

Test Certificate

regarding
Electrical Safety Requirements



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

Test Laboratory

Certificate No.: 611.270.1

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

Product identification:: **measuring device for human alcohol saturation in exhaled breath**

Type/Model/Parameters: **AlcoTrue M**

P/N: **5040112002**

Applied standards: **IEC 60601 1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)**

Classifications and Restrictions: **see 'Attachment 1'**

Test report(s): **# 411.270.1A**

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, 12 October 2012

Head of test laboratory

A handwritten signature in blue ink, appearing to read 'Bernd Schmidt'.

Dipl.-Ing. Bernd Schmidt

see 'Attachment 1' for more details

Classification:

Ratings:

Internal battery.....: 4 x 1.5 V (Mignon, LR6, AA) or
3.7 V, 2200 mAh (Li-Ion rechargeable)

External Mains adapter.....: 5 Vdc, 600 mA

Mains adapter:

This certification includes and is restricted to the combination with the following external charging unit (external DC adapter):

Manufacturer.....: Shenzhen Fujia Appliance Co., Ltd.

Model/Type reference.....: FKS106HSC

Ratings.....: input: 100-240V, 50/60 Hz, max. 0.25A
output: 5.0Vdc, 600mA

Electrical safety:

Protection class: Class II, Type B (not defibrillation proof)

Protection by enclosure: IP43

Clinical environment: not intended to be used in presence of oxygen enriched environments or flammable aesthetic mixtures

Intended user profile.....: professional healthcare personnel

Installation and use.....: hand-held

Supply connection: internally powered
(charging unit: plug-in with detachable DC interface)

Temperature of applied part: < 41 °C

Mode of operation.....: continuous

Essential performance restrictions:

The measurement results obtained may not be used as exclusive indicator for diagnosis and/or treatment.

Environmental condit.:

Operation:

Maximum temperature.....: - 5 – +50 °C

Max. humidity.....: 10 – 100 % rH

Max. altitude/ lowest air press : 4000 m / 600 hPa in measurement mode
2000 m / 800 hPa in charging mode

Transport / Storage:

Maximum temperature.....: -20 - +65 °C

Max. humidity.....: 10 – 100 % rH

Max. altitude/ lowest air press : 4000 m / 600 hPa

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

End of Listing!