

**PHILIPS**

APR 12 2013

**510(k) Summary**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

## 1. The submitter of this Premarket Notification is:

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This summary was prepared on March 14, 2013.

## 2. The name of the device:

## New device:

Trade name: IntelliVue CL Respiration Pod  
 Common name: Telemetry Transceiver

## Modified devices:

Trade name: Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC  
 Common name: Multiparameter Patient Monitors

Trade name: IntelliVue GuardianSoftware  
 Common name: Clinical Information Management System

## Classification of the new IntelliVue CL Respiration Pod:

Device Panel	Classification	ProCode	Description
Anesthesiology Devices	§868.2375, II	BZQ	<b>Monitor, Breathing Frequency</b>
Cardiovascular Devices	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
	-	MSX	System, Network and Communication, Physiological Monitors

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Classification of the modified IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	S870.2700, II	DQA	Oximeter
	S870.1025, II	DSI	Detector and alarm, arrhythmia
	S870.1025, II	MLD	Monitor, ST Segment with Alarm
	S870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	S870.1100, II	DSJ	Alarm, Blood Pressure
	S870.1110, II	DSK	Computer, Blood Pressure
	S870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	S870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	S870.1915, II	KRB	Probe, Thermodilution
	S870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	S870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	S870.2340, II	DPS	Electrocardiograph
	S870.2340, II	MLC	Monitor, ST Segment
	S870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	S870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	S870.2600, I	DRJ	System, Signal Isolation
	S870.2770, II	DSB	Plethysmograph, Impedance
	S870.2800, II	DSH	Recorder, Magnetic tape, Medical
	S870.2810, I	DSF	Recorder, Paper Chart
	S870.2850, II	DRS	Extravascular Blood Pressure Transducer
	S870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	S870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency

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Device Panel	Classification	ProCode	Description
	\$868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
Anesthesiology Devices	\$868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	\$868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	\$868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	\$868.1880, II	BZC	Data calculator Pulmonary-function
	\$868.2375, II	BZQ	Monitor, Breathing Frequency
	\$868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	\$868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	\$880.2910, II	FLL	Thermometer, Electronic, Clinical

Classification of the modified IntelliVue GuardianSoftware:

Device Panel	Classification	ProCode	Description
General Hospital	not classified	NSX	Software, transmission and storage, patient data
Cardiovascular Devices	\$870.2450, II	DXJ	Display, cathode-ray tube, medical

3. The new Philips IntelliVue CL Respiration Pod (SW Rev. B.0) is with respect to the respiration rate and pulse rate substantially equivalent to the previously cleared Philips IntelliVue Patient Monitor MP2 marketed pursuant to K113657, K113441, K110622, K102562, K083517, K082633, K072070, K071426.

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With respect to the basic patient posture the new CL Respiration Pod is substantially equivalent to the Respironics Alice PDx marketed pursuant to K090484.

With respect to the activity feature that provides the approximate activity status of the patient, the new CL Respiration Pod is substantially equivalent to the Respironics Actical marketed pursuant to K060919.

The modified Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, and MP5SC (SW Rev. J.07) are substantially equivalent to the previously cleared IntelliVue Patient Monitors MP2, X2, MP5, MP5T, and MP5SC (SW Rev. J.03) marketed pursuant to K113657, K113441, K110622, K102562, K091395, K083228, K081793, K063725, K062392, K083517, K082633, K072070, and K071426.

The modified Philips IntelliVue GuardianSoftware (SW Rev. A.02) is substantially equivalent to the previously cleared IntelliVue GuardianSoftware marketed pursuant to K111905.

#### 4. Description of the device

The new IntelliVue CL Respiration Pod is a small body-worn, cableless, battery powered, respiration rate and pulse rate measuring and intermittent monitoring device. It uses specifically designed adhesive attachment (Mobile CL Resp Attachment), which holds the CL Respiration Pod at the patient chest.

The CL Respiration Pod provides and communicates measurements values and other information (e.g. battery state) wirelessly via Short Range Radio (SRR) to an assigned compatible IntelliVue Patient Monitor or IntelliVue GuardianSoftware. It can also provide basic information on posture (like supine, prone, upright etc.) and activity status of the patient. The CL Respiration Pod can be controlled from the assigned IntelliVue Patient Monitor or IntelliVue GuardianSoftware.

