

**Scanner,ultrasound,mobile,w/access'**

**GENERAL DESCRIPTION**  
General purpose, portable ultrasound scanner, with obstetrics package and probes.  
  
**INTENDED USE**  
Portable ultrasonic scanning systems are used in physician offices, radiology departments, cardiology departments, emergency departments, critical care units and by mobile imaging service providers. They can also have important applications in disaster triage and mass casualty incidents. The main benefit of point of care ultrasounds units is that it allows physicians to quickly determine whether an abnormality is present so they can make appropriate patient management decisions.  
  
**TECHNICAL SPECIFICATIONS**  
General purpose ultrasound scanner, with obstetrics package and probes.  
System includes scanner and printer mounted on a trolley.  
The system supports B mode and M mode.  
The unit includes: one (1) convex array probe, 2.5-5 MHz and one (1) endovaginal probe, 5.5-7.5 MHz.  
The unit supports user programmable exams (exam pre-sets).  
An obstetrics analysis package is included which provides for foetal weight and anatomy, gestational age and foetal growth calculations.  
The unit comes standard with packages for: abdomen, gynaecology/obstetrics, cardiology and small parts.  
Depending on the model supplied Pulsed Wave Doppler (back/white), is included in the unit.  
Power requirements: 100 - 240 Volts - 50/60 Hz (not necessarily in a single unit).  
  
IMAGE DISPLAY  
Digital callipers.  
Cine loop.  
A minimum of 4 x zoom.  
256 levels of greyscale.  
A freeze function.  
Capable of lateral and vertical inversion in B mode.  
Capable of displaying B+M modes simultaneously.  
Capable of displaying 2B and 4B modes.  
Full screen annotation, for real-time and frozen images.  
  
COMPONENTS  
Time gain control (TGC).  
Tissue harmonic imaging.  
Optional B-mode optimization.  
The unit has a range of pre- and post-processing fetures to enhance images and automated image optimization.  
A black and white display with a minimum of 25 cm (9.7 inch) diagonally.  
Equipped with an alphanumeric keyboard and a trackball.  
Two probe ports can be connected simultaneously, machine selectable from interface.  
  
PRINTER  
A digital printer is included with the unit.  
Data connection to ultrasound.  
support 256 greyscale.  
325 dpi resolution at a minimum.  
Includes printer head cleaning kit.  
  
CART/TROLLEY  
Includes at least two side probe holders.  
Side handle(s) for transport and positioning.  
Surface space for scanner and keyboard.  
Storage space (shelf) for printer.  
Four anti-static braking swivel castors, at least 10 cm high.  
  
DATA STORAGE AND COMMUNICATIONS  
Internal hard drive for limited data storage.  
Supported communication protocols: USB, S-video, VGA, and depending on the model: RS 232 or ethernet).  
Supported formats for image export: JPEG.  
  
PERFORMANCE AND SAFETY  
Self-test is performed each time the machine is switched on.  
System reports, with audio-visual alert on: operational status and malfunctions.  
  
**SUPPLIED WITH**  
Instructions for assembly, use and maintenance in English, French and Spanish:  
1 x Plastic protective dustcover.  
3 x bottle of 100 ml (or 2 X 150 ml) of ECG conductive gel.  
1 x Set 10 video printer paper rolls, length approx. 20m.  
1 x Set of spare fuses.  
  
**OPTIONAL ACCESSORIES AVAILABLE**  
At extra costs additional optional features can be requested:  
- A linear array probe, 5-10 MHz can be included in the unit.  
- A sector array probe, 2-7.5 MHz can be included in the unit. (depending on the model supplied).  
- A rechargeable battery (standard in one model, optional in other model).  
- DICOM 3.0 compatibility (Included standard in one model, optional in other model).  
  
