

# Molly<sup>®</sup> bather<sup>®</sup> - CEN TEST REPORT

In accordance with relevant parts of draft standard EN10535:1998 Revision 1



ISSUE 1  
DATE 02/02/2001



**Dinotec Technical Services**  
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# Molly<sup>®</sup> - CEN TEST REPORT

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Test parameters 1.....

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DATE COMPLETED	CEN REF	DETAIL	DESCRIPTION	MINIMUM OPERATIONS	RESULT	UNITS	REQUIREMENT	ACTUAL RECORDED	NOTES
	4.1.1	Risk assessment	Evaluate risks & how to minimise them						See Page 5
01/03/2001	4.1.2	Ergonomics	Measure against CEN criteria	1	Pass		As CEN list	Complies	See Page 6
27/02/2001	4.1.3	Sound level	Measure against CEN criteria	1	Pass	DBA	60	40	See Page 6
27/02/2001	4.3.1	User rating	Achieve minimum rating	1	Pass	KG	120	140	See Page 6
27/02/2001	4.3.2	EN60601-1	Ensure compliance to Electrical standard		Pass		As CEN list	Complies	See Page 6
01/03/2001	4.3.3 to 4.3.8	General safety	Ensure compliance to requirements	1	Pass		As CEN list	Complies	See Page 6
27/02/2001	4.3.9	Normal lifting - lower	Must not apply excess load to user	1	Pass	N	10	0	See Page 6
27/02/2001	4.3.9.1	Horizontal transfer	Must not apply excess load to user	1	Pass	N	100	0	See Page 6
27/02/2001	4.3.9.2	Normal lifting - raise	Must not apply excess load to user	1	Pass	N	10	0	See Page 6
27/02/2001	4.3.11	Control positioning	Accessibility of controls	1	Pass		Within reach	Complies	See Page 6
27/02/2001	4.3.12	Emergency stop	Power isolation device	1	Pass		Fitted	Complies	See Page 7
27/02/2001	4.3.14	Battery charge	Low battery indication required	1	Pass		Fitted	Complies	See Page 7
27/02/2001	4.3.15	Hold to run controls	Must be held to operate	1	Pass		Must be HTR	Complies	See Page 7
29/03/2001	4.3.16	Max lift capacity	Must only lift up to 1.5x user rating	1	Pass	KG	<210	>140/ <210	See Page 7
01/03/2001	4.3.17	Single fault	Prevention from user falling in SFC	1	Pass		As CEN list		See Page 7
01/03/2001	4.3.19	Belt attachment	Prevention from accidental disengagement	1	Pass	NA	Fitted	NA	See Page 7
01/03/2001	4.3.20	Safety devices	Fitting of safety device to prevent user falling	1	Pass	NA	As CEN list	NA	See Page 8

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Test parameters 2.....

