K120366

PHILIPS

510(k) Summary

JUL 18 2012

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 January 31, 2012.

2. The name of the devices:

Trade name: Philips MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors, Software Revision J.04

Common name: Patient Monitoring Devices

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.2700, II	DQA	Oximeter
	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer

Device Panel	Classification	ProCode	Description
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
	§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
General Hospital and Personal Use Devices	§882.1400, II	GWR	Electroencephalograph
Neurological Devices	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700, and MX800 IntelliVue Patient Monitors, Software Revision J.04 are substantially equivalent to the previously cleared Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 marketed pursuant to: K110474, K110622, K102562,

K101449, K100939, K093268, K091927, K091395, K090360, K083517, K083228, K082633, K082583, K081793, K072070, K071426, K063725, K063315, K062392, K062283, K061610, K061052, K060541, K060221, K053522, K052961, K052801, K051106, K050762, K050141, K042845, K041235, K040917, K040304, K033513, K033444, K032858, K031481, K030038, K023871.

The new SpO2 intelligent alarm delay feature of the Philips IntelliVue Patient Monitors called 'Smart Alarm Delay' is substantially equivalent to the 'SatSeconds' alarm management technique of the Nellcor Pulse Oximeter N-600x, marketed pursuant to K060576.

4. Description of the device

The Philips IntelliVue Patient Monitors family comprises the multiparameter patient monitor series: MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX600, MX700, and MX800. Each monitor consists of a display unit including built-in or separate central processing unit (CPU) and physiological measurement modules. 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: SpO2, pulse, ECG, arrhythmia, ST, QT, respiration, invasive and non-invasive blood pressure, temperature, CO2, spirometry, C.O., CCO, tcpO2/ tcpCO2, SO2, Sv02, ScvO2, EEG, and BIS. They generate alarms, record physiological signals, store derived data, and communicate derived data and alarms to the central station.

IntelliVue series MP2, X2, MP5, MP5T, MP5SC, MP20, and MP30 are robust, portable, lightweight, compact in size and modular in design patient monitors with interfaces to dedicated external measurement devices. Models MP2, X2, MP5, MP5T, and MP5SC also incorporate multiple built-in physiological measurements.

IntelliVue series MP40, MP50, MP60, MP70, MX600, MX700, and MX800 are patient monitors with built-in central processing unit, flat panel display and interfaces to dedicated external measurement devices. Models MX600, MX700, and MX800 have widescreen displays.

IntelliVue series MP80 and MP90 are patient monitors with flat panel display and central processing unit as separate components. They have interfaces to dedicated external measurement devices.

5. Intended Use

The Intended Use and Indications for Use of the subject Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700, and MX800 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:

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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.

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.

Models MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90:

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 MP20/MP30/MP40/MP50 monitors are additionally intended for use in transport situations within hospital environments.
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 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 transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

Models MX600, MX700, and MX800:

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 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 transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
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.

6. Technological Characteristics

The modification of the Philips IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX600, MX700, and MX800 is solely limited to the software change in order to add the new SpO2 alarm delay feature. This minor software modification does not affect technology of the IntelliVue Patient Monitors. The legally marketed and the modified IntelliVue Patient Monitors have the same technological characteristics such as design, material, energy source, portability, user interface, radio technology, measurement principle.
The SpO2 portion of the Philips IntelliVue Patient Monitors has also the same fundamental technology as the predicate Nellcor Pulse Oximeter N-600x. Both Philips and Nellcor devices use the same measurement principle, they have very similar SpO2 and pulse performance specifications, provide technical and physiological SpO2 and pulse alarms such as standard and intelligent SpO2 alarm delays.
The intelligent SpO2 alarm delay feature of Philips monitors, called 'Smart Alarm Delay' and of the Nellcor monitor called 'SatSeconds', is based on the same fundamental principle. The alarm delay time depends on the amount of deviation from the violated SpO2 alarm limit: small alarm limit deviations result in longer alarm delay time and large deviations lead to shorter

alarm delays. The maximum possible SpO2 alarm delay time of Smart Alarm Delay and SatSeconds is 100 sec.

