Instructions for Use

IntelliVue Cableless Measurements

IntelliVue CL SpO2 Pod and CL NBP Pod

Release A.0

Patient Monitoring

PHILIPS

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Introduction and Basic Operation

These Instructions for Use are for clinical professionals using the IntelliVue Cableless Measurements and their respective accessories together with IntelliVue Patient Monitors MP5/MP5T, MP2 or X2 or with the IntelliVue Telemetry System Transceiver TRx4841A/TRx4851A for monitoring and recording arterial oxygen saturation, pulse rate and non-invasive blood pressure of adult and pediatric patients.

This section gives you an overview of the cableless measurements and how they are used. The remaining sections tell you how to perform individual measurements, and how to care for and maintain the equipment.

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 or the telemetry system, refer to and adhere to all warnings in the Instructions for use of the respective device.

In this guide:

- 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.

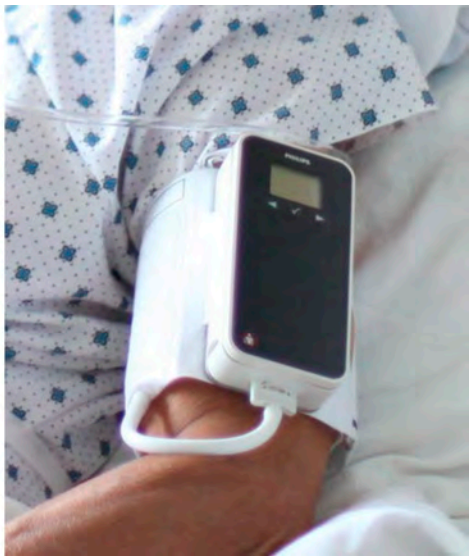
IntelliVue Cableless Measurements refers to the IntelliVue Cableless Measurements product family consisting of the IntelliVue CL SpO_2 Pod and IntelliVue CL NBP Pod with their accessories and auxiliary devices such as the IntelliVue CL Charging Station. **Display** refers to the physical display of the CL device. **Screen** refers to everything you see on the IntelliVue CL measurement's display, such as measurement values, patient data and so forth.

Introducing the IntelliVue Cableless Measurements

The IntelliVue Cableless Measurements family consists of the following components and their respective accessories:

IntelliVue CL SpO_2 Pod

IntelliVue CL NBP Pod



IntelliVue CL Charging Station

The cableless measurement devices provide measurement values on the built-in display and communicate them to other system components using a wireless short range radio (SRR) interface. They can also be controlled via SRR from an assigned patient monitor or an IntelliVue Information Center via a telemetry device. They have an LCD display and three keys for basic operation e.g. to assign the device to a patient.

IntelliVue CL SpO2 Pod

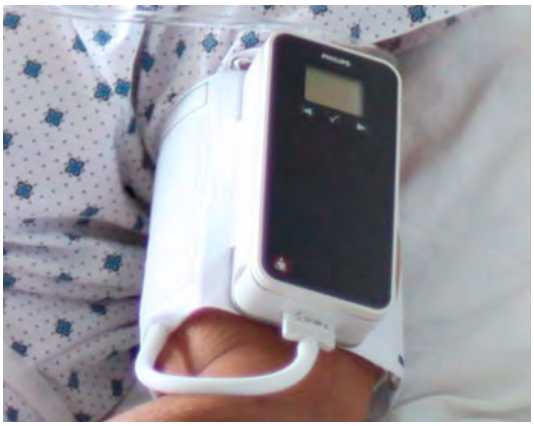
The IntelliVue CL SpO_2 Pod is a battery powered, cableless Pulse Oximetry measuring device. It is a wrist-worn device; you need a Mobile CL SpO_2 Cradle to hold the sensor connector in place and a wristband to fix the cradle to a patient's arm.

Specialized single-patient SpO_2 sensors are available for use with the IntelliVue CL SpO_2 Pod. For details regarding the complete set of single-patient supplies, cradle, wristband and sensors, refer to the Accessories chapter.

IntelliVue CL NBP Pod

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

To measure NBP, you need a Mobile CL NBP Cradle and Mobile CL Cuffs. The cradle is used to attach the Pod to the cuffs and to allow easy removal of the Pod.



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 the Accessories chapter.

IntelliVue CL Charging Station

The IntelliVue CL Charging Station is used to charge the IntelliVue CL SpO_2 Pod and the IntelliVue CL NBP Pod. It contains nine charger slots for IntelliVue Cableless measurement devices. Depending on its size a measurement device may occupy one or two charger slots at a time.

As soon as a device is placed onto a charger slot, the device will switch on and the charging cycle begins automatically.

If the ambient temperature is high, the built-in fan will switch on automatically to cool the charging station.

WARNING

Ensure that the charging station does not come into close contact with implanted pacemakers, to avoid magnetic interference affecting the mode of the pacemaker.

CAUTION

The charging 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 charging station, as the data may be damaged.

Availability of Patient Alarms

When the Cableless Measurement Devices are used alone, without an assignment to a monitor or telemetry device, **no patient alarms will be generated**.

When the Cableless Measurement Devices are assigned to a monitor or telemetry device, alarms may be announced at the host device.

- **When assigned to a 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.
- **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.

Measurement Device Main Parts and Keys

All IntelliVue Cableless Measurement devices have an integrated monochrome LCD display and 3 keys.

1 Integrated monochrome LCD display

2 Hard keys: ◄, ✓, ►

3 Measurement identifier

Operating and Navigating

The following sections describe operation on the IntelliVue Cableless Measurement device itself. For operation from a patient monitor, see "Controls Available with a Patient Monitor" on page 22 and for operation from an Information Center via a telemetry system, see "Controls Available With a Telemetry Device" on page 23.

The IntelliVue CL Cableless Measurement devices have three hard keys for basic operation and a set of configurable SmartKeys which appear on the screen. These are used to navigate through the screen elements and activate the on-screen menus for the individual items.

Switching the Devices On and Off

The first time an IntelliVue Cableless Measurement Device is used, or after a device has been powered off for storage, place it on the IntelliVue CL Charging Station. This will automatically switch the device on. For Power Off details, see the IntelliVue Cableless Measurements Service Guide.

