



Product Service

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Technical Report No. 71313097

Revision: 1

dated 2006-11-03

Client: H.C. Equipment ApS
Gørtlervej 9B
9000 Aalborg
DENMARK

Manufacturing place: H.C. Equipment ApS
Kaolinvej 5
9220 Aalborg Øst
DENMARK

Test object: Patient positioning system
Type: VENDLET

Test specifications: EN 60601-1:1990 + A1:1991 + A2:1995
(*excluded clause: 48*)

Purpose of examination: 1st re-testing due to the points of non-compliance as listed in the Technical Report No. 71310224 according to the test specification.

Test result: The test subject was found to be in compliance with the test specification.

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1 Description of the test subject

The patient positioning system was developed to be mounted on hospital and care beds for turning patients from one side to another in the bed electrically. This can be realized by taking down the safety bed rails and mounting the VENDLET to the fittings on the bed frame. The patients can be turned by a turning sheet fixed between two bars. The system can be controlled via a hand control. For stopping unwanted movement an emergency stop switch is provided. Also the nursing staff must always direct their full attention on the patient when using VENDLET.

The difference between the models is that the bars have to be elevated and lowered mechanically with the HC-2 whereas the V4 offers an electrically adjustment.

1.1 Technical Data

Equipment:	Patient positioning system
Type:	VENDLET
Models:	HC-2 / V4
Rated supply voltage:	230Vac
Rated frequency:	50Hz
Rated power:	100VA
Protection class:	II
Degree of protection:	IPX1
Type of applied part:	B
Max. user weight:	200kg
Operating time:	5% (max. 5min. continuous operation)
Classification 93/42/EEC:	Class 1
Total length:	195cm





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2 Order

2.1 Date of Purchase Order

The re-testing of the patient positioning system has been carried out per purchase order of H.C. Equipment ApS dated at 2006-10-13.

2.2 Date of Receipt of Test Subject

The testing has been performed at TÜV SÜD Product Service, Masurenweg 1-3, D-30163 Hanover. The test subject was delivered to the test laboratory as stated below:

- 2006-07-24, VENDLET HC-2 and V4 system (Version 1.0)
- 2006-09-25, VENDLET V4 system with bed
- 2006-10-16, VENDLET V4 system (Version 2.0)
- 2006-10-25, 3x separate transformers, type DK-13051

3 Test Results

The points of non-compliance as listed in the Technical Report No. 71310224 were removed at the test subject and documents presented for re-testing.

4 Remarks

- 4.1 Testing of the biocompatibility of the turning sheet was not part of the manufacturers order and not part of this testing. Therefore clause 48 has been excluded from testing. (EN 60601-1, clause 48)
- 4.2 Testing of the mechanical safety with regard to the applicable parts of EN 12182:1999 and EN 60601-2-38:1996 + A1:2000 was not part of the manufacturers order and not part of this testing.

5 Summary

The test subject was found to be in compliance with the test specification.

TÜV SÜD Product Service GmbH

i.A. Nikolaus-Peter Ohl
AMP-MGE

TÜV SÜD Product Service GmbH
Project Manager

i.A. Michael Steinmann
Rehabilitation