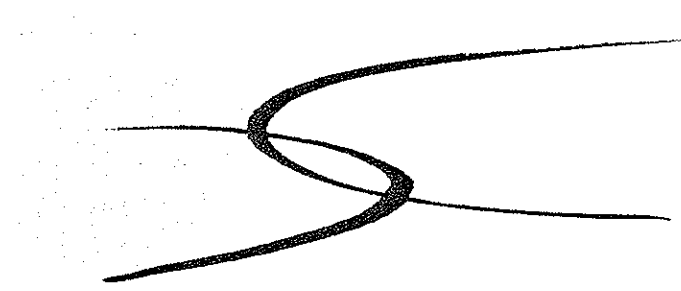


Danish Centre

for technical aids for rehabilitation and education
Gregersensvej - DK - 2630 Taastrup



TESTING REPORT

Testing of beds and bed boards with motorised adjustment of body position.
ISO 18 12 09
according to EN 1970:2000

Testing No.
02.23A

This page is page 1 of a total of 2 pages

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Notice:

This report is not an approval of the product type tested, but a record of testing results for a specific product sample

Product tested	:	Siderail Standard, for OPUS 1
Serial no.	:	158522
Product received	:	01.07.02
Testing notified by	:	K.R. Hospitalsudstyr A/S Mågevej 16 8370 Hadsten
Person to contact	:	Henning Frølund
Product delivered by	:	K.R. Hospitalsudstyr A/S

03-07-2002

Date

Finn Såbye
Testing executive



SUMMARY OF THE TESTING

A sample siderail of type standard has been tested in accordance with all relevant requirements of the following sections of the EN 1970:2000 standard:

With the exception of:

5.11 Electrical requirements

5.12 EMC requirements

5.13 Noise

Which has not been requested.

The testing took place during the period from 01.07.02 to 03.07.02, and was carried out under normal indoor conditions.

Tolerances of the measurements can be informed from the laboratory upon request.

TESTING RESULTS

The detailed testing results are recorded in the enclosed "Testing records" page 3.





Testing records

Testing number: 02.23 A

According to EN 1970:2000
Adjustable beds for disabled persons


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Date Testing executive

Requirements and testing methods are not described in total in "Testing Records". For a full description, see the standard EN 1970:2000.

Items marked with includes results that are not a part of the accredited testing. The result in those cases are therefore based on an estimation in relation to the intended use of the product, as specified in the instructions for use.

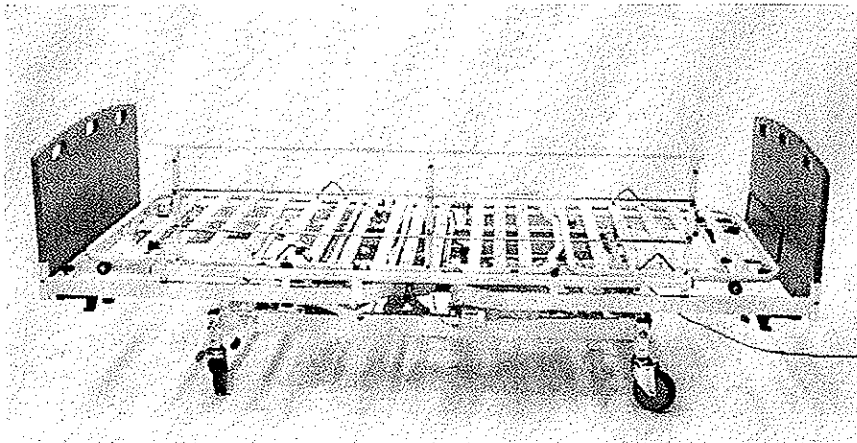
The requirements of the standard are indicated by underlined text.

In the right margin the following symbols are used to indicate how the requirements of the standard are fulfilled:

These indications are not a part of the accredited test.

y	yes, the requirement of the standard is fulfilled
n	no, the requirement of the standard is not fulfilled
na	not applicable, the requirement of the standard is not relevant for this product
nt	not tested, there are no request of the test
com	comment, can be supplemented by a number

Photo:



Brief description of the product:

Foldable steel siderail for mounting at bed side.