In accordance with relevant parts of draft standard EN10535:1998 Revision 1

DATE COMPLETED	CEN REF	DETAIL	DESCRIPTION	MINIMUM OPERATIONS	RESULT	UNITS	REQUIREMENT	ACTUAL RECORDED	NOTES
28/02/2001	4.3.21	Emmission / Immunity	Measure against CEN criteria	1	Pass		Minimum emmissions	None detected	See Page 8
01/03/2001	4.3.22	Electrical splashproofing	Ensure compliance to CEN criteria	1	Pass	IP	As CEN list	IP69	See Page 8
01/03/2001	4.4.18A	Lift belt rating	Perform overload test	1	Pass	KG	See note & Page 7	450kg	See Page 9
01/03/2001	4.4.18B	Lift belt joint rating	Perform overload test	1	Pass	KG		450kg	
01/03/2001	4.10.2	Liquid traps	Prevention from trapping liquid internally	1	Pass	NA	As CEN list	Complies	See Page 9
27/02/2001	4.10.3	Stopping speed	Stopping speed of lift loaded	1	Pass	mm	<50	Instant	See Page 9
27/02/2001	4.12.1	Operating speed	Operating speed loaded	1	Pass	m/s	<0.15	0.01	See Page 9
27/02/2001	4.12.2	Operating speed	Operating speed unloaded	1	Pass	m/s	<0.25	0.01	See Page 9
27/02/2001	4.14A	Operating force	Operating force - finger	1	Pass	N	<5	1	See Page 10
27/02/2001	4.14B	Operating force	Operating force - hand	1	See P10	N	<105	13 ex Battery pack	See Page 10
02/03/2001	4.16.2	Markings	Labelling etc	1	Pass	NA	As CEN list	NA	See Page 10
02/03/2001	4.16.3	Instructions	User guide etc	1	Pass	NA	As CEN list	NA	See Page 10
27/02/2001	4.18.8A	Durability test 1	Cyclic - top - no load (inc. Micro)	1000	Pass	KG	0 x 1000	5x 2050	See Page 10
20/03/2001	4.18.8B	Durability test 2	Cyclic - top - high load	1000	Pass	KG	140	140 x 1140	See Page 10
21/03/2001	4.18.8C	Durability test 3	Cyclic - top - med load	1000	Pass	KG	112	112 x 1055	See Page 11
24/03/2001	4.18.8D	Durability test 4	Cyclic - middle - med load	3000	Pass	KG	112	112 x 3080	See Page 11
27/03/2001	4.18.8E	Durability test 5	Cyclic - middle - low load	5000	Pass	KG	84	84 x 5070	See Page 11
02/03/2001	6.1.4	Limit switching	Backup feature	1	Pass	Ops	Dual feature	10 x Ops	See Page 11
27/03/2001	6.8.1	Static strength	Overload test	1 x 20min	Pass	KG	210	210 x 20min	See Page 12
29/03/2001	8.3	Durability tests	Belt attach / detach	1000	Pass	KG	As CEN list	1000	See Page 12
	9.20.3	Static strength	Buildings attachment	1 x 20min		KG	210		See Page 12

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*Test results  
and details.....*

*4.1.1*

*Risk assessments*

In regular meetings at every stage of the Molly bather development and pre-production, risk assessments have been made to increase the product safety and ease of use. Amongst concerns raised, the following details have been amended:

- A warning label has been fitted indicating maximum unwind position to minimise the belt being lowered too far.
- If a heavy user raises belt to maximum then dismounts, the micro-stop magnet on the belt can withdraw inside the bather. If the user tries raising instead of lowering at this stage, the micro-stop is overridden. - Solution: A second magnet is fitted 30mm behind the primary magnet, this distance being in excess of the maximum withdraw possible and acting as a secondary 'Up' micro-stop.
- To minimise the risk of single fault failure to the operating mechanism, secondary features have been added where necessary on the drive train.
- It was considered that the proposed battery pack handle be changed from a rigid plastic handle to a flexible type. This will prevent a user chafing their fingers on the battery pack cavity during refit.

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*Test results  
and details.....  
4.1.2 to 4.3.11*

- 4.3.2 Ergonomics

The only part that falls within this section complies, being the grab bar, where the distance to another part is 55mm, (should be >35mm), and the tube diameter is Ø25.4mm, (should be >19 and <43mm).

- 4.1.3 Sound level

The unit was checked with an accurate sound level meter and found to comply, being 40dba, (should be <60dba). - See Diagram 1

- 4.3.1 User rating

The unit complies, being rated at 140kg, (should be >120kg).

- 4.3.2 EN60601-1 Electrical standards

The unit complies with this electrical standard, as confirmed on page11from the designer and supplier of the electronics package. (Amrac Engineering Ltd.)

- 4.3.3 to 4.3.8 General safety

The unit has been assessed for general construction under this section and complies.

- Production models will use proprietary fastener and bearing locking fluid where necessary.
- Parts believed to be in risk of corrosion will be either plated or painted, or made in a non-corroding material where necessary.

- 4.3.9 to 4.3.9.2 Forces applied to user

The unit utilises a flexible belt which applies virtually no weight if lowered on to the user. There are no horizontal loads, due to the finger-trap prevention slot, (<8mm wide).

- 4.3.11 Control positioning

All controls are in easy reach of the user, both when on and off of the unit, and when raised or lowered.

