avalon Fetal Monitor in combination with an Avalon CL Transducer System Release J.3 or above
- IntelliVue Information Center Release M or above
- Philips Patient Information Center iX Release A or above
- Telemetry device TRx4841A/TRx4851A Revision D.00.22 or above
- MX40 wearable patient monitor Revision A.0 or above
- IntelliVue GuardianSoftware Revision A.0 or above

#### Availability of Patient Alarms

When the IntelliVue CL  $\text{SpO}_2$  Pod is used alone, without an assignment to a monitor or telemetry device, no patient alarms will be generated.

When the IntelliVue CL  $\text{SpO}_2$  Pod is assigned to a patient monitor or telemetry device and a short range radio connection exists, alarms may be announced at the patient monitor or the Information Center.

When assigned to a patient monitor / fetal monitor: Alarm messages will be displayed and audible alarm indicators sounded at the monitor in the same way and under the same conditions as for its own measurements. See the Instructions for Use of the patient monitor for details.

If a Cableless Measurement Device that is assigned to a patient monitor is selected for use in patient transport at the patient monitor, the Cableless Measurement Device will perform **local attended monitoring**. See the Instructions for Use of the patient monitor for details on how to do this. The patient must be attended by a caregiver during transport, to ensure that alarms on the Cableless Measurement Device are recognized. In local attended monitoring mode, an alarm message text

appears in the alarm status area at the top of the screen indicating the source of the alarm and an alarm tone is issued. See "Alarms" on page 34 for details.

- When assigned to a telemetry device: Measurement values sent via the telemetry device to the IntelliVue Information Center can generate alarms at the Information Center when the values meet the criteria set there for alarms. The alarms will be announced in the same way as measurements from other sources. See the Instructions for Use of the Information Center for details.
- When assigned to GuardianSoftware: Measurement values sent via transmitter, hotspot or MP5 to IntelliVue GuardianSoftware will be visualized in GuardianSoftware. Since IntelliVue GuardianSoftware is a data management system, no alarms are announced. The IntelliVue Cableless Measurement Devices will also not generate physiological alarms when connected to IntelliVue GuardianSoftware. See the Instructions for Use of GuardianSoftware.

#### Assigning an IntelliVue Cableless Measurement Device to a Host

When an IntelliVue CL SpO<sub>2</sub> Pod is used with a host system (patient monitor, telemetry device or GuardianSoftware), the Pod must be assigned to that host system.

The assignment can be done at the CL SpO<sub>2</sub> Pod itself or at the host system (patient monitor or GuardianSoftware).

#### WARNING

Always make sure that the applied CL SpO2 Pod is assigned to the correct patient.

#### WARNING

Short Range Radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n) and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a **No Host Monitoring** INOP on the SpO<sub>2</sub> Pod, or a **cl SpO<sub>2</sub> Disconnect** INOP at the host monitor. Correct channel configuration is important, refer to the Configuration Guide for details.

#### Assignment at the Measurement Device

To make an assignment, select:

the Add/Remove SmartKey



hold the  $\triangleleft$  key pressed.

This opens the **Add To** menu which lists the available patient monitors and telemetry devices within the SRR range. In order to save power, the list is only visible for a short time; the menu is automatically closed after 40 seconds.

**Telemetry device:** A telemetry device must be put into assignment mode by pressing the  $\checkmark$  key on the telemetry device before it can appear in the list. Pressing the  $\checkmark$  key starts an SRR channel search to find the clearest channel available. During the search all 4 LEDs will blink once per second. The search will

take approximately 20-25 seconds. Once a channel is identified, the first LED will light up and blink once per second to indicate that the telemetry device is ready for assignment.

Add To	
Mon 1	
Mon 2	
Tele 33	
Tele 44	

- Select a patient monitor or telemetry system using the 

   If you select a patient monitor, the measurement selection key on that monitor will change to show the type of measurement device.
- 2 Activate the assignment by pressing the ✓ key twice on the measurement device. The Cableless Measurement Device is assigned to the selected patient monitor or telemetry device. A telemetry device plays the assignment tone when the assignment is successful. A patient monitor issues an assignment prompt message.

If the internal measurement in the patient monitor is active (the measurement selection key has a yellow frame), you will need to confirm that it should be deactivated in favor of the Cableless Measurement Device you want to assign. To do this:

- Select the measurement selection key on the monitor.
   A prompt message appears with the **Confirm** and **Cancel** keys.
- 2 Select **Confirm** to deactivate the internal measurement.

When the Cableless Measurement Device is assigned, the A symbol appears on its display indicating that alarming capability has been transferred to the host (to the monitor or, for the telemetry device, to the Information Center). No patient alarms will be announced on the Cableless Measurement Device.

To unassign the measurement device from the monitor or telemetry system, select the **Add/Remove** SmartKey, then select **Remove From**. After confirmation the SRR connection is disconnected.

#### Assignment at the Patient Monitor

#### Assignment at the Patient Monitor

Prepare the Cableless Measurement Device for assignment by activating the Add/Remove SmartKey.

At the patient monitor,

- 1 Select the Measurement Selection key.
- 2 Select the Add cl Msmt pop-up key.

This opens the **Add cl Measurement** window, which shows the available Cableless Measurement Devices:

Add cl Measurement	
NIBP03 id1 SP0203	Measmt.
801654 id1 SP0203	Select.

- 3 Select the device which you want to assign to the patient in the monitor.
- 4 The monitor displays the assignment prompt message.

If the internal measurement in the patient monitor is active, you will need to confirm that it should be deactivated in favor of the Cableless Measurement Device you want to assign.

When the Cableless Measurement Device is assigned, the *symbol appears* on its display indicating that alarms from the device will be sent to the patient monitor.

An assigned Cableless Measurement Device can be removed in the **Measurement Selection** window. For more details see the Instructions for Use for your patient monitor.

#### Assignment with an RFID Reader and Tagged Cableless Devices

You can directly assign all cableless devices that have RFID tags with a Philips HS1-R RFID/barcode reader. The SpO<sub>2</sub> Pod used must have an IntelliVue ProxiTag RFID tag adhesively attached.

1 Hold the cableless device close to the reader.

Depending on its configuration, the reader beeps, vibrates or indicates via the LEDs when it has read the tag.

2 Press any hardkey on the cableless device.

The Cableless Measurement Device is now added to the monitor.

If the corresponding internal measurement in the patient monitor is active, you will be asked to confirm that it should be deactivated in favor of the Cableless Measurement Device by selecting **Replace**.

If a Cableless Measurement of the same type is already assigned to the monitor, you will be asked to confirm that it should be removed by selecting **Replace**.

#### Assignment at the Fetal Monitor

The first time an IntelliVue Cableless Measurement Device is used with an Avalon Fetal Monitor, or after a device has been powered off for storage, place it on the Avalon CL Base Station. This will automatically switch the device on. The device is assigned automatically to the Fetal Monitor working with the CL Base Station.



#### NOTE

When you place a Cableless Measurement Device onto an Avalon CL Base Station to assign it to an Avalon Fetal Monitor, the Cableless Measurement Device is automatically unassigned from the previous patient.

#### **Special Conditions when Working with Fetal Monitors**

The following special conditions apply when CL SpO<sub>2</sub> Pods are operating with an Avalon Fetal Monitor as a host:

- The SpO<sub>2</sub> Pods are intended to measure the maternal SpO<sub>2</sub> and Pulse. The patient category is always **Adult**.
- The Pulse measurement is always On. The Pulse: On/Off setting is not available.
- Physiological alarms are only available at the Avalon Fetal Monitor, not at the Cableless Measurement Devices. Local attended monitoring is not available: Use for Transp. is not supported. (Local attended monitoring is used for displaying alarms locally at the Cableless Measurement Devices during patient transport, when the patient is attended by a caregiver).
- Alarm-related operations (e.g. switching alarms on and off, setting the high and low alarm limits) are
  not available when Alarm Mode is set to INOP only in the Avalon Fetal Monitor. See the Avalon Fetal
  Monitor Instructions for Use and Avalon Fetal Monitor Configuration Guide for further information.

- You can use the **Remove** operation at the host to remove Cableless Measurement Devices, as described in the Avalon Fetal Monitor Instructions for Use.
- Averaging Time is not configurable.
- Smart Alarm Delay is not supported.
- Pulse tone from the CL SpO<sub>2</sub> Pod is not supported at the Avalon Fetal Monitor.
- **Perfusion** is always **Off** and cannot be changed to **On**.
- Perfusion Change Indicator is not supported.
- It is not possible to change the label, it is always SpO2.
- Continuous mode only. The functions for starting a measurement, selecting the measurement mode and setting the repetition time are not supported.
- Configuration of Aging Time (for Aging Numerics) is not possible.
- Pleth wave is not available.

#### Assignment with GuardianSoftware

To assign a Cableless Measurement Device to a patient in GuardianSoftware:

- 1 Select the patient on the **Chalkboard**.
- 2 Take the Cableless Measurement Device from the charger.
- 3 On the **Equipment List** tab, select the Cableless Measurement Device on the **Available Equipment** list, highlighted in green on top of the list. The device on top of the list is always the one with the most recent user interaction (taken off the charger, put on the charger, or key pressed).
- 4 Click **Use for Patient** to assign the device to the patient.

#### **Controls Available with a Patient Monitor**

The controls available when working with the Cableless Measurement Device and a patient monitor are described in the table below.

Action	At the Cableless Measurement Device	At the Patient Monitor	At the IIC
Start SpO <sub>2</sub>	Yes	Yes	No
Change SpO <sub>2</sub> Mode	Yes	Yes	No
Select SpO <sub>2</sub> Repetition Time	Yes	Yes	No
Assign SpO <sub>2</sub> Pod	Yes	Yes	No
Remove SpO <sub>2</sub> Pod	Yes	Yes	No
Change Alarm Limits	Yes*	Yes	No
Place Device in Standby	Yes	Yes	Yes
Alarm Silence	Yes	Yes	Yes
Alarm Off/Pause	Yes	Yes	Yes

\* except when SRR connection to host is lost

#### WARNING

If a patient being monitored by Cableless Measurement Devices moves out of range of the patient monitor, the measurements are not transmitted to the patient monitor or the Information Center. The measurements are available on the Cableless Measurement Device only. If this occurs, the **No Host Monitoring** message is displayed on the measurement device. The measurement device will also sound the INOP tone.

#### **Controls Available with a Telemetry Device**

The controls available when working with the Cableless Measurement Device and a TRx4841/TRx4851A Transceiver or MX40 wearable patient monitor with a short range radio adapter (SRRA) are described in the table below.

Action	At the Cableless Measurement Device	At the IIC
Start SpO <sub>2</sub>	Yes	Yes
Change SpO <sub>2</sub> Mode	Yes	Yes
Select SpO <sub>2</sub> Repetition Time	Yes	No
Assign SpO <sub>2</sub> Pod	Yes	No
Remove SpO <sub>2</sub> Pod	Yes	Yes
Change Alarm Limits	No	Yes
Place Device in Standby	No	No
Alarm Silence	No	Yes
Alarm Off/Pause	No	Yes

#### NOTE

When you unplug the ECG cable from the telemetry device and plug it into the monitor associated with the same patient, the ECG source will automatically be from the monitor. The  $SpO_2$  measurement devices assigned to the telemetry device will continue to source data to the telemetry device and the Information Center. You may need to change screens on the patient monitor to see the measurements.

#### NOTE

The SpO<sub>2</sub> measurement sourced from the telemetry device (label: SpO<sub>2</sub>T) has priority over the IntelliVue CL SpO<sub>2</sub> measurement. The SpO<sub>2</sub>T measurement is sent to the Information Center as long as it is available and the IntelliVue CL SpO<sub>2</sub> measurement is available on the measurement device only.

#### Controls Available with GuardianSoftware

The controls available when working with the Cableless Measurement Device and GuardianSoftware are described in the table below.

Action	At the Cableless Measurement Device	At GuardianSoftware
Start SpO <sub>2</sub>	Yes	Yes
Change Mode	Yes	Yes
Select SpO <sub>2</sub> Repetition Time	Yes	Yes
Assign SpO <sub>2</sub> Pod	Yes	Yes
Remove SpO <sub>2</sub> Pod	Yes	Yes
Place Device in Standby	No	No
Technical Alarm Silence	No	Yes
Alarm Off/Pause	No	No

### Trending

The IntelliVue Cableless Measurement Devices provide data for trending of parameters. The trended data are only available via a host system. For details on trends see the Instructions for Use of your host system.

When the connection to the host is lost during measurement, the IntelliVue Cableless Measurement Devices are able to collect data in a local memory. These data can be uploaded to GuardianSoftware, but not to other host systems, when a connection is established at a later stage.

## **Monitoring SpO2**

Philips pulse oximetry uses a motion-tolerant signal processing algorithm, based on Fourier artifact suppression technology (FAST). A sensor is used that transmits light of two different wavelengths through the tissue of the patient. The measurement principle of pulse oximetry is based on the specific absorption characteristics of oxyhemoglobin and deoxyhemoglobin and the pulsating arteriolar vascular bed at the measurement site. It provides four measurements:

- Oxygen saturation of arterial blood (SpO<sub>2</sub>) percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- Pleth waveform auto-scaled visual indication of patient's pulse which is not directly proportional to the pulse volume (only on patient monitor, GuardianSoftware or Information Center, if assigned).
- Pulse rate (derived from pleth wave) detected pulsations per minute.
- Perfusion indicator numerical value for the pulsatile portion of the measured signal caused by arterial
  pulsation (only on patient monitor, if assigned).

#### NOTE

No alarms are generated for SpO<sub>2</sub> and Pulse when measuring SpO<sub>2</sub> with the SpO<sub>2</sub> Pod not assigned to a patient monitor or telemetry device.

The  $\text{SpO}_2$  measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

#### SpO2 Sensors

Specialized SpO<sub>2</sub> Sensors are available for use with the IntelliVue CL SpO<sub>2</sub> Pod. See the "IntelliVue CL SpO2 Pod Accessories" section for details.

Familiarize yourself with the Instructions for Use supplied with your sensor before using it. In particular, check that the sensor being used is appropriate for your patient category and application site.

#### Additional Information

The following documents contain additional information, depending on which accessories you are using:

- Mobile CL Single-Patient SpO<sub>2</sub> Sensor Instructions for Use
- Mobile CL Reusable SpO<sub>2</sub> Sensor<sup>1</sup> Instructions for Use
- Mobile CL SpO<sub>2</sub> Wristband Instructions for Use

<sup>1</sup> may not be available in all geographies

#### **Connecting SpO2 Sensors**

1 Connect the sensor to the single patient Mobile CL SpO<sub>2</sub> Cradle (if not already connected).



2 Insert the SpO<sub>2</sub> Pod into the Mobile CL SpO<sub>2</sub> Cradle. The correct orientation is indicated by a matching blue dot inside the cradle.



#### CAUTION

Make sure that the contacts of the SpO2 Pod and the sensor are dry and free of residues.

- **3** Secure the cradle on the patient's arm using the wristband.
  - a. Feed the free end of the wristband through the slot in the cradle, starting from the underside of the cradle.
  - b. Slide the wristband onto the patient's arm and pull the free end until the wristband fits snugly.
  - c. Close the wristband using the Velcro patch on the free end of the band.

#### Removing the Pod from the Cradle

To remove the  $SpO_2$  Pod from the cradle, pull on the Pod at the opening in the cradle, while holding the cradle in place on the patient's arm.



#### Applying the Sensor

- 1 Choose a finger of the patient that matches the sensor dimension in a way that the sensor optical components are properly aligned and the sensor is neither too loose nor applies too much pressure to the finger. For small pediatric patients consider the thumb.
- 2 Remove colored nail polish from the application site.
- 3 Apply the sensor to the patient. The application site should match the sensor size so that the sensor can neither fall off, nor apply excessive pressure. See the sections below for details on applying the different sensors.
- 4 Check that the light emitter and the photodetector are directly opposite each other. All light from the emitter must pass through the patient's tissue.

#### WARNING

**Proper Sensor Fit**: If a sensor is too loose, it might compromise the optical alignment or fall off. If it is too tight, for example because the application site is too large or becomes too large due to edema, excessive pressure may be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxemia and tissue malnutrition. Skin irritations or lacerations may occur as a result of the sensor being attached to one location for too long. To avoid skin irritations and lacerations, periodically inspect the sensor application site and change the application site regularly.

**Venous Pulsation**: Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements.

**Ambient Temperature**: At elevated ambient temperatures be careful with measurement sites that are not well perfused, because this can cause severe burns after prolonged application. All listed sensors operate without risk of exceeding 41°C on the skin if the initial skin temperature does not exceed 35°C.

**Extremities to Avoid**: Avoid placing the sensor on extremities with an arterial catheter, an NBP cuff or an intravascular venous infusion line.

#### **Measuring SpO2**

During measurement, ensure that the application site:

- has a pulsatile flow, ideally with a perfusion indicator value above 1.0 or, if the perfusion indicator is
  not available, with signal quality indicator of at least medium.
- has not changed in its thickness (for example, due to edema), causing an improper fit of the sensor.

#### WARNING

- If not specified otherwise in the SpO<sub>2</sub> sensor's instructions for use, the following applies:
  - For fully conscious pediatric or adult patients, who have a normal function of perfusion and sensory perception at the measurement site:

To ensure skin quality and correct optical alignment of the sensor, inspect the application site when the measurement results are suspicious or when the patient complains about pressure at the application site, but at least every 24 hours. Correct the sensor alignment if necessary. Move the sensor to another site, if the skin quality changes.

– For all other patients:

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. Correct the sensor alignment if necessary. If the skin quality changes, move the sensor to another site.

Change the application site at least every four hours.

- Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- Inaccurate measurements may result when the application site for the sensor is deeply pigmented or deeply colored, for example, with nail polish, artificial nails, dye or pigmented cream.
- Interference can be caused by:
  - High levels of ambient light (including IR warmers) or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material.)
  - Another SpO<sub>2</sub> sensor in close proximity (e.g. when more than one SpO<sub>2</sub> measurement is performed on the same patient). Always cover both sensors with opaque material to reduce crossinterference.
  - Electromagnetic interference, especially at perfusion indicator values below 1.0 or signal quality indicator below medium.
  - Excessive patient movement and vibration.

#### **Selecting Measurement Modes**

There are three different modes available for making SpO<sub>2</sub> measurements:

- Continuous mode SpO<sub>2</sub> is measured continuously until the measurement is switched off.
- **Manual mode** a single SpO<sub>2</sub> measurement is made when the **Start SpO**<sub>2</sub> SmartKey or the **Start SpO**<sub>2</sub> menu item is selected. One set of values is then displayed with the time the measurement was made.
- Automatic mode a series of measurements is made with an interval between them. The interval is selected using the **Repeat Time** SmartKey or the **Repeat** menu item. The measurement starts automatically when automatic mode is selected.

The values measured in manual mode or automatic mode will be displayed for a configurable time span. After that the values are regarded as invalid and are no longer displayed. Battery power usage will be appreciably higher when measuring in continuous mode, in comparison to manual or automatic mode, resulting in a reduced battery runtime.

#### Starting and Stopping Measurements

Use the setup menu or SmartKeys to start measurements manually:

Action to be Performed	SpO <sub>2</sub> menu	SmartKeys
Start manual measurement	Start SpO2	Start

When manual measurements are made, there will be no continuous  $SpO_2$  monitoring or alarming. The manual measurement value reflects a momentary status. The numerics from  $SpO_2$  measurements made in manual mode will remain for a time on the main screen. They are annotated with the time that the measurement was made to distinguish them from continuously measured values.

#### Understanding SpO2 Numerics and Symbols



- 1 SpO<sub>2</sub> numeric
- 2 Pulse rate numeric
- 3 Symbol indicating pulse rate
- 4 Measurement mode indicates here that **Auto** mode is active and shows the time to the next measurement.
- 5 Alarms Off symbol for Pulse
- 6 Timestamp
- 7 Alarms Off symbol for SpO<sub>2</sub>

**Note:** The Alarms Off symbols indicate that no physiological alarms are available from the Cableless Measurement Devices when not assigned to a host.

#### SpO2 Signal Quality Indicator

The  $\text{SpO}_2$  numeric is displayed together with a signal quality indicator (if configured and enough space is available) which gives an indication of the reliability of the displayed values.

The level to which the triangle is filled shows the quality of the signal; the indicator below shows a medium signal quality, the signal quality is at a maximum when the triangle is completely filled.



#### Assessing a Suspicious SpO2 Reading

Traditionally, pulse rate from  $SpO_2$  was compared with heart rate from ECG to confirm the validity of the  $SpO_2$  reading. With newer algorithms, such as FAST-SpO<sub>2</sub>, this is no longer a valid criteria because the correct calculation of  $SpO_2$  is not directly linked to the correct detection of each pulse.

When pulse rate is very low, or strong arrhythmia is present, the  $SpO_2$  pulse rate may differ from the heart rate calculated from ECG but this does not indicate an inaccurate  $SpO_2$  value.

If you doubt the measured SpO<sub>2</sub>, use the signal quality indicator (if available) or, when used with a patient monitor, the pleth wave and perfusion indicator on the monitor to assess the signal quality.

#### WARNING

With pulse oximetry, sensor movement, ambient light (especially strobe lights or flashing lights) or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached. Especially bandage-type sensor designs are sensitive to minimal sensor movement that might occur when the sensor is dangling.

#### Changing the Averaging Time

Depending on the monitor configuration, you may be able to change the averaging time for the SpO<sub>2</sub> values.

The averaging time represents the approximate time period used for the calculation. The exact averaging time also depends on the signal conditions. The longer the averaging time, the longer the time needed until the  $SpO_2$  values reflect the physiological event. The same averaging is applied to all numerical values:  $SpO_2$ , pulse rate and perfusion (only available at the patient monitor). Fast averaging is useful for situations where an extremely fast measurement is required or few artifacts are expected. Use slow averaging where you expect the number of artifacts to be relatively high.

- 1 In the SpO<sub>2</sub> menu, select Average.
- 2 Select the required averaging time from the list.

#### Perfusion Numeric (only available on the Patient Monitor)

The perfusion numeric (**Perf**) gives a value for the pulsatile portion of the measured signal caused by the pulsating arterial blood flow.

You can also use the perfusion numeric as a quality indicator for the  $SpO_2$  measurement. Above 1 is optimal, between 0.3-1 is acceptable. Below 0.3 is marginal; reposition the sensor or find a better site.

## Alarms

The IntelliVue Cableless Measurements have two different types of alarm: patient alarms and technical alarms (INOPs).

#### **Patient Alarms**

Patient Alarms are high priority alarms (such as a potentially life threatening situation), also called red alarms, or medium priority alarms, also called yellow alarms.

#### Technical Alarms (INOPs)

Technical alarms, also known as INOPs, indicate that the measuring device cannot measure reliably. If an INOP interrupts monitoring, there will be a question mark in place of the measurement numeric. An INOP tone sounds at the Cableless Measurement Device only when there is no SRR connection to a host. Exception: the Battery empty INOP tone sounds also with SRR connection.

Most INOPs are low priority, however there are a small number of INOPs which, due to their severity, are medium or high priority.

#### Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm indication at the Cableless Measurement Device. This delay has two components:

- The general measurement delay time is the time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing.
- The time between the displayed numerical values crossing an alarm limit and the alarm indication on the device is the system alarm delay. The system alarm delay is the processing time the system needs for any alarm on the Cableless Measurement Device to be indicated after the measurement has triggered the alarm. This delay depends on the Cableless Measurement Device and the connected host system. See the performance specifications in the chapter "IntelliVue CL SpO2 Pod Specifications" on page 133 for the system alarm delay specification of the Cableless Measurement Device.

The alarm delay configured for a specific measurement is normally a fixed time.

#### **Multiple Alarms**

If more than one alarm is active, the alarm messages are shown in the alarm status area in succession. An arrow symbol next to the alarm message informs you that more than one message is active.

The Cableless Measurement Device sounds an audible indicator for the highest priority alarm. If more than one alarm condition is active in the same measurement, the Cableless Measurement Device announces the most severe.

#### NOTE

If you want to use local attended monitoring, make sure to have all Cableless Measurement Devices upgraded to at least Rev. B.02.

#### Visual Alarm Indicators

#### WARNING

- No patient alarms are available on the Cableless Measurement Devices when assigned to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or GuardianSoftware.
- Visual patient alarm indicators are disabled on the Cableless Measurement Devices when connected to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or GuardianSoftware.

#### Alarm Message

Alarm messages are displayed in black on a light gray background in the alarm status area at the top of the screen indicating the source of the alarm and coded according to their severity. If more than one

measurement is in an alarm condition, the message changes every few seconds, and has an arrow ( $\mathbb{T}$ ) at the side. The asterisk symbols (\*) beside the alarm message match the alarm priority: \*\*\* for red alarms, \*\* for yellow alarms. Standard INOPs do not have a symbol, red and yellow INOPs have exclamation marks beside the alarm message: !!! for red INOPs and !! for yellow INOPs.

An alarm message that appears is automatically highlighted. Use the  $\checkmark$  key to silence the message. A **Silence** message is displayed at the bottom of the screen and highlighted. Press  $\checkmark$  again to confirm the acknowledgment of the alarm. After the confirmation, any ongoing alarm message is displayed in the icon tray of the screen.

