

Test Certificate

regarding
Electrical Safety, Electromagnetic Compatibility and
Environmental Conditions Requirements



CEcert GmbH, Alter Holzhafen 19, 23966 Wismar (Germany)

Test Laboratory

Certificate No.: 610.100.2

License Holder: **bluepoint MEDICAL GmbH & Co. KG**
An der Trave 15
23923 Selmsdorf, Germany

Product identification:: Multifunction patient monitor (SpO2, CO2)

Type/Model/Parameters: **CapnoTrue AMP**

P/N: 3090112001

Applied standards: **IEC 60601 1:1988 +A1:1991 + A2:1995 (except clause 48)**
IEC 60601-1-2:2007
IEC 60601-1-4:2000
IEC 60601-1-8:2006
ISO 9919:2005 (except clause 50)
ISO 21647:2004 (except clause 46, 51 and 101)
DIN EN 1789:2007 (clause 6.4.1 and 6.4.2)

Test report(s):
Electrical safety: 409.107.3A, 409.107.4, 409.107.5A,
409.107.6A, 409.107.7A
Electromagnetic compatibility: 409.107.9
Mechanical strength: 409.107.1; 410.100.1

Test result: **PASS**

This test certificate is relevant exclusively to the item(s) submitted for testing.
Consider the test report specified in this certificate and the safety indications specified in the technical documentation to the product.



Deutsche
Akkreditierungsstelle
D-PL-12049-01-01

Wismar, Monday, 28 February 2011

Head of test laboratory

Dipl.-Ing. Bernd Schmidt

see 'Attachment 1' for more details

Classification:

Ratings:	Power supply:	external power supply unit: primary: 100 - 240 V, 50 – 60 Hz, 250 mA secondary: 6.0 Vdc, 1.4 A internal battery: 4 x 1.5 Vdc (AA) or 3.7 Vdc, 2500 mAh (Li-ion)
Electrical safety:	Protection class:	external power supply: Class II, monitor: Internal battery powered, Type BF not defibrillation-proof
	Protection by enclosure:	IPX1 with additional spillage requirements of 44.3
	Clinical environment:	not intended to be used in presence of oxygen enriched environments or flammable aesthetic mixtures
	Installation and use:	hand-held
	Supply connection:	external power supply unit: plug-in, monitor: internally powered
	Temperature of applied part:	< 41 °C
	Sterilization method:	none
	Alarms:	yes
EMC:	Emission class:	Group 1, Class B
	Immunity class	not life-supporting equipment to be used during patient transport outside the healthcare facility
Environmental conditions:	Transportation:	equipment to be used during patient transport outside healthcare facility

The conditions of acceptability listed in the related test reports have to be considered.

End of Listing!