

Test Certificate

regarding
Electrical Safety, Electromagnetic Compatibility and
Environmental Conditions Requirements



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

Test Laboratory

Certificate No.: 609.212.3

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 ASP**

P/N: 3090112002

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 21647:2009 (except clause 46, 51 and 101)
DIN EN 1789:2007 (sub-clause 6.4.1 and 6.4.2)

Test report(s):
Electrical safety: 409.212.2, 409.107.3A, 409.107.5A,
409.107.6A, 409.107.7A
EMC: 409.212.1
Mechanical requirements: 409.212.5, 409.212.6A

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 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:	Class II (external power supply), Internal battery powered (CapnoTrue ASP), Type BF (not defibrillation proof)
	Clinical environment:	not intended to be used in presence of oxygen enriched environments or flammable aesthetic mixtures
	Protection by enclosure:	IPX1 (with spillage testing of sub-clause 44.3)
	Installation and use:	hand-held
	Supply connection:	external power supply: plug-in monitor: internally powered
	Temperature of applied part:	< 41 °C
	Sterilization:	none
EMC:	Alarms:	yes
	Emission class:	Group 1, Class B
	Immunity class	not life-supporting equipment to be used during patient transport outside the healthcare facility (if internally powered)
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!