To switch off a device manually, select the **Main Setup** SmartKey, then select **Device Off**, then **Confirm**. Press any key to turn the device on again.

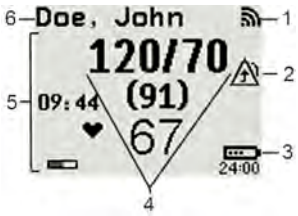
When an IntelliVue Cableless Measurement Device is not operated, it will automatically switch off the screen lighting after a short time.A little later the low-activity screen will be displayed.

Screen Layout

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

Standard Layout

When assigned to a monitor or telemetry device:



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.

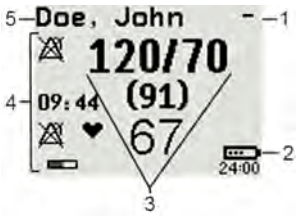
3 Battery indicator

4 Measurement values

5 Measurement-related symbols (see the measurement chapters for details)

6 Patient identification (from a monitor or telemetry device)

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 measurement chapters 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 Patient identification (from a monitor or telemetry device)

INOP Layout

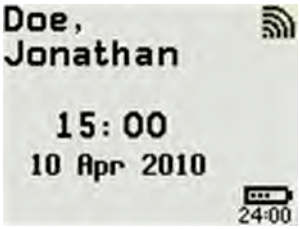
If an INOP occurs the full INOP message appears at the top of the screen. After the INOP message has been acknowledged the INOP indicator is shown as an icon on the right side of the screen.

1 Full length INOP message

2 INOP indicator

Low-Activity Screen

If the 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.



When a Cableless Measurement Device Cannot be Activated

If you cannot activate a device by pressing a key, the battery in the device may have been empty for an extended period of time. In this case, activate the device by placing it on the IntelliVue CL Charging Station and leave it there until the battery is fully charged.

Using the Hard Keys

The IntelliVue CL Cableless Measurement devices have three hardkeys: ◄, ✓, ►.

In the Main Screen, use ◄ and ► **to highlight** screen elements (e.g. numeric, battery symbol) and then ✓ **to select** that element and activate the corresponding menu.

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

✓ 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.

Using the SmartKeys

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

Smart Keys Menu

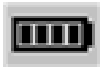
Press the ✓ hardkey (without any screen element highlighted) to get to the SmartKeys menu.

Use the ◄ and ► hardkeys to move along the row of SmartKeys. The highlighted SmartKey is displayed in full above the row of SmartKeys. When you use the ◄ or ► 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 ► hardkey for a couple of seconds to return to the Main Screen.

When the required SmartKey is highlighted, press the ✓ 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
	- start/stop manual NBP measurement - start auto series - stop current automatic measurement within series
	stop any NBP measurement and measurement series
	start NBP STAT measurement
	start venipuncture (inflate cuff to subdiastolic pressure)
	set the NBP repetition time
	start an SpO_2 measurement
	set the SpO_2 repetition time
	**Add/Remove** device
	enter Battery menu

SmartKey	Text Labels
	change Screen
	enter **Profiles** menu
	switch device off
	enter **Patient** menu

Using the Main Setup Menu

In addition to the hard keys 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_2
INOPs
Patient
Equipment
User Interface
Device Off
Profiles
Operating Modes
Date, Time
Battery
Revisions

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. **Patient Category** is the only item of patient data which can be selected 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**.

Removing a Patient From The Device

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.

Adding a New Patient to the Device

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 or to a telemetry device, 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.

Charging IntelliVue Cableless Measurement Devices

All IntelliVue Cableless Measurement Devices are battery powered and need to be recharged using the IntelliVue CL Charging Station. The battery is built in and can only be exchanged by trained service personnel.

To charge a battery, place it onto a charger slot on the charging station. The NBP Pod 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

- 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 power supply 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 both the device's and the charging station's display
- INOP messages
- battery icon on the patient monitor's screen (when assigned to a patient monitor)

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.

Charging Station LEDs

The nine charger slot LEDs show the battery status of the device in their slot, and are switched off if no device is inserted.

If an IntelliVue Cableless Measurement Device is put on a charging station slot, the corresponding LED will flash yellow until the device and its current state have been identified. Then a beep is issued and the LED reflects the device's battery status as described in the table below.

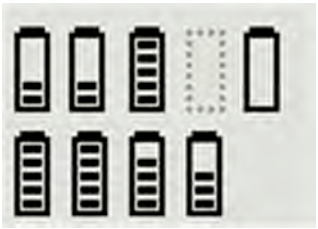
Status	LED
no device on charger slot	off
device put on charger slot	flashing yellow
device not properly recognized, error	cyan
device recognized, battery charging	yellow
device recognized, battery full (≥90%)	green

The **AC Power / Error LED** is

- green when the Charging Station is connected to AC power
- cyan during startup or to indicate a general Charging Station error

Battery Status on the Charging Station Display

The IntelliVue CL Charging Station display provides a quick overview of all the connected devices and their battery status. The screen is arranged in the same layout as the charger slots.



Battery Status on the Cableless Device

All IntelliVue Cableless Measurement Devices 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 symbol using the ◄ and ► keys, then press the ✓ key to open the **Battery** menu. The **Battery** menu provides the following information: full-charge and remaining capacity, voltage, current and temperature.

2

Monitoring with the IntelliVue Cableless Measurements

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 SpO_2 and the NBP Pods can be used together with an MP5/MP5T, MP2 or X2 patient monitor (with a 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 22.

In situations where patients are becoming more mobile (for example, in step-down/intermediate care units) the lightweight, cableless SpO_2 and NBP Pods allow increased mobility within the short range radio range, without giving up vital signs monitoring.

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

A telemetry device can be assigned to a patient monitor equipped with short range radio at the same time as any SpO_2 and NBP Pods are also assigned to this monitor.

If the connection between the monitor and the NBP Pod or SpO_2 Pod is lost, an INOP will be displayed at the monitor: **cl SpO₂ Disconnect** or **cl NBP Disconnect**. A **No System Monitor.** INOP will be displayed on the Pod.