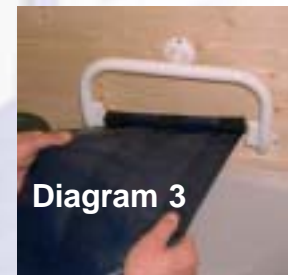


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*Test results  
and details.....  
4.3.12 to 4.3.19*

- **4.3.12 Emergency stop**  
In the event of the hold-to-run handset buttons becoming locked, the unit can be isolated by simply hinging up the seat and pulling out the battery pack, thereby preventing the unit from further motion until the fault is rectified. This ensures compliance with the standard.
- **4.3.14 Battery charge indication**  
The handset has an LED which illuminates when the battery is low. It stays lit when the battery requires charging, leading to a flashing feature when the unit has only a few lifts left. Adequate wording has been entered into the User guide to clearly identify the need to charge immediately when warned by the handset LED. This ensures compliance with the standard.
- **4.3.15 Hold to run controls**  
The handset features 2 soft touch silicone buttons. Both are of the 'Hold-to-run' type, and can only be used individually. This ensures compliance with the standard.
- **4.3.16 Maximum lift capacity**  
In the event of a load being applied to the belt which is between 1.25 and 1.5 times the maximum user rating; an electronic limiting device activates, stopping the unit lifting further, thus preventing damage to the system. This ensures compliance with the standard. (See diagram 2)
- **4.3.17 Single fault failure**  
To minimise the risk of a single fault failure of the operating machinery, secondary features have been added where necessary. This ensures compliance with the standard.
- **4.3.19 Belt attachment**  
To prevent inadvertent disengagement, the belt is fitted with a locking bar that locates into two channels on the inside of the grab bar. The channels have a labyrinth profile to allow only deliberate entry and exit. This ensures compliance with the standard. (See diagram 3)



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*Test results  
and details.....  
4.3.20 to 4.3.22*

- 4.3.20 Safety devices

As part of the design concept, every attention was paid to providing additional safety features compared with existing belt bathers, as follows:

- Hand supports are available on the padded seat and grab bar, allowing safe purchase on both sides of the bath.
- A padded seat is fitted atop of the main unit to allow safe and comfortable transfer onto the lifting belt.
- The belt itself is fully reinforced and securely located on both sides of the bath.
- The fully waterproof hand controls are on a short flexible lead, allowing easy operation without the user having to reach for switches etc. This ensures compliance with the standard.

- 4.3.21 Emission / Immunity

To ensure the Molly bather is free from affecting or being affected by RFI; the following precautions are taken:

- The drive motor is supplied fully EMC compliant.
- The electronics are supplied fully EMC compliant.
- All electrical parts are housed in a metal enclosure.

See diagrams 4 and 5 for testing, showing operation next to a Television, and a transmitting Mobile phone. Neither experienced any noticeable RFI during tests.

This ensures compliance with the standard.

- 4.3.22 Electrical splashproofing

Whilst there are at present no mandatory splashproofing requirements, all electronic parts are fully waterproof to IP69.

This ensures compliance with the standard.





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*Test results  
and details.....  
4.4.18A to 4.12.2*

- 4.4.18A / 4.4.18B Lift belt & joints rating

Whilst there is no mandatory requirement to meet a specific level of safety factor, due to the draft CEN requirement based on an Overhead hoist with a risk of dropping a patient up to 2.5 metres, (a Belt bather which can only raise up to 0.4 metres), it was felt that a factor of  $>3$  x the maximum user weight would be sufficient to ensure the risk of a user applying additional dynamic loads in excess of the normal 'dead weight'. To ensure compliance, a section of production quality belt, together with the production fixing plates was suspended on a cradle, where a load of approximately 450kg was lowered onto it. (850kg VP Metro front off-side with 89kg person directly above belt). This ensures compliance with the standard. See diagram 6 showing belt under load.

- 4.10.2 Liquid traps

To limit the ingress of water into the belt bather, the following precautions are taken:

- Bather mounted outside of the bath and shower area.
- Belt entry slot kept to minimum, ( $<8$ mm deep aperture).
- Splashproof padded seat covers all parts during use.
- Lift belt and reinforcing straps made of water-repellent polypropylene material.

To ensure exit of any water from the internal cavity of the bather, there are 5 downward facing louvres. See diagram 7 during showering the unit at all angles, which following this period the unit was left for 5 minutes prior to inspecting amount of water internally, which was only droplets. Some hours later these droplets had fully evaporated due to the through-flow design of the bather's ventilation design. This ensures compliance with the standard.

