

K140430



JUN 13 2014

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

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Prepared: February 14, 2014

Trade Name: 740 SELECT

Common Name: Monitor, Physiological, Patient

Classification Name: Cardiovascular Monitoring Device 870.2300 (MWI)

Substantially Equivalent Device(s):

The 740 SELECT is equivalent to the following devices:

- CASMED 740 SELECT (Phase 1) Monitor (K130411);
- Masimo Corporation - Radical 7 Pulse Co-Oximeter (K120657);
- Covidien (Nellcor) – Bedside Respiratory Patient Monitoring System (K130320);
- Exergen Corporation - TemporalScanner Thermometer (K011291);
- PHASEIN AB (Masimo) Infrared Sidestream Gas Analyzer (ISA) (K103604);
- PHASEIN AB (Masimo) Infrared Mainstream Gas Analyzer (IRMA) (K123403);
- Oridion (Covidien) Capnostream20 (K094012)

DESCRIPTION

The 740 SELECT is a rugged portable non-invasive multi-parameter device used for spot checking or continuous monitoring of blood pressure, pulse rate, functional oxygen saturation (%SpO₂), body temperature and CO₂ in various modes of operation.

The non-invasive blood pressure (NIBP) parameter automatically inflates an occluding cuff and, using the oscillometric step-deflation measurement technique, determines systolic, diastolic and mean arterial pressure as well as pulse rate. Measurement results along with user prompts and error messages are displayed on the front panel. The frequency of NIBP determination can be selected by the user in

varied times between one and ninety minutes. The auto and manual operating modes cover a variety of clinical uses.

The pulse oximeter parameter (%SpO₂) determines arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. The oximeter requires no routine calibration or maintenance. Oxygen saturation and heart rate are displayed on a light emitting diode (LED) digital display. On each detected pulse, the perfusion LED indicates patient perfusion signals. This bar graph gives the user a pulse-by-pulse visual indication of waveform signal quality. An audio "beep" can be enabled that is generated each time the SpO₂ module detects a pulse. In addition to %SpO₂ the SELECT (equipped with the Masimo rainbow® Pulse CO-Oximetry™ and Masimo SET ® oximetry) can monitor Pulse Rate (PR), Carboxyhemoglobin (SpCO®), Acoustic Respiration Rate (RRa) and Pleth Variability Index (PVI®). Alternately, the customer can choose a Nellcor Pulse Oximeter at this time of ordering.

The predictive temperature parameter has the capability of taking temperature in either normal (predictive) or monitor mode. In the normal mode, the thermometer's microprocessor "predicts" body temperature in about four (4) seconds for oral temperatures, about ten (10) seconds for axillary temperatures and about fifteen (15) seconds for rectal temperatures. The default setting used by the monitor for Temperature determinations is the Predictive (normal) mode. Alternately, the customer can choose an Exergen TemporalScanner (infrared) Thermometer at the time of ordering. The Exergen TemporalScanner Thermometer has the capability of taking Temporal Artery (TA) Temperature in about 3 seconds. The Exergen Temp scanner has the ability to measure the patient's Arterial temperature in °F or °C.

The 740 SELECT has (2) optional choices for the parameter of CO₂ monitoring. The customer may order either the Masimo - Phasein™ Infrared Sidestream Gas Analyzer (ISA™) or the Infrared Mainstream Gas Analyzer (IRMA™). Alternately, the customer can select the option of the Oridion Sidestream MicroPod™ EtCO₂. Each of these CO₂ options is externally attached to the SELECT.

The 740 SELECT Intended Use

The 740 SELECT series of monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring and recording of:

- Blood pressure and pulse rate of adult, pediatric and neonatal patients;
- Functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, pediatric and neonatal patients;
- Additionally the Masimo rainbow® Pulse CO-Oximetry™ and Masimo SET technology provides noninvasive monitoring of carboxyhemoglobin saturation (SpCO®) and/or respiration (RRa). Other information displayed on the 740 SELECT with the Masimo Rainbow SET option includes: Signal IQ Waveform, Low Signal IQ (Low SIQ), Perfusion Index (PI), and/or Pleth Variability Index (PVI®) indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused;
- Carbon Dioxide concentration of the expired and inspired breath and respiration rate and FICO₂ (fractional concentration of inspired CO₂) of adult, pediatric, infant or neonatal patient and included, with the Oridion option, an Integrated Pulmonary Index (IPI);

- Intermittent predictive body temperature (oral, axillary, rectal) of adult, pediatric and neonatal patients;
- Infrared (over the temporal artery) measurement of body temperature of people of all ages.