TESTING RESULTS

The following requirements of the standard were found not to be fulfilled:

4	General safety requirements	n1
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The following notes of the standard were found not to be fulfilled:

5.4.11	Deflection and permanent deformation	(n)
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Contents:

4	General safety requirements
4.2	Maximum mass of knock-down parts
5	Specific safety requirements
5.3	Stability
5.4.11	Side rails and grab handles
5.5.2	Height of seat section
5.5.3	Under bed clearance
5.5.5	Dimensions of side rails and grab handles
6	Instructions for use
7	Marking

<p>4 General safety requirements</p> <p>To ensure that:</p> <p>the bed, when transported, stored, installed operated in normal use, and maintained according to the instructions for use, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application, in normal condition and in single fault condition,</p> <p><u>a risk analysis in accordance with EN 1441 shall be carried out.</u></p> <p>checked by measurements:</p> <ul style="list-style-type: none"> • <u>distances between moving parts within normal reach for fingers of the disabled person, the attendant or other persons shall always be either maximum 8 mm or more than 25 mm.</u> • <u>distances between moving parts and the floor within normal reach for feet of the disabled person, the attendant or other persons, shall always be either maximum 20 mm or fulfil the dimensional requirements given in figure 6.</u> • <u>distances between elements in end panels shall comply with the requirements for distances between elements in side rails (see 5.5.5).</u> <p>Comments:</p> <p>com1: When folded down there are distances in area 8 to 25 mm between:</p> <ul style="list-style-type: none"> • locking mechanism • horizontal elements • vertical and horizontal elements <p>A warning is contained in instruction for use</p>	<p>Risk analysis is carried out</p> <p>Distances are between 8 and 25 mm</p> <p>Distances fulfils dimensions of fig.6</p>	<p>y</p> <p>com1 n</p> <p>y</p> <p>na</p>
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<ul style="list-style-type: none"> • checked by visual inspection • <u>open ends of tubular components shall be capped or otherwise closed.</u> • <u>all edges and corners shall be smooth and shall have no burrs or sharp edges and protruding parts shall be avoided.</u> • <u>the design of the foot end panel shall prevent feet slipping through holes in the panel.</u> • <u>the design of the bed shall allow mounting of side rails and lifting pole.</u> • <u>the design of the bed shall prevent incorrect assembly of knock-down parts and accessories.</u> • <u>the design of the bed shall prevent unintentional activation of moving parts and accessories.</u> • <u>single use components, e.g. wood screws or self tapping screws, shall not be used for the assembly of any components that are intended to be removed when disassembling for the purposes of transportation and storage.</u> • <u>in case of malfunction in the drive system, it shall be possible to bring the back rest section to the horizontal position.</u> • <u>a control unit shall be reachable by the disabled person and the attendant.</u> • <u>a control unit shall have a hold-to-run function.</u> • <u>it shall not be possible to position the bed in a hazardous position for the disabled person. The position of Trendelenburg for medical treatment (see EN 60601-2-38) shall not be possible.</u> which shall be checked by inspection. <p>Comments:</p>	<p>Tubular components are closed</p> <p>There are no especially sharp edges or corners</p> <p>Side rail and liftingpole can be mounted</p> <p>Designed for correct assembly</p> <p>The siderail is designed so that unintentional activation will not occur by intended use</p> <p>Single use components are not used</p>	<p>y</p> <p>y</p> <p>na</p> <p>y</p> <p>y</p> <p>y</p> <p>y</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p>
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<p>4.2 Maximum mass of knock-down parts</p> <p>Weight of:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Side rail</td> <td style="text-align: right;">7,0 kg</td> </tr> <tr> <td></td> <td style="text-align: right;">kg</td> </tr> <tr> <td></td> <td style="text-align: right;">kg</td> </tr> <tr> <td></td> <td style="text-align: right;">kg</td> </tr> <tr> <td></td> <td style="text-align: right;">kg</td> </tr> <tr> <td></td> <td style="text-align: right;">kg</td> </tr> <tr> <td>The total weight of the bed</td> <td style="text-align: right;">kg</td> </tr> </table> <p><u>If a bed is of a knock-down type, the maximum mass of any main part shall be either less than 50 kg or the part shall be labelled with the actual mass which shall be mentioned in the instructions for use.</u></p> <p>Comments:</p>	Side rail	7,0 kg		kg		kg		kg		kg		kg	The total weight of the bed	kg	<p>The bed is of the knock-down type</p>	
Side rail	7,0 kg															
	kg															
	kg															
	kg															
	kg															
	kg															
The total weight of the bed	kg															
<p>5.3 Stability</p> <p>5.3.2.2 Loading onto lifting pole</p> <p>This test shall be carried out just before the test (with the loading of 1500 N) in 5.4.14.</p> <p>Position the lifting pole in the most adverse position in which it is intended to be used by the disabled person.</p> <p>Apply a vertical downward force of 1350 N onto the handle of the lifting pole.</p> <p><u>Examine whether the bed overbalances during the test</u></p> <p>Comments:</p>		<p>na</p>														