- 4.10.3 to 4.12.2

The bather was tested loaded and unloaded. The stopping speed was instant and well inside of the maximum specified operating speed of  $<0.15$ m/s, (achieved 0.01m/s), therefore compliant.



Diagram 6



Diagram 7



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*Test results  
and details.....  
4.14A to 4.18.8B*

- 4.14A Operating force - finger  
The hand-control is fully waterproof and has individual silicon buttons controlling up and down functions. The overall pressure to operate the button is well below the required <5N force, (requires only 1N). This ensures CEN compliance. See diagram 8 showing method of compliance testing.
- 4.14B Operating force - hand  
The only parts handled by the user are the belt attachment bar, the hinging of the seat, and lifting out the battery pack. The overall weight of the battery pack is the greatest effort exceeding ideal requirement of <105N force, (weighs 160N). It was considered a minor compromise to CEN compliance.
- 4.16.2 Markings  
The labels attached to the product provide at least the required details as specified in the CEN specification. This ensures CEN compliance. See page 13 for examples of the production labels.
- 4.16.3 Instructions for use  
The User guide, Technical manual and Test certificate provide at least the required details as specified in the CEN specification. This ensures CEN compliance. See accompanying production documents.
- 4.18.8A Durability test 1  
As part of the cyclic testing of the product, the bather was installed over a bath, loaded with a light load to keep the belt taut, then operated repeatedly up and down, each time operating the up microswitch. The requirement of 1000 cycles was exceeded comfortably without any fault, (achieved 2050 cycles prior to halting test). This ensures CEN compliance. See diagram 9 showing method of compliance testing.
- 4.18.8B Durability test 2  
Following 4.18.8A, the bather was loaded with a full load of 140kg, then operated repeatedly up and down. The requirement of 1000 cycles was exceeded without any fault, (achieved 1140 cycles prior to halting test). This ensures CEN compliance. See diagram 10 showing method of compliance testing.



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*Test results  
and details.....  
4.18.8C to 6.1.4*

- 4.18.8C Durability test 3  
Following 4.18.8B, the bather was loaded with a load of 112kg, then operated repeatedly up and down at the upper to mid end of the range. The requirement of 1000 cycles was exceeded without any fault, (achieved 1054 cycles prior to halting test). This ensures CEN compliance. See diagram 11 showing method of compliance testing.
- 4.18.8D Durability test 4  
Following 4.18.8C, the bather was loaded again with a load of 112kg, then operated repeatedly up and down in the middle of the range. The requirement of 3000 cycles was exceeded without any fault, (achieved 3080 cycles prior to halting test). This ensures CEN compliance.
- 4.18.8E Durability test 5  
Following 4.18.8D, the bather was loaded with a load of 84kg, the bath filled with soapy water and then operated repeatedly up and down in the middle of the range. The requirement of 5000 cycles was exceeded without any fault, (achieved 5070 cycles prior to halting test). This ensures CEN compliance. See diagram 12 showing method of compliance testing.
- 6.1.4 Limit switch backup  
As the bather uses a fully splashproof sealed proximity switch, the most likeliest failure would be the primary belt magnet being withdrawn into the bather if, when at top position, a heavy user dismounts and then tries to raise further. This has been catered for by the addition of a secondary backup belt magnet. In the event of total failure of the proximity system, an electronic cutout will stop the unit before serious damage can occur. This ensures CEN compliance. See diagram 13 showing method of compliance testing.



Diagram 11

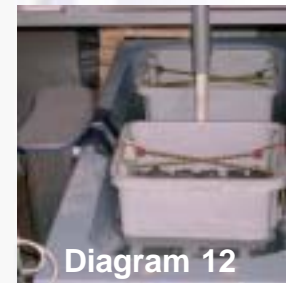


Diagram 12



Diagram 13





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*Test results  
and details.....  
6.8.1 to 9.20.3*