With a Telemetry Device

The SpO_2 and the NBP Pods can be assigned to a patient with the telemetry device TRx4841A/TRx4851A. 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 23.

If the patient name is available at the Information Center, it will be also displayed on the 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 NBP Pod or SpO_2 Pod is lost, an INOP will be displayed at the Information Center: **cl SpO₂ Disconnect** or **cl NBP Disconnect**. A **No System Monitor.** INOP will be displayed on the Pod.

Device Compatibility

The Cableless Measurement Devices require the following software levels in the associated equipment:

- Patient Monitor - Release H.0 or above
- Information Center - Release M or above
- Telemetry device TRx4841A/TRx4851A - Revision D.XX

Assigning an IntelliVue Cableless Measurement Device to a Patient Monitor or Telemetry Device

When an IntelliVue Cableless Measurement Device is used with a patient monitor or telemetry device, the Cableless Measurement Device must be assigned to that monitor/telemetry device.

The assignment can be done at the Cableless Measurement Device itself (this is the only way for a telemetry device) or at the patient monitor.

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 DECT 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 Cableless Measurement Device or a **cl NBP Disconnect** or **cl SpO₂ 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 Assignment SmartKey  , or
- the connection status symbol  (or  if the device is not assigned), or
- hold the ◀ key pressed.

If the device was not assigned, 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.

A telemetry device must be put into assignment mode by pressing the ✓ key on the telemetry device before it can appear in the list. Pressing the ✓ key starts an SRR channel search to find the clearest channel available. During the search all 4 LEDs flash 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

1 Select a patient monitor or telemetry system using the ◄ and ► keys.

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 is yellow), you will need to confirm that it should be deactivated in favor of the cableless measurement device you want to assign. To do this:

1 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  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.

If the device was assigned, this opens a menu for the patient monitor or telemetry system. To unassign the measurement device from that monitor or telemetry system, select **Remove From**. After confirmation the SRR connection is disconnected.

Assignment at the Patient Monitor

The cableless measurement device must be prepared for assignment by activating the **Add/Remove** SmartKey.

At the patient monitor,

1 Open the **Add Cableless** window, e.g. using the measurement selection key followed by the **Add Cbleless** 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 in the monitor.

3 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.

Controls Available with a Patient Monitor

The controls available when the Cableless Measurement Device is assigned to a patient monitor are described in the table below.

Action	At Cableless Measurement Device	At Patient Monitor	At IIC
SpO_2			
Start SpO_2	Yes	Yes	No
Change SpO_2 Mode	Yes	Yes	No
Select SpO_2 Repetition Time	Yes	Yes	No
Assign SpO_2 Pod	Yes	Yes	No
Remove SpO_2 Pod	Yes	Yes	No
Change Alarm Limits	No	Yes	No
Place Device in Standby	No	Yes	Yes
Alarm Silence	No	Yes	Yes
Alarm Off/Pause	No	Yes	Yes
NBP			
Start/Stop/Stat NBP	Yes	Yes	Yes
Change NBP Mode	Yes	Yes	No
Change NBP Repetition Time	Yes	Yes	No
Change Alarm Limits	No	Yes	No
Assign NBP Pod	Yes	Yes	No
Remove NBP Pod	Yes	Yes	No
Place Device in Standby	No	Yes	Yes
Alarms 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 available on the Cableless Measurement Device only. They are not transmitted to the patient monitor or the Information Center. If this occurs, the **No Host Monitoring** message is displayed on the measurement device. The measurement device will also sound the INOP tone. No alarms will be available for the measurements when the devices are out of range, as alarms are only available on the patient monitor.

Keep the patient monitor with the patient during transport.

Controls Available With a Telemetry Device

The controls available when the Cableless Measurement Device is assigned to a TRx4841/TRx4851A Transceiver with a short range radio adapter (SRRA) are described in the table below.

Action	At the Cableless Measurement Device	At the IIC
SpO_2		
Start SpO_2	Yes	Yes
Change SpO_2 Mode	Yes	Yes
Select SpO_2 Repetition Time	Yes	No
Assign SpO_2 Pod	Yes	No
Remove SpO_2 Pod	Yes	Yes
Change Alarm Limits	No	Yes
Place Device in Standby	No	No
Alarm Silence	No	Yes
Alarm Off/Pause	No	Yes
NBP		
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
Alarms 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 and/or 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.

NOTE

The SpO_2 measurement sourced from the telemetry device (label: SpO_2T) has priority over the IntelliVue CL SpO_2 measurement. The SpO_2T measurement is sent to the Information Center as long as it is available and the IntelliVue CL SpO_2 measurement is available on the measurement device only.

3

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_2) - percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- Pleth waveform - visual indication of patient's pulse (only on patient monitor 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_2 and Pulse when measuring SpO_2 with the SpO_2 Pod not assigned to a host.

SpO2 Sensors

Specialized SpO_2 Sensors are available for use with the IntelliVue CL SpO_2 Pod. See “Accessories” on page 55 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

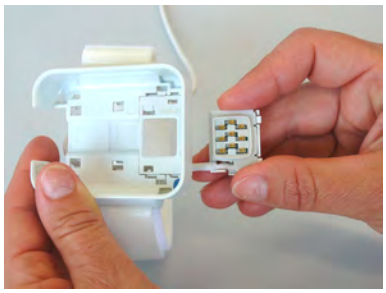
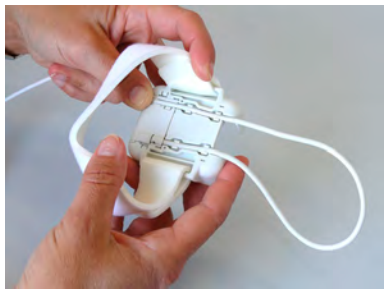
The following documents contain additional information, depending on which accessories you are using:

- Mobile CL Single-Patient SpO_2 Sensor Instructions for Use
- Mobile CL Reusable SpO_2 Sensor[1] Instructions for Use
- Mobile CL SpO_2 Wristband Instructions for Use

[1] may not be available in all geographies

Connecting SpO2 Sensors

1 Connect the sensor to the single patient Mobile CL SpO_2 Cradle (if not already connected).

2 Insert the SpO_2 Pod into the Mobile CL SpO_2 Cradle. The correct orientation is indicated by a matching blue dot inside the cradle.