The modified IntelliVue Patient Monitor models MP2, X2, MP5, MP5T, and MP5SC consist of a display unit including built-in central processing unit (CPU) and multiple physiological measurements. All monitors share the same architecture of CPU units and exactly the same software is executed on each monitor.

The monitors measure physiological parameters such as: SpO<sub>2</sub>, pulse, ECG, arrhythmia, ST, QT, respiration, invasive and non-invasive blood pressure, temperature, CO<sub>2</sub>, spirometry, C.O., CCO, and BIS. They generate alarms, record physiological signals, store derived data, and communicate derived data and alarms to the central station. These monitor models are robust, portable, lightweight, compact in size and modular in design, with interfaces to dedicated external measurement devices.

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The modified IntelliVue GuardianSoftware is a Clinical Information Management System. It collects and manages vital signs data acquired from the IntelliVue Cableless Measurements and IntelliVue patient monitors. The IntelliVue GuardianSoftware provides trending, review, reporting, notification, clinical documentation, calculations, clinical advisories including EWS deterioration status, remote viewing and operating, interfacing, storage, and printing. The IntelliVue GuardianSoftware is software only product intended to be installed on a customer supplied PC or Server.

## 5. Intended Use

Intended Use of the new Philips IntelliVue CL Respiration Pod:

The IntelliVue CL Respiration Pod is indicated for use by health care professionals whenever there is a need for intermittent or spot-check acquisition and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms. It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms.

The intended use of the IntelliVue CL Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate alarms for, respiration rate and pulse rate of adult patients.

The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult patients for a clinical information management system.

The IntelliVue CL Respiration Pod is intended for use by health care professionals. It is not intended for home use. It is not a therapeutic device.

The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm).

The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate). For monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor.

### Warning:

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

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The Intended Use and Indications for use of the modified Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, and MP5SC have not changed as a result of the device modification.

The devices have the following detailed Indications for Use Statements in their Instructions for Use:

## Models MP2 and X2:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.

The monitor is also intended for use during patient transport inside and outside of the hospital environment.

The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

## Models MP5, MP5T, and MP5SC:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

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The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

The Intended Use and Indications for use of the modified Philips IntelliVue GuardianSoftware have not changed as a result of the device modification.

The device has the following detailed Indications for Use Statements in its Instructions for Use:

The IntelliVue GuardianSoftware is indicated for use by healthcare providers whenever there is a need for generation of a patient record.

The IntelliVue GuardianSoftware is intended for use in the collection, storage and management of data from IntelliVue Cableless Measurements and IntelliVue Patient Monitors that are connected through networks.

## 6. Technological Characteristics

The new IntelliVue CL Respiration Pod has substantially equivalent technological characteristics, such as design, materials, energy source, portability, user interface, radio technology, measurement principle, as the legally marketed predicate devices.

The new CL Respiration Pod is a small, battery powered, wireless, and body worn respiration and pulse rate measuring and monitoring device. It is attached to the patient's left costal arch using a specialized accessory, the adhesive Mobile CL Resp Attachment. The CL Respiration Pod has a multicolor LED and a single key to display states and allow basic operation locally. The CL Respiration Pod is connected during its use wirelessly via SRR to a compatible IntelliVue Patient Monitor or IntelliVue GuardianSoftware.

The new CL Respiration Pod uses a measurement principle that is based on the thoracic movements. Inclination changes of the incorporated accelerometer sensor, caused by chest and abdomen movements during breathing and heart contraction, produce a voltage signal, from which respiration and pulse rate signals are derived.

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The CL Respiration Pod uses the same measurement principle (respiratory effort and heart contraction/beating) to derive the respiration and pulse signal as the predicate Philips IntelliVue Patient Monitor MP2. Instead of two ECG electrodes that measure impedance and body surface electrical potential, the CL Respiration Pod measures a voltage generated in the accelerometer sensor.

With the means of the built-in accelerometer sensor, the CL Respiration Pod can detect basic posture and activity status of the patient. This is the same technology as used in the legally marketed predicate Respiroics Alice PDX for the patient posture detection (K090484) and in the Respiroics Actical for the activity detection (K060919).