- 6.8.1 Static strength - bather and grab bar  
The bather belt and seat were independently loaded with a load of 210kg while fully raised. This load was maintained for 20 minutes, whereafter the load was removed and the bather checked for normal operation. No visible signs of damage were apparent, and the unit performed normally. This ensures CEN compliance. See diagram 14 & 15 showing method of compliance testing.
- 8.3 Durability test of bather belt attachment  
The bather belt attachment is designed to be removed from the grab bar cradle for servicing and to allow more ambulant users normal bathing. To ensure reliability of the attachment, the device was detached and re-attached repeatedly for 1000 cycles. The device was still fully operational and undamaged after the 1000 operations and is therefore compliant.
- 9.20.3 Static strength - building attachment 2  
The grab bar was previously tested in 6.8.1 while attached to wooden studding uprights, however in many case the grab bar will be fitted to a concrete or brick wall, requiring alternative fastenings. The wall was drilled to suit wallplugs, then the grab bar was fastened to the wall using suitable screws. The bather was again loaded with a load of 210kg while fully raised. This load was maintained for 20 minutes, whereafter the load was removed and the wall, grab bar and bather checked for normal operation. No visible signs of damage were apparent, and the unit performed normally. This ensures CEN compliance. See diagram 16 showing method of compliance testing.




**Diagram 16**

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Data sheets.....  
Labelling

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- Attached are examples of the production labelling on the Molly bather. (Not to scale)




MAX




MID



MIN




**Molly bather®**  
Max 140kg / 22st / 308lb







**Molly bather®**  
....battery care

- Do not charge in the bathroom
- Steady red light on the handset indicates low battery, please charge after use
- Flashing red light on the handset indicates very low battery, must charge **immediately**
- Charging your battery regularly will prolong it's life
- Please refer to the User Guide for further help

**Specification**  
Voltage..... 12V dc  
Rating..... 2.1Ah  
Serial code.....   
Class..... 

Dinotec Healthcare Limited  
Moat Road  
West Wilts Trading Estate  
Westbury  
Wiltshire BA13 4JB  
United Kingdom  
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Fax: +44 (0)1380-871056  
Email: support@molly-bather.co.uk  
Web: www.molly-bather.co.uk



**STOP - DO NOT LOWER FURTHER**



**Molly bather®**  
Max 140kg / 22st / 308lb



**Molly bather®**

**Molly bather®**





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*Data sheets.....  
Amrac EN60601-1  
compliance*

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# Molly bathers® - CEN TEST REPORT

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Data sheets.....  
Openhouse lift belt

*Openhouse*

FAO: Roy McDine  
Dinotec

As requested here are the specifications for the Powermesh 226

<b>Fibre Content</b>	100 % Polypropylene
<b>Yarn Type</b>	Warp: 525 Denier 525 Denier Fill: 11.5 mil black
<b>Construction</b>	34 x 20
<b>Finish</b>	Heat Set and Calendered
<b>Weight</b>	4.0 oz/yd <sup>2</sup> ≈ 135g/m <sup>2</sup>
<b>Gauge</b>	0.010 ± 3
<b>Selvage</b>	Woven
<b>Tensile Strength</b> (ASTM D-1682, Grab Method)	Warp: 240Lbs Fill: 23%
<b>Elongation</b> (ASTM D-1682, Grab Method)	Warp: 240Lbs Fill: 23%
<b>Burst Strength</b> (ASTM D-751)	385 Lbs/in <sup>2</sup>
<b>Puncture Strength</b> (ASTM D-751)	100 Lbs/in <sup>2</sup>
<b>Waterflow</b>	100 gal/ft <sup>2</sup> /min

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Directors: Brian E. Jones · Bruce Burns · Helen L. Jones



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## LIFTING BELT FABRIC

SPECIFICATIONS	
FIBRE CONTENT	100% Polypropylene
YARN TYPE	Warp: 525 denier Fill: 11.5 mil Black
CONSTRUCTION	34 X 20
FINISH	Heat Set and Calendered
WEIGHT	4.0 oz/yd <sup>2</sup> - 135g/m <sup>2</sup>
GAUGE	0.010 ± 3
SELVAGE	Woven
TENSILE STRENGTH	Warp: 240 lbs Fill: 150 lbs
ASTM D-1682, Grab Method	
ELONGATION	Warp: 19% Fill: 23%
ASTM D-1682, Grab Method	
BURST STRENGTH	385 lbs/in <sup>2</sup>
ASTM D-751	
PUNCTURE STRENGTH	100 lbs
ASTM D-751	
WATER FLOW	100 gal/ft <sup>2</sup> /min
STANDARD WIDTH	73"
PUT-UP	150 Yard Rolls

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