

Test Report issued under the responsibility of:



an Accredited Testing Laboratory. Accredited by Swedac, No. 1003, ISO/IEC 17025

**IEC 60601-1**  
**Medical electrical equipment**  
**Part 1: General requirements for basic safety and essential performance**

**Report Reference No.**.....: 1117291-1  
**Date of issue** .....: 15 October 2012 .....  
**Total number of pages**.....: 43 .....

**CB Testing Laboratory**.....: **Intertek Semko AB**  
**Address** .....: Torshamnsgatan 43, Box 1103  
SE-164 22 Kista, Sweden

**Applicant's name**.....: **Aggero Medtech AB**  
**Address** .....: MT, Danderyds Sjukhus,  
SE-182 88 Stockholm, Sweden

**Test specification:**  
**Standard** .....: **IEC 60601-1:1988 + A1:1991 + A2:1995**  
**Test procedure**.....: **STC**  
**Non-standard test method**.....: **-**

**Test Report Form No.**.....: **IEC60601\_1C\_II**  
**Test Report Form Originator** .....: **Underwriters Laboratories Inc.**  
**Master TRF** .....: **Dated 2011-11**



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**Test item description** .....: Measuring device for patients with lesions in central nervous system.  
**Trade Mark** .....: NeuroFlexor  
**Manufacturer**.....: Aggero Medtech AB  
**Model/Type reference**.....: NeuroFlexor  
**Ratings** .....: 100-240V~, 50/60Hz, 25-45VA, Class I, Type B

<b>Testing procedure and testing location:</b>	
<input checked="" type="checkbox"/> <b>CB Testing Laboratory:</b>	<b>Intertek Semko AB</b>
Testing location/ address .....	Torshamnsgatan 43, SE-164 22 Kista, Sweden
<input type="checkbox"/> <b>Associated CB Test Laboratory:</b>	
Testing location/ address .....	
Tested by (name + signature) ..:	Jenny Larsson 
Approved by (+ signature) .....	Mikael Ivarsson 
<input type="checkbox"/> <b>Testing procedure: TMP</b>	
Tested by (name + signature) ..:	
Approved by (+ signature) .....	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: WMT</b>	
Tested by (name + signature) ..:	
Witnessed by (+ signature) .....	
Approved by (+ signature) .....	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: SMT</b>	
Tested by (name + signature) ..:	
Approved by (+ signature) .....	
Supervised by (+ signature).....:	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: RMT</b>	
Tested by (name + signature) ..:	
Approved by (+ signature) .....	
Supervised by (+ signature).....:	
Testing location/ address .....	

**List of Attachments (including a total number of pages in each attachment):**

Attachment A: 5 pages, photo document

**Summary of testing****Tests performed (name of test and test clause):**

See Test report form.

**Testing location:**

See page 2

**Summary of compliance with National Differences**

List of countries addressed: CENELEC

The product fulfils the requirements of IEC 60601-1:1988 + A1+ A2 except the following applicable requirements which have not been evaluated:

- Programmable electrical medical system according to IEC 60601-1-4:1996 + A1
- Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment according to IEC/EN 60601-2-40:1998
- Biocompatibility according to ISO 10993