#### **Alarm States**

Depending on the alarm state of your Cableless Measurement Device, the following icons may be displayed on the device:

Icon	Description
$\mathbb{A}$	No local alarming on Cableless Measurement Device. The device is connected to a host monitor or telemetry device and has no visual or audible patient alarm indicators. The device will only display INOP messages.
28	Alarms are switched off.
数	Alarm volume is set to 0.

#### **Audible Alarm Indicators**

Audible alarm indicator patterns are repeated until you acknowledge the alarm by switching it off or pausing it, or until the alarm condition ceases (if audible alarm indication is set to non-latching).

Cableless Measurements Devices alone (without host, e.g. a patient monitor) are not suitable for unattended monitoring due to their limited alarm volume.

#### WARNING

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm
  volume to a low level or off during patient monitoring may result in patient danger. Remember that the
  most reliable method of patient monitoring combines close personal surveillance with correct
  operation of monitoring equipment.
- No patient alarms are available on the Cableless Measurement Devices when connected to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or to GuardianSoftware.
- When connected to a host monitor or GuardianSoftware, no alarm tones are available on the Cableless Measurement Devices (unless they are selected for use in patient transport at the monitor they are assigned to).

#### Silencing an Alarm

To silence an alarm, select the alarm message and press the  $\checkmark$  key.

This will silence the alarm tone and clear the alarm message. If the condition which caused the alarm is still present, the alarm indicator will be displayed in the icon tray of the screen.



When using a Cableless Measurement Pod with an IntelliVue Information Center iX Release A, make sure to remove the pod at the telemetry device and only when in SRR range of the telemetry device. Otherwise you will get a technical alarm (**cl SpO<sub>2</sub> Disconnect**) that can not be silenced at the telemetry device. You will then have to reboot the telemetry device to remove the message.

#### **Displaying a List of Current Alarms**

To display a list of the currently active alarms,

- 1 Select the Alarms SmartKey or Main Setup SmartKey, followed by Alarms.
- 2 Select Alarm Messages.

#### Setting the Volume of the Alarm Tone

To set the volume for the Alarm tone,

- 1 Select the Alarms SmartKey or Main Setup SmartKey, followed by Alarms.
- 2 Select AlarmVol and select a volume setting. The maximum is 10 and the minimum depends on your configuration.

If the volume of the Alarm tone is set to zero, the following symbol is displayed on the right icon tray of the

Cableless Measurement Device screen:

#### NOTE

No Alarm tone will sound at the device as long as it is within the SRR range.

#### Minimum Volume for No Host Monitoring INOP

If your device is connected to a host monitor, and the connection is interrupted, the INOP message **No Host Monitoring** will appear within 30 seconds, accompanied by an INOP tone. To help ensure that this INOP, and any other active alarm, is not overlooked, the INOP and alarm tones may be configured to have a minimum volume. In this case, INOP and alarm tones will sound even if the device alarm volume is set to zero.
# **Alarm Reminder**

If **Reminder** is configured on your device, you will get an audible reminder of alarm conditions that remain active after you have silenced the alarm. This reminder may take the form of a repetition of the alarm tone for a limited time, or an unlimited repetition of the alarm tone (this is the same as a new alarm). Alarm Reminder is not available for standard, light blue INOPs but for yellow and red INOPs.

In Configuration Mode, you can set the interval between silencing the alarm and sounding the reminder tone to one, two, or three minutes.

# Pausing or Switching Off Alarms

If you want to temporarily prevent alarms from sounding, for example while you are moving a patient, you can pause alarms. Depending on your device configuration, alarms are paused for one, two, or three minutes, or infinitely. Infinite alarm pause is equivalent to switching the alarms off.

To view the alarm pause setting chosen for your unit,

- 1 In the SmartKeys Menu select Main Setup, Alarms, then OffDurat.
- 2 Check the setting.

This setting can only be changed in Configuration Mode.

#### To Pause or Switch Off Alarms



Select the key in the SmartKeys Menu followed by **Alarms**. Press the  $\checkmark$  hardkey to switch to **Paused**. If your device is configured to infinite pause time, selecting this option switches alarms off.

#### **Restarting Paused Alarms**

To manually switch on alarm indication again after a pause, select the key



Alarm indication starts again automatically after the pause period expires. If the device is configured to stay



again to restart alarm indication.

#### Alarm Limits

The alarm limits you set determine the conditions that trigger yellow and red limit alarms. For  $SpO_2$ , where the value ranges from 100 to 0, setting the high alarm limit to 100 switches the high alarm off. In these cases, the alarms off symbol is not displayed.

#### WARNING

Be aware that the devices in your care area may each have different alarm settings, to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.

#### Adjusting the Alarm Limits

- 1 Select the Alarms SmartKey followed by Alarm Limits (or select Main Setup followed by SpO2):
- 2 Select **High Lim** then choose the high alarm limit.
- 3 Select Low Lim then choose the low alarm limit.

#### WARNING

High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high alarm off.

#### Adjusting the Desat Limit Alarm

The Desat alarm is a high priority (red) alarm notifying you of potentially life threatening drops in oxygen saturation.

- 1 In the **SpO**<sub>2</sub> menu, select **DesatLim**.
- 2 Adjust the limit.

#### Setting Up Tone Modulation

Only when the Cableless Measurement Device is not connected to a host:

If tone modulation is on, the pulse tone pitch lowers when the SpO<sub>2</sub> level drops.

Select Main Setup followed by User Interface. In this menu, select Tone Modulation to switch between Yes (for on) and No (for off).

#### NOTE

If the SpO<sub>2</sub> level drops below 52%, two short tones will be issued rather than one long tone.

#### Latching Alarms

The alarm latching setting for your device defines how the alarm indicators behave when you do not acknowledge them. When alarms are set to non-latching, their indicators end when the alarm condition ends. Switching alarm latching on means that visual and/or audible alarm indications are still displayed or announced by the device after the alarm condition ends. The indication lasts until you acknowledge the alarm.

# Viewing the Alarm Latching Settings

To see the alarm latching setting for your device,

- 1 In the Main Setup menu, select Alarms.
- 2 Here you can see the Visual Latching and Audible Latching settings.

This setting can only be changed in Configuration Mode. You should be aware of the settings chosen for your unit. There are three possible choices each for visual and audible latching, red only, red and yellow, and off. These choices can be combined to give the following settings:

Visual Latching	Audible Latching
Red&Yellow	Red&Yellow
Red&Yellow	Red Only
Red&Yellow	Off
Red Only	Red Only
Red Only	Off
Off	Off

# **Alarm Latching Behavior**

Red & Yellow M Alarms	easurement	Non-latching alarms	Visual and audible latching	Visual latching, audible non-latching
Alarm has not been	Alarm condition still present.	Alarm tone on. Alarm message.	Alarm tone on. Alarm message.	Alarm tone on. Alarm message.
acknowledged.	Alarm condition no longer present.	All audible and visual alarm indicators automatically stop.	Alarm tone on. Alarm message.	Alarm message. Audible alarm indicators automatically stop.
Alarm has been acknowledged.	Alarm condition still present.	All audible and visual alarm indicators automatically stop.	All audible and visual alarm indicators automatically stop.	All audible and visual alarm indicators automatically stop.
	Alarm condition no longer present.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.

All INOPs are non-latching.

### **Testing Alarms**

When you switch the CL SpO<sub>2</sub> Pod on, a selftest is started. You must check that the backlight switches on, and that you hear a single tone. This indicates that the alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

### Alarm Behavior at Power On

If the device is switched off (**Standby**), all alarm settings are maintained. If the device is switched off completely (**Power Off**), or the battery is completely empty, resulting in complete power loss, all alarm settings will be lost unless they were actively saved by storing the active profile before the device was switched off. See "Switching the Device Off" on page 17 and "Using Profiles" on page 18 for details.

When the device is switched back on from either state, it will start in Profile A and you may have to switch to the desired profile which contains your alarm settings.

After any of these situations, you should check that the alarm settings are appropriate for your patient and monitoring situation, and if necessary, select the correct profile and patient category.

Reference List of Patient Alarms	Reference	List of	Patient	Alarms
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Alarm Message, Indication	Source	Condition	
*** Brady (Pulse)	SpO <sub>2</sub>	The heart rate from the Pulse signal has fallen below the bradycardia limit.	
*** Desat	SpO <sub>2</sub>	The SpO2 value has fallen below the desaturation alarm limit.	
** Pulse High	SpO <sub>2</sub>	The pulse rate has exceeded the high alarm limit.	
** Pulse Low	SpO <sub>2</sub>	The pulse rate has dropped below the low alarm limit.	
** <spo2 label=""> High</spo2>	SpO <sub>2</sub>	The arterial oxygen saturation has exceeded the high alarm limit.	
** <spo2 label=""> Low</spo2>	SpO <sub>2</sub>	The arterial oxygen saturation has dropped below the low alarm limit.	
*** Tachy (Pulse)	SpO <sub>2</sub>	The Pulse Rate from the Pleth signal has exceeded the tachycardia limit	

# Reference List of all INOPs

INOP Message, Indication	Source	What to do
Batt Incompatible INOP tone	Battery	Battery cannot be used with this Cableless Measurement Device. Replace battery with one that has been approved for use with this Cableless Measurement Device. Contact your service personnel.
Batt Malfunction INOP tone	Battery	Malfunction of the battery system detected (charger circuit or battery). Contact your service personnel.
Battery Empty INOP tone	Battery	The remaining monitoring time is below 30 minutes. Charge battery.
Battery Low INOP tone	Battery	The remaining monitoring time is below 2 hours.
<b>Check Batt Temp</b> INOP tone	Battery	The temperature of the battery is critically high. Check that Cableless Measurement Device is not covered and not exposed to a heat source. If INOP persists, remove Cableless Measurement Device from patient and contact your service personnel.
Check Battery INOP tone	Battery	The maximum number of charge/discharge cycles of the battery will be reached in less than 50 cycles. Contact your service personnel to replace the battery.
Check Charger I/F INOP tone	Battery	Overvoltage or undervoltage detected at the charger interface. Clean contacts of charger interface at Cableless Measurement Device and charging station. If the INOP persists, contact your service personnel.

INOP Message, Indication	Source	What to do
cl SpO2 Chk Sett INOP tone	Cableless Measurement Device	If this INOP appears and an INOP tone sounds, check the Cableless Measurement Device and patient settings before you resume making measurements. If the settings are unexpected, there may be a problem with the Cableless Measurement Device software. Contact your service personnel.
		If this INOP is acknowledged at the Cableless Measurement Device, it is cleared. If it is silenced remotely, only the tone is cleared.
cl SpO2 Disconnect only at the host	Cableless Measurement Device	The SpO <sub>2</sub> Pod has lost the SRR connection to the telemetry device or the patient monitor.
<b>No Host Monitoring</b> INOP tone	Cableless Measurement Device	There is a problem with the communication to the assigned patient monitor or telemetry device and monitoring is currently not possible (no patient alarms or information). Check the connection. Contact your service personnel.
No System	Cableless Measurement Device	There is a problem with the communication to the assigned IntelliVue GuardianSoftware and monitoring is currently not possible (no patient alarms or information). Check the connection. Contact your service personnel.
<b>Remove From Pat</b> INOP tone	Cableless Measurement Device	Displayed on the Cableless Measurement Device. The temperature of the battery is too high. Remove the Cableless Measurement Device from the patient and contact service personnel.
Service Battery INOP tone	Battery	Maximum number of charge/discharge cycles for battery exceeded. Charging of the battery is inhibited. Contact your service personnel to replace battery.
<spo2 label=""> Equip Malf Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	The SpO <sub>2</sub> Pod is faulty. Contact your service personnel.
<spo<sub>2 Label&gt; Erratic Numeric is replaced by -?- INOP tone</spo<sub>	SpO <sub>2</sub>	Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
< <b>SpO2 Label&gt; Extd.Update</b> Numeric is replaced by -?-	SpO <sub>2</sub>	The update time for displayed values is extended due to an NBP measurement on the same limb or an excessively noisy signal.
<spo<sub>2 Label&gt;Interference Numeric is replaced by -?- INOP tone</spo<sub>	SpO <sub>2</sub>	There is too much interference, caused by a high level of ambient light and/or electrical interference. Cover the sensor to minimize ambient light. If the INOP persists, make sure that the sensor cable is not damaged or positioned too close to power cables.
< <b>SpO2 Label&gt; Low Perf</b> Numeric is replaced by -?-	SpO <sub>2</sub>	Accuracy may be compromised due to very low perfusion. Stimulate circulation at sensor site. If INOP persists, change the measurement site.
<spo<sub>2 Label&gt; NeoPatient? Numeric is replaced by -?- INOP tone</spo<sub>	SpO <sub>2</sub>	The patient monitor the SpO <sub>2</sub> Pod is assigned to is in neonatal mode. The INOP will remain active until the monitor is changed to adult or pediatric mode.

INOP Message, Indication	Source	What to do	
< <b>SpO<sub>2</sub> Label&gt; No Pulse</b> Numeric is replaced by -?- INOP tone	SpO <sub>2</sub>	Check the perfusion at the measurement site. If necessary, stimulate circulation or change the measurement site. If the INOP is due to an NBP measurement on the same limb, wait until the NBP measurement is finished.	
<spo2 label=""> No Sensor Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	Make sure the $\text{SpO}_2$ sensor is connected. If the INOP persists, try another sensor. If you acknowledge this INOP, the measurement will be switched off.	
<spo2 label=""> NoisySignal Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	Excessive patient movement or electrical interference is causing irregular pulse patterns. Try to reduce patient movement or to relieve the cable strain on the sensor.	
<spo2 label=""> Poor Signal</spo2>	SpO <sub>2</sub>	The signal quality of the $\text{SpO}_2$ measurement is poor. The accuracy may be compromised.	
<spo2 label=""> Pulse? Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	The detectable pulsations of the $SpO_2$ signal are outside specified pulse rate range.	
<spo2 label=""> Searching Numeric is unavailable</spo2>	SpO <sub>2</sub>	The patient signal is analyzed, but no valid numerics are available yet.	
<spo2 label=""> Sensor Malf Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	The $SpO_2$ sensor is faulty. Try another sensor. If the INOP persists, contact your service personnel.	
<spo2 label=""> Sensor Off Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	The algorithm has determined that a sensor is connected, but not properly applied to the patient. The ability of the algorithm to detect this condition depends on the used sensor type.	
<spo2 label=""> Unkn.Sensor Numeric is replaced by -?- INOP tone</spo2>	SpO <sub>2</sub>	The connected $\text{SpO}_2$ sensor is not supported by this measurement hardware.	
<spo2 label=""> Upgrade Numeric is replaced by -?-</spo2>	SpO <sub>2</sub>	$SpO_2$ in upgrade mode, no patient monitoring possible.	

# Local Attended Monitoring

When working with an IntelliVue MP5, MP5SC, MP5T Patient Monitor with software revision J.2 or higher as a host, or with an IntelliVue X2 Multi-Measurement Module with software revision K.2 or higher, the IntelliVue CL  $SpO_2$  and NBP Pods can be used for local attended monitoring. This is for situations where you want to have alarm indications at the CL Pods when they are out of reach of the patient monitor (disconnected). The patient monitor setting to switch CL Measurement Alarms on and off (cl Alarms On/Off) is used to enable and disable this functionality. As a default, the CL Measurement Alarms are on.

# Local Attended Monitoring Enabled

At the CL Pod:

At the CL Pod:

physiological alarms

alarms only

Indication of technical

By default, the patient monitor is set to receive alarms from the CL Pods (can only be changed in configuration mode). This scenario is used for patients who require uninterrupted monitoring. The various alarms from the CL Pods are indicated at the patient monitor if they are enabled at the monitor. When the CL Pod is disconnected from the patient monitor and the caregiver has activated the transport mode at the monitor, physiological alarms are indicated locally at the CL Pod. A **cl SpO2 Disconnect** INOP is shown at the monitor if the SRR connection is lost and the transport mode has not been activated.

#### CL Pod connected to a patient monitor and CL Measurement Alarms On (Standard Use Model):



SRR connection



At the monitor: Indication of physiological and technical alarms from CL Pods

CL Pod disconnected from patient monitor and CL Measurement Alarms On, Local Attended Monitoring:



Indication of technical and

No SRR connection



At the monitor: No indication of physiological alarms from CL Pods. No indication of technical alarms after disconnection.

## Local Attended Monitoring Disabled

The patient monitor is set to **cl Alarms Off** (this can only be done in configuration mode). This scenario is used if the patients do not require permanent monitoring and are mobile, but vital signs are taken from time to time. All alarms from the CL Pods are switched off at the monitor. If the SRR connection is lost, no **cl SpO<sub>2</sub> Disconnect** INOP is shown at the monitor in this scenario.

#### CL Pod connected to a patient monitor and CL Measurement Alarms Off:



SRR connection

At the CL Pod: Indication of technical alarms only



At the monitor: **No** indication of physiological alarms from CL Pods. Indication of technical alarms from CL Pods.

#### CL Pod disconnected from patient monitor and CL Measurement Alarms Off:



At the CL Pod:

alarms only

Indication of technical





At the monitor: **No** indication of physiological and technical alarms from CL Pods.

# Alarm Availability: Standard Use Model versus Local Attended Monitoring with CL Measurement Alarms On



Action / Event	Situation	Alarm Availability at CL Pod	Alarm Availability at Patient Monitor
Standard Use Model: normal operation, no special action	CL Pod connected to the patient monitor (1)	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

Activation of Local Attended Monitoring: Caregiver activates Local Attended Monitoring and disconnects CL Pod temporarily by setting <b>Use for Transp.</b> in the Patient Monitor's <b>Equipment</b> window	Patient is in transport without connection to the host system, caregiver attends the patient (2)	Technical alarms (own) Physiological alarms (own)	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod
Deactivation of Local Attended Monitoring: Caregiver deactivates Local Attended Monitoring and reconnects CL Pod to a patient monitor by setting Use with Monitor in the patient monitor's Equipment window	Patient returns from transport. Back to the standard use model (1)	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

Special Case: Connection lost while in Standard Use Model			
Action / Event	Situation	Alarm Availability at CL Pod	Alarm Availability at Patient Monitor
Alternative Use Model: CL Pod temporarily disconnected from a monitor due to unintentional loss of connection (e.g. out of range), Local Attended Monitoring has not been activated by the caregiver	No Host Monitoring INOP at CL Pod cl SpO2 Disconnect INOP at patient monitor Local Attended Monitoring is automatically activated (2)	Technical alarms (own) Physiological alarms (own)	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod

# Alarm Availability: Standard Use Model versus Local Attended Monitoring with CL Measurement Alarms Off



Action / Event	Situation	Alarm Availability at CL Pod	Alarm Availability at Patient Monitor
Connected, but no CL Alarms (CL Measurement Alarms	CL Pod connected to the patient monitor ( <b>3</b> )	Technical alarms (own)	Technical alarms (own + from Pod)
Off): normal operation, no special action		No physiological alarms No Local Alarming icon is displayed:	Physiological alarms (own)

Patient is leaving the vicinity of the monitor: no special action	Patient is mobile without connection to the host system (4)	Technical alarms (own) No physiological alarms <b>Alarms Off</b> icon is displayed in front of each numeric:	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod
Patient returns to the vicinity of the monitor: no special action	Patient returns. Back to connected status ( <b>3</b> )	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

# **SpO2 Default Settings**

These are the most important default settings of your IntelliVue CL  $SpO_2$  Pod as they are delivered from the factory. For a comprehensive list and explanation of default settings, see the Configuration Guide supplied with your devices. The default settings can be permanently changed in Configuration Mode. When the Pod is assigned to a patient monitor, the settings defined at the patient monitor will overwrite the settings defined at the Pod.

SpO <sub>2</sub> Settings	Factory Defaults		
	Adult	Pedi	Neo
Mode	Continuous	Continuous	Continuous
Repeat Time	15 min	15 min	15 min
Alarms	On	On	On
Pulse Volume	1	1	1
ToneMod.	Yes	Yes	Yes
Perfusion	On	On	On
Average	10 sec	10 sec	10 sec
NBP Alarm Suppr.	On	On	On
Aging Time	10 min	10 min	10 min
Color	<b>Cyan</b> (light blue)	<b>Cyan</b> (light blue)	<b>Cyan</b> (light blue)
Average in Mon.	No	No	No
Signal Quality	On	On	On
Label	SpO <sub>2</sub>	SpO <sub>2</sub>	SpO <sub>2</sub>

SpO <sub>2</sub> Alarm Default Settings			
Setting	Adult	Pedi	Neo
DesatLim	80	80	80
Low Lim	90	90	85
High Lim	100	100	95
Desat Delay	20 sec	20 sec	20 sec
High Alarm Delay	10 sec	10 sec	10 sec
Low Alarm Delay	10 sec	10 sec	10 sec

Pulse Settings	Factory Defaults		
	Adult	Pedi	Neo
Pulse	On	On	On
Alarms	On	On	On
High Lim	120	160	200
Low Lim	50	75	100
Δ Brady	20	20	20
Brady Clamp	40	40	50

Pulse Settings	Factory Defaults		
	Adult	Pedi	Neo
Δ Tachy	20	20	20
Tachy Clamp	200	220	240

# **Integrated Battery Handling**

Only qualified and authorized service personnel (biomedical engineers or technicians) should change batteries.

# **Battery Care**

Battery care begins when you receive a new IntelliVue Cableless Measurement Device with built-in battery and continues throughout the life of the device. The table below lists battery care activities and when they should be performed.

Activity	When to perform
Perform a visual inspection	Before using the IntelliVue Cableless Measurement Device
Charge the battery	Upon receipt, after use, or if a low battery state is indicated. To optimize performance, a fully (or almost fully) discharged battery should be charged as soon as possible.
Store the device in a state of charge in the range of 40-50% and power off the device completely.	When not in use for an extended period of time, or when the device is shipped.

# Handling Precautions

Lithium ion batteries store a large amount of energy in a small package. Use caution when handling the IntelliVue Cableless Measurement Devices with built-in battery; misuse or abuse could cause bodily injury and/or property damage.

- Handle with care.
- Do not expose the device to liquids.
- Do not attempt to disassemble the device.
- Do not put device in autoclave.
- Damaged devices should not be used anymore.

#### WARNING

- Do not crush or puncture mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- Do not incinerate the devices or expose them to temperatures above 60°C (140°F).

#### Storage

If unused IntelliVue Cableless Measurement Devices are stored for an extended period of time:

- they should be powered off for storage
- they should be stored in a cool place, ideally between 15°C and 25°C (60°F and 77°F)
- the state of charge should be between 40 and 50%
- they should be recharged every six months

Storing in a cool place slows the aging process of the batteries. They should be fully charged prior to use. Do not store the device at a temperature outside the range of  $-20^{\circ}$ C ( $-4^{\circ}$ F) to  $60^{\circ}$ C( $140^{\circ}$ F).

Do not store cableless devices in direct sunlight.

#### NOTE

Storing the devices at temperatures above 40°C (104°F) for extended periods of time could significantly reduce the battery's life expectancy.

#### **Battery Lifetime Management**

The lifetime of a Lithium Ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 4 years or 400 complete charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. We therefore strongly recommend that lithium ion batteries be replaced after 4 years or 400 complete charge-discharge cycles.

To see the date of manufacture and the number of charge-discharge cycles:

- 1 Select the Battery Smartkey or Main Setup followed by Battery.
- 2 Press the  $\checkmark$  hardkey to view the battery details.

The date of manufacture and the number of charge-discharge cycles are listed with other battery data on the screen. Use the  $\blacktriangleleft$  hardkey to scroll through the list.

The age of a lithium ion battery begins at the date of manufacture.

# Accessories

You can order parts and accessories from Philips supplies at www.medical.philips.com or consult your local Philips representative for details. Also consult the accessories' Instructions for Use, if available.

#### WARNING

**Reuse:** Never reuse single-patient sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard, in particular with regard to cross-contamination.

**Philips' approval:** Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance and cause a potential hazard.

## Accessories Compliant with EMC Standards

All accessories listed in the accessories sections comply, in combination with the IntelliVue Cableless Measurements, with the requirements of IEC 60601-1-2.

### IntelliVue CL SpO2 Pod Accessories

All listed sensors operate without risk of exceeding 41°C on the skin, if the initial skin temperature does not exceed 35°C.

Make sure that you use only the accessories that are specified for use with this device, otherwise patient injury can result.

Part Number	Description	Contents
989803165941	Mobile CL 20 <b>single patient</b> SpO <sub>2</sub> Sensors and Cradles for use on pediatric and adult patients >10 kg	<ul> <li>20 Single-Patient Mobile CL DSpO<sub>2</sub>-1A Sensors</li> <li>20 Single-Patient Wristbands</li> <li>20 Single-Patient Cradles</li> <li>pre-assembled</li> </ul>
989803165921	Mobile CL 20 <b>single patient</b> SpO <sub>2</sub> Sensors for use on pediatric and adult patients >10 kg	20 Single-Patient Mobile CL DSpO <sub>2</sub> -1A Sensors
989803165931 <sup>1</sup>	Mobile CL <b>reusable</b> SpO <sub>2</sub> Sensor and Cradles for use on pediatric and adult patients > 15 kg	1 Reusable Mobile CL RSpO <sub>2</sub> -1A Sensor 20 Single-Patient Cradles with pre-attached Wristbands
989803165951	Mobile CL 20 SpO <sub>2</sub> Cradles ( <b>single patient</b> )	20 Single-Patient Cradles with pre-attached Wristbands
989803165961	Mobile CL 50 SpO <sub>2</sub> Wristbands ( <b>single patient</b> )	50 Single-Patient Wristbands
989803168861	Mobile CL SpO <sub>2</sub> Battery Kit	1 Battery 1 disassembly tool 1 front housing

<sup>1</sup> May not be available in all geographies

# Maintenance and Troubleshooting

#### WARNING

**Schedule**: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

**Contact**: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.

#### Inspecting the Equipment and Accessories

You should perform a visual inspection before every use, and in accordance with your hospital's policy. With the device switched off:

- 1 Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
- 2 Inspect all accessories (cables, sensors and so forth). If any show signs of damage, do not use them.