5.4.11/12 Test of the strength and rigidity of side rails and grab handles

Position the side rail in the highest, upright position. The side rail shall be positively latched.

Apply a horizontal outward force of 500 N ten times for 30 seconds onto the side rail/grab handle in the most adverse point of its total length at a point that is not more than 50 mm under the highest point of the side rail/grab handle.

If the side rail has a locking mechanism, those of the forces as given above which will result in shear forces in the locking mechanism, shall also be applied to the element closest to the locking mechanism in any fixed height position.

Apply a force of 350 N ten times for 30 seconds onto the weakest point/element (in relation to deflection during application of loads and in relation to permanent deformation) of the side rail in the most adverse direction.

	Before loading	During loading	After loading	Deflection	Permanent deformation
A 500 N	30	33	30	3	0 mm
B 750 N	30	29	30	1	0 mm
C 500 N	\	\	\	\	\ mm
D 500 N	\	\	\	\	\ mm
E 500 N	100	30	88	70	12 mm
F 500 N	100	170	105	70	5 mm
G					mm

	Loading direction	Loading point
A	vertically upwards	upper bar opposite locking
B	vertically downwards	upper bar opposite locking
C	longitudinal towards foot end	upper bar opposite locking
D	longitudinal towards head end	upper bar opposite locking
E	horizontally inwards	upper bar at locking
F	horizontally outwards	upper bar opposite locking
G	locking mechanism	see C
H	weakest point	see E and F

When tested in accordance with 5.4.12 the side rail and grab handle shall still function normally and present no hazards:
Any locking mechanism of the side rail shall still be locked

Note: The deflection of the side rail/grab handle should not be greater than 50 mm during application of the loads and not greater than 10 mm at any point in relation to the bed board after removal of the loads

Comments:

the side rail functions normally is still locked

y
y

(n)
(n)

<p>5.5.2 Height of seat section</p> <p>h1 = 0 mm h2 = 70 mm d1 = 70 mm t1 = 100 mm</p> <p><u>With the seat section in any position, the mattress top shall be 20 mm higher than the bed board frame / side structure and the upper part of the lowered side rail</u> (d1 ≤ t1 - 20 mm, see figure 14).</p> <p>Comments: Requirement fulfilled with mattress higher than 90 mm</p>		y
<p>5.5.3 Under bed clearance</p> <p>Dist. from floor to a fixed element in under bed clearance = mm Dist. from floor to a movable elem. in under bed cleara. = mm</p> <p><u>With the mattress support platform lowered to any position higher than 400 mm, the height of the under bed clearance shall be at least 150 mm at a length of at least 500 mm positioned on each side of the symmetry plane of the mattress support platform, see figure 15.</u></p> <p><u>If the bed/bed lift is intended and designed to be used with certain identified hoists only, the under bed clearance need not to fulfil the above given requirement if information is given in the instructions for use</u></p> <p>Comments:</p>		na na

5.5.5/6 Test of dimensions of side rails and grab handles

Press the relevant cone as specified in 5.2.6 between any elements of the side rail/grab handle and/or between any elements of the side rail/grab handle and their supporting structure with 30 N