The modification to the IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, and the IntelliVue GuardianSoftware, which is subject of this premarket notification, is solely limited to a minor software adaptation necessary to support the use of these devices together with the new IntelliVue CL Respiration Pod. This minor change does not affect the technological characteristics.

## 7. Summary of V&V activities

- Non-Clinical Performance Tests (bench testing):  
Verification of respiration rate and pulse rate range, accuracy, resolution and signal quality, by comparison of the reported respiration and pulse rate with the simulated values. The test results have shown that the respiration rate and pulse rate accuracy, resolution, and signal quality met in the whole measurement range the defined specifications. The CL Respiration Pod is substantially equivalent to the predicate IntelliVue Patient Monitor MP2 with respect to these measurement parameters.
- Verification and validation of basic patient posture and activity by comparison of determined values against the specifications and by comparison of the new IntelliVue CL Respiration Pod with the predicate devices Respiroics Alice PDX and Actical. The tests have been performed as bench tests and as validation with test persons. The test results demonstrate the substantial equivalency of the CL Respiration Pod with the respective predicate devices with regard to the measurement parameters patient posture and activity.
- Clinical Performance Tests  
To determine substantial equivalence of the new IntelliVue CL Respiration Pod with the predicate IntelliVue Patient Monitor MP2 with respect to the physiological measurement parameters respiration rate and pulse rate, clinical performance testing has been conducted.

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The clinical testing comprised two test series. In the first series of tests a complete head to head comparison of the subject device's respiration rate and pulse rate with the predicate device's respiration rate and heart rate was performed. 39 patients (26 male and 13 female) aged between 16 and 86 years were evaluated.

A head to head comparison between the subject device's pulse rate and the predicate device's heart rate on patients with rapid, irregular heart rates greater than 110bpm was not performed. The measurement data was analyzed using the Bland-Altman statistical method. The low standard deviation (less than 2rpm for respiration rate and less than 3bpm for pulse rate respectively heart rate) between the subject device and the predicate demonstrates that the new CL Respiration Pod measures respiration rate and pulse rate as accurate as the predicate MP2 monitor in the specified measurement range.

In the second series of clinical tests the pulse rate calculation algorithm of the subject device has additionally been validated using annotated ECG traces from the AHA arrhythmia database. Eight 35min episodes in the database showing irregularity in heart rate were selected. The curve progression of the pulse rate traces of the subject device and the heart rate traces of the predicate device were analyzed. The similarity of the curve progression demonstrates that for the applied irregular heart rate episodes the pulse rate calculation of the CL Respiration Pod performs as accurate as that of the predicate MP2 monitor. The performed clinical performance validation testing demonstrates the substantial equivalence of the IntelliVue CL Respiration Pod with the predicate IntelliVue Patient Monitor MP2 with respect to the respiration and pulse rate in the specified measurement ranges, i.e. 5 to 60rpm for the respiration rate, 30 to 220bpm for the pulse rate, and 30 to 110bpm for the pulse rate of patients with rapid, irregular heart rates.

- Clinical Usability Testing to evaluate acceptance and effectiveness of the design and implementation of the new CL Respiration Pod and to evaluate wearing comfort and user friendliness of its specialized accessory the Mobile CL Resp Attachment. All defined pass criteria have been met.
- Testing according to the recognized consensus standards:
  - IEC 60601-1-2:2007, Ed.3 (Electromagnetic Compatibility),
  - AAMI/ANSI ES 60601-1:2005 (Basic safety and essential performance),
  - IEC 62304:2006, Ed.1.0 (Software life cycle processes),
  - IEC 60601-1-8:2006, Ed.2 (Alarms)All applicable requirements have been met.
- Testing as identified in the Hazard Analysis. All specified pass/fail criteria have been met. The test results have confirmed the effectiveness of implemented design risk mitigation measures.