#### WARNING

If the IntelliVue Cableless Measurement Device is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient, contact your service personnel.

#### Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation supplied on the IntelliVue Cableless Measurements documentation DVD. These tasks are for Philips-qualified service professionals only.

Ensure that these tasks are carried out as indicated by the device's maintenance schedule, or as specified by local laws. Contact a Philips-qualified service provider if your device needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

#### Troubleshooting

If a device will not switch on when you press a key, place it onto a charger slot on the charging station.

If you suspect a problem with an individual measurement device, read the Instructions for Use and double check that you have set up the measurement correctly. Check also that the measurement has not been switched off at the patient monitor that the device is assigned to.

If you suspect an intermittent, system-wide problem call your service personnel.

# IntelliVue CL NBP Pod

To measure NBP, you need Philips standard cuffs, a Mobile CL NBP Cradle and a pouch and extension air hose, or a Mobile CL NBP Cradle and Mobile CL Cuffs. When using Mobile CL Cuffs, the cradle is used to attach the Pod to the cuffs and to allow easy removal of the Pod.



Standard Philips cuffs and specialized single-patient and reusable NBP cuffs are available for use with the IntelliVue CL NBP Pod. For details regarding the cuffs and single-patient cradle, refer to "IntelliVue CL NBP Pod Accessories" on page 94.

# General Operation of the NBP Pod

The following sections describe operation on the NBP Pod itself. For operation from a patient monitor, see "Controls Available with a Patient Monitor" on page 67. For operation from an Information Center via a telemetry system, see "Controls Available with a Telemetry Device" on page 68. For operation with IntelliVue GuardianSoftware, see "Controls Available with GuardianSoftware" on page 68.

The NBP Pods have three hardkeys for basic operation and a set of configurable SmartKeys which appear on the screen. These are used to activate and navigate through the on-screen menus and to select individual items. The typical operator's position is such that everything on the device's display can be read clearly and easily.

# Switching the Devices On

The first time an NBP Pod is used, or after the device has been powered off for storage, place it on the IntelliVue CL Charging Station. This will automatically switch the device on.

If the NBP Pod has only been switched off temporarily (see "Switching the Device Off" on page 17), press any hardkey to turn the device on again.

When an NBP Pod is not operated, it will automatically switch off the screen lighting after a short time. A little later the low-activity screen will be displayed.

### **Screen Layout**

There are three variations of the Main Screen layout depending on the Alarm status and the general activity level.

#### **Standard Layout**

When assigned to a monitor, telemetry device or a patient in GuardianSoftware:



- 1 Connection status indicator
- 2 Indicator that alarming capability has been transferred to the host (to the monitor or, for the telemetry device, to the Information Center). No patient alarms will be announced on the Cableless Measurement Device.
- 3 Battery indicator
- 4 Measurement values
- 5 Measurement-related symbols (see the "Monitoring NBP" section for details)
- 6 Patient identification

When not assigned to a monitor or telemetry device:



- 1 Connection status indicator
- 2 Battery indicator
- 3 Measurement values
- 4 Measurement-related symbols (see the "Monitoring NBP" section for details). The Alarms Off symbols indicate that no physiological alarms are available from the Cableless Measurement Devices when not assigned to a host.
- 5 Cableless Measurement Device equipment label

#### **Alarm Layout**

If an alarm occurs the full alarm message appears at the top of the screen. After the alarm message has been silenced the alarm indicator is shown as a symbol on the right side of the screen.



56

### Low-Activity Screen

If the Cableless Measurement Device has not been operated for a while, the screen lighting will switch itself off and a little later the screen will switch to a pre-configured "low-activity" screen.

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# When a Cableless Measurement Device Cannot be Activated

If you cannot activate a device by pressing a key, place it on the IntelliVue CL Charging Station. The device becomes active. Check the battery status. If necessary, leave the device on the charger until the battery is fully charged.

# **Using the Hardkeys**

The IntelliVue Cableless Measurement Devices have three hardkeys:  $\blacktriangleleft, \checkmark, \triangleright$ .

Use  $\blacktriangleleft$  and  $\blacktriangleright$  to navigate through SmartKeys and menus and  $\checkmark$  to select items or to silence alarms.

The three hardkeys also have an additional function when the key is held down for a couple of seconds:

- opens the Add To screen to assign a device (or to unassign it when it is already assigned)
- ✓ opens the SmartKeys menu
- returns to the Main Screen. If already on the Main Screen, it locks the keys and a lock symbol appears on the screen above the battery symbol. If keys are already locked, it unlocks the keys and the lock symbol disappears

# Using the SmartKeys

A SmartKey is a graphical key which appears on the screen and gives you fast access to functions.

# SmartKeys Menu

Press the ✓ hardkey (without any screen element highlighted) to get to the SmartKeys menu.



Use the  $\blacktriangleleft$  and  $\triangleright$  hardkeys to move along the row of SmartKeys. The highlighted SmartKey is displayed in full above the row of SmartKeys. When you use the  $\blacktriangleleft$  or  $\triangleright$  hardkey at the end of the row, an **Exit** screen appears and then with further presses you move on to the next page of SmartKeys. To leave the SmartKeys menu you can use the **Exit** screen or press the  $\triangleright$  hardkey for a couple of seconds to return to the Main Screen.

When the required SmartKey is highlighted, press the  $\checkmark$  key to activate the corresponding function.

To get to the next page of the SmartKeys menu, highlight the rightmost SmartKey then press the ▶ key.

# List of Available SmartKeys

SmartKey	Text Labels
	Main Setup
¢∎⊗	<ul> <li>start/stop manual NBP measurement</li> <li>start auto series</li> <li>start measurement sequence</li> <li>stop current automatic measurement within series</li> </ul>
¢∎®	stop any NBP measurement and measurement series
₽	start NBP STAT measurement
<b>"</b> †	start venipuncture (inflate cuff to subdiastolic pressure)
, <b>,</b>	set the NBP repetition time
	Add/Remove device
	enter Battery menu
Q	change Screen
	enter <b>Profiles</b> menu
Ċ	put the device in standby mode (or power off when pressed for more than two seconds)
÷ 🛉	enter Patient menu
$\square$	enters the <b>Alarms</b> menu to access: <b>Alarm Messages</b> , <b>Alarm Limits</b> , Alarms On/ Off/Pause, Alarm Volume.
	change alarm volume
<u> </u>	change pulse tone volume
¢∎≕	access NBP mode selection and setup, with direct start/stop function

# Using the Main Setup Menu

In addition to the hardkeys and SmartKeys for the most needed functions, the **Main Setup** menu gets you to all settings that can be adjusted for the respective device. Select the **Main Setup** SmartKey to get to the **Main Setup** menu.

Main Setup
NBP
Alarms
Patient
Equipment
User Interface
Standby
Profiles
Operating Modes
Date, Time
Battery
Revisions

# Switching the Device Off

To put the device in standby mode, select the Standby SmartKey, then Confirm.

If you keep Standby pressed for more than two seconds, you can choose between Standby or Power Off.

- **Standby** means that the display is switched off and the measurements are disabled. Use this option if your device is not used temporarily. Press any hardkey to turn the device on again.
- Power Off means that the device is switched off completely and can only be switched on again by
  putting it on a charger. Use this option when the device is not used for a longer time or prepared for
  storage or shipping.

#### Auto Standby and Auto Power Off

The device can be configured to automatically go into standby mode after a configurable time span of inactivity. When in standby mode, the device can be automatically powered off after a configurable time span. See the IntelliVue Cableless Measurements Configuration Guide for details on how to configure these settings.

# **Operating Modes**

Your device has four operating modes. Some are passcode protected.

- Monitoring Mode: This is the normal, every day working mode that you use for making measurements. You can change elements such as measurement modes, patient category and so forth. When you remove the patient from the device, these elements return to their default values. Changes can be stored permanently only in Configuration Mode. You may see items, such as some menu options, that are visible but 'grayed out' so that you can neither select nor change them. These are present for your information only and can be changed only in Configuration Mode.
- **Demonstration Mode**: Passcode protected, this is for demonstration purposes only. You must not change into Demonstration Mode during monitoring.
- **Configuration Mode**: Passcode protected, this mode is for personnel trained in configuration tasks. These tasks are described in the Configuration Guide. During installation the Cableless Measurement Device is configured for use in your environment. This configuration defines the default settings you work with when you switch on.
- Service Mode: Passcode protected, this is for trained service personnel.

When you switch the device on, it starts up in monitoring mode. To change to a different mode:

- 1 Use the Main Setup SmartKey to get to the Main Setup menu.
- 2 Select **Operating Modes** and choose the mode you require.

#### Standby Mode

The IntelliVue Cableless Measurement Devices do not have standby mode. However, when connected to a monitor that is in standby mode, the IntelliVue Cableless Measurement Device will show a standby screen.

#### Using the Patient Menu

The **Patient** menu allows you to see patient demographics information and to remove a patient from a device. Patient Demographic information is only displayed if the Cableless Measurement Device is assigned to a patient monitor or GuardianSoftware. **Patient Category** is the only item of patient data which can be changed at the Cableless Measurement Device, but only when the device is not assigned to a patient monitor or telemetry device.

#### **Displaying the Patient Menu**

To display the Patient menu,

- select the Patient SmartKey, or
- select the Main Setup SmartKey followed by Patient.

#### Stop Using a Device for a Patient

To remove a patient from the Cableless Measurement Device,

in the Patient menu select Free Device.

All patient data is cleared, settings are reset to the defaults and the device is removed from the monitor or telemetry device.

#### NOTE

Depending on your configuration, when the device is put on the charger, patient data will also be cleared and the device will be free for another patient.

#### Using the Device for a New Patient

To use a device for a new patient,

in the Patient menu, select New Patient.

If the device was not free, the existing data will be deleted and the profile set to the default.

#### Using Profiles

A profile is a set of measurement and general settings which have been customized for a particular purpose. The Cableless Measurement Devices can have four different profiles configured to your requirements. The default profile is marked with a symbol.

To select a different profile,

- 1 Select the **Profiles** SmartKey or the **Main Setup** SmartKey followed by **Profiles**.
- 2 Select the required profile from the list.

Selecting New Patient or Free Device will always reset the profile to the default.

## Setting the Date and Time

If the Cableless Measurement Device is assigned to a patient monitor, telemetry device or GuardianSoftware, the date and time will be taken from the host. If this is not the case, you can set the date and time on the Cableless Measurement Device,

- 1 Select the Main Setup SmartKey and then Date, Time.
- 2 Enter the data for date and time one after another.
- 3 Select Store Date, Time.

If the time has not been set, --:-- will display on the device.

### **Battery Status**

The IntelliVue CL NBP Pods show their battery status on their display both in operating and charging condition. The battery status indicator is located in the lower right corner of the screen during operation and in the middle of the screen during charging.

## **Battery Status Menu**

Select the **Battery** SmartKey or **Main Setup** followed by **Battery** using the  $\triangleleft$  and  $\triangleright$  keys, then press the  $\checkmark$  key to open the **Battery** menu. The **Battery** menu provides the following information: full-charge and remaining capacity, voltage, current and temperature.

# **Connection with Host Systems**

The following sections describe how the IntelliVue Cableless Measurement Devices work together with host systems (Patient Monitors, Fetal Monitors, Telemetry Devices / Information Center or GuardianSoftware).

#### IntelliVue Cableless Measurements Use Models

With these patient-worn measurement devices you can measure and transmit a patient's vitals regularly or on an intermittent data collection basis. There are four typical use models:

#### With a Patient Monitor

The IntelliVue Cableless Measurement Devices can be used together with an MP5/MP5SC/MP5T, MP2 or X2 patient monitor (with an SRR interface). They can communicate their measurement values via short range radio to the monitor. The monitor may be assigned to a patient sector at the IntelliVue Information Center (IIC). When assigned to the Information Center, certain actions can be performed at both the patient monitor and the Information Center. See the table "Controls Available with a Patient Monitor" on page 67.

In situations where patients are becoming more mobile (for example, in step-down/intermediate care units) the lightweight Cableless Measurement Devices allow increased mobility within the short range radio range, without giving up vital signs monitoring.

When assigned to a patient monitor, the Cableless Measurement Device can be selected for use in patient transport at the patient monitor (for details see the Patient Monitor Instructions for Use). In this case, the Cableless Measurement Device will perform **local attended monitoring**. The patient must be attended by a caregiver during transport, to ensure that alarms on the Cableless Measurement Device are recognized. In local attended monitoring mode, an alarm message text appears in the alarm status area at the top of the screen indicating the source of the alarm and an alarm tone is issued. See "Alarms" on page 34 for details.

A telemetry device can be assigned to a patient monitor equipped with short range radio at the same time as any Cableless Measurement Devices are also assigned to this monitor.

When assigned to a patient monitor, the admitted patient name is displayed on the NBP Pod.

If the connection between the monitor and the Cableless Measurement Device is lost, an INOP will be displayed at the monitor: **cl NBP Disconnect**. A **No Host Monitoring** INOP will be displayed on the NBP Pod, and an INOP tone will sound. In this case, visual and audible alarms are still available at the NBP Pod, but it is not possible to change the alarm settings.

#### With a Fetal Monitor

In combination with an Avalon CL Transducer System, the IntelliVue CL NBP Pod can be used together with an Avalon FM 20-50 Fetal Monitor. The NBP Pods are assigned to the fetal monitor by docking them at the Avalon CL Base Station. For information about Avalon Fetal Monitors, the Avalon CL Transducer System and the Avalon CL Base Station, please refer to the Avalon Fetal Monitor Instructions for Use.

#### With a Telemetry Device

The Cableless Measurement Devices can be assigned to a patient with the telemetry device TRx4841A/ TRx4851A or an MX40 wearable patient monitor. They can communicate their measurement values via short range radio to the telemetry device which communicates them to an IntelliVue Information Center to provide a consolidated set of patient values.

Some of the measurement tasks can be performed remotely from the Information Center. See the table "Controls Available with a Telemetry Device" on page 68.

If the patient name is available at the Information Center, it will be also displayed on the NBP Pod.

When a Cableless Measurement Device is assigned to a telemetry device, it is not possible for the telemetry device to be wirelessly assigned or directly connected to a patient monitor.

If the connection between the telemetry device and the Cableless Measurement Device is lost, an INOP will be displayed at the Information Center: **cl NBP Disconnect**. A **No System Monitor**. INOP will be displayed on the NBP Pod, and an INOP tone will sound.

#### With IntelliVue GuardianSoftware

The Cableless Measurement Devices can be used together with IntelliVue GuardianSoftware. GuardianSoftware collects non-continuous vital signs data that are transmitted via a Transmitter, Hotspot or MP5 from the Cableless Measurement Devices. Using the collected data, it provides trending, review, reporting and notification. The Guardian Early Warning Scoring (Guardian EWS) application provides basic assessment guidance, helping you to recognize the early signs of deterioration in your patients. GuardianSoftware is not intended for monitoring in combination with Cableless Measurement Devices.

Some of the measurement tasks can be performed remotely from GuardianSoftware. See the table "Controls Available with GuardianSoftware" on page 68. GuardianSoftware also manages the patient data.

If the connection between GuardianSoftware and the Cableless Measurement Device is lost, the connection symbol will be displayed gray at GuardianSoftware. A **No System** INOP will be displayed on the NBP Pod (no alarm sound).

If a patient name is available at GuardianSoftware, it will be also displayed on the Pod. Any update of patient data will be synchronized between the Pods and GuardianSoftware. The only patient management action available directly at the Pod is **Free Device**. Selecting **Free Device** removes the current patient from the Pod and resets the Pod to the default profile. The Pod is unassigned.

#### **Device Compatibility**

The IntelliVue CL NBP Pods require the following software levels in the associated equipment:

- IntelliVue Patient Monitor Release H.0 or above
- Avalon Fetal Monitor in combination with an Avalon CL Transducer System Release J.3 or above
- IntelliVue Information Center Release M or above
- Philips Patient Information Center iX Release A or above
- Telemetry device TRx4841A/TRx4851A Revision D.00.22 or above
- MX40 wearable patient monitor Revision A.0 or above
- IntelliVue GuardianSoftware Revision A.0 or above

#### Availability of Patient Alarms

When the IntelliVue CL NBP Pod is used alone, without an assignment to a monitor or telemetry device **no patient alarms will be generated**.

When the IntelliVue CL NBP Pod is assigned to a patient monitor or telemetry device and a short range radio connection exists, alarms may be announced at the patient monitor or the Information Center.

• When assigned to a patient monitor / fetal monitor: Alarm messages will be displayed and audible alarm indicators sounded at the monitor in the same way and under the same conditions as for its own measurements. See the Instructions for Use of the patient monitor for details.

If a Cableless Measurement Device that is assigned to a patient monitor is selected for use in patient transport at the patient monitor, the Cableless Measurement Device will perform **local attended monitoring**. See the Instructions for Use of the patient monitor for details on how to do this. The patient must be attended by a caregiver during transport, to ensure that alarms on the Cableless Measurement Device are recognized. In local attended monitoring mode, an alarm message text appears in the alarm status area at the top of the screen indicating the source of the alarm and an alarm tone is issued. See "Alarms" on page 34 for details.

- When assigned to a telemetry device: Measurement values sent via the telemetry device to the IntelliVue Information Center can generate alarms at the Information Center when the values meet the criteria set there for alarms. The alarms will be announced in the same way as measurements from other sources. See the Instructions for Use of the Information Center for details.
- When assigned to GuardianSoftware: Measurement values sent via transmitter, hotspot or MP5 to IntelliVue GuardianSoftware will be visualized in GuardianSoftware. Since IntelliVue GuardianSoftware is a data management system, no alarms are announced. The IntelliVue Cableless Measurement Devices will also not generate physiological alarms when connected to IntelliVue GuardianSoftware. See the Instructions for Use of GuardianSoftware.

#### Assigning an IntelliVue Cableless Measurement Device to a Host

When an IntelliVue CL NBP Pod is used with a host system (patient monitor, telemetry device or GuardianSoftware), the Cableless Measurement Device must be assigned to that host system.

The assignment can be done at the CL NBP Pod itself or at the host system (patient monitor or GuardianSoftware).

#### WARNING

Always make sure that the applied CL NBP Pod is assigned to the correct patient.

#### WARNING

Short Range Radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n) and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a **No Host Monitoring** INOP on the NBP Pod, or a **cl NBP Disconnect** INOP at the host monitor. Correct channel configuration is important, refer to the Configuration Guide for details.

#### Assignment at the Measurement Device

To make an assignment, select:

- the Add/Remove SmartKey , o

This opens the **Add To** menu which lists the available patient monitors and telemetry devices within the SRR range. In order to save power, the list is only visible for a short time; the menu is automatically closed after 40 seconds.

**Telemetry device:** A telemetry device must be put into assignment mode by pressing the  $\checkmark$  key on the telemetry device before it can appear in the list. Pressing the  $\checkmark$  key starts an SRR channel search to find the clearest channel available. During the search all 4 LEDs will blink once per second. The search will

take approximately 20-25 seconds. Once a channel is identified, the first LED will light up and blink once per second to indicate that the telemetry device is ready for assignment.

Add To	
Mon 1	
Mon 2	
Tele 33	
Tele 44	

- Select a patient monitor or telemetry system using the 

   If you select a patient monitor, the measurement selection key on that monitor will change to show the type of measurement device.
- 2 Activate the assignment by pressing the ✓ key twice on the measurement device. The Cableless Measurement Device is assigned to the selected patient monitor or telemetry device. A telemetry device plays the assignment tone when the assignment is successful. A patient monitor issues an assignment prompt message.

If the internal measurement in the patient monitor is active (the measurement selection key has a yellow frame), you will need to confirm that it should be deactivated in favor of the Cableless Measurement Device you want to assign. To do this:

- Select the measurement selection key on the monitor.
   A prompt message appears with the **Confirm** and **Cancel** keys.
- 2 Select **Confirm** to deactivate the internal measurement.

When the Cableless Measurement Device is assigned, the A symbol appears on its display indicating that alarming capability has been transferred to the host (to the monitor or, for the telemetry device, to the Information Center). No patient alarms will be announced on the Cableless Measurement Device.

To unassign the measurement device from the monitor or telemetry system, select the **Add/Remove** SmartKey, then select **Remove From**. After confirmation the SRR connection is disconnected.

#### Assignment at the Patient Monitor

#### Assignment at the Patient Monitor

Prepare the Cableless Measurement Device for assignment by activating the Add/Remove SmartKey.

At the patient monitor,

- 1 Select the Measurement Selection key.
- 2 Select the Add cl Msmt pop-up key.

This opens the **Add cl Measurement** window, which shows the available Cableless Measurement Devices:

Add cl Measurement	
NIBP03 id1 SP0203	Measmt.
801654 id1 SP0203	Select.

- 3 Select the device which you want to assign to the patient in the monitor.
- 4 The monitor displays the assignment prompt message.

If the internal measurement in the patient monitor is active, you will need to confirm that it should be deactivated in favor of the Cableless Measurement Device you want to assign.

When the Cableless Measurement Device is assigned, the *symbol* appears on its display indicating that alarms from the device will be sent to the patient monitor.

An assigned Cableless Measurement Device can be removed in the **Measurement Selection** window. For more details see the Instructions for Use for your patient monitor.

#### Assignment with an RFID Reader and Tagged Cableless Devices

You can directly assign all cableless devices that have RFID tags with a Philips HS1-R RFID/barcode reader. The Respiration Pod has a built-in RFID tag. The NBP Pod used must have an IntelliVue ProxiTag RFID tag adhesively attached.

1 Hold the cableless device close to the reader.

Depending on its configuration, the reader beeps, vibrates or indicates via the LEDs when it has read the tag.

2 Press any hardkey on the cableless device.

The Cableless Measurement Device is now added to the monitor.

If the corresponding internal measurement in the patient monitor is active, you will be asked to confirm that it should be deactivated in favor of the Cableless Measurement Device by selecting **Replace**.

If a Cableless Measurement of the same type is already assigned to the monitor, you will be asked to confirm that it should be removed by selecting **Replace**.

#### Assignment at the Fetal Monitor

The first time an IntelliVue Cableless Measurement Device is used with an Avalon Fetal Monitor, or after a device has been powered off for storage, place it on the Avalon CL Base Station. This will automatically switch the device on. The device is assigned automatically to the Fetal Monitor working with the CL Base Station.



#### NOTE

When you place a Cableless Measurement Device onto an Avalon CL Base Station to assign it to an Avalon Fetal Monitor, the Cableless Measurement Device is automatically unassigned from the previous patient.

#### Special Conditions when Working with Fetal Monitors

The following special conditions apply when CL NBP Pods are operating with an Avalon Fetal Monitor as a host:

- The CL NBP Pods are intended to measure the maternal NBP and Pulse. The patient category is always Adult.
- The Pulse measurement is always On. The Pulse: On/Off setting is not available.
- Physiological alarms are only available at the Avalon Fetal Monitor, not at the Cableless Measurement Devices. Local attended monitoring is not available: Use for Transp. is not supported. (Local attended monitoring is used for displaying alarms locally at the Cableless Measurement Devices during patient transport, when the patient is attended by a caregiver).
- Alarm-related operations (e.g. switching alarms on and off, setting the high and low alarm limits) are not available when **Alarm Mode** is set to **INOP only** in the Avalon Fetal Monitor. See the Avalon Fetal Monitor Instructions for Use and Avalon Fetal Monitor Configuration Guide for further information.

- You can use the **Remove** operation at the host to remove Cableless Measurement Devices, as described in the Avalon Fetal Monitor Instructions for Use.
- STAT mode is not supported.
- Accelerated Measurement mode is not supported.

#### Assignment with GuardianSoftware

To assign a Cableless Measurement Device to a patient in GuardianSoftware:

- 1 Select the patient on the **Chalkboard**.
- 2 Take the Cableless Measurement Device from the charger.
- 3 On the **Equipment List** tab, select the Cableless Measurement Device on the **Available Equipment** list, highlighted in green on top of the list. The device on top of the list is always the one with the most recent user interaction (taken off the charger, put on the charger, or key pressed).
- 4 Click **Use for Patient** to assign the device to the patient.

#### **Controls Available with a Patient Monitor**

The controls available when working with the Cableless Measurement Device and a patient monitor are described in the table below.

Action	At the Cableless Measurement Device	At the Patient Monitor	At the IIC
Start/Stop/Stat NBP	Yes	Yes	Yes
Change NBP Mode	Yes	Yes	No
Change NBP Repetition Time	Yes	Yes	No
Change Alarm Limits	Yes*	Yes	No
Assign NBP Pod	Yes	Yes	No
Remove NBP Pod	Yes	Yes	No
Place Device in Standby	Yes	Yes	Yes
Alarm Silence	No	Yes	Yes
Alarm Off/Pause	No	Yes	Yes

\* except when SRR connection to host is lost

#### WARNING

If a patient being monitored by Cableless Measurement Devices moves out of range of the patient monitor, the measurements are not transmitted to the patient monitor or the Information Center. The measurements are available on the Cableless Measurement Device only. If this occurs, the **No Host Monitoring** message is displayed on the measurement device. The measurement device will also sound the INOP tone.