CAUTION

Make sure that the contacts of the SpO_2 Pod and the sensor are dry and free of residues.

3 Secure the cradle on the patient's arm using the wristband.

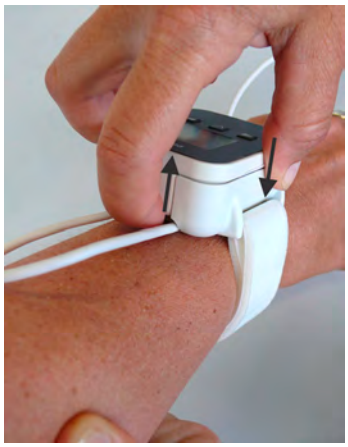
a. Feed the free end of the wristband through the slot in the cradle, starting from the underside of the cradle.

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. For large adults the little finger might be suitable.
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

Loose Sensor: 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 at least every four hours.

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

- 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_2 sensor in close proximity (e.g. when more than one SpO_2 measurement is performed on the same patient). Always cover both sensors with opaque material to reduce cross-interference.
  - Electromagnetic interference, especially at perfusion numeric values below 1.0 or signal quality indicator below medium.
  - Excessive patient movement and vibration.

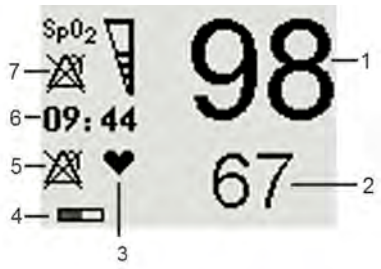
Selecting Measurement Modes

There are three different modes available for making SpO_2 measurements:

- **Continuous mode** - SpO_2 is measured continuously until the measurement is switched off.
- **Manual mode** - a single SpO_2 measurement is made when the **Start SpO2** SmartKey or the **Start SpO2** 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 one hour. After that the values are regarded as invalid and are no longer displayed.

Understanding SpO2 Numerics and Symbols



1 SpO_2 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

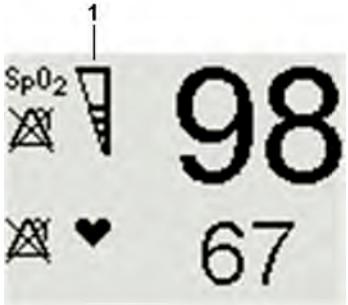
7 Alarms Off symbol for SpO_2

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 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.



1 SpO_2 Quality Indicator

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_2, 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_2, 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_2 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 Index (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 **SpO2** menu, select **Average**.

2 Select the required averaging time from the list.

Understanding SpO2 Alarms

If you are using the SpO_2 pod with an assigned patient monitor, you will see SpO_2 alarms and pulse rate alarms (if configured) on the monitor.

There is a delay between a physiological event at the measurement site and the corresponding alarm at the host system. This delay has two components:

- The general system 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 and the configured averaging time. The longer the averaging time configured, the longer the time needed until the numerical values reflect the physiological event.

- The time between the displayed numerical values crossing an alarm limit and the alarm indication on the monitor. This delay depends on the host system.

Refer to the Instructions for Use of the monitor for information about the SpO_2 and pulse rate alarms.

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.

4

Monitoring NBP

The IntelliVue CL NBP Pod uses the oscillometric method for measuring NBP. The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10:2002/(R)2008 + A1:2003/(R)2008) 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.

The accuracy of the mean arterial pressure (MAP) was validated by comparative laboratory testing to the M3000A Multi-Measurement Server using an NBP simulator and a patient signal database. The accuracy of the MAP of the M3000A was validated in a clinical evaluation using the intra-arterial reference method.

The NBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 60601-2-30:1999/EN 60601-2-30:2000.

A physician must determine the clinical significance of the NBP information.

Introducing the Oscillometric NBP Measurement

Oscillometric devices measure the amplitude of pressure changes 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.

Unattended measurement: Use clinical judgement to decide whether to perform frequent unattended blood pressure measurements in cases of severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.

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

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.

The effectiveness of this sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.

Measurement Modes

There are four modes for measuring NBP:

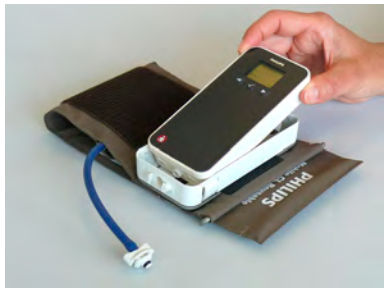
- **Manual** - measurement on demand.
- **Auto** - continually repeated measurements (between one minute and 24 hours adjustable interval).
- **Sequence** - up to four measurement cycles which will run consecutively, with number of measurements and interval between them configurable for each cycle.
- **STAT** - rapid series of measurements over a five minute period, then the monitor returns to the previous mode. Use only on supervised patients.

Reference Method

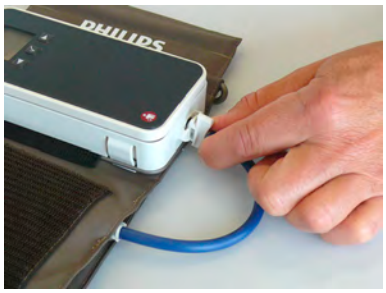
The measurement reference method is always Auscultatory (manual cuff). For further information, see the Application Note supplied on the documentation DVD.

Preparing to Measure NBP

1 Attach the cradle to the NBP cuff and insert the NBP Pod into the cradle.

2 Plug the air tubing into the NBP Pod. 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 unrestricted through the tubing.




3 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.

4 Apply the cuff to the upper arm at the same level as the heart. If it is not at heart level, you must use the measurement correction formula to correct the measurement.

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.

Apply the cuff so that the NBP Pod is located at the outside of the arm. The bladder of the cuff is then automatically over the artery. Make sure that the D-ring is not over the artery as this can lead to missing or inaccurate readings. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Inspect the application site 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.

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

Using a Carrying Pouch

As an alternative to fixing the NBP Pod on the cuff, you can insert it in a telemetry pouch which can be worn. In this case the NBP Pod is connected via an extension hose to the cuff.

