



Urgent Field Safety Notice

REA Azalea Base – Combination with Alternative Seating Systems

Date: 22th October 2012

Invacare incident ref: TW 20767

MHRA reference: 2011/012/020/081/001

MPA reference: 444:2012/69833

Urgent Safety Information:

In the interests of the safety of our customers we would like to bring your attention to the fitment of seating systems to the REA Azalea Base.

Invacare REA Azalea Base is manufactured at Invacare REA, Sweden. The product is ordered via a prescription form and delivered without seating. Customized seating systems are selected and fitted to suit the individual needs of the patient, following assessment and recommendation by the occupational therapist, or other suitably qualified personnel.

Invacare has successfully crash tested the REA Azalea Base, but prior to November 2012 tie-down labels have not been delivered with the wheelchair. Invacare are aware, however, that not all seating systems currently available have been crash tested and therefore advise the following action:

Please read Invacare REA Azalea user manual, part number 1488727 (section “Transportation”) delivered with your wheelchair. A complete, current version (date 2012-07-01 or newer) of the user manual can also be found on Invacare’s website: www.invacare.co.uk and other national Invacare websites.

- Confirm whether a combination agreement exists for the make / model of seating system being fitted (see table below for existing agreements).
- If there is no combination agreement, confirm with the manufacturer of the seating system if it has been successfully tested for use as a seat in transportation.
- Complete and document risk assessment to establish how the seating system could affect the safety and performance of the completed wheelchair, and whether it is safe to use as a seat in transportation. Please also consider other aspects which could be affected such as weight, stability etc.



Invacare® Limited
Pencoed Technology Park ·
Pencoed · Bridgend CF35 5AQ
Tel: +44 1 656 776 222
Fax: +44 1 656 776 220

Invacare® Ireland Ltd
Unit 5 · Seatown Business Campus
Seatown Road · SWORDS · County,
Dublin
Tel. +353 1 8107084
Fax +353 1 8107085



- Should you consider your REA Azalea Base and seating system is suitable for use as a seat in transportation, apply the tie-down labels to the appropriate locations on your custom wheelchair.
- Tie-down labels and instruction can be ordered from Your Invacare representative free of charge. Part number: 1563977.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and / or any organisation where the potentially affected devices have been transferred. Please also ensure that awareness is maintained for an appropriate period.

Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

INSERT LOCAL INVACARE REPRESENTATIVE ADDRESS.

Invacare confirm that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

Crash tested seating systems according to 7176-19:2008

Manufacturer	Seating System
Invacare	Flex 2 back / Flosshape cushion
Invacare	Flex 3 back /
Leckey	MyGo
Leckey	Kit
Motion Concepts	MatrX Personal back

Invacare Combination Agreement Exists

Manufacturer	Seating System
Motion Concepts	MatrX Personal back



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1.11 INTENDED USE

REA AZALEA BASE

The Rea[®] Azalea Base is a part of the Azalea family that is meant as a wheelchair base for different seating systems such as individually adapted anatomic seats manufactured by different companies.

The Rea[®] Azalea Base is intended for use both indoors and outdoors.

The maximum allowed weight load on the Rea[®] Azalea Base is 135 kg. This includes both user and seating system.

The Azalea range is CE-marked, but since the Rea[®] Azalea Base is not to be considered as a complete product and it is only when the base and the seating system have been combined that an evaluation of the safety can be done, it rests upon the company that mounts the seating system to perform such an evaluation.

However, if there is an agreement between Invacare and the manufacturer of the seating system that regulates the responsibility between the companies, the product can maintain its CE-marking. In other cases, the company mounting the seating system will be responsible for the CE-marking or that the chair will be registered and documented as a specially made medical technical product.

The Rea[®] Azalea Base has been crash tested together with the Invacare standard back and seat, but no other combinations have been tested and Invacare can in no way predict the effect of an accident with other configurations.

Other tests performed on the Azalea Base have also been carried out with the standard back and seat from the Azalea range mounted.



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