### **Controls Available with a Telemetry Device**

The controls available when working with the Cableless Measurement Device and a TRx4841/TRx4851A Transceiver or MX40 wearable patient monitor with a short range radio adapter (SRRA) are described in the table below.

Action	At the Cableless Measurement Device	At the IIC
Start/Stop/Stat NBP	Yes	No
Change NBP Mode	Yes	No
Change NBP Repetition Time	Yes	No
Change Alarm Limits	No	Yes
Assign NBP Pod	Yes	No
Remove NBP Pod	Yes	Yes
Place Device in Standby	No	No
Alarm Silence	No	Yes
Alarm Off/Pause	No	Yes

#### NOTE

When you unplug the ECG cable from the telemetry device and plug it into the monitor associated with the same patient, the ECG source will automatically be from the monitor. The NBP measurement devices assigned to the telemetry device will continue to source data to the telemetry device and the Information Center. You may need to change screens on the patient monitor to see the measurements.

### **Controls Available with GuardianSoftware**

The controls available when working with the Cableless Measurement Device and GuardianSoftware are described in the table below.

Action	At the Cableless Measurement Device	At GuardianSoftware
Start/Stop/Stat NBP	Yes	Yes
Change NBP Mode	Yes	Yes
Change NBP Repetition Time	Yes	Yes
Assign NBP Pod	Yes	Yes
Remove NBP Pod	Yes	Yes
Place Device in Standby	No	No
Alarm Silence	No	Yes
Alarm Off/Pause	No	No

# Trending

The IntelliVue Cableless Measurement Devices provide data for trending of parameters. The trended data are only available via a host system. For details on trends see the Instructions for Use of your host system.

When the connection to the host is lost during measurement, the IntelliVue Cableless Measurement Devices are able to collect data in a local memory. These data can be uploaded to GuardianSoftware, but not to other host systems, when a connection is established at a later stage.

# Monitoring NBP

The IntelliVue CL NBP Pod uses the oscillometric method for measuring NBP. The blood pressure measurements determined with this device were clinically validated according to ISO 81060-2 in relation to mean error and standard deviation, when compared to auscultatory measurements (depending on the configuration) in a representative patient population. The fifth Korotkoff sound was used to determine the diastolic pressure for adult/adolescent subjects and the 4th for pediatric subjects.

The accuracy of the mean arterial pressure (MAP) was validated using the approximation:  $MAP_{ref} = (SYS_{ref} + 2*DIA_{ref}) / 3$ 

with SYS<sub>ref</sub> and DIA<sub>ref</sub> being the blood pressure measured by the auscultatory method.

The NBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

## Introducing the Oscillometric NBP Measurement

Oscillometric devices measure the amplitude of pressure changes (oscillations) in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

Studies show that, especially in critical cases (arrhythmia, vasoconstriction, hypertension, shock), oscillometric devices are more accurate and consistent than devices using other noninvasive measuring techniques.

#### WARNING

**Patient Category**: Do not use the IntelliVue CL NBP Pod on neonatal patients. The initial inflation pressure and overpressure safety limits are too high for neonatal patients and could cause fractures and bruises.

Intravenous infusion: Do not use the NBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

Skin Damage: Do not measure NBP in cases of sickle-cell disease or any condition where skin damage has occurred or is expected.

Existing Wounds: Do not apply the cuff over a wound as this can cause further injury.

**Mastectomy**: Avoid applying the cuff on the side of the mastectomy, as the pressure increases the risk of lymphedema. For patients with a bilateral mastectomy, use clinical judgement to decide whether the benefit of the measurement outweighs the risk.

**Unattended Measurement:** Use clinical judgement to decide whether to perform frequent unattended blood pressure measurements. Too frequent measurements can cause blood flow interference potentially resulting in injury to the patient. In cases of severe blood clotting disorders frequent measurements increase the risk of hematoma in the limb fitted with the cuff.

**Temporary Loss of Function**: The pressurization of the cuff can temporarily cause loss of function of monitoring equipment used simultaneously on the same limb.

#### CAUTION

If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.

#### **Measurement Limitations**

NBP readings can be affected by the position of the patient, their physiological condition, the measurement site, and physical exercise. Thus a physician must determine the clinical significance of the NBP information.

Measurements are impossible with heart rate extremes of less than 40 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- with excessive and continuous patient movement such as shivering or convulsions
- if a regular arterial pressure pulse is hard to detect with cardiac arrhythmias
- with rapid blood pressure changes
- with severe shock or hypothermia that reduces blood flow to the peripheries
- with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- on an edematous extremity.

#### Accelerated Measurement

When the **accelerated measurement** is used the minimum number of oscillations per deflation step is 1, instead of the 2 in the standard measurement. This allows a faster measurement result but requires that the patient keeps the limb in question still. The accelerated measurement is recommended for use when very few or no artifacts are expected, for example with sedated patients.

You can see whether the accelerated measurement is in use by looking in the patient monitor's **Setup NBP** menu. The **Accelerated Msmt** setting shows whether the accelerated measurement is **Off**, on for **Manual** measurements or on for **All** measurements. You can see this setting in Monitoring Mode but it can only be changed in Configuration Mode.

When the accelerated measurement is in use, no pulse rate is derived from NBP.

#### **Measurement Modes**

There are three modes for measuring NBP:

- Manual measurement on demand.
- Auto continually repeated measurements (between one minute and 24 hours adjustable interval).
- Sequence up to four measurement cycles which will run consecutively, with number of measurements and interval between them configurable for each cycle.

**Auto** and **Sequence** modes must be set up, before a measurement series can be started. See "Enabling Automatic Mode and Setting Repetition Time" on page 74 and "Enabling Sequence Mode and Setting Up The Sequence" on page 75.

Additionally, you have the possibility to start an immediate, one-time measurement series at any time:

**STAT** - rapid series of measurements over a five minute period. Use only on supervised patients.

After a STAT measurement series, the monitor returns to the previous mode. If an **Auto** or **Sequence** measurement series was running before the STAT measurement, it will continue to run afterwards.

#### **Reference Method**

The measurement reference method is always Auscultatory (manual cuff). For further information, see the Application Note supplied on the documentation DVD.

# Preparing to Measure NBP with Standard Cuffs

1 Apply the carrying pouch to the patient.



2 Apply the cuff to the patient's upper arm at the same level as the heart.



If the cuff is not at heart level, you must use the measurement correction formula to correct the measurement.

Make sure that you are using a Philips-approved correct sized cuff and that the bladder inside the cover is not folded or twisted.

A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements. The width of the cuff should be in the range from 37% to 47% of the limb circumference.

Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities.

**3** Connect the extension air hose to the cuff.



4 Connect the extension air hose to the cradle.



Hold the flat part of the connector vertically when plugging it into the inlet, then twist it clockwise to lock into place. Avoid compression or restriction of pressure tubes. Air must pass unrestrictedly through the tubing.

### WARNING

Kinked or otherwise restricted tubing can lead to a continuous cuff pressure, causing blood flow interference and potentially resulting in injury to the patient.

5 Place the NBP Pod into the cradle.



6 Put the NBP Pod into the carrying pouch.



Make sure to pinch the velcro enclosures firmly together around the extension hose exiting from the pouch.

#### CAUTION

Make sure that the air vent, located next to the air tubing connector on the NBP Pod, is not covered during operation. If air cannot enter the air vent, the pump may be damaged.
#### WARNING

Inspect the application site of the cuff regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or stat measurements.

### Attaching the Pod Directly to a Mobile CL Cuff

As an alternative to using a carrying pouch, you can attach the NBP Pod directly to the cuff. In this case you do not need the extension hose.

- 1 Attach the cradle to the NBP cuff.
- 2 Plug the air tubing into the cradle.
- 3 Apply the cuff to the patient's upper arm. Apply the cuff so that the cradle is located at the outside of the arm. The bladder of the cuff is then automatically over the artery.
- 4 Insert the NBP Pod into the cradle.

#### **Additional Information**

The following documents contain additional information, depending on which accessories you are using:

- Mobile CL Reusable NBP Cuffs Instructions for Use
- Mobile CL Single-Patient NBP Cuffs Instructions for Use
- Mobile CL NBP Cradle Instructions for Use
- Mobile CL Extension Air Hose Instructions for Use

#### **Recommendations For Measurements Used in Diagnosis of Hypertension**

To make a measurement for use in the diagnosis of hypertension, follow the steps below:

- 1 Ensure the patient is comfortably seated, with their legs uncrossed, feet flat on the floor and back and arm supported.
- 2 Ask the patient to relax and not talk before and during the measurement.
- 3 If possible, wait 5 minutes before making the first measurement.

## **Starting and Stopping Measurements**

Use the setup menu or SmartKeys to start and stop measurements.

Action to be Performed	NBP Setup menu	SmartKeys
Start manual measurement Start Auto series Start measurement sequence	Start/Stop	Start/Stop
Start STAT measurement	Start NBP Stat	Start NBP STAT
Stop Manual measurements	Start/Stop	Start/Stop
Stop current Auto/sequence measurement	Start/Stop	Start/Stop
Stop current STAT measurement and end STAT mode	Start/Stop	Start/Stop
Stop Auto, Manual or STAT measurement, end STAT mode AND Auto/Sequence series	Stop All	Stop All

Depending on the configuration of the NBP Auto/Sequence series, measurements are automatically started within 3 seconds (Automatic Start set to Fast) or 3 minutes (Automatic Start set to Slow) after the NBP Pod has been inserted into the cradle. With Automatic Start set to Off, the Auto/Sequence series have to be started manually.

No pulse can be derived from the NBP measurement in Accelerated and STAT mode.

If accelerated measurement mode is configured for manual or manual and Auto/Sequence measurements, make sure that the patient is not moving during the measurements.

#### CAUTION

Use clinical judgment to decide whether to perform repeated series of STAT measurements because of the risk of purpura, ischemia and neuropathy in the limb with the cuff.

## **Enabling Automatic Mode and Setting Repetition Time**

- 1 In the NBP menu, select Mode and select Auto from the pop-up menu.
- 2 For an automatic measurement, select **Repeat** and set the time interval between two measurements.

### **Enabling Sequence Mode and Setting Up The Sequence**

- 1 In the NBP menu, select Mode and select Sequence from the pop-up menu.
- 2 Select Setup Sequence to open the Setup Sequence menu.
  - Up to four measurement phases can be setup which will run consecutively. For each phase you can set the number of measurements and the interval between them. If you want to run less than four phases in a sequence, you can set the number of measurements for one or more phases to **Off**.
- **3** Select each phase in turn (A, B, C and D) and select the number of measurements and the time interval between the measurements.
- 4 To have measurements continue after the sequence, set the number of measurements for your last phase to **Cont** and this phase will run indefinitely.

#### CAUTION

Be aware that, if none of the phases are set to **Cont**, NBP monitoring will end after the last measurement of the last phase.

When the NBP measurement mode is set to **Sequence**, the repetition time for **Auto** mode cannot be changed.

#### Announcement Tone:

Depending on the configuration of the NBP Pod, a tone before each measurement announces the next measurement. Please inform the patient to stop moving, and especially stop moving the arm with the cuff, when the tone sounds and the cuff inflates in order to allow a fast and accurate measurement.

### Understanding the NBP Numerics and Symbols



- **1** Systolic/Diastolic pressure
- 2 Mean pressure
- **3** Pulse rate
- 4 Pulse rate indicator
- 5 Measurement mode (see below)
- 6 Alarms Off symbol for Pulse (Pulse from NBP does not have alarm capability, therefore it cannot be switched on)
- 7 Timestamp
- 8 Alarms Off symbol for NBP

**Note:** The Alarms Off symbols indicate that no physiological alarms are available from the Cableless Measurement Devices when not assigned to a host.

Measurement modes with a series of measurements can be indicated with two different symbols:

- indicates that a series is running and shows the relative time to the next measurement.
- indicates that auto or sequence mode is selected but the measurement series has not yet started.

An **S** in front of the symbol indicates **Sequence** mode and an **A**, **B**, **C** or **D** indicates which phase of the sequence is currently running.

#### **During Measurements**

The cuff pressure is displayed instead of the timestamp.

#### Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level, to the displayed value

Add 0.75 mmHg (0.10 kPa) for each <b>centimeter</b> higher or	Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower or
Add 1.9 mmHg (0.25 kPa) for each <b>inch</b> higher.	Deduct 1.9 mmHg (0.25 kPa) for each inch lower.

#### When Unexpected Values are Measured

When values measured are higher or lower than expected, check the following potential causes:

Possible Cause	Solution
The patient was talking or moving before or during the measurement.	Allow the patient to rest quietly, then try again after three to five minutes.
The incorrect cuff size was used or the cuff was not at heart level	Check the cuff size, level, and position then repeat the measurement.
Measurement limitations have not been taken into account.	Check the list in "Measurement Limitations" on page 70.

#### Switching Pulse from NBP On/Off

In the process of making the NBP measurement, a pulse value can be derived and displayed. The pulse value is displayed together with the time the measurement was made. After one hour the value becomes invalid. There are no alarms associated with pulse from NBP.

When the accelerated measurement is in use, no pulse value can be derived.

To switch the display of the pulse value on or off:

In the **NBP** menu select **Pulse**.

### **Assisting Venous Puncture**

You can use the NBP cuff to cause subdiastolic pressure. The cuff deflates automatically after a set time (adult/pediatric 170 seconds) if you do not deflate it.

- 1 In the NBP menu select Veni Puncture, or select the Veni Puncture SmartKey.
- 2 Puncture vein and draw blood sample.
- 3 Reselect Veni Puncture to deflate the cuff.

During measurement, the NBP display shows the inflation pressure of the cuff and the remaining time in venous puncture mode.

### Calibrating NBP

NBP is not user-calibrated. NBP pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional. See the Service Guide for details.

## Alarms

The IntelliVue Cableless Measurements have two different types of alarm: patient alarms and technical alarms (INOPs).

#### Patient Alarms

Patient Alarms are high priority alarms (such as a potentially life threatening situation), also called red alarms, or medium priority alarms, also called yellow alarms.

#### Technical Alarms (INOPs)

Technical alarms, also known as INOPs, indicate that the measuring device cannot measure reliably. If an INOP interrupts monitoring, there will be a question mark in place of the measurement numeric. An INOP tone sounds at the Cableless Measurement Device only when there is no SRR connection to a host. Exception: the Battery empty INOP tone sounds also with SRR connection.

Most INOPs are low priority, however there are a small number of INOPs which, due to their severity, are medium or high priority.

#### Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm indication at the Cableless Measurement Device. This delay has two components:

- The general measurement delay time is the time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing.
- The time between the displayed numerical values crossing an alarm limit and the alarm indication on the device is the system alarm delay. The system alarm delay is the processing time the system needs for any alarm on the Cableless Measurement Device to be indicated after the measurement has triggered the alarm. This delay depends on the Cableless Measurement Device and the connected host system. See the performance specifications in the chapter "IntelliVue CL NBP Pod Specifications" on page 135 for the system alarm delay specification of the Cableless Measurement Device.

The alarm delay configured for a specific measurement is normally a fixed time.

#### Multiple Alarms

If more than one alarm is active, the alarm messages are shown in the alarm status area in succession. An arrow symbol next to the alarm message informs you that more than one message is active.

The Cableless Measurement Device sounds an audible indicator for the highest priority alarm. If more than one alarm condition is active in the same measurement, the Cableless Measurement Device announces the most severe.

#### NOTE

If you want to use local attended monitoring, make sure to have all Cableless Measurement Devices upgraded to at least Rev. B.02.

## Visual Alarm Indicators

#### WARNING

- No patient alarms are available on the Cableless Measurement Devices when assigned to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or GuardianSoftware.
- Visual patient alarm indicators are disabled on the Cableless Measurement Devices when connected to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or GuardianSoftware.

#### Alarm Message

Alarm messages are displayed in black on a light gray background in the alarm status area at the top of the screen indicating the source of the alarm and coded according to their severity. If more than one

measurement is in an alarm condition, the message changes every few seconds, and has an arrow ( $\mathbb{T}$ ) at the side. The asterisk symbols (\*) beside the alarm message match the alarm priority: \*\*\* for red alarms, \*\* for yellow alarms. Standard INOPs do not have a symbol, red and yellow INOPs have exclamation marks beside the alarm message: !!! for red INOPs and !! for yellow INOPs.

An alarm message that appears is automatically highlighted. Use the  $\checkmark$  key to silence the message. A **Silence** message is displayed at the bottom of the screen and highlighted. Press  $\checkmark$  again to confirm the acknowledgment of the alarm. After the confirmation, any ongoing alarm message is displayed in the icon tray of the screen.

#### Alarm States

Depending on the alarm state of your Cableless Measurement Device, the following icons may be displayed on the device:

Icon	Description
$\mathbb{A}$	No local alarming on Cableless Measurement Device. The device is connected to a host monitor or telemetry device and has no visual or audible patient alarm indicators. The device will only display INOP messages.
28	Alarms are switched off.
数	Alarm volume is set to 0.

### **Audible Alarm Indicators**

Audible alarm indicator patterns are repeated until you acknowledge the alarm by switching it off or pausing it, or until the alarm condition ceases (if audible alarm indication is set to non-latching).

Cableless Measurements Devices alone (without host, e.g. a patient monitor) are not suitable for unattended monitoring due to their limited alarm volume.

#### WARNING

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm
  volume to a low level or off during patient monitoring may result in patient danger. Remember that the
  most reliable method of patient monitoring combines close personal surveillance with correct
  operation of monitoring equipment.
- No patient alarms are available on the Cableless Measurement Devices when connected to a host monitor (unless they are selected for use in patient transport at the monitor they are assigned to) or to GuardianSoftware.
- When connected to a host monitor or GuardianSoftware, no alarm tones are available on the Cableless Measurement Devices (unless they are selected for use in patient transport at the monitor they are assigned to).

#### Silencing an Alarm

To silence an alarm, press the ✓ key.

This will silence the alarm tone and clear the alarm message. If the condition which caused the alarm is still present, the alarm indicator will be displayed on the right hand side of the screen.



When using a Cableless Measurement Pod with an IntelliVue Information Center iX Release A, make sure to remove the pod at the telemetry device and only when in SRR range of the telemetry device. Otherwise you will get a technical alarm (**cl NBP Disconnect**) that can not be silenced at the telemetry device. You will then have to reboot the telemetry device to remove the message.

#### Displaying a List of Current Alarms

To display a list of the currently active alarms,

- 1 Select the Alarms SmartKey or Main Setup SmartKey, followed by Alarms.
- 2 Select Alarm Messages.

### Setting the Volume of the Alarm Tone

To set the volume for the Alarm tone,

- 1 Select the Alarms SmartKey or Main Setup SmartKey, followed by Alarms.
- 2 Select AlarmVol and select a volume setting. The maximum is 10 and the minimum depends on your configuration.

If the volume of the Alarm tone is set to zero, the following symbol is displayed on the right icon tray of the

Cableless Measurement Device screen:

### Minimum Volume for No Host Monitoring INOP

If your device is connected to a host monitor, and the connection is interrupted, the INOP message **No Host Monitoring** will appear within 30 seconds, accompanied by an INOP tone. To help ensure that this INOP, and any other active alarm, is not overlooked, the INOP and alarm tones may be configured to have a minimum volume. In this case, INOP and alarm tones will sound even if the device alarm volume is set to zero.

#### Alarm Reminder

If **Reminder** is configured on your device, you will get an audible reminder of alarm conditions that remain active after you have silenced the alarm. This reminder may take the form of a repetition of the alarm tone for a limited time, or an unlimited repetition of the alarm tone (this is the same as a new alarm). Alarm Reminder is not available for standard, light blue INOPs but for yellow and red INOPs.

In Configuration Mode, you can set the interval between silencing the alarm and sounding the reminder tone to one, two, or three minutes.

## **Pausing or Switching Off Alarms**

If you want to temporarily prevent alarms from sounding, for example while you are moving a patient, you can pause alarms. Depending on your device configuration, alarms are paused for one, two, or three minutes, or infinitely. Infinite alarm pause is equivalent to switching the alarms off.

To view the alarm pause setting chosen for your unit,

- 1 In the SmartKeys Menu select Main Setup, Alarms, then OffDurat.
- 2 Check the setting.

This setting can only be changed in Configuration Mode.

### To Pause or Switch Off Alarms



Select the key in the SmartKeys Menu followed by **Alarms**. Press the  $\checkmark$  hardkey to switch to **Paused**. If your device is configured to infinite pause time, selecting this option switches alarms off.

### **Restarting Paused Alarms**

To manually switch on alarm indication again after a pause, select the key



Alarm indication starts again automatically after the pause period expires. If the device is configured to stay



paused infinitely, you must select again to restart alarm indication.

### **Choosing the NBP Alarm Source**

You can monitor for alarm conditions in systolic, diastolic and mean pressure, either singly or in parallel. Only one alarm is given, with the priority of mean, systolic, diastolic.

In the **NBP** menu, select **Al. from** and choose from:

Menu Option	Displayed as	Pressure value monitored
Sys.	Sys.	systolic
Dia.	Dia.	diastolic
Mean	Mean	mean
Sys & Dia	S & D	systolic and diastolic in parallel
Dia & Mean	D & M	diastolic and mean in parallel
Sys & Mean	S & M	systolic and mean in parallel
Sys&Dia&Mean	S&D&M	all three pressures in parallel

If **Mean** is not selected as alarm source (**Sys.**, **Dia.**, or **Sys & Dia** selected), but the monitor can only derive a mean value, mean alarms will nevertheless be announced using the most recent mean alarm limits. Check that the mean alarm limits are appropriate for the patient, even when not using mean as the alarm source. When no value can be derived an **NBP Measure Failed** INOP will be displayed.

#### Alarm Limits

The alarm limits you set determine the conditions that trigger limit alarms.

#### WARNING

Be aware that the devices in your care area may each have different alarm settings, to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.

#### Adjusting the Alarm Limits

- 1 Select the Alarms SmartKey followed by Alarm Limits (or select Main Setup followed by NBP).
- 2 Depending on your alarm source:
- a. Select Sys.High, Dia.High and/or MeanHigh then choose the high alarm limit.
- b. Select Sys. Low, Dia. Low and/or Mean Low then choose the low alarm limit.

### Latching Alarms

The alarm latching setting for your device defines how the alarm indicators behave when you do not acknowledge them. When alarms are set to non-latching, their indicators end when the alarm condition ends. Switching alarm latching on means that visual and/or audible alarm indications are still displayed or announced by the device after the alarm condition ends. The indication lasts until you acknowledge the alarm.

#### Viewing the Alarm Latching Settings

To see the alarm latching setting for your device,

- 1 In the Main Setup menu, select Alarms.
- 2 Here you can see the Visual Latching and Audible Latching settings.

This setting can only be changed in Configuration Mode. You should be aware of the settings chosen for your unit. There are three possible choices each for visual and audible latching, red only, red and yellow, and off. These choices can be combined to give the following settings:

Visual Latching	Audible Latching
Red&Yellow	Red&Yellow
Red&Yellow	Red Only
Red&Yellow	Off
Red Only	Red Only
Red Only	Off
Off	Off

### Alarm Latching Behavior

As NBP is an aperiodic parameter, "Alarm condition no longer present" means either that for a measurement in alarm the alarm limits are changed in such a way that the value is now within the limits, or that a new measurement is done with a value within the limits.

Red & Yellow M Alarms	easurement	Non-latching alarms	Visual and audible latching	Visual latching, audible non-latching
Alarm has not been	Alarm condition still present.	Alarm tone on. Alarm message.	Alarm tone on. Alarm message.	Alarm tone on. Alarm message.
acknowledged.	Alarm condition no longer present.	All audible and visual alarm indicators automatically stop.	Alarm tone on. Alarm message.	Alarm message. Audible alarm indicators automatically stop.
Alarm has been acknowledged.	Alarm condition still present.	All audible and visual alarm indicators automatically stop.	All audible and visual alarm indicators automatically stop.	All audible and visual alarm indicators automatically stop.
	Alarm condition no longer present.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.	Audible and visual alarm indicators automatically stop.

All INOPs are non-latching. NBP specific INOPs generated by the CL Pod are latching.

## **Testing Alarms**

When you switch the CL NBP Pod on, a selftest is started. You must check that the backlight switches on, and that you hear a single tone. This indicates that the alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

## Alarm Behavior at Power On

If the device is switched off (**Standby**), all alarm settings are maintained. If the device is switched off completely (**Power Off**), or the battery is completely empty, resulting in complete power loss, all alarm settings will be lost unless they were actively saved by storing the active profile before the device was switched off. See "Switching the Device Off" on page 17 and "Using Profiles" on page 18 for details.

When the device is switched back on from either state, it will start in Profile A and you may have to switch to the desired profile which contains your alarm settings.

After any of these situations, you should check that the alarm settings are appropriate for your patient and monitoring situation, and if necessary, select the correct Profile and patient category.