Side rails

A	Dimension between elements	105 mm
B	Thickness of mattress	120 mm
C	Distance from side rail top to mattress top	220 mm
D	Distance to end panels / accessories	300 mm
E	Distance between segmented side rails	- mm
F	Opening below side rail	25 mm
G	Length	1410 mm
H	Distance between end panels	2095 mm

Grab handles

A	Dimension between elements	mm
B	Thickness of mattress	mm
C	Distance from grab handle top to mattress top	mm
D	Distance to end panels / accessories	mm
E	Distance between grab handles	mm
F	Opening below grab handle	mm
G	Length	mm
H	Distance between end panels	mm

Distances (see figures 20 and 21) between elements of side rails/grab handles and between side rails/grab handles and elements of the bed/accessories shall fulfil the requirements given in table 1.

Comments:

<p>6 Instructions for use</p> <p>The bed shall be accompanied by instructions for use which shall include the following information as a minimum:</p> <p>a <u>Name of the manufacturer;</u> <u>NOTE: A trademark or logo is not sufficient to specify the manufacturer</u></p> <p>b <u>The address and telephone number of the manufacturer</u></p> <p>c <u>The intended use, e.g. that the bed is intended for adults from 12 years of age;</u></p> <p>d <u>Full operating, e.g. how to immobilize a bed supplied with wheels</u> <u>installation, e.g</u> <u>that care should be taken, so that an electrically operated bed is placed with</u> <u>a distance to the power supply plug, and assembly instructions;</u></p> <p>e <u>Requirements on inspection and servicing;</u></p> <p>f <u>Cleaning and maintenance instructions;</u></p> <p>g <u>Overall dimensions and mass, including the mass of main parts;</u></p> <p>h <u>Safe working load (see 4.1)</u></p> <p>i <u>Safety precautions and any warnings, e.g.:</u> <u>a warning that precautions shall be taken if accessories not listed are used;</u> <u>warning, if only to be used with certain identified hoists</u></p> <p>j <u>Description of all symbols used for marking;</u></p> <p>k <u>The weighted sound power level (see 5.13) if not included in the marking;</u></p> <p>l <u>Identification of those accessories that are intended to be used with the bed.</u></p> <p><u>If electrically driven, the bed shall also be followed by instructions for use in</u> <u>accordance with the requirements of EN 60601-1.</u></p> <p>NOTE: Further guidance on instructions for use can be obtained from EN 1041</p> <p>Comments:</p>	<p>Instruction includes the following informations</p> <p>y</p> <p>y</p> <p>y</p> <p>y</p> <p>y</p> <p>y</p> <p>na</p> <p>na</p> <p>y</p> <p>y</p> <p>na</p> <p>y</p> <p>na</p>	
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<p>7 Marking</p> <p><u>The bed/bed lift shall be clearly and permanently marked with the following information:</u></p> <p>A <u>Name, address and telephone number of the manufacturer;</u></p> <p>B <u>Product identification (model number or reference);</u></p> <p>C <u>Lot and individual production number;</u></p> <p>D <u>Year and month of production;</u></p> <p>E <u>If the bed is of knock-down type, the mass of any main part with a mass of more than 50 kg (see 4.2);</u></p> <p>F <u>Safe working load (as specified in 4.1 and 4.2);</u></p> <p>G <u>Electrical protection class (class I, II or III in accordance with EN 60601-1);</u></p> <p>H <u>The range of width of the carriage in the case of adjustable carriage of the bed lift;</u></p> <p>I <u>The functions of controls;</u></p> <p>J <u>The weighted sound power level (see 5.13) if not included in the instructions for use;</u></p> <p>K <u>The class of IPX (see 5.11).</u></p> <p><u>If electrically driven, the bed shall also be marked in accordance with the requirements of EN 60601-1.</u></p> <p>Comments:</p>	<p>The product is marked with the following informations</p>	<p>y</p> <p>y</p> <p>y</p> <p>y</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p> <p>na</p>
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Additional specifications

