Passport 2® Portable Bedside Monitor

GENERAL DESCRIPTION

The Passport 2 is a portable bedside monitor that can be configured to meet the demands of many hospital departments.

The Passport 2, with rechargeable batteries, allows continuous vital signs monitoring during patient transport.

SUMMARY OF FEATURES AND BENEFITS

- 10.4 inch color TFT display with auto-adjustable large numerics optimizes visibility
- Navigator™ knob and dedicated function keys provide instant access to critical monitoring functions
- Standard features include 6 waveforms, 3 or 5-lead ECG, lead-selectable respiration, NIBP, Masimo SET® motion tolerant SpO_2 and temperature
- Many options available including ventricular arrhythmia analysis, Microstream® $ETCO_2$, Nellcor® SpO_2, dual invasive pressures, 3-lead ST analysis with trends and alarms and dual trace recorder
- Optional View 12™ ECG Analysis Module includes 12-leads of continuous ST, arrhythmia and diagnostic interpretations printable to a laser printer
- List and graph trends store up to 120 patient time measurements - expandable to 500 entries with extended memory
- Software enhancements, memory expansion, and data transfers are quick and easy with the use of dual PCMCIA ports
- Complete 5-agent auto ID, CO_2, O_2 and N_2O analysis available with optional Gas Module SE™
- Network to Panorama™ Central Station for continuous data storage

Now with up to 5 hours run time on lithium-ion batteries.

AGENCY COMPLIANCES

This monitor complies with the following industry standards:

Safety:	IEC 60601-1:1988 + A1:1991 + A2:1995, UL 60601-1:2003, CSA Standard C22.2 No. 601.1M90, EN 60601-1-1:2001/IEC 601-1-1:2000, IEC 60601-1-2:Ed 2.1, EN 60601-1-4:1996 + A1:1999/ IEC 601-1-4:1996 + A1:1999, EN 60601-2-30:2000/IEC 601-2-30:1999, EN 60601-2-34:2000/ IEC 601-2-34:2000, EN 60601-2-49:2001/IEC 60601-2-49:2001 3/5 Lead ECG: EN 60601-2-25:1993/IEC 60601-2-25:1993 + A1:1999, section 36.202.101, EN 60601-2-27:1994/IEC 601-2-27:1994 12 Lead ECG: EN 60601-2-25:1993/IEC 601-2-25:1993 + A1:1999
Hazard Analysis (Risk Management):	EN ISO 14971:2000 + A1:2003
Performance / Accuracy:	EN 475:1995, EN 864:1996, EN 865:1997, EN 1060-1:1995 + A1:2002, EN 1060-3:1997 + A1:2005, ANSI/AAMI/ISO 10993-10:1995, ANSI/AAMI/ISO 10993-1:1995, AAMI SP10:1996, AAMI EC13:1992, AAMI EC11:1991, ISO 3744:1994
Environmental / EMC:	IEC 60068-2-6:1995 + Corrigendum 1, IEC 60068-2-27:1987, IEC 60068-2-64:1994 + Corrigendum 1, EN60529:1991 + A1:2001 + Corrigendum 1, EN 55011:1998 + A1:1999 + A2:2002 (CISPR 11), EN 61000-3-2:2000 + A1:2001 + A2:2005, EN 61000-3-3:1995 + A1:2001 + A2:2005, EN 61000-4-6: 2003 + A1:2004 + A2:2006, EN 61000-4-3:2006, EN 61000-4-8:1993 + A1:2001, EN 61000-4-2:1995 + A1:1998 + A2:2001, EN 61000-4-4:2004, EN 61000-4-5:2005, EN 61000-4-11:2004, ECRI PB-296892:1979 (for Drop and Impact requirements), ISTA: 1994 procedure 1A, 2002/96/EC: 2003

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Datascope®
PATIENT MONITORING

Passport 2® PERFORMANCE SPECIFICATIONS

DISPLAY

Size:	10.4 inch (26.4 cm) Color TFT
Resolution:	VGA 640-480
Waveforms:	3 to 6

ECG (3-LEAD AND 5-LEAD)