## **Reference List of Patient Alarms**

Alarm Message, Indication	Source	Condition
** NBPs High ** NBPd High	NBP	The measured NBP value is above the high alarm limit. s, d, or m after the label indicates whether the systolic,
** NBPm High		diastolic or mean pressure has crossed the limit.
** NBPs Low	NBP	The measured NBP value is below the low alarm limit.
** NBPd Low		s, d, or m after the label indicates whether the systolic, diastolic or mean pressure has crossed the limit
** NBPm Low		diastone of mean pressure has crossed the mint.

## **Reference List of all INOPs**

INOP Message, Indication	Source	What to do	
Batt Incompatible INOP tone	Battery	Battery cannot be used with this Cableless Measurement Device. Replace battery with one that has been approved for use with this Cableless Measurement Device. Contact your service personnel.	
Batt Malfunction INOP tone	Battery	Malfunction of the battery system detected (charger circuit or battery). Contact your service personnel.	
Battery Empty INOP tone	Battery	The remaining monitoring time is below 30 minutes. Charge battery.	
Battery Low INOP tone	Battery	The remaining monitoring time is below 2 hours.	
Check Batt Temp INOP tone	Battery	The temperature of the battery is critically high. Check that Cableless Measurement Device is not covered and not exposed to a heat source. If INOP persists, remove Cableless Measurement Device from patient and contact your service personnel.	
Check Battery INOP tone	Battery	The maximum number of charge/discharge cycles of the battery will be reached in less than 50 cycles. Contact your service personnel to replace the battery.	
<b>Check Charger I/F</b> INOP tone	Battery	Overvoltage or undervoltage detected at the charger interface. Clean contacts of charger interface at Cableless Measurement Device and charging station. If the INOP persists, contact your service personnel.	
cl NBP ChkSettings INOP tone	Cableless Measurement Device	nt If this INOP appears and an INOP tone sounds, check the Cableless Measurement Device and patient settings before you resume making measurements. If the settings are unexpected, there may be a problem with the Cableless Measurement Device software. Contact your service personnel.	
		If this INOP is acknowledged at the Cableless Measurement Device, it is cleared. If it is silenced remotely, only the tone is cleared.	
<b>cl NBP Disconnect</b> only at the host	Cableless Measurement Device	The NBP Pod has lost the SRR connection to the telemetry device or the patient monitor.	
<b>Cuff Not Deflated</b> Numeric is replaced by -?-	NBP	The NBP cuff pressure has exceeded 15 mmHg (2 kPa) for more than 3 minutes.	
INOP tone During this INOP, alarms cannot be paused or switched off.		Remove the cuff from the patient. Make sure that the tubing is not kinked or twisted and that the correct patient category is selected. Try repeating the measurement. You can acknowledge the INOP, but the INOP message remains visible until the next NBP measurement is started or the <b>Stop All</b> SmartKey is selected.	

INOP Message, Indication	Source	What to do	
<b>NBP Check Cuff</b> Numeric is replaced by -?- INOP tone	NBP	Check if cuff is connected to the NBP Pod and cuff is applied to the patient; check tubing and cuff for leakage. Try restarting the measurement. If the INOP occurs repeatedly, contact your service personnel. You can silence this INOP, but the INOP message remains visible until the next measurement is started or the <b>Stop All</b> SmartKey is selected. This INOP arises when the maximum time for inflation is exceeded or when there is a significant change in inflation	
		time between two successive measurements in auto and sequence mode.	
NBP Cuff Overpress Numeric is replaced by -?- INOP tone During this INOP, alarms cannot be paused or switched off.	NBP	The NBP cuff pressure exceeds the overpressure safety limits. Remove the cuff from the patient. Make sure that the tubing is not kinked or twisted and that the correct patient category is selected. Try restarting the measurement. You can acknowledge this INOP, but the INOP message remains visible until the next measurement is started or the <b>Stop All</b> SmartKey is selected.	
<b>NBP Equip Malf</b> Numeric is replaced by -?- INOP tone	NBP	Remove the NBP Pod and cuff from the patient. The NBP hardware is faulty. Contact your service personnel. You can acknowledge this INOP, but the INOP message remains visible until the next measurement is started or the <b>Stop All</b> SmartKey is selected.	
NBP Interrupted Numeric is replaced by -?- INOP tone	NBP	Check the tubing and cuff for leakages or kinks. Check that you are using the correct cuff size and placement, and that the correct patient category is selected. Try restarting the measurement. If the INOP occurs repeatedly, contact your service personnel. You can silence this INOP, but the INOP message remains visible until the next measurement is started or the <b>Stop All</b> SmartKey is selected. This INOP arises when the measurement needed longer than the maximum time for deflation or the total measurement.	
<b>NBP Measure Failed</b> Numeric is replaced by -?- INOP tone	NBP	Check that you are using the correct cuff size and placement, and that the correct patient category is selected. Try restarting the measurement. You can silence this INOP, but the INOP message remains visible until the next measurement is started or the <b>Stop All</b> SmartKey is selected. Check the condition and suitability of the patient for NBP monitoring. Use another cuff to continue measuring.	
<b>NBP Neo Patient?</b> Numeric is replaced by -?- INOP tone	NBP	The patient monitor that the NBP pod is assigned to is in neonatal mode or a neonatal cuff has been detected. The monitor must be in adult or pediatric mode.	
<b>No Cradle</b> Numeric is replaced by -?- INOP tone	NBP	The NBP Pod is not in the cradle. You can silence this INOP, but the INOP message remains visible until the NBP Pod is inserted into the cradle and the next measurement is started or the <b>Stop All</b> SmartKey is selected.	
		remove and replace the cradle.	

INOP Message, Indication	Source	What to do
<b>No Host Monitoring</b> INOP tone	Cableless Measurement Device	There is a problem with the communication to the assigned patient monitor and monitoring is currently not possible (no patient alarms or information). Check the connection. Contact your service personnel.
No System	Cableless Measurement Device	There is a problem with the communication to the network and central monitoring is currently not possible. Check the connection.
<b>Remove From Pat</b> INOP tone	Cableless Measurement Device	Displayed on the Cableless Measurement Device. The temperature of the battery is too high. Remove the Cableless Measurement Device from the patient and contact service personnel.
Service Battery INOP tone	Battery	Maximum number of charge/discharge cycles for battery exceeded. Charging of the battery is inhibited. Contact your service personnel to replace battery.

## Local Attended Monitoring

When working with an IntelliVue MP5, MP5SC, MP5T Patient Monitor with software revision J.2 or higher as a host, or with an IntelliVue X2 Multi-Measurement Module with software revision K.2 or higher, the IntelliVue CL  $SpO_2$  and NBP Pods can be used for local attended monitoring. This is for situations where you want to have alarm indications at the CL Pods when they are out of reach of the patient monitor (disconnected). The patient monitor setting to switch CL Measurement Alarms on and off (cl Alarms On/Off) is used to enable and disable this functionality. As a default, the CL Measurement Alarms are on.

## Local Attended Monitoring Enabled

At the CL Pod:

At the CL Pod:

physiological alarms

alarms only

Indication of technical

By default, the patient monitor is set to receive alarms from the CL Pods (can only be changed in configuration mode). This scenario is used for patients who require uninterrupted monitoring. The various alarms from the CL Pods are indicated at the patient monitor if they are enabled at the monitor. When the CL Pod is disconnected from the patient monitor and the caregiver has activated the transport mode at the monitor, physiological alarms are indicated locally at the CL Pod. A **cl NBP Disconnect** INOP is shown at the monitor if the SRR connection is lost and the transport mode has not been activated.

CL Pod connected to a patient monitor and CL Measurement Alarms On (Standard Use Model):



SRR connection



At the monitor: Indication of physiological and technical alarms from CL Pods

CL Pod disconnected from patient monitor and CL Measurement Alarms On, Local Attended Monitoring:



Indication of technical and

No SRR connection



At the monitor: No indication of physiological alarms from CL Pods. No indication of technical alarms after disconnection.

## Local Attended Monitoring Disabled

The patient monitor is set to **cl Alarms Off** (this can only be done in configuration mode). This scenario is used if the patients do not require permanent monitoring and are mobile, but vital signs are taken from time to time. All alarms from the CL Pods are switched off at the monitor. If the SRR connection is lost, no **cl NBP Disconnect** INOP is shown at the monitor in this scenario.

#### CL Pod connected to a patient monitor and CL Measurement Alarms Off:



SRR connection

At the CL Pod: Indication of technical alarms only



At the monitor: **No** indication of physiological alarms from CL Pods. Indication of technical alarms from CL Pods.

#### CL Pod disconnected from patient monitor and CL Measurement Alarms Off:



At the CL Pod:

alarms only

Indication of technical



No SRR connection



At the monitor: **No** indication of physiological and technical alarms from CL Pods.

# Alarm Availability: Standard Use Model versus Local Attended Monitoring with CL Measurement Alarms On



		at CL Pod	at Patient Monitor
Standard Use Model: normal operation, no special action	CL Pod connected to the patient monitor (1)	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

Activation of Local Attended Monitoring: Caregiver activates Local Attended Monitoring and disconnects CL Pod temporarily by setting <b>Use for Transp.</b> in the Patient Monitor's <b>Equipment</b> window	Patient is in transport without connection to the host system, caregiver attends the patient (2)	Technical alarms (own) Physiological alarms (own)	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod
Deactivation of Local Attended Monitoring: Caregiver deactivates Local Attended Monitoring and reconnects CL Pod to a patient monitor by setting Use with Monitor in the patient monitor's Equipment window	Patient returns from transport. Back to the standard use model (1)	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

Special Case: Connection lost while in Standard Use Model			
Action / Event	Situation	Alarm Availability at CL Pod	Alarm Availability at Patient Monitor
Alternative Use Model: CL Pod temporarily disconnected from a monitor due to unintentional loss of connection (e.g. out of range), Local Attended Monitoring has not been activated by the caregiver	No Host Monitoring INOP at CL Pod cl NBP Disconnect INOP at patient monitor Local Attended Monitoring is automatically activated (2)	Technical alarms (own) Physiological alarms (own)	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod

# Alarm Availability: Standard Use Model versus Local Attended Monitoring with CL Measurement Alarms Off



Action / Event	Situation	Alarm Availability at CL Pod	Alarm Availability at Patient Monitor
Connected, but no CL Alarms (CL Measurement Alarms	CL Pod connected to the patient monitor ( <b>3</b> )	Technical alarms (own)	Technical alarms (own + from Pod)
Off): normal operation, no special action		No physiological alarms No Local Alarming icon is displayed:	Physiological alarms (own)
		<u>/f\</u>	

Patient is leaving the vicinity of the monitor: no special action	Patient is mobile without connection to the host system (4)	Technical alarms (own) No physiological alarms <b>Alarms Off</b> icon is displayed in front of each numeric:	Technical alarms (own) Physiological alarms (own) No alarms from CL Pod
Patient returns to the vicinity of the monitor: no special action	Patient returns. Back to connected status ( <b>3</b> )	Technical alarms (own) No physiological alarms <b>No Local Alarming</b> icon is displayed:	Technical alarms (own + from Pod) Physiological alarms (own + from Pod)

## **NBP Default Settings**

These are the most important default settings of your IntelliVue CL NBP Pod as they are delivered from the factory. For a comprehensive list and explanation of default settings, see the Configuration Guide supplied with your devices. The default settings can be permanently changed in Configuration Mode. When the Pod is assigned to a patient monitor, the settings defined at the patient monitor will overwrite the settings defined at the Pod.

NBP Settings		
	Adult	Pedi
Mode	Auto	Auto
Al. from	Sys.	Sys.
Sys.High	160	120
Dia.High	90	70
MeanHigh	110	90
Sys. Low	90	70
Dia. Low	50	40
Mean Low	60	50
Alarms	On	On
NBP	On	On
Repeat Time	10 min	10 min
Pulse	On	On
Unit	mmHg	mmHg
Done Tone	Off	Off
Start Time	Synchronized	Synchronized
VP Pressure	60 mmHg	40 mmHg
Reference	Auscultatory	Auscultatory

NBP Settings		
	Adult	Pedi
Aging Time	10 min	10 min
Color	Red	Red
AnnouncementTone	Off	Off
Automatic Start	Off	Off
Accelerated Msmt	Off	Off

## **Integrated Battery Handling**

Only qualified and authorized service personnel (biomedical engineers or technicians) should change batteries.

## **Battery Care**

Battery care begins when you receive a new IntelliVue Cableless Measurement Device with built-in battery and continues throughout the life of the device. The table below lists battery care activities and when they should be performed.

Activity	When to perform
Perform a visual inspection	Before using the IntelliVue Cableless Measurement Device
Charge the battery	Upon receipt, after use, or if a low battery state is indicated. To optimize performance, a fully (or almost fully) discharged battery should be charged as soon as possible.
Store the device in a state of charge in the range of 40-50% and power off the device completely.	When not in use for an extended period of time, or when the device is shipped.

### **Handling Precautions**

Lithium ion batteries store a large amount of energy in a small package. Use caution when handling the IntelliVue Cableless Measurement Devices with built-in battery; misuse or abuse could cause bodily injury and/or property damage.

- Handle with care.
- Do not expose the device to liquids.
- Do not attempt to disassemble the device.
- Do not put device in autoclave.
- Damaged devices should not be used anymore.

#### WARNING

- Do not crush or puncture mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- Do not incinerate the devices or expose them to temperatures above 60°C (140°F).

#### Storage

If unused IntelliVue Cableless Measurement Devices are stored for an extended period of time:

- they should be powered off for storage
- they should be stored in a cool place, ideally between 15°C and 25°C (60°F and 77°F)
- the state of charge should be between 40 and 50%
- they should be recharged every six months

Storing in a cool place slows the aging process of the batteries. They should be fully charged prior to use. Do not store the device at a temperature outside the range of  $-20^{\circ}$ C ( $-4^{\circ}$ F) to  $60^{\circ}$ C( $140^{\circ}$ F).

Do not store cableless devices in direct sunlight.

#### NOTE

Storing the devices at temperatures above 40°C (104°F) for extended periods of time could significantly reduce the battery's life expectancy.

#### **Battery Lifetime Management**

The lifetime of a Lithium Ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 4 years or 400 complete charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. We therefore strongly recommend that lithium ion batteries be replaced after 4 years or 400 complete charge-discharge cycles.

To see the date of manufacture and the number of charge-discharge cycles:

- 1 Select the Battery Smartkey or Main Setup followed by Battery.
- 2 Press the ✓ hardkey to view the battery details.

The date of manufacture and the number of charge-discharge cycles are listed with other battery data on the screen. Use the  $\blacktriangleleft$  hardkey to scroll through the list.

The age of a lithium ion battery begins at the date of manufacture.

## Accessories

You can order parts and accessories from Philips supplies at www.medical.philips.com or consult your local Philips representative for details. Also consult the accessories' Instructions for Use, if available.

#### WARNING

**Reuse:** Never reuse single-patient sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard, in particular with regard to cross-contamination.

**Philips' approval:** Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance and cause a potential hazard.

#### Accessories Compliant with EMC Standards

All accessories listed in the accessories sections comply, in combination with the IntelliVue Cableless Measurements, with the requirements of IEC 60601-1-2.

## IntelliVue CL NBP Pod Accessories

## Mobile CL Cuffs and Accessories

Part Number	Description	Limb Circumference Range	Contents
989803163171	Mobile CL Reusable Small Adult Cuff	21 - 27 cm	1 cuff
989803163191	Mobile CL Reusable Adult Cuff	26.0 - 34.5 cm	1 cuff
989803163211	Mobile CL Reusable Large Adult Cuff	33.5 - 45.0 cm	1 cuff
989803163181	Mobile CL Single-Patient Small Adult Cuff	21 - 27 cm	20 cuffs
989803163201	Mobile CL Single-Patient Adult Cuff	26.0 - 34.5 cm	20 cuffs
989803163221	Mobile CL Single-Patient Large Adult Cuff	33.5 - 45.0 cm	20 cuffs
989803163251	Mobile CL NBP Cradle Kit	-	20 cradles
989803163131	Mobile CL Extension Air Hose, 1.0 m	-	1 extension air hose
989803187431	Mobile CL Air Hose - Bayonet Connector	-	1 adapter air hose
989803163261	Mobile CL NBP Battery Kit	-	1 Battery 1 disassembly tool 1 front housing
989803137831	Telemetry Pouch with window	-	50 pouches
989803140371	Telemetry Pouch with window	-	4 boxes of 50 pouches
989803101971 (9300-0768-050)	White Telemetry Pouch with Snaps; box of 50	-	50 pouches
989803101981 (9300-0768-200)	White Telemetry Pouch with Snaps; 4 boxes of 50	-	4 boxes of 50 pouches

## **Comfort Care Reusable Cuffs**

Part Number	Description	Limb Circumference Range
M1571A	Infant cuff	10.0 - 15.0 cm
M1572A	Pediatric cuff	14.0 - 21.5 cm
M1573A	Small adult cuff	20.5 - 28.0 cm
M1573XL	Small adult cuff, XL	20.5 - 28.0 cm
M1574A	Adult cuff	27.0 - 35.0 cm
M1574XL	Adult cuff, XL	27.0 - 35.0 cm
M1575A	Large adult cuff	34.0 - 43.0 cm
M1575XL	Large adult cuff, XL	34.0 - 43.0 cm

Part Number	Description	Limb Circumference Range
M1576A	Thigh cuff	42.0 - 54.0 cm
M1577A	Kit of small cuffs (M1571A to M1574A)	
M1578A	Kit of large cuffs (M1573A to M1576A)	
M1579A	Kit of all cuffs (M1571A to M1576A)	

## Easy Care Reusable Cuffs

Part Number	Description	Limb Circumference Range
M4552B	Infant cuff	10.0 - 15.0 cm
M4552B5	Pack of 5 M4552B cuffs	
M4553B	Pediatric cuff	14.0 - 21.5 cm
M4553B5	Pack of 5 M4553B cuffs	
M4554B	Small adult cuff	20.5 - 28.5 cm
M4554B5	Pack of 5 M4554B cuffs	
M4555B	Adult cuff	27.5 - 36.0 cm
M4555B5	Pack of 5 M4555B cuffs	
M4556B	Adult cuff, XL	27.5 - 36.0 cm
M4556B5	Pack of 5 M4556B cuffs	
M4557B	Large adult cuff	35.0 - 45.0 cm
M4557B5	Pack of 5 M4557B cuffs	
M4558B	Large adult cuff, XL	35.0 - 45.0 cm
M4558B5	Pack of 5 M4558B cuffs	
M4559B	Thigh cuff	44.0 - 56.0 cm
M4559B5	Pack of 5 M4559B cuffs	
864288	Assortment pack of one small adult, one adult, one large adult and one thigh cuff	
864289	Assortment pack of one infant, one pediatric, one small adult and one adult cuff	
864290	Assortment pack of one infant, one pediatric, one small adult, one adult, one large adult and one thigh cuff	
864291	Assortment pack of one small adult, one adult, one adult XL, one large adult, one large adult XL and one thigh cuff	

## Multi Care Cuffs

Part Number	Description	Limb Circumference Range
989803183311	Infant cuff	10.0 - 15.0 cm
989803183321	Pediatric cuff	14.0 - 21.5 cm
989803183331	Small adult cuff	20.5 - 28.0 cm
989803183341	Adult cuff	27.0 - 35.0 cm
989803183351	Adult cuff, XL	27.0 - 35.0 cm

Part Number	Description	Limb Circumference Range
989803183361	Large adult cuff	34.0 - 43.0 cm
989803183371	Thigh cuff	42.0 - 54.0 cm

## Single Patient, Gentle Care Cuffs

Part Number	Description	Limb Circumference Range
M4572B	Infant cuff	10.0 - 15.0 cm
M4573B	Pediatric cuff	14.0 - 21.5 cm
M4574B	Small adult cuff	20.5 - 28.5 cm
M4575B	Adult cuff	27.5 - 36.0 cm
M4576B	Adult cuff, XL	27.5 - 36.0 cm
M4577B	Large adult cuff	35.0 - 45.0 cm
M4578B	Large adult cuff, XL	35.0 - 45.0 cm
M4579B	Thigh cuff	44.0 - 56.0 cm

## Single Care Cuffs

Part Number	Description	Limb Circumference Range
989803182281	Pediatric cuff	14.0 - 21.5 cm
989803182291	Small adult cuff	20.5 - 28.5 cm
989803182301	Adult cuff	27.5 - 36.0 cm
989803182311	Adult cuff, XL	27.5 - 36.0 cm
989803182321	Large adult cuff	35.0 - 45.0 cm

## Value Care Cuffs

Part Number	Description	Limb Circumference Range
989803160811	Infant cuff	10.0 - 15.0 cm
989803160821	Pediatric cuff	14.0 - 21.5 cm
989803160831	Small adult cuff	20.5 - 28.5 cm
989803160841	Adult cuff	27.0 - 35.0 cm
989803160851	Adult cuff, XL	27.0 - 35.0 cm
989803160861	Large adult cuff	34.0 - 43.0 cm

## Maintenance and Troubleshooting

#### WARNING

**Schedule**: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

**Contact**: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.

### Inspecting the Equipment and Accessories

You should perform a visual inspection before every use, and in accordance with your hospital's policy. With the device switched off:

- 1 Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
- 2 Inspect all accessories (cables, sensors and so forth). If any show signs of damage, do not use them.

#### WARNING

If the IntelliVue Cableless Measurement Device is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient, contact your service personnel.

#### Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation supplied on the IntelliVue Cableless Measurements documentation DVD. These tasks are for Philips-qualified service professionals only.

Ensure that these tasks are carried out as indicated by the device's maintenance schedule, or as specified by local laws. Contact a Philips-qualified service provider if your device needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

#### Troubleshooting

If a device will not switch on when you press a key, place it onto a charger slot on the charging station.

If you suspect a problem with an individual measurement device, read the Instructions for Use and double check that you have set up the measurement correctly. Check also that the measurement has not been switched off at the patient monitor that the device is assigned to.

If you suspect an intermittent, system-wide problem call your service personnel.

# IntelliVue CL Respiration Pod

For respiration measurement, attach the Cableless Respiration Pod to the patient's left costal arch using the Mobile CL Respiration Pod Attachment. As an option, the Respiration Pod also provides pulse measurement. The CL Respiration Pod also provides information about patient posture (positions like supine, prone, upright,...) and activity (e.g. very high or very low activity).



For details regarding the adhesive attachment (Mobile CL Respiration Pod Attachment), refer to "IntelliVue CL Respiration Pod Accessories" on page 111.

## **General Operation of the Respiration Pod**

The IntelliVue CL Respiration Pod does not have a display and is generally operated via the host system (e.g. patient monitor). The Pod reports the measured values and status information to the host system via SRR.

The IntelliVue CL Respiration Pod has a multi-color LED and a single operation key to display states and allow some basic operation locally.

## **Putting the Pod into Operation**

The first time a CL Respiration Pod is used, place it on the IntelliVue CL Charging Station. This will automatically switch the device on, and the device will become visible to the host (patient monitor or GuardianSoftware).

## **Checking the Battery Status**

Press the key once to check the battery status:

Status	LED
Battery OK	green
Battery low	yellow
Battery empty	red
Battery or system malfunction	cyan

If the LED is blinking, this means that the Pod is currently not assigned to a host.

#### **Recharging the Pod**

To recharge the pod, place it on the charging station. During loading, the pod's LED shows the status:

Status	LED
Battery full (≥90%)	green
Battery loading	yellow
Battery malfunction	cyan

#### **Power Off**

To power off the IntelliVue CL Respiration Pod, take the device from the charging station, then press and hold the key on the pod for five seconds until the LED blinks red. Release the key and press it again to confirm power off. The LED will switch to solid red and fade out. To switch it back on, you must place the device on a charging station. Use this option when the device is not used for a longer time or prepared for storage or shipping.

## **Connection with Host Systems**

The following sections describe how the IntelliVue Cableless Measurement Devices work together with host systems (Patient Monitors or GuardianSoftware).

#### IntelliVue Cableless Measurements Use Models

With these patient-worn measurement devices you can measure and transmit a patient's vitals regularly or on an intermittent data collection basis. There are two typical use models:

#### With a Patient Monitor

The IntelliVue Cableless Measurement Devices can be used together with an MP5/MP5SC/MP5T, MP2 or X2 patient monitor (with an SRR interface). They can communicate their measurement values via short range radio to the monitor. The monitor may be assigned to a patient sector at the IntelliVue Information Center (IIC). When assigned to the Information Center, certain actions can be performed at both the patient monitor and the Information Center. See the table "Controls Available with a Patient Monitor" on page 102.

In situations where patients are becoming more mobile (for example, in step-down/intermediate care units) the lightweight Cableless Measurement Devices allow increased mobility within the short range radio range, without giving up vital signs monitoring.

A telemetry device can be assigned to a patient monitor equipped with short range radio at the same time as any Cableless Measurement Devices are also assigned to this monitor.

If the connection between the monitor and the Cableless Measurement Device is lost, an INOP will be displayed at the monitor: **cl Resp Disconnect**.

#### With IntelliVue GuardianSoftware

The Cableless Measurement Devices can be used together with IntelliVue GuardianSoftware. GuardianSoftware collects non-continuous vital signs data that are transmitted via a Transmitter, Hotspot or MP5 from the Cableless Measurement Devices. Using the collected data, it provides trending, review, reporting and notification. The Guardian Early Warning Scoring (Guardian EWS) application provides basic assessment guidance, helping you to recognize the early signs of deterioration in your patients. GuardianSoftware is not intended for monitoring in combination with Cableless Measurement Devices.