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- Functionality testing on the new IntelliVue CL Respiration Pod, the modified IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC and the IntelliVue GuardianSoftware. All specified criteria have been met. The test results have confirmed that the Respiration Pod and the compatible devices have functioned safe, effective and according to the specifications and Instructions for Use in the intended environment of use.
- Regression testing of the related, unchanged parts of the modified IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC and the IntelliVue GuardianSoftware. All specified criteria have been met. The test results have confirmed that the modified devices have functioned safe, effective and according to the specifications and Instructions for Use in the intended environment of use.
- Environmental testing (temperature, humidity, and altitude), mechanical testing (shock, vibration, and free fall) and ingress protection testing. All specified test requirements have been met. The test have confirmed that the CL Respiration Pod worked safely and according to the specifications during or after tests simulating general hospital conditions, transport in hospital environments, rough handling, and storage.
- Radio Frequency (RF) wireless communication testing on the new CL Respiration Pod with the compatible medical devices based on the FDA guidance document 'Radio-Frequency Wireless Technology in Medical Devices'. All specified test requirements have been met. The test results have confirmed that radio related functions have worked correctly, reliable and in accordance to their specifications in the intended environment of use.

## 8. Conclusion

Verification and validation testing activities were conducted to establish the performance, safety, functionality, usability, effectiveness, and reliability characteristics of the new and modified devices.

V&V testing included clinical and bench performance tests, clinical usability, electrical safety, EMC, system level, functionality and regression, environmental, mechanical, and radio tests.

All clinical and non-clinical tests were successfully completed.

The results demonstrate that the new Philips IntelliVue CL Respiration Pod, its specialized accessory Mobile CL Resp Attachment, and the modified compatible IntelliVue Patient Monitors and IntelliVue GuardianSoftware are as safe, as effective and perform as well as the predicate devices.

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The new and modified devices are substantially equivalent in intended use and fundamental technological characteristics to the appropriate predicate devices. The devices introduce no new questions concerning the safety or efficacy and are, therefore, substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

April 12, 2013

Mr. Markus Stacha  
Philips Medizin Systeme Boeblingen GmbH  
Hewlett-Packard-Street 2  
Boeblingen, Germany D-71034

Re: K122223

Trade/Device Name: Philips IntelliVue CL Respiration Pod  
Philips IntelliVue Patient Monitors MP2, X2  
Philips IntelliVue Patient Monitors MP5, MP5T, MP5SC  
Philips IntelliVue GuardianSoftware

Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing Frequency Monitor  
Regulatory Class: II  
Product Code: BZQ  
Dated: March 14, 2013  
Received: March 18, 2013

Dear Mr. Stacha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

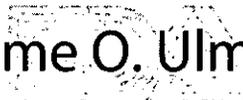
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122223

**Device Name:**

- Philips IntelliVue CL Respiration Pod
- Philips IntelliVue Patient Monitors MP2, X2
- Philips IntelliVue Patient Monitors MP5, MP5T, MP5SC
- Philips IntelliVue GuardianSoftware

**IntelliVue CL Respiration Pod:**

The IntelliVue CL Respiration Pod is indicated for use by health care professionals whenever there is a need for intermittent or spot-check acquisition and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms. It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms.

The intended use of the IntelliVue CL Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate alarms for, respiration rate and pulse rate of adult patients.

The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult patients for a clinical information management system.

The IntelliVue CL Respiration Pod is intended for use by health care professionals. It is not intended for home use. It is not a therapeutic device.

Continued on next 2 pages

Prescription Use Yes  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use No  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S  c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=130  
0059331; cn=Albert E. Moyal -S  
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(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
infection Control, Dental Devices

Page 1

510(k) Number: K122223

**Indications for Use (continued):**

The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm).

The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate). For monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor.

**Warning:**

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

**IntelliVue Patient Monitors MP2 and X2:**

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment. The monitor is also intended for use during patient transport inside and outside of the hospital environment.

The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

**IntelliVue Patient Monitors MP5, MP5T, and MP5SC:**

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

**Indications for Use (continued):**

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment.

The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

**IntelliVue GuardianSoftware:**

The IntelliVue GuardianSoftware is indicated for use by healthcare providers whenever there is a need for generation of a patient record.

The IntelliVue GuardianSoftware is intended for use in the collection, storage and management of data from IntelliVue Cableless Measurements and IntelliVue Patient Monitors that are connected through networks.