Leads:	I, II, III, aVR, aVL, aVF, V
Cable Detection:	Autodetecting Datascope 3 or 5 wire
Display Sensitivity:	0.25, 0.5, 1.0, 2.0, 3.0, 4.0, cm/mV ± 10%
Frequency Response To Screen	
Extended Mode:	0.05 – 100 Hz, -3db max @ 1mVpp input
Monitor Mode:	0.5 – 40 Hz, -3db max @ 1mVpp input (ESU filter disabled)
ST Mode:	0.05 – 40 Hz, -3db max @ 1mVpp input
CMRR:	90 db min, Maximum output of 1mVp-p (RTI) over 60 seconds at 50/60 Hz, with parallel combination 51K Ω and 0.047 uF imbalance and ± 300 mV DC offset per AAMI EC13-1992 3.2.9.10
ECG Sync Pulse for Cardioversion:	
Delay:	≤35 ms max between QRS Peak and rising edge of Sync Pulse
Amplitude:	2Vp minimum into a 5k ohm load
Width:	2-7 msec
Analog Output (ECG):	Supports slaving of an IABP with ECG
Delay:	25 ms max
Sensitivity:	1 V/mV of input, ± 10%
Defibrillator Overload Protection:	
	Withstand 360 Joule discharge as per IEC 60601-2-27, 51.101.1
Recovery Time:	Time for recovery to within 1mV in < 8 seconds automatically. 3 seconds from 1Vpp at 60Hz

ECG (12-LEAD)

Leads:	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Connection Type:	Type II PCMCIA card to be installed in PCM 1 slot
Cable Detection:	Automatically enabled when 12-lead Card is inserted into PCM 1 slot
Frequency Response	
Extended Mode:	0.05 – 100 Hz, -3db max @ 1mVpp input
Monitor Mode:	0.5 – 40 Hz, -3db max @ 1mVpp input (ESU filter disabled)
ST Mode:	0.05 – 40 Hz, -3db max @ 1mVpp input
CMRR:	90 db min, Maximum output of 1mVp-p (RTI) over 60 second period at 50/60 Hz, with a parallel combination 51K Ω and 0.047 uF imbalance and ± 300 mV DC offset per ANSI/AAMI EC11-1991, 3.2.11
Analog Output (ECG):	Disabled when 12-lead ECG analysis is enabled
Defibrillator Overload Protection:	
	Withstand 360 joule discharge as per IEC 60601-2-27, 51.101.1

HEART RATE METER

Range:	30 – 300 BPM Adult/Pediatric, 30 – 350 BPM Neonate 3-lead and 5-lead/ 30 – 300 BPM 12-lead
Accuracy:	± 3 BPM or ± 3% at 30 – 250 BPM whichever is greater, ± 5% at 251 – 350 BPM
Pacer Rejection:	Rejects all pulses of amplitude ± 2.0 mV to 700 mV and duration 0.1 to 2 ms with no tail. AAMI EC-13-1992 3.1.4.1 (3-Lead and 5-Lead) Rejects all pulses of amplitude ± 2.0 mV to 700 mV and duration 0.1 to 2 ms with 100 ms time constant tail of less than 2.0 mV, or 4 ms time constant tail of < 2.0 mV per AAMI EC-13-1992 3.1.4.2
Tall T-Wave Rejection:	Rejects all T-Waves less than 120% of 1 mV QRS and Q-T interval of 350 ms per AAMI EC-13-1992 3.1.2.1 (c)

ST ANALYSIS

3-lead or 5-lead Range:	-9.9 mm to +9.9 mm
12-lead Absolute Range:	-10 mm to +10 mm
12-lead Delta Range:	-20 mm to +20 mm
Resolution:	0.1 mm
Default ST Measuring Point:	
	80 ms after J point for HR ≤ 120 BPM, 60 ms after J point for HR >120 BPM

ARRHYTHMIA ANALYSIS

3-lead or 5-lead cables:	
Adult / Pediatric Only:	Asystole, Irregular Heart Rate, Couplets, Bigeminy, Trigeminy, Ventricular Tachycardia, Ventricular Fibrillation, PVC's per minute, Runs, Ventricular Rhythm and Bradycardia
12-lead:	
Adult / Pediatric Only:	Asystole, Couplets, Runs, Bigeminy, Trigeminy, Ventricular Tachycardia, Ventricular Fibrillation, PVC's per minute, Ventricular Rhythm, and Pause

RESPIRATION (ECG)

Range:	4 to 199 BPM
Accuracy:	± 2% or 2 breaths per minute whichever is greater from 4 to 150 BPM, ± 4% from 151 to 199 BPM
Lead:	I or II

TEMPERATURE

Scale:	Selectable C˚ or F˚
Range:	15˚ to 45˚ C / 59˚ to 113˚ F
Accuracy:	± 0.1˚ C (15˚ C to 45˚ C) exclusive of probe errors. ± 0.2˚ F (59˚ F to 113˚ F) exclusive of probe errors.