7. Summary of V&V activities

Clinical Evaluation:
The objective of the clinical evaluation was to validate that the information presented in the IntelliVue Patient Monitors Instructions for Use has been adequate and sufficient to give the users of the monitors a clear mental model of the new SpO2 Smart Alarm Delay feature.
Two user groups - one consisting of physicians and one consisting of nurses - have been asked questions regarding their grasp of the Smart Alarm Delay feature, as described in the monitor Instructions for Use. The users have also been asked whether they have regarded the new feature useful and its function as clinically meaningful.
The result of the clinical evaluation was that the vast majority of test persons understood the implications of using the new SpO2 Smart Alarm Delay feature and that they regarded it as a helpful alternative to the existing SpO2 standard alarm delay.

Functionality and Regression tests:

- Testing as identified in the Hazard Analysis. The test results have confirmed the effectiveness of implemented design risk mitigation measures.

- Functionality testing of the modified software portion of the IntelliVue Patient Monitors. All specified criteria have been met. The test results have confirmed that the SpO2 alarm derivation and the SpO2 alarm delays of the modified IntelliVue Monitors have functioned safe, effective and according to the specifications and Instructions for Use.

- Regression tests of the related, unmodified software parts of the IntelliVue Patient Monitors. All specified criteria have been met. The test results have confirmed that the SpO2 parameter of the modified IntelliVue Monitors have functioned safe, effective and according to the specifications and Instructions for Use.

- Regression tests of alarms of the IntelliVue Patient Monitors. All specified criteria have been met. The test results have confirmed that the alarms of the modified IntelliVue Monitors have functioned safe, effective and according to the specifications and Instructions for Use.

Performance tests:
For the introduction of the alternative SpO2 alarm delay feature, called 'Smart Alarm Delay', only a very small section of the common IntelliVue software has been changed.

The new 'Smart Alarm Delay' feature is isolated from the SpO2 measurement algorithm, i.e. signal acquisition and numeric processing.
The devices hardware and all accessories including, but not limited to the SpO2 sensors remain completely unchanged.
Therefore, the modification does not affect device performance in general and device accuracy in particular.
The modification does also not affect any safety and performance aspects covered by the SpO2 standard ISO 9919. Therefore, verification and validation executed on the subject IntelliVue Patient Monitors according to the standard ISO 9919 prior to the minor modification, which is subject of this Premarket Notification, is still valid and covers the modified devices.

8. Conclusion

Verification and validation testing activities were conducted to establish the safety, functionality, usability, effectiveness, and reliability characteristics of the modified devices.
V&V testing included functionality and regression tests, system tests, and clinical evaluation. All tests were successfully completed.
The results demonstrate that the modified IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX600, MX700, and MX800 are as safe, as effective and perform as well as the predicate devices.
The modified devices are substantially equivalent in intended use and fundamental technological characteristics to the appropriate predicate devices. The modified devices introduce no new questions concerning the safety or efficacy and are, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 18 2012

Philips Medizinsysteme Boeblingen Gmbh
c/o Mr. Markus Stacha
Senior Regulatory Affairs Engineer
Hewlett-Packard Str. 2
Boeblingen 71034 (Germany)

Re: K120366
Trade/Device Name: Philips MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitor, Software Revision J.04
Regulation Number: 21 CFR 878.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX, DQA, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DSB, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, FLL, GWR, GWS
Dated: June 27, 2012
Received: June 29, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120366

Indications for Use

510(k) Number (if known):_____

Device Name: Philips MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors, Software Revision J.04

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.

continued on next pages

Prescription Use (Part 21 CFR 801 Subpart D) Yes AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) No

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120366

Page 1 of 4

Indications for Use (continued):

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.

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.

Models MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90:

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 MP20/MP30/MP40/MP50 monitors are additionally intended for use in transport situations within hospital environments.
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.

Indications for Use (continued):

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 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 transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

Models MX600, MX700, and MX800:

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 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 transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.

Indications for Use (continued):

Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
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.