**ESTIMATED LIFE SPAN**  
Five years.  
  
**WARRANTY**  
Two years from shipping date.  
  
**ENVIRONMENTAL CONDITIONS**  
- Operating conditions: 5°C – 40°C / 25% - 80% RH.  
- Storage conditions: -20°C - 55°C / 25% - 93% RH.  
- Atmospheric pressure: 860 ~ 1060 hPa.  
  
**WEIGHT AND VOLUME (packaged)**  
Weight: 118.00 kg.  
Volume: 511.00 dm³.  
  
**ESTIMATED DELIVERY LEAD TIME**  
120 days.  
  
**INSTALLATION REQUIREMENTS**  
This product does not have complex assembly and/or commissioning needs requiring a technician.  
  
**TRAINING REQUIREMENTS**  
User training prior to utilization is recommended.  
  
**MAINTENANCE/USER REQUIREMENTS**  
As per user and service manuals.  
  
**COMPONENT OF A KIT**  
No part of a kit.  
  
**QUALITY MANAGEMENT SYSTEM**  
- Manufacturer is certified for ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes.  
- Supplier (if not the manufacturer) at a minimum is certified for ISO 9001 Quality management systems – Requirements.  
  
**CLASSIFICATION**  
Classified either under EU MDD 93/42/ECC, or under EU MDR 2017/745 as Class IIa device  
  
**SAFETY & PRODUCT STANDARDS**  
- IEC 60601-1:2005 + A1:2012(E) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.  
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.  
- IEC 60601-2-37:2007+AMD1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.  
  
**NOMENCLATURE**  
- GMDN code: General-purpose ultrasound imaging system (40761).  
- UMDNS code: Scanning Systems, Ultrasonic, General-Purpose (15976).

**ECG recorder,portable,w/access**

Electrocardiograph (ECG) digital monitor and recorder, 12-leads detection, multi-channel recording, portable, AC and battery powered , with printer and accessories

**GENERAL DESCRIPTION**  
Multichannel, interpretive electrocardiograph, including printer.  
  
**INTENDED USE**  
Electrocardiographs detect the electrical signals associated with cardiac activity and produce an ECG, a graphic record of the voltage versus time. They are used to diagnose and assist in treating some types of heart disease and arrhythmias. Electrocardiographs differ from ECG monitors, which provide a continuous real-time display of the ECG waveform and other physiologic measurements on a screen and warn of potentially life-threatening or precursor rhythms. Electrocardiographs are used to diagnose cardiac abnormalities, determine a patient's response to drug therapy, and reveal trends or changes in heart function. Multichannel electrocardiographs record and display signals from two or more leads simultaneously.  
  
**TECHNICAL SPECIFICATIONS**  
ECG analysis and full interpretation (rhythm and events), real-time and manual interpretation.  
Three (3) or more recording channels.  
  
SIGNAL ACQUISITION  
Simultaneous 12 lead acquisition ( aVR, aVL, aVF, I, II, III and V1 - V6) derived from 10 electrodes (RA, LA, RL, LL, V1 - V6).  
Arrythmia and ST elevation detection.  
Minimum gain/sensitivity settings include 2.5, 5, 10 and 20 mm/mV.  
Lead switching, either manual, automatic or both (manual and auto options).  
Adjustable trace speeds include 5, 10 (and/or 12.5), 25 and 50 mm/s.  
Minimum HR range 30 – 300 bpm with rhythm analysis.  
Minimum guaranteed diagnostic frequency response of 0.05 – 150 Hz.  
Common Mode Rejection Ratio (CMRR) at 60 Hz > 105 dB or better.  
Calibration signal of 1 mV, manual and/or automatic.  
Selectable/adjustable filters for baseline drift, muscle artefacts, mains power.  
Pacemaker detection.  
Accuracy of input signal reproduction ± 5 % or ± 40 μV, whichever is greater.  
Input impedance > 50 MΩ.  
Internal noise level < 12.5 µV peak-to-peak.  
Automatic baseline centring.  
Defibrillation fluctuation/overload protection.  
Baseline recovery < 5 s after defibrillation.  
AC fluctuation protection.  
  