NON-INVASIVE BP

Technique:	Oscillometric
Systolic Range:	Adult – 55-235 mmHg Pediatric – 55-160 mmHg Neonate – 45-120 mmHg
Diastolic Range:	Adult – 30-200 mmHg Pediatric – 30-150 mmHg Neonate – 20-100 mmHg
Systolic Accuracy:	Mean Error less than ± 5 mmHg, Standard Deviation less than ± 8 mmHg
Diastolic Accuracy:	Mean Error less than ± 5 mmHg, Standard Deviation less than ± 8 mmHg
Pulse Rate Range:	Adult/Pediatric: 35 to 245 BPM Neonate: 70 to 245 BPM
Pulse Rate Accuracy:	± 3 BPM or 3% whichever is greater
Connector Type:	Rectus
Cuff Inflation:	Volume of 500cc to 300 mmHg in ≤35 sec

PULSE OXIMETRY

Classification per ISO 9919:	Functional Saturation Oximeter
Masimo SET® SpO_2 Accuracy Saturation with no motion conditions	
Adult/Pediatric:	70% to 100% ± 2 digits SpO_2, 0-69% unspecified
Neonate:	70% to 100% ± 3 digits SpO_2, 0-69% unspecified
Ear Sensor (Adult/Pediatric):	70% to 100% ± 4 digits SpO_2, 0-69% unspecified
Masimo SET® SpO_2 Accuracy Saturation during motion conditions	
Adult/Pediatric/Neonate:	70% to 100% ± 3 digits SpO_2
Response Time:	18 seconds to 95% of final step of % SpO_2 value from 60-95% at 75 BPM. Averaging set at 8 seconds.
Pulse Rate Range Masimo with no motion conditions	
Adult/Pediatric/Neonate:	30-235 ± 3 BPM, Ear Sensor (Adult/Pediatric) 30-235 ± 3 BPM
Pulse Rate Range Masimo during motion conditions	
Adult/Pediatric/Neonate:	30-235 ± 5 BPM
Low Perfusion Performance	
Masimo:	> 0.02% Pulse Amplitude and % Transmission > 5% / Saturation (% SpO_2) ± 2 digits; Pulse ± 3 digits
Nellcor® OxiMax® SpO_2 Saturation Accuracy	
Adult/Pediatric/Neonate:	70% to 100% ± 3 digits
Pulse Rate Range Nellcor:	20-249 ± 3 BPM

IBP

Range:	Sys/Dia/Mean -30 – +300 mmHg
Accuracy:	± 2 mmHg or 2% whichever is greater
Scale:	-10 to 10, 0-20, 0-40, 0-160, 0-225, 0-320, 60-140 mmHg
Zero Range:	± 120 mmHg
Excitation:	5V DC ± 2%
Frequency Response:	DC to 16 Hz ± 1Hz, -3db
Analog Output (IBP):	Supports slaving of an IABP with IBP
Delay:	25 ms max
Sensitivity:	1 V/100 mmHg ± 10%

RECORDER

Speed:	3.125, 6.25, 12.5, 25mm, and 50mm/sec Note: 3.125 speed is for CO_2/Resp only.

CO_2 (MICROSTREAM® MINIMEDI)

Range:	0 – 99 mmHg
Accuracy:	0 – 38 mmHg: ± 2 mmHg
	39 – 99 mmHg: ± 5% of reading + 0.8% for every 1 mmHg above 38 mmHg
Respiration Rate:	0 – 150 breaths per minute
Respiration Accuracy:	0 – 70 BPM: ± 1 BPM
	71 – 120 BPM: ± 2 BPM
	121 – 150 BPM: ± 3 BPM
Sampling Rate:	50 ml/min ± 7.5 ml/min

ELECTRICAL RATINGS

AC Voltage:	100 – 240 VAC ± 10%, 50/60 Hz ± 3 Hz
Battery Type:	Lithium-ion
Number of Batteries:	2
Battery Voltage:	11.1 Vdc
Battery Capacity:	4.4 AH each
Battery Run Time:	5 hrs from two fully charged batteries at 25˚ C with ECG, SpO_2 and 1 NIBP every 15 minutes, no recording, no CO_2
Recharge Time:	5 hrs max

ENVIRONMENTAL CONDITIONS

Storage Temperature:	-20˚C - + 60˚C/-4˚F - +140˚F
Storage Humidity:	10 to 95% non-condensing
Operating Altitude:	-1250 to 9,889 feet ASL, 1060hPa to 700hPa, 795 mmHg to 525 mmHg
Operating Temperature:	5˚C to 40˚C/41˚F - 104˚F
Operating Humidity:	15% to 95%, non-condensing

PHYSICAL DIMENSIONS

Monitor Size:	24.1cm H X 30.2cm W X 18.8cm D 9.5" H x 11.9" W x 7.4" D
Weight:	5.9 kg (13 lbs.) including (2) lithium-ion batteries 5.2 kg (11.4 lbs.) excluding batteries

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