Some of the measurement tasks can be performed remotely from GuardianSoftware. See the table "Controls Available with GuardianSoftware" on page 103. GuardianSoftware also manages the patient data.

If the connection between GuardianSoftware and the Cableless Measurement Device is lost, the connection symbol will be displayed gray at GuardianSoftware.

#### **Device Compatibility**

The IntelliVue CL Respiration Pod requires the following software levels in the associated equipment:

- Patient Monitor Release J.2 or above
- IntelliVue GuardianSoftware Revision B.0 or above

The IntelliVue CL Respiration Pod Pediatric Mode requires the following software levels in the associated equipment:

- Patient Monitor Release M.0 or above
- IntelliVue GuardianSoftware Revision D.0 or above

#### Availability of Patient Alarms

When the IntelliVue CL Respiration Pod is assigned to a host and a short range radio connection exists, alarms will be announced at the host device.

- When assigned to a patient monitor: Alarm messages will be displayed and audible alarm indicators sounded at the patient monitor in the same way and under the same conditions as for its own measurements. See the Instructions for Use of the patient monitor for details.
- When assigned to GuardianSoftware: Measurement values sent via transmitter, hotspot or MP5 to IntelliVue GuardianSoftware will be visualized in GuardianSoftware. Since IntelliVue GuardianSoftware is a data management system, no alarms are derived. The IntelliVue Cableless Measurement Devices will also not generate physiological alarms when connected to IntelliVue GuardianSoftware. See the Instructions for Use of GuardianSoftware.

### Assigning an IntelliVue Cableless Measurement Device to a Host

When an IntelliVue CL Respiration Pod is used with a host system (patient monitor or GuardianSoftware), the Pod must be assigned to that host system.

The assignment must be done at the host system.

#### WARNING

Always make sure that the applied CL Respiration Pod is assigned to the correct patient.

#### WARNING

Short Range Radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n) and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a **cl Resp Disconnect** INOP at the host monitor. Correct channel configuration is important, refer to the Configuration Guide for details.

#### Assignment at the Patient Monitor

#### **Manual Assignment**

Prepare the Pod for assignment by pressing the hardkey once (LED shows battery and assignment status).

At the patient monitor,

1 Open the Add cl Measurement window, e.g. by using the measurement selection key followed by the Add cl Msmt pop-up key.

The available Cableless Measurement Devices are shown in the window.

- 2 Select the device which you want to assign to the patient on the monitor.
- 3 The monitor displays the assignment prompt message.

When the Cableless Measurement Device is assigned, the LED changes from blinking to solid.

An assigned Cableless Measurement Device can be removed in the **Measurement Selection** window. For more details see the Instructions for Use for your patient monitor.

#### Assignment with an RFID Reader and Tagged Cableless Devices

You can directly assign all cableless devices that have RFID tags with a Philips HS1-R RFID/barcode reader. The Respiration Pod has a built-in RFID tag.

- Hold the cableless device close to the reader.
   Depending on its configuration, the reader beeps, vibrates or indicates via the LEDs when it has read the tag.
- 2 Press any hardkey on the cableless device.

The Cableless Measurement Device is now added to the monitor.

If a Cableless Measurement of the same type is already assigned to the monitor, you will be asked to confirm that it should be removed by selecting **Replace**.

#### Assignment with GuardianSoftware

To assign a Cableless Measurement Device to a patient in GuardianSoftware:

- 1 Select the patient on the **Chalkboard**.
- 2 Take the Cableless Measurement Device from the charger.
- 3 On the **Equipment List** tab, select the Cableless Measurement Device on the **Available Equipment** list, highlighted in green on top of the list. The device on top of the list is always the one with the most recent user interaction (taken off the charger, put on the charger, or key pressed).
- 4 Click Use for Patient to assign the device to the patient.

#### **Controls Available with a Patient Monitor**

The controls available when working with the Cableless Measurement Device and a patient monitor are described in the table below.

Action	At the Cableless Measurement Device	At the Patient Monitor	At the IIC
Start Resp/Pulse Measurement	Yes	Yes	No
Change Measurement Mode	No	Yes	No
Change Repetition Time	No	Yes	No
Change Alarm Limits	No	Yes	No
Assign Respiration Pod	No	Yes	No

Action	At the Cableless Measurement Device	At the Patient Monitor	At the IIC
Remove Respiration Pod	Yes	Yes	No
Dynamic Repetition Mode On/Off	No	Yes	No
Posture On/Off	No	Yes	No
Activity On/Off	No	Yes	No
Alarm Silence	No	Yes	Yes
Alarm Off/Pause	No	Yes	Yes

#### WARNING

If a patient being monitored by Cableless Measurement Devices moves out of range of the patient monitor, the measurements are not transmitted to the patient monitor or the Information Center.

Keep the patient monitor with the patient during transport.

## Controls Available with GuardianSoftware

The controls available when working with the Cableless Measurement Device and GuardianSoftware are described in the table below.

Action	At the Cableless Measurement Device	At GuardianSoftware
Start Resp/Pulse Measurement	Yes	Yes
Change Measurement Mode	No	Yes
Change Repetition Time	No	Yes
Change Alarm Limits	No	Yes
Assign Respiration Pod	No	Yes
Remove Respiration Pod	Yes	Yes
Dynamic Repetition Mode On/Off	No	Yes
Posture On/Off	No	Yes
Activity On/Off	No	Yes
Technical Alarm Silence	No	Yes

## Trending

The IntelliVue Cableless Measurement Devices provide data for trending of parameters. The trended data are only available via a host system. For details on trends see the Instructions for Use of your host system.

When the connection to the host is lost during measurement, the IntelliVue Cableless Measurement Devices are able to collect data in a local memory. These data can be uploaded to GuardianSoftware, but not to other host systems, when a connection is established at a later stage.

## **Monitoring Respiration**

The CL Respiration Pod derives the respiration and pulse signal from the chest and abdomen movements measured with a built-in acceleration sensor. The CL Respiration Pod gets attached with a Mobile CL Respiration Pod Attachment to the left costal arch on the patient's chest.

When configured, the CL Respiration Pod provides information on the basic patient posture and patient activity. Various postures such as supine, upright and lying on left/right side are detected and updated after a posture change has occurred and posture is stable again. The activity is determined once per second, and an average activity level between 0 and 10 is reported once per minute to the connected host system. The activity status information provides only an approximate indication of the actual patient activity.

#### WARNING

The CL Respiration Pod is not an apnea monitor and does not provide apnea alarming.

Excessive patient movement can interfere with the measured signal. This may result in inaccurate measurements.

The CL Respiration Pod does not provide continuous measurement. When configured in frequent mode, the fastest update rate for pulse is 8 sec.

If the patient has a condition where the respiration rate approaches the upper limit of the measurement range (60 rpm), use other means of respiration rate measurement.

Do not use the CL Respiration Pod in an environment where continuous monitoring is needed, such as intensive care units or operating rooms, because life-critical events might be missed due to the intermittent mode of measurement.

Do not use the CL Respiration Pod on patients with rapid, irregular heart rates greater than 110 bpm. Use under these conditions has not been clinically validated.

#### **Measurement Modes**

There are three different modes available for performing respiration/pulse measurements: Manual Mode, Automatic Mode and Frequent Mode. The mode can only be set on the host system:

- **Manual Mode** a single respiration and pulse measurement is performed when a measurement is started at the host or when the key on the Respiration Pod is pressed (key must be pressed twice if the LED is off).
- Automatic Mode respiration and pulse measurements are performed with an interval between them. The interval is selected at the host. The first measurement starts immediately after entering the automatic measurement mode. If configured: When the respiration rate rises above or falls below the defined alarm limits, the measurement mode changes temporarily to frequent mode. The automatic mode will resume if the respiration rate readings are valid for at least 1 minute and no respiration rate reading within the last minute violates the respiration rate alarm.
- **Frequent Mode** respiration and pulse measurement is active all the time. The respiration rate is updated with every new detected breath. The shortest update interval for the pulse rate is 8 seconds.

If Dynamic Repetition is enabled (this is setting available in Configuration mode, see IntelliVue Patient Monitor Configuration Guide for details), and the respiration rate violates the high or low respiration rate limit, the measurement switches automatically to Frequent mode. As soon as the respiration rate values are within the limits again, and the values are valid for at least 1 minute, Dynamic Repetition switches back to Automatic mode.

## Assigning the Pod

Take the pod from the charging station. The multi-color LED blinks if the pod is not assigned to a host system.

#### When working with a patient monitor:

Go to the patient monitor you want to use and select **Add cl Msmt**. The LED on the pod changes from blinking to solid.

#### When working with GuardianSoftware:

In GuardianSoftware:

- 1 Select the patient on the **Chalkboard**.
- 2 On the **Equipment List** tab, select the Cableless Measurement Device on the **Available Equipment** list. The LED on the Respiration pod blinks.
- 3 Click **Use for Patient** to assign the pod to the patient.

## Attaching the Pod to the Patient

1 Put the pod front side up onto the adhesive attachment according to the positioning markers.





2 Remove the protective cover from the strap with the adhesive patch.



3 Fold the straps over the front of the pod, beginning with the strap that has no adhesive patch.



4 Fold the second strap over the pod and make sure that the pod is securely and tightly enclosed by the straps.



The arrow symbols on the upper strap must be in line with the end of the lower strap:



5 Remove the protective cover from the back of the adhesive attachment.



6 Place the pod on the patient's skin in the region of the left costal arch, with the operation key facing upwards. Press down the adhesive attachment all around the pod.



#### CAUTION

The patient's skin should be dry, clean and free of excessive hair.

Make sure that the CL Respiration Pod is attached the right way round, with the operation key facing upwards. Otherwise, the posture detection will not provide correct readings.

#### WARNING

Do not use an adhesive attachment on a patient with a history of skin irritation, allergies or hypersensitivity to adhesives. Do not use on patients with lesions, infections or skin inflammations.

To avoid skin irritations and lacerations, periodically inspect the sensor application site and change the application site regularly. After use, clean the patient's skin to remove residual adhesive.

Always make sure that the attached pod is assigned to the correct patient. For this purpose, it may be helpful to put the equipment label on the pod (for example by using a stick-on label) and to write the patient name on the adhesive attachment.

Do not reuse an adhesive attachment on another patient due to risk of cross-infection.

### **Measuring Respiration**

If the LED is on, press the key once to start a measurement. If the LED is off, press the key twice. Alternatively, start the measurement from the host system.

If the measurement has been started directly at the pod, the LED blinks white while the measurement is in progress.

When the measurement has finished successfully: The LED changes to solid white.

If a measurement fails: The LED blinks white quickly.

For a description of the way the measurement results are displayed on the host (Monitor or GuardianSoftware), see the Instructions for Use of the product used as a host.

### **Unassigning the Respiration Pod**

To unassign the CL Respiration Pod from a host:

Put the pod on the IntelliVue CL Charging Station

or:

Keep the key pressed for 2 seconds, until the LED is blinking yellow. Press the key once more to confirm. LED changes to solid yellow and fades out (CL Respiration Pod unassigned).

#### Posture and Activity Information

The CL Respiration Pod can also provide information on basic patient posture (body positions). The patient's position is determined and the corresponding information is displayed at the host:

- Supine
- Prone
- Lying Left (lying on left side)
- Lying Right (lying on right side)
- Lying (unspecific)
- Upright
- Reclined
- Forward
- Upside Down
- Sitting
- Standing

- **Rolling** (in bed; example: patient is agitated)
- Walking
- Wheelchair (unassisted)

Additionally, the activity level is displayed at the host as a numerical value that ranges in normal operation between level 1 (very low activity) and level 10 (very high activity). Activity level 0 indicates that no physiological signal can be detected (for example when the device has fallen off and is lying on the ground).

#### NOTE

The information on basic patient posture and activity is not intended for monitoring or diagnostic purposes. The basic patient posture and activity information is only for reference, showing clinical personnel the approximate posture and activity status of the patient.

The activity level does not provide information on a specific activity pattern (e.g. if a patient is walking, or if a patient is rolling over in bed). The activity information is also not intended to recognize abnormal body movements caused by specific diseases, like Parkinson's disease, or other neurological conditions.

## **Technical Alarms (INOPs)**

Technical alarms, also known as INOPs, indicate that the measuring device cannot measure reliably. If an INOP interrupts monitoring, there will be a question mark in place of the measurement numeric on the host monitor.

The IntelliVue CL Respiration Pod does not provide any INOP displays or sounds locally at the device itself. INOPs will be announced visually and audibly at the host monitor.

Some INOPs have a severity indication: !! for a medium severity INOP and !!! for a high severity INOP.

INOP Message, Indication	Source	What to do	
Can't Analyze cmRR	Resp	Unable to analyze respiration signal	
Can't AnalyzePulse	Resp	Unable to analyze pulse signal	
<b>cl Resp Batt Empty</b> INOP tone	Battery	The remaining monitoring time is below 30 minutes. Charge battery.	
<b>cl Resp Batt Incmp</b> INOP tone	Battery	Battery cannot be used with this Cableless Measurement Device. Contact your service personnel.	
<b>cl Resp Batt Low</b> INOP tone	Battery	The remaining monitoring time is below 2 hours.	
<b>cl Resp Batt Malf</b> INOP tone	Battery	Malfunction of the battery system detected (charger circuit or battery). Contact your service personnel.	
<b>cl Resp Batt Temp</b> INOP tone	Battery	The temperature of the battery is critically high. Remove Cableless Measurement Device from patient and contact your service personnel.	
<b>cl Resp Check Batt</b> INOP tone	Battery	The maximum number of charge/discharge cycles of the battery will be reached in less than 50 cycles. Contact your service personnel.	
<b>cl Resp Chk Sett</b> INOP tone	Resp	If this INOP appears, check the Cableless Measurement Device and patient settings before you resume taking measurements. If the settings are unexpected, there may be a problem with the Cableless Measurement Device software. Contact your service personnel.	

## **Reference List of all INOPs**
INOP Message, Indication	Source	What to do	
cl Resp Disconnect	Resp	The Respiration Pod has lost the SRR connection to the host.	
<b>cl Resp Remove</b> INOP tone	Resp	The temperature of the battery is too high. Take the Cableless Measurement Device away from the patient and contact service personnel.	
<b>cl Resp Serv Batt</b> INOP tone	Battery	Maximum number of charge/discharge cycles for battery exceeded. Charging of the battery is inhibited. Contact your service personnel.	
clResp License Req	Resp	Unlicensed exchange device. Contact your service personnel.	
<b>cmResp NeoPatient?</b> Numeric is replaced by -?- INOP tone	Resp	The patient monitor the Respiration Pod is assigned to is in neonatal mode. The INOP will remain active until the monitor is changed to adult mode.	
cmResp No Signal	Resp	No active signal can be detected.	
cmRespCan'tAnalyze	Resp	Unable to analyze respiration and pulse signal	
<b>cmRespPediPatient?</b> Numeric is replaced by -?- INOP tone	Resp	The patient monitor the Respiration Pod is assigned to is in pediatric mode. The INOP will remain active until the monitor is changed to adult mode.	

## **Respiration Default Settings**

These are the most important default settings of your IntelliVue CL Respiration Pod as they are delivered from the factory. For a comprehensive list and explanation of default settings, see the Configuration Guide supplied with your devices. The default settings can be permanently changed in the Support Tool Configuration Editor.

Respiration Settings	Factory Defaults
Mode	Auto
Repeat Time	15 min
cmResp	On
Pulse	On
Dyn. Repetition	Enabled
Posture	Off
Activity	Off
Aging Time	10 min
Color	Yellow

### **Integrated Battery Handling**

### **Battery Care**

The IntelliVue CL Respiration Pod has a built-in battery that is not exchangeable. Battery care begins when you receive a new pod and continues throughout the life of the pod. The table below lists battery care activities and when they should be performed.

Activity	When to perform
Charge the battery	Upon receipt, after use, or if a low battery state is indicated. To optimize performance, a fully (or almost fully) discharged battery should be charged as soon as possible.
Store the device in a state of charge in the range of 40-50% and power off the device completely.	When not in use for an extended period of time.

### **Handling Precautions**

Lithium ion batteries store a large amount of energy in a small package. Use caution when handling the IntelliVue Cableless Measurement Devices with built-in battery; misuse or abuse could cause bodily injury and/or property damage.

- Handle with care.
- Do not expose the device to liquids.
- Do not attempt to disassemble the device.
- Do not put device in autoclave.
- Damaged devices should not be used anymore.

### WARNING

- Do not crush or puncture mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- Do not incinerate the devices or expose them to temperatures above 60°C (140°F).

### Storage

If unused IntelliVue Cableless Measurement Devices are stored for an extended period of time:

- they should be powered off for storage
- they should be stored in a cool place, ideally between 15°C and 25°C (60°F and 77°F)
- the state of charge should be between 40-50%
- they should be recharged every six months

Storing in a cool place slows the aging process of the batteries. They should be fully charged prior to use. Do not store the device at a temperature outside the range of  $-20^{\circ}$ C ( $-4^{\circ}$ F) to  $60^{\circ}$ C ( $140^{\circ}$ F).

Do not store cableless devices in direct sunlight.

### NOTE

Storing the devices at temperatures above 40°C (104°F) for extended periods of time could significantly reduce the battery's life expectancy.

### **Battery Lifetime Management**

The lifetime of a Lithium Ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 4 years or 400 complete charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. The batteries of the IntelliVue CL Respiration Pod cannot be exchanged, so the device itself must be replaced after 4 years or 400 complete charge-discharge cycles.

### Accessories

You can order parts and accessories from Philips supplies at www.medical.philips.com or consult your local Philips representative for details. Also consult the accessories' Instructions for Use, if available.

### WARNING

**Reuse:** Never reuse single-patient sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard, in particular with regard to cross-contamination.

**Philips' approval:** Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance and cause a potential hazard.

### IntelliVue CL Respiration Pod Accessories

Part Number	Description	Contents
989803179541	Mobile CL Respiration Pod Attachment	50 attachments

### Maintenance and Troubleshooting

#### WARNING

**Schedule**: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

**Contact**: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.

### Inspecting the Equipment and Accessories

You should perform a visual inspection before every use, and in accordance with your hospital's policy:

Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.

#### WARNING

If the IntelliVue Cableless Measurement Device is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient, contact your service personnel.

### Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation supplied on the IntelliVue Cableless Measurements documentation DVD. These tasks are for Philips-qualified service professionals only.

Ensure that these tasks are carried out as indicated by the device's maintenance schedule, or as specified by local laws. Contact a Philips-qualified service provider if your device needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

### Troubleshooting

If the status LED does not light up when you press a key, place the device onto a charger slot on the charging station.

If you suspect a problem with an individual measurement device, read the Instructions for Use and double check that you have set up the measurement correctly. Check also that the measurement has not been switched off at the patient monitor that the device is assigned to.

If you suspect an intermittent, system-wide problem call your service personnel.

# **Cableless Measurement Auxiliary Devices**

IntelliVue CL Transmitter and IntelliVue CL Hotspot



IntelliVue CL Transmitter

IntelliVue CL Hotspot

The IntelliVue CL Transmitter and the IntelliVue CL Hotspot are auxiliary network devices that convert the SRR radio technology from the IntelliVue CL SpO<sub>2</sub> Pod, the IntelliVue CL NBP Pod and the IntelliVue CL Respiration Pod into WLAN or LAN technology. This allows data from the measurement devices to be transmitted to a PC for use with IntelliVue GuardianSoftware.

The IntelliVue CL Transmitter is a mobile device which can be worn by the patient or by an attending caregiver. It transmits vital signs data to IntelliVue GuardianSoftware while the patient is moving around. The display on the CL Transmitter shows only technical data that may be useful for troubleshooting system problems.

The IntelliVue CL Hotspot serves as an access point in a fixed location, to provide communication to IntelliVue GuardianSoftware for any CL Pods currently in its transmission area. The CL Hotspots will normally be located in areas where mobile patients regularly pass by or spend time. When the patient comes into the transmission area, any available measurement results will be automatically communicated to GuardianSoftware.

The IntelliVue CL Transmitter is battery-powered while the IntelliVue CL Hotspot is powered by an external power supply or PoE (Power over Ethernet).

### WARNING

The IntelliVue CL Hotspot may not be used in the patient vicinity.

### **Screen Layout**

The CL Transmitter and CL Hotspots have the same hardkeys and display as the CL  $SpO_2$  and NBP Pods.

However, there is no user interaction required during normal operation.

This is the standard screen of a CL Transmitter or CL Hotspot:

Screen of a CL Transmitter / CL Hotspot:		
1 DE007W0324	1	Equipment label
	2	Number of GuardianSoftware Servers connected
് പ് എം 1 പ _ കീ വ		Network status symbols (LAN and WLAN)
5	4 Connection status	
		Number of Cableless Measurement Devices connected
v	6	Battery gauge

The network status symbols show one of the following states:

State	LAN symbol	WLAN symbol
off	- (no symbol displayed)	- (no symbol displayed)
not connected	Ь.	×
no IP address	F	æ ا
no Guardian server connected	e -	
normally connected		(p)

### **CL Transmitter Integrated Battery Handling**

### **Battery Care**

Battery care begins when you receive a new IntelliVue Cableless Measurement Device with built-in battery and continues throughout the life of the device. The table below lists battery care activities and when they should be performed.

Activity	When to perform
Perform a visual inspection	Before using the IntelliVue Cableless Measurement Device
Charge the battery	Upon receipt, after use, or if a low battery state is indicated. To optimize performance, a fully (or almost fully) discharged battery should be charged as soon as possible.
Store the device in a state of charge in the range of 40-50% and power off the device completely.	When not in use for an extended period of time, or when the device is shipped.

#### **Handling Precautions**

Lithium ion batteries store a large amount of energy in a small package. Use caution when handling the IntelliVue Cableless Measurement Devices with built-in battery; misuse or abuse could cause bodily injury and/or property damage.

- Handle with care.
- Do not expose the device to liquids.
- Do not attempt to disassemble the device.
- Do not put device in autoclave.
- Damaged devices should not be used anymore.

#### WARNING

- Do not crush or puncture mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- Do not incinerate the devices or expose them to temperatures above 60°C (140°F).

#### Storage

If unused IntelliVue Cableless Measurement Devices are stored for an extended period of time:

- they should be powered off for storage
- they should be stored in a cool place, ideally between 15°C and 25°C (60°F and 77°F)
- the state of charge should be between 40 and 50%
- they should be recharged every six months

Storing in a cool place slows the aging process of the batteries. They should be fully charged prior to use. Do not store the device at a temperature outside the range of  $-20^{\circ}$ C ( $-4^{\circ}$ F) to  $60^{\circ}$ C( $140^{\circ}$ F).

Do not store cableless devices in direct sunlight.

#### NOTE

Storing the devices at temperatures above 40°C (104°F) for extended periods of time could significantly reduce the battery's life expectancy.

#### **Battery Lifetime Management**

The lifetime of a Lithium Ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 4 years or 400 complete charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. We therefore strongly recommend that lithium ion batteries be replaced after 4 years or 400 complete charge-discharge cycles.

To see the date of manufacture and the number of charge-discharge cycles:

- 1 Select the **Battery** Smartkey or **Main Setup** followed by **Battery**.
- 2 Press the  $\checkmark$  hardkey to view the battery details.

The date of manufacture and the number of charge-discharge cycles are listed with other battery data on the screen. Use the  $\blacktriangleleft$  hardkey to scroll through the list.

The age of a lithium ion battery begins at the date of manufacture.

### Accessories

You can order parts and accessories from Philips supplies at www.medical.philips.com or consult your local Philips representative for details. Also consult the accessories' Instructions for Use, if available.

#### WARNING

**Reuse:** Never reuse single-patient sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard, in particular with regard to cross-contamination.

**Philips' approval:** Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance and cause a potential hazard.

### IntelliVue CL Transmitter Accessories

Order Number	Description	Contents
989803168881	Mobile CL 20 Transmitter Cradle Kit	20 Single-Patient cradles and straps
989803168871	Mobile CL Transmitter Battery Kit	1 Battery 1 disassembly tool 1 front housing

### IntelliVue CL Transmitter Base Station

(shown here with the transmitter inserted)



The IntelliVue CL Transmitter Base Station is used with the IntelliVue CL Transmitter. When the patient is in their room, the Transmitter can be inserted into the Base Station where it is powered and recharged and also remains connected to the WLAN to communicate vital signs data.

#### WARNING

- The IntelliVue CL Transmitter Base Station may not be used in the patient vicinity.
- Ensure that the CL Transmitter Base Station does not come into close contact with implanted pacemakers, to avoid magnetic interference affecting the mode of the pacemaker.
- Electrical shock hazard: Do not open the device housing. Refer all servicing to qualified service personnel.

### CAUTION

The CL Transmitter Base Station generates a magnetic field. Do not store magnetic media (such as identity cards or credit cards with magnetic strips or magnetic tapes/disks) near to the Base Station, as the data may be damaged.

### IntelliVue CL Charging Station

This section contains some general information about charging IntelliVue Cableless Measurement Devices. For detailed information about the IntelliVue CL Charging Station, please see the separate IntelliVue CL Charging Station Instructions for Use.

### Charging IntelliVue Cableless Measurement Devices

All IntelliVue Cableless Measurement Devices and Auxiliary Devices except the CL Hotspot are battery powered and need to be recharged using the IntelliVue CL Charging Station. The batteries are built in and can only be exchanged by trained service personnel, with the exception of the IntelliVue CL Respiration Pod, where the whole device needs to be exchanged.