1 Apply the cuff as described in step 4 above.

2 Secure the pouch on the patient, with the upper ties around the patient's head and arm and the lower ties around the patient's torso.

3 Insert the NBP Pod into the cradle.

4 Attach the extension hose to the NBP Pod in the cradle.

5 Insert the NBP cradle into the pouch

6 Connect the extension hose to the cuff.

See the Accessories chapter for ordering details for pouches and extension hose.

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/Stop	 Start/Stop
Start STAT measurement	Start NBP Stat	 Start NBP STAT
Stop Manual measurements	Start/Stop	 Start/Stop
Stop current Auto 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

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.

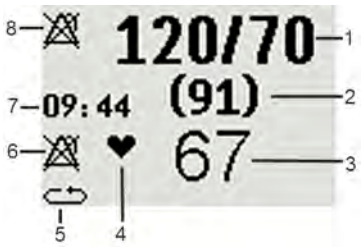
4 To have measurements continue after the sequence, set the number of measurements for your last phase to **Cont** and this phase will run indefinitely.

CAUTION

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

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

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
7 Timestamp
8 Alarms Off symbol for NBP

Note: The Alarms Off symbols indicate that no physiological alarms are available on 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 **centimeter** higher or	deduct 0.75 mmHg (0.10 kPa) for each **centimeter** lower or
add 1.9 mmHg (0.25 kPa) for each **inch** higher.	deduct 1.9 mmHg (0.25 kPa) for each **inch** lower.

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.

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 sub-diastolic 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. Cuff-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.

5

Technical Alarms (INOPs)

Technical alarms, also known as INOPs, indicate that the measuring device cannot measure reliably. If an INOP interrupts monitoring (for example, **NBP INTERRUPTED**), 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 monitor.

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

NOTE

The IntelliVue Cableless Measurements do not provide physiological alarms locally on the IntelliVue CL SpO_2 Pod and the IntelliVue CL NBP Pod.

Display of INOPs

INOP messages are shown in black on a light gray background and coded according to their severity:

A status or INOP message that appears is automatically highlighted. Use the ✓ key to acknowledge the message. An acknowledge message is displayed at the bottom of the screen and highlighted. Press ✓ again to confirm the acknowledgment of the INOP. After the confirmation, any ongoing INOP message is displayed in the icon tray on the right side of the screen.

Acknowledging an INOP

To acknowledge an INOP, select the INOP message and press the ✓ key.

This will silence the INOP tone and clear the INOP message. If the condition which caused the INOP is still present, the INOP icon will be displayed on the right hand side of the screen (see “INOP Layout” on page 12).

Displaying a List of Current INOPs

To display a list of the currently active INOPs,

1 Select the **Main Setup** SmartKey.

2 Select **INOPs**.

3 Select **INOP Messages** Messages

Setting the Volume of the INOP Tone

To set the volume for the INOP tone,

1 Select the **Main Setup** SmartKey.

2 Select **INOPs**.

3 Select **Inop Vol** and select a volume setting.The maximum is 10 and the minimum depends on your configuration.

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.
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.
Check Settings 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.

INOP Message, Indication	Source	What to do
cl NBP Disconnect at Information Center or at patient monitor	Cableless Measurement Device	The NBP Pod has lost the SRR connection to the telemetry device or the patient monitor.
cl SpO_2 Disconnect at Information Center or at patient monitor	Cableless Measurement Device	The SpO_2 Pod has lost the SRR connection to the telemetry device or the patient monitor.
CUFF NOT DEFLATED Numeric is replaced by -?- INOP tone During this INOP, alarms cannot be paused or switched off.	NBP	The NBP cuff pressure has exceeded 15mmHg (2kPa) for more than 3 minutes. 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 **Stop All** SmartKey is selected.
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 **Stop All** SmartKey is selected.
NBP EQUIP MALF 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 **Stop All** 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 **Stop All** SmartKey is selected. This INOP arises when the measurement needed longer than the maximum time for inflation, deflation or the total measurement.
NBP MEASURE FAILED 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 **Stop All** SmartKey is selected. Check the condition and suitability of the patient for NBP monitoring. Use another cuff to continue measuring.

INOP Message, Indication	Source	What to do
NBP Neo Patient? 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.
No Cradle 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 **Stop All** SmartKey is selected. If INOP appears with the NBP Pod inserted into the cradle, remove and replace the cradle.
No Host Monitoring 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 Monitor.	Cableless Measurement Device	There is a problem with the communication to the network and central monitoring is currently not possible. Check the connection. Contact your service personnel.
Remove From Pat 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	SpO_2	The SpO_2 Pod is faulty. Contact your service personnel.
<SpO₂ Label> ERRATIC Numeric is replaced by -?- INOP tone	SpO_2	Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
<SpO₂ Label> EXTD.UPDATE Numeric is replaced by -?-	SpO_2	The update time for displayed values is extended due to an NBP measurement on the same limb or an excessively noisy signal.
<SpO₂ Label> INTERFERNCE Numeric is replaced by -?- INOP tone	SpO_2	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.
<SpO₂ Label> LOW PERF Numeric is replaced by -?-	SpO_2	Accuracy may be compromised due to very low perfusion. Stimulate circulation at sensor site. If INOP persists, change the measurement site.
<SpO₂ Label> NeoPatient? Numeric is replaced by -?- INOP tone	SpO_2	The patient monitor the SpO_2 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
<SpO₂ Label> NO SENSOR Numeric is replaced by -?- INOP tone	SpO_2	Make sure the 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> NOISY SIGN. Numeric is replaced by -?- INOP tone	SpO_2	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> NON-PULSAT. Numeric is replaced by -?- INOP tone	SpO_2	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> POOR SIGNAL	SpO_2	The signal quality of the SpO_2 measurement is poor. The accuracy may be compromised.
<SpO₂ Label> PULSE? Numeric is replaced by -?- INOP tone	SpO_2	The detectable pulsations of the SpO_2 signal are outside the specified pulse rate range.
<SpO₂ Label> SEARCHING Numeric is unavailable	SpO_2	The patient signal is analyzed, but no valid numerics are available yet.
<SpO₂ Label> SENSOR MALF Numeric is replaced by -?- INOP tone	SpO_2	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	SpO_2	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	SpO_2	The connected SpO_2 sensor is not supported by this measurement hardware.
<SpO₂ Label> UPGRADE Numeric is replaced by -?-	SpO_2	SpO_2 in upgrade mode, no patient monitoring possible.

