

Test Certificate

regarding
Electrical Safety and Environmental Conditions Requirements



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

Test Laboratory

Certificate No.: 610.163.2

License Holder: **bluepoint Medical GmbH & Co.KG**
An der Trave 15
D-23923 Selmsdorf (Germany)

Product identification:: multifunction patient gas monitoring equipment

Type/Model/Parameters: **CapnoTrue MG**

Particulars: Multigas monitor (et)Co₂, (Fi)CO₂, N₂O, anaesthetic agents;
Pulseoximetry, Pulse rate;
Respiration rate and MAC value

Applied standards: **IEC 60601-1:1988 +A1:1991 + A2:1995**
IEC 60601-1-4:2000
IEC 60601-1-8:2006
ISO 9919:2005
ISO 21647:2004 + Corrigendum 1:2005

Test report(s): 409.107.4B, 409.107.3B, 409.107.5B, 409.107.6B, 409.107.7B

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.



Wismar, Friday, 03 February 2012

Head of test laboratory

Dipl.-Ing. Bernd Schmidt

see 'Attachment 1' for more details

Classification:

Ratings:	Extern. power supply unit:	100 - 240 V, 50 – 60 Hz, 250 mA
	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 unit) Type BF (not-defibrillation-proof)
	Protection by enclosure:	IPX1
	Clinical environment:	not intended to be used in presence of oxygen enriched environments or flammable aesthetic mixtures
	Operator profile:	to be used under supervision of professional healthcare personnel
	Patient profile:	adults, paediatric and infants
	Installation and use:	hand-held
	Supply connection:	internally powered (with external detachable power adapter)
Environmental conditions:	Temperature of applied part:	< 41 °C
	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!](#)