To charge a battery, place the device onto a charger slot on the charging station. The NBP Pod and Transmitter should always be placed on one of the slots in the upper row. The battery power indicators will supply information about the charge status.

#### WARNING

- Electrical shock hazard: Do not open the device housing. Refer all servicing to qualified service personnel.
- Always use the supplied power cord with the grounded mains plug to connect the charging station to a grounded AC mains socket. Never adapt the mains plug from the charging station to fit an ungrounded AC mains socket.
- Do not use AC mains extension cords or multiple portable socket outlets. If a multiple portable socket outlet without an approved isolation transformer is used, the interruption of its protective grounding may result in enclosure leakage currents equal to the sum of the individual ground leakage currents, so exceeding allowable limits.
- Do not connect any devices that are not supported as part of a system.

### **Battery Power Indicators**

There are various indications which help you keep track of the battery power status:

- LEDs on the charging station slots
- battery status information on the charging station's display, the NBP/SpO<sub>2</sub> Pod's display and the Respiration Pod's LED
- INOP messages
- battery symbol on the patient monitor's screen (when assigned to a patient monitor)
- battery symbol in GuardianSoftware (when assigned to a patient in GuardianSoftware)

The indicators always show the remaining capacity in relation to the battery's actual maximum capacity, which may lessen as the battery ages. You can see the actual capacity in the **Battery** menu.

### Maintenance and Troubleshooting

#### WARNING

**Schedule**: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

**Contact**: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.

### Inspecting the Equipment and Accessories

You should perform a visual inspection before every use, and in accordance with your hospital's policy. With the device switched off:

- 1 Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
- 2 Inspect all accessories (cables, sensors and so forth). If any show signs of damage, do not use them.

### WARNING

If the IntelliVue Cableless Measurement Device is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient, contact your service personnel.

### Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation supplied on the IntelliVue Cableless Measurements documentation DVD. These tasks are for Philips-qualified service professionals only.

Ensure that these tasks are carried out as indicated by the device's maintenance schedule, or as specified by local laws. Contact a Philips-qualified service provider if your device needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

### Troubleshooting

If a device will not switch on when you press a key, place it onto a charger slot on the charging station.

If you suspect a problem with an individual measurement device, read the Instructions for Use and double check that you have set up the measurement correctly. Check also that the measurement has not been switched off at the patient monitor that the device is assigned to.

If you suspect an intermittent, system-wide problem call your service personnel.

# **Care and Cleaning**

Use only the Philips-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Philips makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "Guideline for Disinfection and Sterilization in Healthcare Facilities" issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia, 2008. See also any local policies that apply within your hospital, and country.

### **General Points**

Keep your IntelliVue Cableless Measurement Devices and accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to Philips, decontaminate it first.

Observe the following general precautions:

- Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not allow liquid to enter the case.
- Do not immerse any part of the equipment or any accessories in liquid if it is not explicitly allowed and described in the respective accessory Instructions for Use.
- Do not pour liquid onto the charging station.
- Never use abrasive material (such as steel wool or silver polish).

#### WARNING

If you spill liquid on the charging station or accessories, or if any device or accessory is accidentally immersed in liquid, contact your service personnel or Philips service engineer. Do not operate the equipment before it has been tested and approved for further use.

Do not use flammable agents for disinfecting cableless measurement devices in an oxygen-enriched environment, as this might lead to sudden ignition of vapors, resulting in injury to the patient or staff.

### Cleaning and Disinfecting the IntelliVue Cableless Measurement Devices

The following instructions apply to the IntelliVue CL SpO2 Pod, the IntelliVue CL Respiration Pod, the IntelliVue CL NBP Pod, the corresponding single patient Mobile CL Cradles and the auxiliary devices: IntelliVue CL Charging Station, IntelliVue CL Transmitter, IntelliVue CL Transmitter Base Station and IntelliVue CL Hotspot.

Clean with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap, a diluted noncaustic detergent, tenside, ammonia- or alcohol-based cleaning agent. Do not use strong solvents such as acetone or trichloroethylene.

### CAUTION

Solutions: Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

**Hospital policy:** Disinfect the product as determined by your hospital's policy only using the cleaning agents specified below, to avoid long term damage to the cableless device.

**Drying devices**: Do not use heat sources, such as ovens or hairdryers, to dry the devices. Do not put the devices in a microwave.

No sterilizing: Do not put the devices in an autoclave, they are not sterilizable.

Rinse the Pods in water, paying special attention to the contact area to remove all residues. Wipe them dry with a clean cloth and then leave them to dry completely.

Do not allow any liquid to enter the charging station case and avoid pouring it on the charging station while cleaning.

The wristbands used with the Mobile CL SpO<sub>2</sub> Cradles are single-patient items and cannot be cleaned or disinfected.

Refer to the accessory Instructions for Use for cleaning and disinfection information for SpO<sub>2</sub> sensors.

### **Recommended Disinfection Agents**

We recommend that you use one of the following disinfectants:

Product Name	Product Type	Manufacturer	Dilution
Isopropanol	liquid	-	80%
Sodium Hypochlorite, bleach	liquid	-	1%
Hydrogen Peroxide	liquid	-	3%

Product Name	Product Type	Manufacturer	Dilution
Bacillol <sup>®</sup> AF	liquid, spray	BODE Chemie GmbH	According to
Dismozon <sup>®</sup> plus	liquid	BODE Chemie GmbH	manufacturer's instructions
Meliseptol <sup>®</sup>	liquid, spray	B. Braun Melsungen AG	
Incidin <sup>®</sup> Foam	liquid	Ecolab Inc.	
Oxivir <sup>®</sup> Tb Cleaner Disinfectant	liquid, spray	Diversey Inc.	
Super Sani-Cloth <sup>®</sup>	wipes	PDI Inc.	
Germicidal Disposable Wipes			
Sani-Cloth <sup>®</sup> Plus	wipes	PDI Inc.	
Germicidal Disposable Wipes			
Mikrozid <sup>®</sup> Sensitive Wipes	wipes	Schülke & Mayr GmbH	
Mikrozid <sup>®</sup> PAA Wipes	wipes	Schülke & Mayr GmbH	
Descogen <sup>®</sup> Liquid rfu	liquid	Antiseptica Dr. Hans-Joachim Molitor GmbH	
Lysoformin	liquid	Lysoform Dr. Hans Rosemann GmbH	
Descosept PUR	liquid	Dr. Schumacher GmbH	

Refer to the accessory Instructions for Use for cleaning and disinfection information for SpO<sub>2</sub> sensors and NBP cuffs.

### **Disposing of the IntelliVue Cableless Measurement Devices**

### WARNING

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the IntelliVue Cableless Measurement Devices appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

You will find detailed disposal information on the following webpage:

www.healthcare.philips.com/main/about/Sustainability/Recycling/pm.wpd

The Recycling Passports located there contain information on the material content of the equipment, including potentially dangerous materials which must be removed before recycling (for example, batteries and parts containing mercury or magnesium).



Do not dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered.

For information in disposal of accessories, refer to the accessory Instructions for Use.

# **Specifications**

The specifications in this section apply to the:

- IntelliVue CL SpO<sub>2</sub> Pod
- IntelliVue CL NBP Pod
- IntelliVue CL Respiration Pod
- IntelliVue CL Charging Station
- IntelliVue CL Transmitter
- IntelliVue CL Transmitter Base Station
- IntelliVue CL Hotspot

The IntelliVue Cableless Measurement Devices might not meet the performance specification listed in this chapter, if stored or operated outside the specified environmental conditions.

#### WARNING

The IntelliVue Cableless Measurement Devices are not intended for use in an MRI environment or in an oxygen-enriched environment (e.g. hyperbaric chambers). During MR imaging, remove all IntelliVue Cableless Measurement Devices and sensors from the patient. Induced currents could cause burns.

### **Indications for Use**

### IntelliVue CL SpO2 Pod:

The IntelliVue CL SpO<sub>2</sub> Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters SpO<sub>2</sub> and pulse rate wirelessly.

The intended use of the IntelliVue CL  $\text{SpO}_2$  Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring and recording of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients.

The IntelliVue CL SpO<sub>2</sub> Pod is also intended for local attended monitoring of, and to generate alarms for, arterial oxygen saturation and pulse rate of adult and pediatric patients. Local attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL SpO2 Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

The IntelliVue CL SpO<sub>2</sub> Pod is also intended for acquisition of arterial oxygen saturation and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL  $\text{SpO}_2$  Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

#### IntelliVue CL NBP Pod:

The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters noninvasive blood pressure and pulse rate wirelessly.

The intended use of the IntelliVue CL NBP Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring and recording of, and to generate alarms for, systolic, diastolic, and mean pressure and pulse rate of adult and pediatric patients.

The IntelliVue CL NBP Pod is also intended for local attended monitoring of, and to generate alarms for, systolic, diastolic, and mean pressure, and to measure pulse rate of adult and pediatric patients. Local attended monitoring refers to situations where clinical staff is close to the patient such that acoustic alarming of the IntelliVue CL NBP Pod will be noticed. Example: In-hospital transport of a patient by hospital staff to a procedure room.

The IntelliVue CL NBP Pod is also intended for acquisition of systolic, diastolic, and mean pressure and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL NBP Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

#### IntelliVue CL Respiration Pod:

The IntelliVue CL Respiration Pod is indicated for use by health care professionals whenever there is a need for intermittent or spot-check acquisition and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms. It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms.

The intended use of the IntelliVue CL Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate alarms for, respiration rate and pulse rate of adult and pediatric patients.

The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL Respiration Pod is intended for use by health care professionals. It is not intended for home use. It is not a therapeutic device.

The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm).

The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate). For monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor.

#### WARNING

Do not use the CL Respiration Pod on patients with rapid, irregular heart rates greater than 110 bpm. Use under these conditions has not been clinically validated.

Rx only: US Federal Law restricts these devices to sale by or on the order of a physician.

### **Compatible Medical Devices**

- IntelliVue Patient Monitors MP5/MP5SC/MP5T, MP2 or X2
- IntelliVue Telemetry System Transceivers TRx4841A/TRx4851A and MX40 wearable patient monitors<sup>1</sup>
- Avalon Fetal Monitors<sup>1</sup>
- Clinical information management system: IntelliVue GuardianSoftware

<sup>1</sup> not compatible with the CL Respiration Pod

# Compatible Medical Devices supporting local attended monitoring together with CL SpO2 and NBP Pods:

IntelliVue Patient Monitors MP5/MP5SC/MP5T

### **Symbols**

These symbols can appear on the IntelliVue Cableless Measurement Devices.

Symbols			
$\triangle$	Caution is necessary when operating the device.	Ĩ	Operating instructions should be considered when operating the device.
	Follow instructions for use.		
	Protective earth	$\bigtriangledown$	Equipotential grounding
$\langle$	Alternating current	┥ <b>●</b> ⊦	Connector has special protection against electric shocks and is defibrillator proof
L	Error LED	((( • )))	Built-in wireless network (WLAN)
•	USB interface	$((\cdot,\cdot))$	Non-ionizing radiation symbol
	NBP identifier	Some of the second seco	$SpO_2$ identifier
X	Always use separate collection for waste electrical and electronic equipment (WEEE)	$\sim$	Indicates manufacturing date
	Indicates location of the date of manufacture and/or name and address of manufacturer	SN	Indicates location of serial number
REF	Indicates location of catalog number	SERVICE#	Indicates location of service number

Symbols			
IP	Followed by two alphanumeric characters, indicates ingress protection grade	50	China RoHS
(	Do not reuse	LAN	LAN connection indicator for connection to a wired network
Ń	Resp identifier	X	Not made with natural rubber latex
Ъ́ххх	Mass in kilogram (kg)		RCM compliance mark
EHC	EAC mark	C S US	CSA US mark
FCC ID	Federal Communications Commission: FCC ID xxxx	CMIIT ID	Chinese Radio marking: CMIIT ID (China Ministry of Industry and Information Technology)
<b>CE</b> 0123	CE marking accompanied by the Notified Body number 0123		

IC: 8888X-XXXX8	IC-ID (Industry Canada ID) One IC-ID labeling for each built in radio: OBR, SRR
R 202-SMB025 R 202-SMB026	Japanese Radio marking: Radio mark + [R]-symbol + ID
XXXX88XX8888888	Taiwan Radio Label (NCC Logo) + ID
KTL XX88888-8888	Korea radio mark: KC logo, KCC ID number, and Conformity assessment information

### **Manufacturer's Information**

You can write to Philips at this address

Philips Medizin Systeme Boeblingen GmbH Hewlett-Packard-Str. 2 71034 Boeblingen Germany

### Australia Sponsor:

Philips Electronics Australia Ltd 65 Epping Road, North Ryde, NSW Australia 2113

Visit our website at: www.healthcare.philips.com.

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### **Regulatory and Safety Specifications**

### General Conditions for Cableless Measurements

The IntelliVue Cableless Measurements are compliant with IEC 60601-1 Ed. 3. However, they can still be used with IntelliVue Patient Monitors MP5/MP5SC/MP5T, MP2/X2, Avalon Fetal Monitors, IntelliVue Telemetry System Transceivers TRx4841A/TRx4851A, MX40 wearable patient monitors, that are compliant with IEC 60601-1 Ed. 2.

IntelliVue CL SpO2 Pod, CL NBP Pod and CL Respiration Pod:

# **CE**<sub>0123</sub>

IntelliVue CL Charging Station and CL Transmitter:

# CE

The IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod, CL Respiration Pod, CL Charging Station, and CL Transmitter comply with the Medical Device Directive 93/42/EEC.

In addition, the IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod, CL Respiration Pod, CL Charging Station and CL Transmitter comply with:

IEC 60601-1:2005 + Cor.1:2006 + Cor.2:2007 + A1:2012; EN 60601-1:2006 + AC:2010 + A1:2013; ANSI/ AAMI ES60601-1:2005/(R)2012; CAN/CSA C22.2 No. 60601-1-14

The possibility of hazards arising from software errors was minimized in compliance with: ISO 14971:2007; EN ISO 14971:2012, IEC 60601-1-4:1996 + A1:1999; EN 60601-1-4:1996 + A1:1999; IEC 60601-1-6:2010 / EN 60601-1-6:2010; IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+AC:2010; IEC 60601-2-49:2011 / EN 60601-2-49:2001 (NBP Pod and SpO<sub>2</sub> Pod only).

Classification (according to IEC 60601-1):

IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod, CL Respiration Pod: Internally powered equipment, Type CF, Continuous Operation

IntelliVue CL Transmitter: Internally powered equipment, Continuous Operation

IntelliVue CL Charging Station: Class I equipment, Continuous Operation

IntelliVue CL Transmitter Base Station and CL Hotspot:



The IntelliVue CL Transmitter Base Station and CL Hotspot comply with the Low Voltage Directive 2014/35/EC.

In addition, these devices comply with:

IEC 60950-1:2005; EN 60950-1:2006+A11:2009 +A1:2010 +A12:2011 +A2:2013.

### EMC and Radio Regulatory Compliance

### FCC and Industry Canada Radio Compliance

IntelliVue CL SpO2 Pod, CL NBP Pod, CL Respiration Pod, CL Charging Station, CL Transmitter

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.

#### IntelliVue CL Transmitter Base Station

This Class B digital apparatus complies with Canadian ICES-003. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

#### IntelliVue CL Hotspot

This Class A digital apparatus complies with Canadian ICES-003. Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

These devices comply with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) these devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radiofrequency interference and void your authority to operate this equipment.

Usage of license-exempt local area network (LE-LAN) in Canada:

#### IntelliVue CL Transmitter and CL Hotspot

The maximum antenna gain permitted (for devices in the bands 5250-5350 MHz and 5470-5725 MHz) complies with the e.i.r.p. limits as stated in RSS-210.

The maximum antenna gain permitted (for devices in the 5725-5825 MHz band) complies with the e.i.r.p. limits specified for point-to-point operation, as stated in RSS-210.

The device for the band 5150-5250 MHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

#### CAUTION

High power radars are allocated as primary users (meaning they have priority) of the bands 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and/or damage to LE-LAN devices.

## Japanese Radio Law and Japanese Telecommunications Business Law Compliance

IntelliVue CL Respiration Pod and CL Hotspot

This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法).

本製品は、電波法および電気通信事業法に基づき認可されています。

### **R&TTE Directive Compliance**

IntelliVue CL SpO2 Pod, CL NBP Pod, CL Respiration Pod, and CL Charging Station

CE

IntelliVue CL Transmitter, and CL Hotspot

**CEO** Philips Medizin Systeme Boeblingen GmbH hereby declares that these products are in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio and Telecommunications Terminal Equipment Directive).

The IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod, CL Respiration Pod, CL Charging Station, CL Transmitter, and CL Hotspot incorporate a SRR module, which is Class 1 radio equipment.

The IntelliVue CL Transmitter and CL Hotspot incorporate additionally the IntelliVue 802.11 Adapter, which is Class 2 radio equipment. The products are intended to be connected to the Publicly Available Interfaces (PAI) and used throughout the EEA. Individual countries may apply restrictions on putting this device into service or placing on the market.

To obtain a copy of the original Declaration of Conformity, please contact Philips at the address as stated in the "Manufacturer's Information".

### WARNING

- The IntelliVue CL Charging Station is Class A professional equipment. This equipment is not intended for use in domestic establishments or connection to the public mains network. In domestic establishments or when connected to the public mains network, this equipment may cause radio interference or may disrupt the operation of nearby equipment.
- The IntelliVue CL Hotspot is a Class A product. In a domestic environment this product may cause radio interference, in which case the user may be required to take adequate measures.
- This equipment generates, uses and radiates radiofrequency energy, and if it is not installed and used in accordance with its accompanying documentation, may cause interference to radio communications.
- The device, equipped with a wireless network interface, intentionally receives RF electromagnetic energy for the purpose of its operation. Therefore, other equipment may cause interference, even if that other equipment complies with CISPR emission requirements.

### **EMC Directive Compliance**

IntelliVue CL Transmitter Base Station and CL Hotspot

C The IntelliVue CL Transmitter Base Station and CL Hotspot comply with the EMC Directive 2014/30/EC.

In addition these devices comply with:

ETSI EN 301 489-1:V1.9.2, ETSI EN 301 489-17:V2.2.1

CISPR 22:2008 / EN55022:2010/AC 2011 and CISPR 24:2010 / EN55024:2010

### **Radiofrequency Radiation Exposure Information**

### IntelliVue CL Transmitter

For body worn operation, this device has been tested and meets FCC RF exposure guidelines when used in the standard configuration with the rear side towards the body, without a gap. Alternatively, it can be used with any accessory that positions the front side of the device a minimum of 10 mm from the body. The accessory itself must not contain any metal parts. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

Nevertheless it is strongly recommended to operate the CL Transmitter with the rear side towards the body to achieve best possible radio performance.

### Safety and Performance Tests

You must follow and apply any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. Required safety and performance tests, and what to do if the Cableless Measurements do not meet these specifications, are described in the IntelliVue Cableless Measurements Service Guide.

### Electromagnetic Compatibility (EMC)

Take special precautions regarding electromagnetic compatibility (EMC) when using the IntelliVue Cableless Measurements. Operate the IntelliVue Cableless Measurements according to the EMC information provided in these Instructions for Use and in the IntelliVue Cableless Measurements Service Guide. Portable and mobile radiofrequency (RF) communications equipment can affect the IntelliVue Cableless Measurements.

### WARNING

For paced patients: The radiated SRR power of the IntelliVue  $SpO_2$ , NBP and Respiration Cableless Measurement Devices, the CL transmitter, and other sources of radiofrequency energy, when used in very close proximity of a pacemaker, might be sufficient to interfere with pacemaker performance. Due to shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring paced patients.

In order to minimize the possibility of interference, avoid positioning and wearing the Cableless Measurement Devices in very close proximity to a pacemaker. Consult the pacemaker manufacturer for information on the RF susceptibility of their products.

#### WARNING

**For paced patients:** The radiated **WLAN power** of the IntelliVue CL Transmitter, and other sources of radiofrequency energy, when used in the **proximity** of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patients.

In order to minimize the possibility of interference, position the IntelliVue CL Transmitter, when body worn, as far away from the pacemaker as possible. Consult the pacemaker manufacturer for information on the RF susceptibility of their products.

### Accessories Compliant with EMC Standards

All IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod and CL Respiration Pod accessories comply, in combination with the IntelliVue Cableless Measurement Devices, with the requirements of IEC 60601-1-2:2001 + A1 2004; EN 60601-1-2:2001 + A1 2006 or IEC 60601-1-2:2007; EN 60601-1-2:2007.

#### WARNING

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the IntelliVue Cableless Measurement Devices.

### **Electrosurgery Interference/Defibrillation**

The IntelliVue CL SpO<sub>2</sub> Pod, CL NBP Pod and CL Respiration Pod including all accessories are suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator.

Measurement accuracy may be temporarily decreased or measurement may be interrupted while performing electrosurgery or defibrillation. The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. This does not affect patient or equipment safety. Do not expose the equipment to X-ray or strong magnetic fields (MRI).

### IntelliVue CL SpO2 Pod Specifications

Physical Specifications	
Size (W x H x D)	54 mm x 27 mm x 65 mm $\pm$ 5% (2.1 in x 1.1 in x 2.6 in $\pm$ 5%) (without cradle and sensor)
Weight	82 g ±10% (2.8 oz ±10%)
Robustness	Provides essential performance during exposure to random vibration according to IEC TR 60721-4-7 Class 7M1
	Survives shock, random vibration and bump according to IEC TR 60721-4-7 Class 7M3 as well as a 1 m drop
Ingress Protection	IP34 according to IEC 60529 (protection against ingress of water when water drips, falls or splashes from any direction, and protection against contact with or ingress of objects larger than 2.5 mm)

Complies with ISO 80601-2-61:2011 / EN ISO 80601-2-61:2011.

Environmental Specifications	
Operating Temperature Range	0 to 40°C (32 to 104°F)
Operating Humidity Range	≤95% RH @ 40°C (104°F)
Operating Altitude Range	-500 to 3000 m
Storage/Transportation Temperature Range	-20 to 60°C (-4 to 140°F)
Storage/Transportation Humidity Range	≤90% RH @ 60°C (140°F) no condensation
Storage/Transportation Altitude Range	-500 to 4600 m

**Measurement Validation:** The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed,

only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

Display Update Period: Typical: 2 seconds, Maximum: 30 seconds. Maximum with NBP INOP suppression on: 60 seconds.

Performance Specifications		
SpO <sub>2</sub>		
Measurement Range	0 to 100%	
Accuracy The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values	Mobile CL DSpO <sub>2</sub> -1A single patient sensor: 3% (70 to 100%) Mobile CL RSpO <sub>2</sub> -1A reusable sensor (may not be available in all geographies): 3% (70 to 100%)	
Resolution	1%	
Pulse Oximeter Calibration Range	70% to 100%	
Pulse		
Measurement Range	30 to 300 bpm	
Accuracy	$\pm 2\%$ or 1 bpm, whichever is greater	
Resolution	1 bpm	
Sensors		
LED Power Dissipation	Temperature rise at sensor skin interface in compliance with ISO 9919	
Optical Output Power	≤15 mW	
Wavelength Range	500 to 1000 nm	
Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed)		
For further information on accessory specifications, refer to the accessory Instructions for Use.		
Display Specifications		
Туре	monochrome (4 gray scales), passive LCD (STN), positive/transflective	
Viewing Area	25.6 mm x 19.2 mm	
Dot Size	0.2 mm x 0.2 mm	
Resolution	128 x 96 pixel	
Backlight	white LED	
Sounds	Hardkey operation tone Assignment tone Alarm tone Pulse tone with and without tone modulation	
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter	

Performance Specifications	
Runtime (fully charged battery)	Continuous measurement: Typically 24 hours Minimum 12 hours in continuous mode
	Intermittent measurement: Typically 60 hours with repetition interval of 2 minutes Typically 3 days with repetition interval of 5 minutes
Charging Time	max 2.5 hours
Short Range Radio Specifications	
Туре	built in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency band	2.4 GHz ISM (2.400 - 2.483 GHz) MBAN (2.360 - 2.400 GHz, for US / FCC regulated countries only) <sup>1</sup>
Modulation	DSSS (O-QPSK)
Bandwidth	5 MHz
Effective radiated power (ERP)	max. 0 dBm (1 mW)
Electronic Article Surveillance (EAS)	EAS tag inside the housing
Real Time Clock Accuracy	better than 5 seconds per day (typically) as long as device is in power state "Device on" or "Standby". Automatically synchronized with assigned host system.

<sup>1</sup>Approval pending

### IntelliVue CL NBP Pod Specifications

Complies with IEC 80601-2-30:2010 + A1:2013/EN 80601-2-30:2010.

#### **Measurement Validation**

Clinical investigation according ISO 81060-2:2013 with the auscultatory reference method

- the 5th Korotkoff sound (K5) was used in adult / adolescent subjects and the 4th Korotkoff sound (K4) was used in pediatric subjects to determine the diastolic reference pressures
- the approximation MAP = (2\*DIA + SYS) / 3 was used to calculate reference MAP (mean arterial pressure) values from the systolic and diastolic reference pressures.

### NOTE

The effectiveness of this sphygmomanometer has been established in pregnant, including pre-eclamptic patients.