5 Technical Alarms (INOPs)

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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.

Cleaning and Disinfecting the IntelliVue Cableless Measurements

The following instructions apply to the IntelliVue CL SpO_2 Pod, the IntelliVue CL NBP Pod, the corresponding single patient Mobile CL Cradles and the IntelliVue CL Charging Station. Clean with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap, a diluted non-caustic 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 Pods. Do not put the Pods in a microwave.

No sterilizing: Do not put the Pods in an autoclave, the devices are not sterilizable.

Rinse the SpO_2 Pod and the NBP Pod 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_2 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_2 sensors, NBP cuffs and hoses.

Recommended Disinfection Agents

We recommend that you use one of the following disinfectants:

Product Name	Product Type	Ingredients
Isopropanol	liquid	Isopropanol 80%
Bacillol® AF	liquid, spray	100 g concentrate contains: Propan-1-ol 45.0 g; Propan-2-ol 25.0 g; Ethanol 4.7 g
Bacillol®25	liquid	Ethanol 100 mg/g Propan-2-ol (= 2-Propanol) 90 mg/g; Propan-1-ol (= 1-Propanol) 60 mg/g
Meliseptol®	spray	50% 1-Propanol
Accel TB RTU	liquid	0.5% accelerated hydrogen peroxide
Oxivir® Tb Cleaner Disinfectant	spray	0.5% accelerated hydrogen peroxide
Oxivir® Tb Wipes	wipes	0.5% accelerated hydrogen peroxide

Product Name	Product Type	Ingredients
Carpe Diem$^{TM/MC}$ Tb Ready-to-Use General Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	spray	0.5% accelerated hydrogen peroxide
Carpe Diem$^{TM/MC}$ Tb Wipes	wipes	0.5% accelerated hydrogen peroxide
Super Sani-Cloth Germicidal Disposable Wipes	wipes	isopropanol 55% quaternary ammonium chlorides 0.5%
SANI-CLOTH® PLUS Germicidal Disposable Wipes	wipes	isopropanol 15% quaternary ammonium chlorides 0.25%
SANI-CLOTH® HB Germicidal Germicidal Disposable Wipes	wipes	isopropanol < 0.15% quaternary ammonium chlorides 0.14%

Refer to the accessory Instructions for Use for cleaning and disinfection information for SpO_2 sensors, NBP cuffs and hoses.

6 Care and Cleaning

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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.

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:

http://www.healthcare.philips.com/in_en/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.

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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 switch 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 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°C (-4°F) to 60°C(140°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.

The age of a lithium ion battery begins at the date of manufacture. To see the date of manufacture and the number of charge-discharge cycles:

1 Select the battery symbol on the Main Screen.

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.

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Accessories

You can order parts and accessories from Philips supplies at www.medical.philips.com or consult your local Philips representative for details.

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 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.

Order Number	Description	Contents
989803165941	Mobile CL 20 **single patient** SpO_2 Sensors and Cradles for use on pediatric and adult patients >10kg	20 Single-Patient Mobile CL $DSpO_2$-1A Sensors 20 Single-Patient Wristbands 20 Single-Patient Cradles pre-assembled
989803165921	Mobile CL 20 **single patient** SpO_2 Sensors for use on pediatric and adult patients >10kg	20 Single-Patient Mobile CL $DSpO_2$-1A Sensors

Order Number	Description	Contents
989803165931[1]	Mobile CL **reusable** SpO_2 sensor and Cradles for use on pediatric and adult patients >15kg	1 Reusable Mobile CL $RSpO_2$-1A Sensor 20 Single-Patient Cradles with pre-attached Wristbands
989803165951	Mobile CL 20 SpO_2 Cradles (**single patient**)	20 Single-Patient Cradles with pre-attached Wristbands
989803165961	Mobile CL 50 SpO_2 Wristbands (**single patient**)	50 Single-Patient Wristbands
989803168861	Mobile CL SpO_2 Battery Kit	1 Battery 1 disassembly tool 1 front housing

[1] May not be available in all geographies

IntelliVue CL NBP Pod Accessories

Order Number	Description	Limb Circumference Range	Bladder Width	Contents
989803163171	Mobile CL Reusable Small Adult Cuff	21 - 27 cm	10.5 cm	1 cuff
989803163191	Mobile CL Reusable Adult Cuff	26.0 - 34.5 cm	13.0 cm	1 cuff
989803163211	Mobile CL Reusable Large Adult Cuff	33.5 - 45.0 cm	16.0 cm	1 cuff
989803163181	Mobile CL Single-Patient Small Adult Cuff	21 - 27 cm	10.5 cm	20 cuffs
989803163201	Mobile CL Single-Patient Adult Cuff	26.0 - 34.5 cm	13.0 cm	20 cuffs
989803163221	Mobile CL Single-Patient Large Adult Cuff	33.5 - 45.0 cm	16.0 cm	20 cuffs
989803163251	Mobile CL NBP Cradle Kit	-	-	20 cradles
989803163131	Mobile CL Extension Air Hose, 1.0 m	-	-	1 extension air hose
989803163261	Mobile CL NBP Battery Kit	-	-	1 Battery 1 disassembly tool 1 front housing

Order Number	Description	Limb Circumference Range	Bladder Width	Contents
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

Miscellaneous Accessories

IntelliVue CL Transmitter Base Station - Product Number 865237

Used for service-related activities, refer to IntelliVue Cableless Measurements Service Guide for details.

WARNING

The IntelliVue CL Transmitter Base Station may not be operated 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.

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 charging station, as the data may be damaged.

9 Accessories

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Specifications

The specifications in this section apply to the IntelliVue CL SpO_2 Pod, the IntelliVue CL NBP Pod, IntelliVue CL Charging Station and the IntelliVue CL Transmitter.

The IntelliVue Cableless Measurements 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.