740 SELECT Monitor Technologies Compared to Predicate Devices

The 740 SELECT compares substantially to the cited predicate device(s) in that it uses fundamentally the same technologies, adopted from the parameters manufacturer, without alteration. The non-invasive blood pressure component is the CASMED MAXIQ™ an oscillometric instrument having neither a stethoscope nor a microphone and does not need the quiet environment necessary to detect the auscultatory sounds. They work on the principle that when the artery opens during a portion of the pressure cycle, an oscillation is superimposed on the pressure inside the cuff due to a tiny enlargement of the circumference of the limb caused by the surge of blood under the cuff. The amplitude of the oscillometric signals change over the course of the deflation of the cuff. Oscillometric devices look for oscillation amplitude of certain percentages of the maximum amplitude at mean arterial pressure (MAP), defining one percentage as the systolic point and another as the diastolic point. Alternatively, a combination of the amplitude, the slope of the increase or decrease, and some other complex factors are used to find these points.

The 740 SELECT pulse oximeter can include either of two industry leading components specific to the customer's requirement. Masimo rainbow Pulse CO-Oximetry™ and Masimo SET® or Covidien (Nellcor's) OxiMax technology. The pulse oximeter parameter (%SpO₂) determines arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. Additional leading edge functions, as offered by the pulse oximeters manufacturer, are made available to the customer with the 740 SELECT.

The FILACT™ 3000 temperature parameter has the capability of taking temperature in either normal (predictive) or monitor mode. In the normal mode, the thermometer's microprocessor "predicts" body temperature in about four (4) seconds for Oral temperatures, about ten (10) seconds for Axillary temperatures and in about fifteen (15) seconds for Rectal temperatures. Exergen's TemporalScanner is a hand held device that measures the skin temperature over the temporal artery. The Exergen TemporalScanner Thermometer has the capability of taking Temporal Artery (TA) Temperature in about 3 seconds. The Exergen Temp scanner has the ability to measure the patient's Arterial temperature in °F or °C.

For the CO₂ parameter, the 740 SELECT allows for the external attachment of a choice of two manufacturers solutions. Offered are the Masimo -PhaseIn™ (Masimo) Sidestream Gas Analyzer (ISA) or the Mainstream Gas Analyzer (IRMA). The other choice is the Oridion Micro Pod™ capnography module.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The 740 SELECT has successfully undergone performance, safety, electromagnetic, and environmental testing to ensure it has been found to be substantially equivalent to the primary and secondary predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software and systems verification and validation studies of the monitor and accessories.

Clinical Testing to Show Substantial Equivalence

The 740 SELECT has successfully undergone clinical validation for the indicated use. The premarket notification cites clinical validation reports for the NIBP, and the OEM's clinical work for the pulse oximeters, CO2 and the temperature functions.

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing, software and systems validation demonstrate the 740 SELECT is substantially equivalent to the predicate device(s).



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

June 13, 2014

CAS Medical Systems, Inc.
Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K140430
Trade/Device Name: 740 Select
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (With Cardiometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: May 5, 2014
Received: May 6, 2014

Dear Mr. Jeffrey,

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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

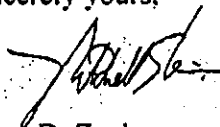
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 Industry and Consumer Education 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

Indications for Use

510(k) Number:

Device Name: **740 SELECT**

The 740 SELECT series of monitors is indicated for use as a portable, multi-parameter, variable acuity device for use by health care professionals, clinicians and medically qualified personnel, in a variety of clinical environments and hospital departments, for non-invasive spot checking, and/or continuous monitoring and recording of:

- Blood pressure and pulse rate of adult, pediatric and neonatal patients;
- Functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric and neonatal patients;
- Additionally the Masimo Rainbow SET technology provides noninvasive monitoring of carboxyhemoglobin saturation (SpCO) and/or respiration (RRa). Other information displayed on the 740 SELECT with the Masimo Rainbow SET option includes: Signal IQ Waveform, Low Signal IQ (Low SIQ), Perfusion Index (PI), and/or Pleth Variability Index (PVI) indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused;
- Carbon Dioxide concentration of the expired and inspired breath and respiration rate of adult, pediatric, infant or neonatal patient and included, with the Oridion option, an Integrated Pulmonary Index (IPI);
- Intermittent predictive body temperature (oral, axillary, rectal) of adult, pediatric and neonatal patients;
- Infrared (over the temporal artery) measurement of body temperature of people of all ages.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____ (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)



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Page 1 of 1