Electrical equipment, type

Motor for

Motor for

Motor for

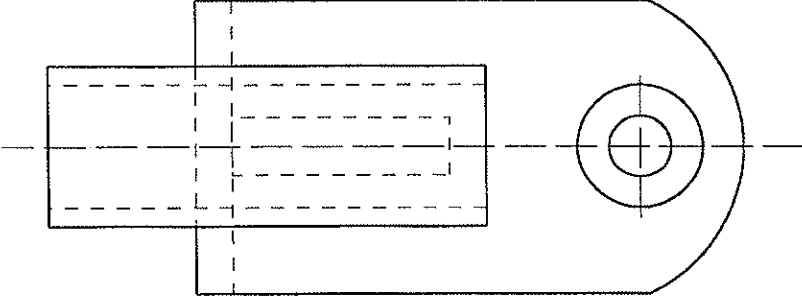
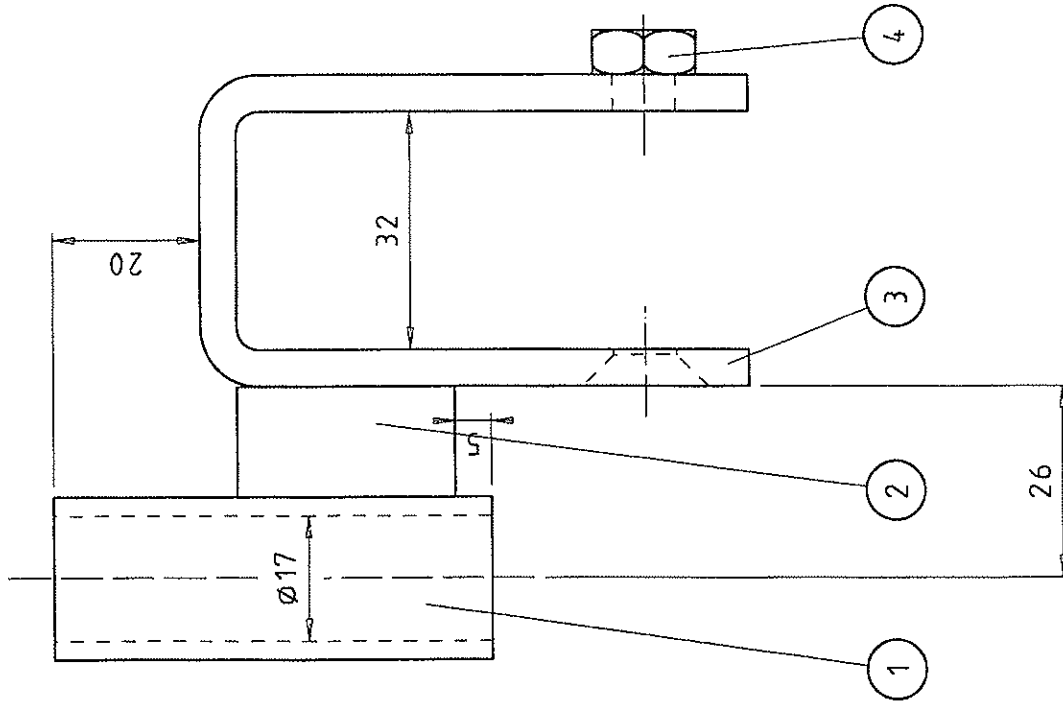
Transformer/connector box