Intended Use

IntelliVue CL SpO_2 Pod:

The intended use of the IntelliVue CL SpO_2 Pod when used together with IntelliVue Patient Monitors MP5/MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A/TRx4851A is for monitoring, recording, and alarming arterial oxygen saturation and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is NOT intended for home use.

The IntelliVue CL SpO_2 Pod is not a therapeutic device.

IntelliVue CL NBP Pod:

The intended use of the IntelliVue CL NBP Pod when used together with IntelliVue Patient Monitors MP5/MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A/TRx4851A, is for monitoring, recording, and alarming of systolic, diastolic and mean pressure and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is NOT intended for home use.

The IntelliVue CL NBP Pod is not a therapeutic device.

Rx only: US Federal Law restricts these devices to sale by or on the order of a physician.

Manufacturer's Information

You can write to **Philips** at this address

Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
71034 Boeblingen
Germany

Visit our website at: www.healthcare.philips.com/us/.

Symbols

These symbols can appear on the cableless measurement devices and associated equipment.

Symbols					
	Caution, consult accompanying documents		Refer to accompanying documents		Protective earth
	Equipotential grounding		Alternating current		Connector has special protection against electric shocks and is defibrillator proof
	Error LED		Built-in wireless network (WLAN)		USB interface
	Non-ionizing radiation symbol		NBP identifier		SpO_2 identifier
	Always use separate collection for waste electrical and electronic equipment (WEEE)		Identifies year and month of manufacture		Indicates location of the date of manufacture and/or name and address of manufacturer
	Indicates location of serial number		Indicates location of catalog number		Indicates location of service number
IP	Indicates location of ingress protection grade				

Installation Safety Information

Grounding	The charging station must be grounded during operation. If a three-wire receptacle is not available, consult the hospital electrician. Never use a three-wire to two-wire adapter.
Equipotential Grounding	If the charging station is used in an OR, ensure that the room incorporates an equipotential grounding system to which the charger has a connection.
Combining Equipment	Combinations of medical equipment with non-medical equipment must comply with IEC 60601-1-1. Never use a multiple portable socket-outlet or extension cord when combining equipment unless the socket outlet is supplied specifically for use with that equipment.
Fusing	The charging station uses double pole/neutral fusing.

Safety Specifications

IntelliVue CL SpO_2 Pod, CL NBP Pod:

CE 0366

CL Charging Station, CL Transmitter:

CE

The devices comply with the Medical Device Directive 93/42/EEC.

In addition, the devices comply with:

IEC 60601-1:1988 + A1:1991 + A2:1995; EN60601-1:1990 + A1:1993 + A2:1995; UL 60601-1:2003; CAN/CSA C22.2#601.1-M90 + S1 + A2; JIS T 0601-1:1999; IEC 60601-1-1:2000; EN 60601-1-1:2001; IEC 60601-1-2:2001 + A1 2004; EN 60601-1-2:2001 + A1 2004.

The possibility of hazards arising from software errors was minimized in compliance with ISO 14971:2007, EN60601-1-4:1996 + A1:1999 and IEC 60601-1-4:1996 + A1:1999.

Classification (according to IEC 60601-1):

IntelliVue CL SpO_2 Pod, CL NBP Pod, CL Transmitter: Class II, Type CF, Continuous Operation

IntelliVue CL Charging Station: Class I, Continuous Operation

EMC And Radio Regulatory Compliance

FCC and Industry Canada Radio Compliance

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme a la norme NMB-001 du Canada.

This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device 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 radio frequency interference and void your authority to operate this equipment.

Devices Including the Short Range Radio Interface

CE Philips Medizin Systeme Boeblingen GmbH hereby declares that the radio component used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive). Class 1 radio equipment.

In addition the product complies with: ETSI EN 300 328; AS/NZS 4771+A1; ARIB STD-T66.

To obtain a copy of the original Declaration of Conformity, please contact Philips at the address as stated in the "Manufacturer's Information" section of these Instructions for Use.

WARNING

- This equipment generates, uses and radiates radio-frequency 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.

IntelliVue 802.11 WLAN Adapter

FCC and Industry Canada Radio Compliance: This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device 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 radio frequency interference and void your authority to operate this equipment.

The maximum antenna gain permitted (for devices in the 5250-5350 MHz and 5470-5725 MHz bands) 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.

The OEM radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. This product is intended to be connected to the Publicly Available Interfaces (PAI) and used throughout the EEA.

CAUTION

High power radars are allocated as primary users (meaning they have priority) of 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and /or damage to LE-LAN devices.

IntelliVue 802.11 WLAN Adapter CE compliances:

CE This device is compliant to Council Directive 73/23/EEC (Low voltage directive) & 89/336/EEC (EMC directive) & 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive)

CE ! The radio component contained in this device is compliant to Council Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive)

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 10mm from the body and itself contains no metal parts. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

IntelliVue CL SpO2 Pod Specifications

Complies with ISO 9919:2005 / EN ISO 9919:2009.

Physical Specifications	
Size (W X D X H)	53.5 mm x 65 mm x 27 mm ±5% (without cradle and sensor)
Weight	80 g ±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 1m drop
Ingress Protection	IP34 according to IEC 60529 (protection against ingress of water when water drips, falls or splashes from any direction)

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_2 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_2	
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 $DSpO_2$-1A single patient sensor: 3% (70 to 100%) Mobile CL $RSpO_2$-1A reusable sensor: 3% (70 to 100%)
Resolution	1%
Pulse Oximeter Calibration Range	70% to 100%
Pulse	
Measurement Range	30 to 300 bpm
Accuracy	±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 Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed)	500 to 1000 nm
For further information on accessory specifications, refer to the accessory Instructions for Use.	
Display Specifications	
Type	monochrome (4 gray scales), passive LCD (STN), positive/transflective

Performance Specifications	
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 INOP tone
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter
Runtime (fully charged battery)	**Continuous measurement:** Typically 24 hours Minimum 12 hours **Intermittent measurement:** Typically > 32 hours with repetition interval of 2.5 minutes
Charging Time	max 2.5 hours
Short Range Radio Specifications	
Type	built in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency band	2.4 GHz ISM (2.400 - 2.483 GHz)
Modulation	DSSS (O-QPSK)
Receiver 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	less than 5 seconds per day (typically) as long as device is in power state "Device on" or "Device off". Automatically synchronized with assigned patient monitor/telemetry device.