Physical Specifications	
Size (W x H x D)	66 mm x 138 mm x 31 mm $\pm$ 5% (2.6 in x 5.4 in x 1.2 in $\pm$ 5%) (without cradle and cuff)
Weight	234 g ±10% (8.3 oz ±10%) (without cradle and cuff)

Physical Specifications	
Robustness	Provides essential performance during exposure to random vibration according to IEC TR 60721-4-7 Class 7M1
	Survives shock, random vibration and bump according to IEC TR 60721-4-7 Class 7M3 as well as a 1 m drop
Ingress Protection	IP32 according to IEC 60529 (protected against ingress of water when the water is dripping vertically and the CL NBP Pod is tilted up to 15° and protected against contact with or ingress of objects larger than 2.5 mm)

Environmental Specifications	
Operating Temperature Range	0 to 40°C (32 to 104°F)
Operating Humidity Range	≤95% RH @ 40°C (104°F) (non-condensing)
Operating Altitude Range	-500 to 3000 m
Storage/Transportation Temperature Range	-20 to 60°C (-4 to 140°F)
Storage/Transportation Humidity Range	≤90% RH @ 60°C (140°F) (non-condensing)
Storage/Transportation Altitude Range	-500 to 4600 m

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

IntelliVue CL NBP Pod Performance Specifications		
Display Specifications		
Туре	monochrome (4 gray scales), passive LCD (STN), positive/transflective	
Viewing Area	25.6 mm x 19.2 mm	
Dot Size	0.2 mm x 0.2 mm	
Resolution	128 x 96 pixel	
Backlight	white LED	
Sounds	Hardkey operation tone Assignment tone NBP Announcement tone NBP done tone Alarm tone	
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter	
Runtime (fully charged battery)	Minimum 12 hours @ 4 measurements per hour Typical 4 days @ 2 measurements per hour Typical 5 days @ 1 measurement every 2 hours	
Charging Time	Maximum 2.5 hours	
Short Range Radio Specifications		
Туре	built in interface with integrated antenna	
Technology	IEEE 802.15.4	
Frequency band	2.4 GHz ISM (2.400 - 2.483 GHz) MBAN (2.360 - 2.400 GHz, for US / FCC regulated countries only) <sup>1</sup>	

IntelliVue CL NBP Pod Performance Specifications	
Modulation	DSSS (O-QPSK)
Bandwidth	5 MHz
Effective radiated power (ERP)	max. 0 dBm (1 mW)
Electronic Article Surveillance (EAS)	EAS tag inside the housing
Real Time Clock Accuracy	better than 5 seconds per day (typically) as long as device is in power state "Device on" or "Standby". Automatically synchronized with assigned host system.
Measurement Ranges	Adult: Systolic: 30 to 270 mmHg (4.0 to 36.0 kPa) Mean: 20 to 255 mmHg (2.5 to 34.0 kPa) Diastolic: 10 to 245 mmHg (1.5 to 32.0 kPa) Pediatric: Systolic: 30 to 180 mmHg (4.0 to 24.0 kPa)
	Mean: 20 to 160 mmHg (2.5 to 21.0 kPa) Diastolic: 10 to 150 mmHg (1.5 to 20.0 kPa)
Rated Range of Cuff Pressure	max. 300 mmHg (40.0 kPa)
Pressure Transducer Accuracy (0 to 300 mmHg)	±3 mmHg @ 15 to 25°C ±(3 mmHg or 2% whichever is greater) @ 10 to 40°C
Blood Pressure Measurement Accuracy	8 mmHg standard deviation ±5 mmHg mean error
Pulse Rate Measurement Range	40 to 300 bpm
Pulse Rate Measurement Accuracy	40 - 100 bpm: ±5 bpm 101 - 200 bpm: ±5% of reading 201 - 300 bpm: ±10% of reading (average over NBP measurement cycle)
Measurement Time	Auto/manual/sequence mode: Typical 40 seconds @ >60 bpm and normal adult cuff Maximum 180 seconds STAT and Accelerated Mode:
	Typical 30 seconds @ >60 bpm and normal adult cuff Maximum 180 seconds
STAT Mode Cycle Time	5 minutes
Initial Cuff Inflation Pressure	Adult: 165 ±15 mmHg Pediatric: 130 ±15 mmHg
Venipuncture Pressure Range	Adult: 20 to 120 mmHg in steps of 5 mmHg Pediatric: 20 to 80 mmHg in steps of 5 mmHg
Venipuncture Pressure Accuracy	±10 mmHg
Cuff size detection	INOP, if neonatal cuff size is detected

<sup>1</sup>Approval pending

## IntelliVue CL Respiration Pod Specifications

Physical Specifications	
Size (W x H x D)	45 mm x 14 mm x 65 mm $\pm$ 5% (1.7 in x 0.5 in x 2.5 in $\pm$ 5%) (without accessories)
Weight	$35 \text{ g} \pm 10\% (1.2 \text{ oz} \pm 10\%)$
Robustness	Survives shock, random vibration and bump according to IEC TR 60721-4-7 Class 7M3 as well as a 1 m drop
Ingress Protection	IP67 according to IEC 60529

Complies with ISO 80601-2-61:2011 / EN ISO 80601-2-61:2011.

Environmental Specifications	
Operating Temperature Range	0 to 40°C (32 to 104°F)
Operating Humidity Range	$\leq$ 95% RH @ 40°C (104°F), no condensation
Operating Altitude Range	-500 to 3000 m
Storage/Transportation Temperature Range	-20 to 60°C (-4 to 140°F)
Storage/Transportation Humidity Range	$\leq$ 90% RH @ 60°C (140°F), no condensation
Storage/Transportation Altitude Range	-500 to 4600 m
Storage/Transportation Ambient Pressure (Altitude Range)	1075 hPa to 570 hPa (-500 m to 4600 m / -1650 ft to 15000 ft)

Performance Specifications	
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter
Runtime (fully charged battery)	Minimum 12 hours in frequent measurement mode with posture and activity detection
	Typically 18 hours in frequent measurement mode with posture and activity detection
	Minimum 1.5 days @ 4 measurements per hour without posture and activity detection
	Typical 3 days @ 4 measurements per hour without posture and activity detection
	Minimum 1 day $@$ 4 measurements per hour with posture and activity detection
	Typical 2 days @ 4 measurements per hour with posture and activity detection
Charging Time	max 2.5 hours
Short Range Radio Specifications	
Туре	built in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency band	2.4 GHz ISM (2.400 - 2.483 GHz) MBAN (2.360 - 2.400 GHz, for US / FCC regulated countries only) <sup>1</sup>
Modulation	DSSS (O-QPSK)

Performance Specifications	
Bandwidth	5 MHz
Effective radiated power (ERP)	max. 2 dBm (1.6 mW)
Real Time Clock Accuracy	better than 5 seconds per day (typically) as long as device is in power state "Device on". Automatically synchronized with assigned host system.
Respiration	
Measurement Range	5 to 60 rpm
Accuracy	±1 rpm
Resolution	1 rpm
Pulse	
Measurement Range	Adult: 30 to 220 bpm For rapid, irregular heart rates: 30 to 110 bpm
	Pediatric: 30 to 220 bpm
Accuracy	$\pm 3\%$ or $\pm 1$ bpm (whichever is greater)
Resolution	1 bpm
Posture Information	14 patient postures (supine, prone, upright, reclined, forward, lying on left side, lying on right side, lying (unspecific), sitting, standing, rolling (in bed), walking, wheelchair (self), upside down)
Activity Information	10 levels from 1 (very low activity) to 10 (very high activity); level 0: no signal

### <sup>1</sup>Approval pending

Attachment Specifications	
Size (W X H)	196 mm x 64 mm (7.7 in x 2.5 in)
Environmental Specifications	
Operating temperature range	0 to 40°C (32 to 104°F)
Storage / Transportation Temperature	Storage: 12 to 35°C (54 to 95°F)
Range	Transportation: -20 to 60°C (-4 to 140°F)
Storage / Transportation Humidity Range	Storage: 18% RH to 78% RH
	Transportation: $\leq 90\%$ RH @ 60°C (140°F); no condensation
Storage / Transportation Ambient Pressure (Altitude Range)	1075 hPa to 570 hPa (-500 m to 4600 m / -1650 ft to 15000 ft)

### Alarm Specifications for CL NBP, CL SpO2 and CL Resp Pod

When the CL Respiration Pod is used alone, without an assignment to a host, **no physiological alarms** will be generated.

When the CL SpO<sub>2</sub> Pod or CL NBP Pod are used for local attended monitoring, the following specifications apply:

Alarm Signal	
System Alarm Delay	less than 4 seconds
The system alarm delay is the processing time the system needs for any alarm to be indicated on the device, after the measurement has triggered the alarm.	
Delay for alarm availability on the network	less than 5 seconds
This is the time needed after alarm indication on the device until the alarm signal is available on the network, to the monitor or to other systems.	
Sound Pressure Range	min. 0 dB(A) max. 30-65 dB(A)

SpO <sub>2</sub> Alarm Specifications	Range	Adjustment
SpO <sub>2</sub>	Adult: 50 to 100% Pedi: 30 to 100%	1% steps
Desat	Adult: 50 to Low alarm limit Pedi: 30 to Low alarm limit	1% steps
Pulse	30 to 300 bpm	Adult: 1 bpm steps (30 to 40 bpm) 5 bpm steps (40 to 300 bpm) Pedi: 1 bpm steps (30 to 50 bpm) 5 bpm steps (50 to 300 bpm)
Tachycardia	Difference to high limit 0 to 50 bpm	5 bpm steps
	Clamping at 150 to 300 bpm	5 bpm steps
Bradycardia	Difference to low limit 0 to 50 bpm	5 bpm steps
	Clamping at 30 to 100 bpm	5 bpm steps

SpO <sub>2</sub> Alarm Specifications (cont.)	Standard Delay
$\mathbf{SpO}_2$ high and low limit alarms	0 to 30 seconds (adjustable in 1 second steps) + system alarm delay
Desat	0 to 30 seconds (adjustable in 1 second steps) + system alarm delay
Pulse	10 seconds + system alarm delay
Tachycardia	10 seconds + system alarm delay
Bradycardia	10 seconds + system alarm delay

NBP Alarm Specifications	Range	Adjustment
Systolic	Adult: 30 to 270 mmHg (4 to 36 kPa)	10 to 30 mmHg: 2 mmHg (0.5 kPa)
	Pedi: 30 to 180 mmHg (4 to 24 kPa)	>30 mmHg: 5 mmHg (1 kPa)
Diastolic	Adult: 10 to 245 mmHg (1.5 to 32 kPa)	
	Pedi: 10 to 150 mmHg (1.5 to 20 kPa)	
Mean	Adult: 20 to 255 mmHg (2.5 to 34 kPa)	
	Pedi: 20 to 160 mmHg (2.5 to 21 kPa)	

When the Cableless Measurement Devices are assigned to a monitor or telemetry device, alarms may be announced at the host monitor (for the telemetry device, at the Information Center). See the respective Instructions for Use for detailed alarm specifications.

Alarm delay times are as specified in the Instructions for Use of your patient monitor or IntelliVue Information Center plus 4 seconds.

### NOTE

If the SRR connection between the Cableless Measurement Device and the patient monitor or telemetry device is interrupted, the patient monitor or telemetry device will issue an INOP within 5 seconds.

### **Telemetry Device Battery Runtime Specifications**

Operating Mode	Battery Runtime
ECG Only Telemetry Device with CL SpO <sub>2</sub> /NBP Pod connected	20 hours
Telemetry Device is host to CL SpO <sub>2</sub> /NBP Pod	
<b>ECG/SpO</b> <sub>2</sub> (continuous) Telemetry Device with internal SpO <sub>2</sub> running in continuous mode and CL SpO <sub>2</sub> /NBP Pod connected	8 hours
Telemetry Device is host to CL SpO2/NBP Pod	

## IntelliVue CL Transmitter Specifications

Physical Specifications	
Size (W x H x D)	55 mm x 27 mm x 122 mm $\pm$ 5% (2.2 in x 1.0 in x 4.8 in $\pm$ 5%) (without cradle)
Weight	154 g ±10% (5.4 oz ±10%) (without cradle)
Robustness	Provides essential performance during exposure to random vibration according to IEC TR 60721-4-7 Class 7M1
	Survives shock, random vibration and bump according to IEC TR 60721-4-7 Class 7M3 as well as a 1 m drop
Ingress Protection	IP32 according to IEC 60529 (protected against ingress of water when the water is dripping vertically and the CL Transmitter is tilted up to 15° and protected against contact with or ingress of objects larger than 2.5 mm)

Environmental Specifications	
Operating Temperature Range	0 to 40°C (32 to 104°F)
	0 to 35°C (32 to 95°F) when charging the battery with an active WLAN connection
Operating Humidity Range	≤95% RH @ 40°C (104°F) no condensation
Operating Altitude Range	-500 to 3000 m
Storage / Transportation Temperature Range	-20 to 60°C (-4 to 140°F)
Storage / Transportation Humidity Range	≤90% RH @ 60°C (140°F) (non-condensing)
Storage / Transportation Altitude Range	-500 to 4600 m

Performance Specifications		
Display Specifications		
Туре	monochrome (4 grey scales), passive LCD (STN), positive/transflective	
Viewing Area	25.6 mm x 19.2 mm	
Dot Size	0.2 mm x 0.2 mm	
Resolution	128 x 96 pixel	
Backlight	white LED	
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter	
Runtime (fully charged battery)	Typical 8 hours	
Charging Time (WLAN and SRR not active)	Maximum 2.5 hours	
Electronic Article Surveillance (EAS)	EAS tag inside the housing	
Short Range Radio Specifications		
Туре	built in interface with integrated antenna	
Technology	IEEE 802.15.4	
Frequency Band	2.4 GHz ISM (2.400 - 2.483 GHz) MBAN (2.360 - 2.400 GHz, for US / FCC regulated countries only) <sup>1</sup>	
Modulation	DSSS (O-QPSK)	
Bandwidth	5 MHz	
Effective Radiated Power (ERP)	max. 0 dBm (1 mW)	
WLAN Specifications		
Туре	Internal wireless adapter	
Technology	IEEE 802.11a/b/g/n	

Performance Specifications	
Frequency Band	USA: 2.400 - 2.483 GHz, 5.15 - 5.35 GHz, 5.725 - 5.825 GHz
	Europe: 2.400 - 2.483 GHz, 5.15 - 5.35 GHz, 5.47 - 5.725 GHz
	Japan: 2.400 - 2.483 GHz, 5.150 - 5.250 GHz, 5.25 - 5.35 GHz, 5.470 - 5.725 GHz
	China: 2.400 - 2.483 GHz, 5.725 - 5.85 GHz
Modulation Technique	802.11b/g
	DSSS (DBPSK, DQPSK, CCK)
	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
	802.11a
	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Effective Radiated Power (ERP)	2.400 - 2.483 GHz: max. 18 dBm (63 mW)
	5.150 - 5.725 GHz: max. 19 dBm (79 mW)
	5.745 - 5.825 GHz: max. 14 dBm (25 mW)
Realtime Clock Accuracy	less than 5 seconds per day (typically) as long as device is in power state "Device on" or "Standby". Automatically synchronized with assigned patient monitor/ telemetry device.

<sup>1</sup>Approval pending

## IntelliVue CL Transmitter Base Station Specifications

Physical Specifications	
Size (W x H x D)	75 mm x 45 mm x 173 mm ±5% (3.0 in x 1.8 in x 6.8 in ±5%)
Weight	236 g ±10% (8.3 oz ±10%)
Robustness	Operating within specification during exposure to random vibration according to IEC TR 60721-4-7 Class 7M1
	Survives shock and 0.05 m free fall according to IEC TR 60721-4-7 Class 7M1
Ingress Protection	IP21 according to IEC 60529 (protection against ingress of water when the water is dripping vertically)

Environmental Specifications		
Operating Temperature Range	0 to 40°C (32 to 104°F)	
Operating Humidity Range	≤95% RH @ 40°C (104°F)	
Operating Altitude Range	-500 to 3000 m -500 to 2000 m when powered from external power supply 865222 #E90	
Storage/Transportation Temperature Range	-20 to 60°C (-4 to 140°F)	
Storage/Transportation Humidity Range	≤90% RH @ 60°C (140°F) no condensation	
Storage/Transportation Altitude Range	-500 to 4600 m	

Performance Specifications		
Charging Interface (output)		
Power output (PoE powered)	5 V ±10%	
Power output (USB powered)	USB input voltage - 180 mV (@ 500 mA)	
Communication	USB 2.0 full speed	
USB Interface		
Standard	USB 2.0 full speed Device Port	
Power Input	4.5 V - 5.5 V (8 W) power requirement for service and upgrade of connected Cableless Measurement Devices 2.5 W	
Connector	USB series "Standard-B" receptacle	
Network		
Standards	IEEE 802.3 100-Base-T, IEEE 802.3af (PoE Class 3)	
Connector	RJ45 (8 pin)	
External AC/DC 5V requirements (connection to USB)		
Output voltage	5 V +/-5%	
Power output	min. 8 W	
Isolation	double according to IEC 60950-1 Class II	
Classification	Limited Power Source according to IEC 60950-1	
External AC/DC 48V requirements (connection to RJ45)		
Output Voltage	48 V +/-10%	
Power output	min. 8 W	
Compliancy	IEEE 802.3af (PoE Class 3)	
Isolation	double according to IEC 60950-1 Class II	
Classification	Limited Power Source according to IEC 60950-1	
Connector	RJ45 (Data-in), RJ45 (Data&Power Out)	

# IntelliVue CL Hotspot Specifications

Physical Specifications	
Size (W x H x D)	75 mm x 53 mm x 177 mm ±5% (3.0 in x 2.1 in x 7.0 in ±5%)
Weight	367 g ±10% (12.9 oz ±10%)
Robustness	Provides essential performance during exposure to random vibration according to IEC TR 60721-4-7 Class 7M1
	Survives shock and 0.05 m free fall according to IEC TR 60721-4-7 Class 7M1

Environmental Specifications		
Operating Temperature Range	0 to 40°C (32 to 104°F)	
Operating Humidity Range	$\leq$ 95%RH @ 40°C (104°F) no condensation	
Environmental Specifications		
---	--	
Operating Altitude Range	-500 to 3000 m -500 to 2000 m when powered from external power supply 865222 #E90	
Storage / Transportation Temperature Range	-20 to 60°C (-4 to 140°F)	
Storage / Transportation Humidity Range	≤90% RH @ 60°C (140°F) (non-condensing)	
Storage / Transportation Altitude Range	-500 to 4600 m	

Performance Specifications	
Display Specifications	
Туре	monochrome (4 gray scales), passive LCD (STN), positive/transflective
Viewing Area	25.6 mm x 19.2 mm
Dot Size	0.2 mm x 0.2 mm
Resolution	128 x 96 pixel
Backlight	white LED
Short Range Radio Specifications	
Туре	built in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency Band	2.4 GHz ISM (2.400 - 2.483 GHz) MBAN (2.360 - 2.400 GHz, for US / FCC regulated countries only) <sup>1</sup>
Modulation	DSSS (O-QPSK)
Bandwidth	5 MHz
Effective Radiated Power (ERP)	max. 0 dBm (1 mW)
WLAN Specifications	
Туре	Internal wireless adapter
Technology	IEEE 802.11a/b/g/n
Frequency Band	USA: 2.400 - 2.483 GHz, 5.15 - 5.35 GHz, 5.725 - 5.825 GHz
	Europe: 2.400 - 2.483 GHz, 5.15 - 5.35 GHz, 5.47 - 5.725 GHz
	Japan: 2.400 - 2.483 GHz, 5.150 - 5.250 GHz, 5.25 - 5.35 GHz, 5.470 - 5.725 GHz
	China: 2.400 - 2.483 GHz, 5.725 - 5.85 GHz
Modulation Technique	802.11b/g
	DSSS (DBPSK, DQPSK, CCK)
	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
	802.11a
	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Effective Radiated Power (ERP)	2.400 - 2.483 GHz: max. 18 dBm (63 mW)
	5.150 - 5.725 GHz: max. 19 dBm (79 mW)
	5.745 - 5.825 GHz: max. 14 dBm (25 mW)

Performance Specifications		
Realtime Clock Accuracy	less than 5 seconds per day (typically) as long as device is in power state "Standby" or "Device off". Automatically synchronized with assigned patient monitor/telemetry device.	
USB Interface		
Standard	USB 2.0 full speed Device Port	
Power Input	4.5 V - 5.5 V (3 W) power requirement for service and upgrade of connected Cableless Measurement devices 2.5 W	
Connector	USB series "Standard-B" receptacle	
LAN Network		
Standards	IEEE 802.3 100-Base-T, IEEE 802.3af (PoE Class 3)	
Connector	RJ45 (8 pin)	
External AC/DC 5V requirements (connection to USB)		
Output voltage	5 V +/-5%	
Power output	min. 3 W	
Isolation	double according to IEC 60950-1 Class II	
Classification	Limited Power Source according to IEC 60950-1	
External AC/DC 48V requirements (connection to RJ45)		
Output Voltage	48 V +/-10%	
Power output	min. 3 W	
Compliancy	IEEE 802.3af (PoE Class 3)	
Isolation	double according to IEC 60950-1 Class II	
Classification	Limited Power Source according to IEC 60950-1	
Connector	RJ45 (Data-in), RJ45 (Data&Power Out)	

<sup>1</sup>Approval pending

# Index

#### A

activity 107 alarms off symbol 32, 75 ambient light 31 assignment 22 at the measurement device 22 at the patient monitor 23 assignment mode 22 auto power off 17 automatic mode 74 automatic mode SpO2 31 averaging time 33 changing 33

#### В

battery 50 care 50 lifetime management 51 power indicators 118 status menu 19 status on the cableless device 19

## С

care and cleaning 121 caution, definition 5 charging 118 cleaning and disinfecting 122 compatibility (NBP) 63 compatibility (SpO2) 21 configuration mode 17 connection status symbol 22 continuous mode SpO2 31

#### D

date and time 19 default profile 18 demonstration mode 17 device compatibility (NBP) 63 device compatibility (SpO2) 21 disinfecting 122 disinfecting agents 122 disposing of the IntelliVue Cableless Measurement Device 123

# Ε

electromagnetic compatibility (EMC) 132

electrosurgery 69 electrosurgery interference/ defibrillation 133 elevated ambient temperatures 30 EMC 130 directive compliance 131 radio regulatory compliance 130

# F

FCC and industry canada radio compliance 130 fetal monitors (NBP) 66 fetal monitors (SpO2) 24 free device 18, 107

#### Η

hardkeys 15

#### Ι

infection control 121 ingress protection (NBP Pod) 135 ingress protection (SpO2 Pod) 133 injected dyes 31 INOP 14, 56 layout 14 NBP 82 Resp 108 SpO2 40 tone 36 inspecting the equipment and accessories 53 IntelliVue CL hotspot specifications 144 IntelliVue CL NBP Pod 94 accessories 94 specifications 135 IntelliVue CL Respiration Pod 99 IntelliVue CL SpO2 Pod 52 accessories 52 specifications 133 IntelliVue CL Transmitter 116 accessories 116 specifications 141 IntelliVue CL transmitter and IntelliVue CL hotspot 113 IntelliVue CL transmitter base station 117 specifications 143 intended use 125 interference 22, 31

intravenous infusion 69

## L

local attended monitoring 43 loose sensor 30 low-activity screen 15

#### Μ

main setup menu 17, 59 maintenance task and test schedule 53 manual mode SpO2 31 monitoring mode 17 MR imaging 125

#### Ν

NBP 94 accessories 94 default settings 91 numerics 75 specifications 135 new patient 18 adding 18 no host monitoring 22, 25, 64, 67

# 0

operating modes 17 oscillometric NBP measurement 69 oxygen saturation 28

# Р

patient category 18 patient demographics 18 patient menu 18 patient movement 31 perfusion indicator 28, 31 perfusion numeric 33 pleth waveform 28 posture 107 posture detection 107 profiles 18 pulsatile flow 31 pulse oximetry 28 pulse rate 28 pulse rate numeric 32, 75

## R

R&TTE directive compliance 131 radiofrequency radiation exposure information 132 removing a patient from the device 18 removing the pod from the cradle 30 repetition time 74 respiration measurement 104 Respiration sensor 104

# S

safety and performance tests 132 safety specifications 129 screen layout 14 sensor (Resp) 105 applying 105 sensor (SpO2) 30 applying 30 sequence mode 75 service mode 17 setup sequence 75 short range radio 22 short range radio (SRR) 10 signal quality indicator 32 skin damage 69, 105 smartkeys 15 SpO2 52 accessories 52 default settings 49 numerics 32 sensors 28 signal quality indicator 32 specifications 133 SpO2 accessories 52 SpO2 numerics 32 SpO2 Sensors 29 Connecting 29 SpO2 specifications 133 standby mode 60 starting and stopping measurements (NBP) 74 suspicious SpO2 reading 33 symbols 127

# Т

technical alarms (INOPs, NBP) 82 technical alarms (INOPs, Resp) 108 technical alarms (INOPs, SpO2)) 40 telemetry device 20 telemetry device battery runtime specifications 141 test schedule 53 timestamp 75 timestamp SpO2 32 transceiver 26 transmitter base station specifications 143 troubleshooting 53

## U

use models 20

# V

venipuncture 76 venous pulsation 30 visual inspection 53

## W

warning 5



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