RECORDER AND PRINTER  
Minimum of 3 recording channels.  
Recorder display includes date/time, patient data and heart rate and basic settings.  
Capable of displaying one group of at least three channels simultaneously.  
Recorder waveform display includes lead marker and timing marker.  
Integrated/built-in printer.  
Capable of printing user selected number of channels.  
Capable of printing one group of at least three channels simultaneously.  
Paper speeds include 5, 10 (or 12.5), 25 and 50 mm/s.  
Compatible with Z-fold paper and optionally with roll paper also (indicate compatibility).  
  
DATA INPUT/OUTPUT, STORAGE AND ALARMS  
Integrated alpha-numeric keyboard.  
Patient data input fields include name, age, height and weight, gender.  
Backlit Liquid Crystal Display (LCD) display screen, minimum of 12.7 cm (5 inches) diagonally.  
Capable of internally storing a minimum of 10 waveforms for later retrieval, printing and/or transmission.  
Expandable storage for additional waveforms if required, via USB.  
Capable of exporting waveform data and reports, via USB or LAN.  
Visual alarms for patient connection (lead faults), heart rate, printer and paper errors, and system errors.  
Automatic self-test at start up.  
  
POWER PROVISIONS  
Built-in rechargeable lithium-ion battery.  
Minimum battery operating time is 100 ECG exams or 4 hours of continuous recording.  
Automatic switch to battery in case of power failure, automatic recharge on connection to mains.  
Maximum battery charging time to full charge is 8 hours.  
Power requirements: 100 - 240 Volts - 50/60 Hz.  
Designed for frequent and easy dismount and disinfection with hospital-grade products.  
  
**SUPPLIED WITH**  
Instructions for assembly, use and maintenance in English, French and Spanish.  
1 x Plastic protective dustcover.  
1 x Patient cable.  
2 x full sets of chest electrodes.  
2 x full sets of limb electrodes.  
1 x supply of 960 Z-folded sheets suitable for the unit. (if accepts Z-folded sheets), or 5 x supply of rolls suitable for the unit (if the unit accepts rolls).  
3 x bottle of 100 ml of ECG conductive gel.  
1 x spare rechargeable battery pack.  
  
**ESTIMATED LIFE SPAN**  
Five years.  
  
**WARRANTY**  
Two years from shipping date.  
  
**ENVIRONMENTAL CONDITIONS**  
- Operating conditions: 5°C – 40°C / 25% - 85% RH.  
- Storage conditions: -20°C - 40°C / 25% - 95% RH.  
- Atmospheric pressure: 860 ~ 1060 hPa.  
  
**WEIGHT AND VOLUME**  
Weight: 10.00 kg.  
Volume: 80.00 dm³.  
  
**ESTIMATED DELIVERY LEAD TIME**  
120 days  
  
**INSTALLATION REQUIREMENTS**  
This product does not require assembly or installation.  
  
**TRAINING REQUIREMENTS**  
User training prior to utilization is recommended.  
  
**MAINTENANCE/USER REQUIREMENTS**  
As per user and service manuals.  
  
**RELATED PRODUCTS**  
S0002058, Defibrillator,AED,w/access  
S0002059, Defibrillator,basic,w/access  
  
**COMPONENT OF A KIT**  
No part of a kit.  
  
**QUALITY MANAGEMENT SYSTEM**  
- Manufacturer is certified for ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes.  
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**CLASSIFICATION**  
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**SAFETY & PRODUCT STANDARDS**  
- IEC 60601-1:2005 + A1:2012(E) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.  
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.  
- IEC 60601-2-25:2011 Medical Electrical Equipment – Part 2-25: Particular requirements for the safety of electrocardiographs.  
  
**NOMENCLATURE**  
- GMDN code: Electrocardiograph, professional, multichannel (16231)  
- UMDNS code: Electrocardiographs, Multichannel, Interpretive (16231)