IntelliVue CL NBP Pod Specifications

Complies with IEC 60601-2-30:1999/EN 60601-2-30:2000.

NOTE

The effectiveness of this sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.

Physical Specifications	
Size (H x W x D)	138 x 65 x 30.5 mm ±5% (without cradle and cuff)
Weight	220 g ±10% (without cradle and cuff)
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 monitor 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)
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

IntelliVue CL NBP Pod Performance Specifications	
Display Specifications	
Type	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 done tone INOP tone
Battery	Integrated rechargeable Li-Ion battery with battery gauge and cycle counter

IntelliVue CL NBP Pod Performance Specifications	
Runtime (fully charged battery)	Minimum 8 hours @ 4 measurements per hour Typical 24 hours @ 2 measurements per hour
Battery Recharge Time	Maximum 2.5 hours
Short Range Radio Specifications	
Type	built in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency band	2.4 GHz ISM (2.400 - 2.483 GHz)
Modulation	DSSS (O-QPSK)
Receiver 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	less than 5 seconds per day (typically) as long as device is in power state "Device on" or "Device off". Automatically synchronized with assigned patient monitor/telemetry device.
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)
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	According to ANSI/AAMI SP10:2002/(R)2008 + A1:2003 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)

IntelliVue CL NBP Pod Performance Specifications	
Measurement Time	Auto/manual/sequence mode: Typical 40 seconds @ >60 bpm and normal adult cuff Maximum 180 seconds STAT 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

Measurement Validation: The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10:2002/(R)2008 + A1:2003/(R)2008) in relation to mean error and standard deviation, when compared to auscultatory measurements in representative patient population. For the auscultatory reference the 5th Korotkoff sound was used to determine the diastolic pressure.

Alarm Specifications

When the Cableless Measurement Devices are used alone, without an assignment to a monitor or telemetry device, **no patient alarms will be generated**.

When the Cableless Measurement Devices are assigned to a monitor or telemetry device, alarms may be announced at the host device (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_2/NBP Pod connected Telemetry Device is host to CL SpO_2/NBP Pod	20 hours
ECG/SpO_2 (continuous) Telemetry Device with internal SpO_2 running in continuous mode and CL SpO_2/NBP Pod connected Telemetry Device is host to CL SpO_2/NBP Pod	8 hours

IntelliVue CL Charging Station Specifications

The IntelliVue CL Charging Station is intended for recharging and performing battery maintenance procedures for the IntelliVue Cableless Measurement devices. The IntelliVue CL Charging Station is intended for use in medically used rooms (including use within the patient vicinity) which fulfill the requirements regarding electrical installation according to IEC 60364-7-710 "Requirements for special installations or locations - Medical locations", or corresponding local regulations.

Physical Specifications	
Size (W X D X H)	343 mm x 172 mm x 117 mm ±5%
Weight	2000 g ±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

Environmental Specifications	
Operating Temperature Range	0 to 35°C (32 to 104°F) A temperature-controlled fan becomes active at operating temperatures above 30°C (typical)
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

Performance Specifications	
Display Specifications	
Type	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
Sounds	Hardkey operation tone
Charging Current (all slots)	max. 4.8A (24W @5V)
Charging Current (one slot)	max. 2A (10W @ 5V)
Mains Power	50/60 Hz; 1.3 - 0.7A; 100 - 240V~
USB Downstream	Standard: USB 2.0 low/full speed Host Port Power Output: 5V ± 5%, 500 mA max Connector: USB series "Standard-A" receptacle
USB Upstream	Standard: USB 2.0 full speed Device Port Power input: "self powered device" Connector: USB series "Standard-B" receptacle

IntelliVue CL Transmitter Base Station Specifications

Physical Specifications	
Size (W X D X H)	75 mm x 173 mm x 45 mm ±5%
Weight	210 g ±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 IEC60529 (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
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)	5V ±10%
Power output (USB powered)	USB input voltage - 100mV (@500mA)
Communication	USB 2.0 full speed
USB Interface	
Standard	USB 2.0 full speed Device Port
Power Input	4.5V - 5.5V (8W)
Connector	USB series “Standard-B” receptacle
Network	
Standards	IEEE 802.3 10-Base-T, IEEE 802.3af (PoE Class 3)
Connector	RJ45 (8 pin)
External AC/DC 5V requirements (connection to USB)	
Output voltage	5V +/-5%
Power output	min. 8 W
Isolation	double according to IEC60950-1 Class II
Classification	Limited Power Source according to IEC60950-1
External AC/DC 48V requirements (connection to RJ45)	
Output Voltage	48V +/-10%
Power output	min. 8 W
Compliancy	IEEE 802.3af (PoE Class 3)
Isolation	double according to IEC60950-1 Class II
Classification	Limited Power Source according to IEC60950-1
Connector	RJ45 (Data-in), RJ45 (Data&Power Out)

Safety and Performance Tests

You must observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. See the maintenance section for a list of required tests. Safety and performance tests, and what to do if the instrument does not meet these specifications, are described in the IntelliVue Cableless Measurements Service Guide.

Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using the IntelliVue Cableless Measurements. You must operate your IntelliVue Cableless Measurements according to the EMC information provided in this book and in the Cableless Measurements Service Guide. Portable and mobile radio frequency (RF) communications equipment can affect the IntelliVue Cableless Measurements.

WARNING

For paced patients: The output power of the Pods' SRR transceivers and other sources of radio frequency 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 Pods in very close proximity of a pacemaker. Consult the pacemaker manufacturer for information on the RF susceptibility of their products.

Accessories Compliant with EMC Standards

All IntelliVue CL SpO_2 Pod and CL NBP Pod accessories comply, in combination with the IntelliVue Cableless Measurements, with the requirements of IEC 60601-1-2:2001 + A1:2004.

WARNING

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the IntelliVue Cableless Measurements.

Electrosurgery Interference/Defibrillation

Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to X-ray or strong magnetic fields (MRI).

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