Control unit

Mattress

Dimension, max height 120 mm

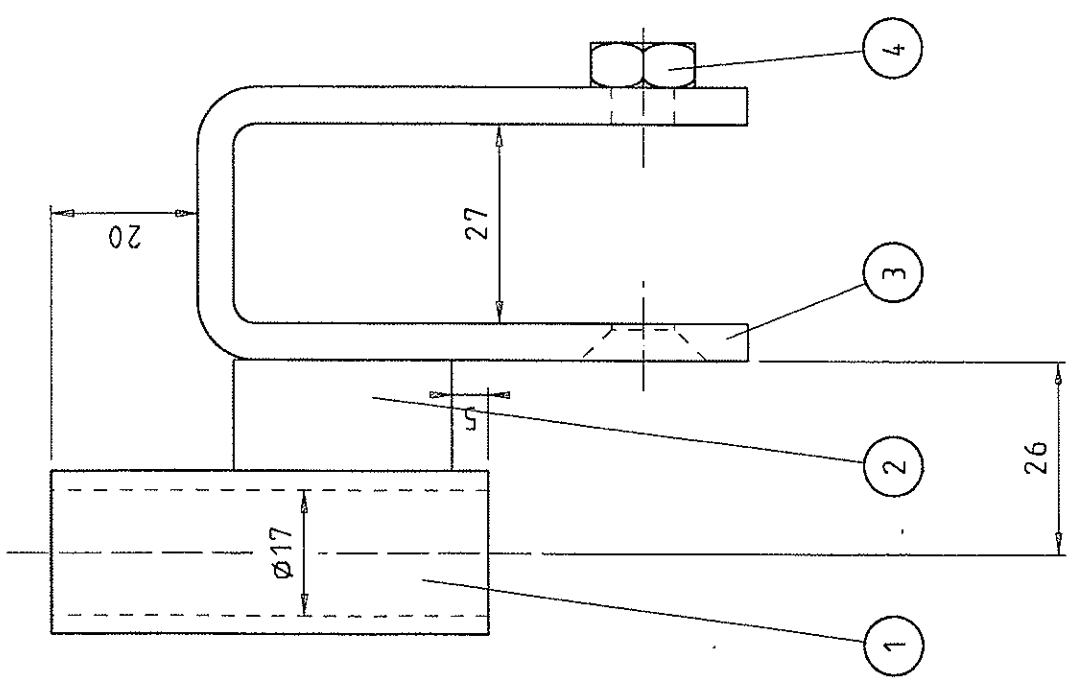
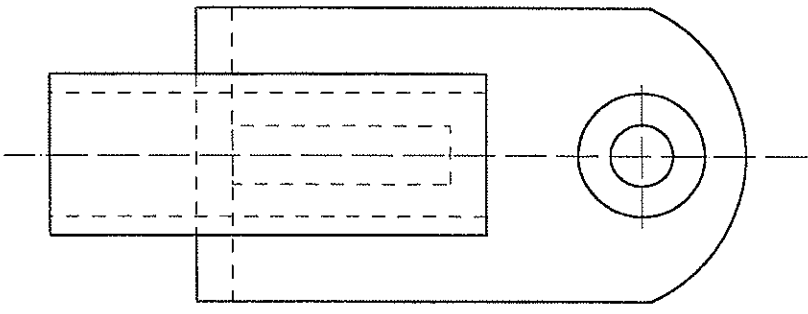
Type



4	1	Svejsemøtrik M8	942280
3	1	U-Beslag 40/5-(175)	600.139.4
2	1	Beslag 30/8x15	495.491.4
1	1	Bøsning Ø22/2.5x60	495.492.4

Pos. Anm.	Dimension/Materiale
Afdeling:	
Tolerancer:	
Overflade:	
Målestok: 1:1	
Mål: 0,29 Kg	
Materiale:	
Rensning:	
Type:	
Beskrivelse:	
Beslag, SV.	
Før: 1495 las beslag/sidehengt sengehøst	
Tegning Nr.: 495.490.2	
Side 1 af 1	
ECS. af:	

Hospitalstusystem A/S
 Dato: _____ Navn: _____
 Godk.: _____
 MS-DOS Navn: _____



4	1	Svejsemøtrik M8	942280	
3	1	U-Beslag 40/5-(27x75)	600.138.4	
2	1	Beslag 30/8x15	495.491.4	
1	1	Bøsning $\varnothing 22/2.5 \times 60$	495.492.4	
Pos. Antal		Tegnings Nr.: Dimension/Materiale		
Måling:		Målestok: 1:1 Vegt: 0.29 kg		
Tolerancer:		Materiale: RABENNE: Type:		
Overflade:		Beskrivelse: Gaffelbeslag, SV.		
Bolo		Før: DEUS løs beslag/sidehængt sengehest		
Tegn. 15.04.98 HF		Tegning Nr.: 495.489.2		
Bokk.		Side 1 af 1		
Mørk		Ers. af:		
RS-005 Mørk		Ers. af:		
R Hospitalssutstyr A/S		Ers. af:		
Opp.	Ændring	Date	Navn	Original: