Invacare® *Flo-tech*® *Contour Visco*

EN **Cushion** *User Manual*

CE

This manual MUST be given to the user of the product.
BEFORE using the product, read this manual and save it for future reference!

INVACARE®

Yes, you can.®

Contents

1 General

1.1 General information

The first prevention of pressure ulcers in a sitting position is to rise up regularly whenever it's possible to limit prolonged compression of vessels next to the bony prominences and to allow tissues perfusion. Essential nursing care is pivotal in pressure ulcer prevention.

This cushion is intended to the pressure ulcers' prevention score < 14 on the Norton scale or the equivalent on another scale.

Education, clinical judgement and action based planning based on vulnerability are fundamental factors in prevention of pressure ulcers.

A range of assessment scales can be used as a formal method of assessing risk from pressure ulcer development, and should be used in conjunction with an informal assessment (informed nursing judgement). Informal assessment is considered to be of greater importance and clinical value.

This user manual contains important information about the handling of the product. In order to ensure safety when using the product, read the user manual carefully and follow the safety instructions.
For further information contact Invacare® in your country (addresses see back page of this manual).

1.2 Symbols

Symbols in this manual

In this User Manual warnings are indicated by symbols. The warning symbols are accompanied by a heading that indicates the severity of the danger.

WARNING
Indicates a hazardous situation that could result in serious injury or death if it is not avoided.

CAUTION
Indicates a hazardous situation that could result in minor or slight injury if it is not avoided.

IMPORTANT
Indicates a hazardous situation that could result in damage to property if it is not avoided.

Gives useful tips, recommendations and information for efficient, trouble-free use.

This product complies with Directive 93/42/EEC concerning medical devices. The launch date of this product is stated in the CE declaration of conformity.

Manufacturer

1.3 Warranty

We provide a manufacturer's warranty for the product in accordance with our General Terms and Conditions of Business. Warranty claims can only be made through the relevant specialist dealer.

Standard Invacare Terms

This is to certify that your Invacare Flotech® product is warranted by Invacare Ltd for a period stated in the Table "Technical Data" of this user guide.

The Warranty of your Invacare product is valid from time of shipping.

If a defect or fault is discovered the Invacare dealer or Local Business Development Manager from whom the appliance was obtained must be notified immediately.

The manufacturer will not accept responsibility for damage caused by misuse or non-observance of the instructions set out in this user guide.

During the period of the warranty any products that have become defective due to faulty workmanship or materials will be renewed without charge.

The warranty will be forfeited should any unauthorized alteration be made to the equipment.

Both warranty and fire retardancy certification will become null and void if non-Invacare spares are used on any Invacare Flotech® products.

The purchaser's statutory rights under the Consumer Protection Act are not affected.

Quality and flame retardancy

Quality is fundamental to the company's operation, working within the disciplines of ISO 13485 and ISO 9001.

The Invacare Flotech® cushions features the CE mark, in compliance with the Medical Device Directive 93/42/EEC Class 1.

Invacare is continuously working towards ensuring that the company's impact on the environment, locally and globally, is reduced to a minimum. It is Invacare's goal to ensure that we, at the widest possible range, use REACH compliant materials and components.

The foam and cover used to manufacture the Invacare Flotech® range is independently tested and certified in accordance with EN 1021-1 and EN 1021-2.

For further information please contact Invacare in your country (addresses see back page of this manual).

1.4 Intended use

This pressure reducing cushion is intended to be used as part of an overall pressure ulcer prevention program of care.

This product has been designed to deliver effective pressure reduction and postural support to users, when the product is in normal use which is defined by Invacare Ltd as when the Flotech product is placed without additional covers or padding between the user and the support surface.

Replace the cover in case of damage which may reduce the tightness or elasticity of the protection. Do not use with another cover that advocated.

1.5 Service life

We estimate a life expectancy of three years for these products, provided they are used in strict accordance with the intended use as set out in this document and all maintenance and service requirements are met. The estimated life expectancy can be exceeded if the product is carefully used and properly maintained, and provided technical and scientific advances do not result in technical limitations. The life expectancy can also be considerably reduced by extreme or incorrect usage.

The fact that we estimate a life expectancy for these products does not constitute an additional warranty.

1.6 Limitation of Liability

The warranty does not extend to the consequential costs from fault clearance, in particular freight and travel costs, loss of earnings, expenses, etc.

- Natural wear and tear.
- Inappropriate or incorrect use.
- Defective assembly or setting-up by the purchaser or third parties.
- Defective or neglectful treatment.
- Use of unsuitable spares.

2 Safety

2.1 Safety information

WARNING

- Do not use this product or any available optional equipment without first completely reading and understanding these instructions and any additional instructional material such as user manuals, service manuals or instruction sheets supplied with this product or optional equipment. Invacare product manuals are available on the internet or your local dealer (Addresses are displayed on the back cover of this manual).
- If you are unable to understand the warnings, cautions or instructions, please contact a healthcare professional, dealer or technical personnel before attempting to use this equipment – otherwise, injury or damage may occur.

WARNING

Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers have not been tested by Invacare and are not recommended for use with Invacare products.

The introduction of certain third party products between the cushion surface and the user may reduce or impede the clinical effectiveness of this product.

'Third party products' may include, but are not limited to items including under blankets, plastic sheets and sheepskins, etc.

WARNING

Any object between the user and the pressure reducing surface may result in the development of pressure ulcers.

- Make sure that the support surface in contact with the user is kept free from crumbs and other food debris.
- Drip cables, stents and other foreign objects must not become entrapped between the user and the pressure reducing surface of the cushion.

IMPORTANT

The information contained in this document is subject to change without notice.

- Check all parts for shipping damage and test before using.
- In case of damage, do not use.
- Contact Invacare/Carrier for further instructions.

2.2 Symbols on the product

	Do not pierce or cut		Do not tumble dry
	Do not put near flame		Machine wash temperature 80 °C (wipedown)
	Do not bleach		Tumble dry Ingress resistant cover only
	Orientation Label		Do not dry clean
	Do not iron		Do not smoke

3 Description

3.1 Product description

The Invacare Flo-tech Contour Visco cushion is moulded from visco-elastic (memory) foam, which is temperature-sensitive to the body. This foam provides a better pressure distribution for the user's body area in contact with the cushion.

The cover is multi stretch, waterresistant and vapour-permeable. The cover features an anti-slip base and carry handle.

4 Usage

4.1 Safety information

WARNING

- Invacare advise that the patient is measured and assessed by a suitably trained healthcare professional to ensure the correct size and seating requirements to achieve the best pressure and postural care and also position for the individual needs are met.

WARNING

It is very important for the patient to reposition themselves, or to be repositioned, on a regular basis. This relieves pressure which helps prevent both tissue compression and potential ulcer formation. This must be based on the clinical judgement of a qualified healthcare professional.

- Always consult a qualified healthcare professional before using the product.
- Monitor the patient frequently.

CAUTION

- Please ensure that the cushion is put in place in co-ordination with the orientation label which is situated on the left hand side of the cushion cover at the end of the zip.

IMPORTANT

In domestic settings common causes of damage include cigarette burns and the claws of pets that puncture covers, allowing fluid ingress and staining.

IMPORTANT

- To prevent accidental cover damage, please ensure that sharp objects are not placed on the cover. When using patient transfer aids, care should be taken not to damage the Flotech® cover. All transfer aids should be checked for sharp edges or burrs before use.
- It is important to ensure that the Flotech product is not jammed or damaged by sharp edges when used on wheelchairs.

4.2 Using the cushion

1. Remove all packaging before use.
2. Place the Invacare Flotech® product directly on the wheelchair or standard armchair.

5 Transport

5.1 Safety information

IMPORTANT

- Take care when handling the Flotech® product to ensure no damage to the product.
- Avoid contact with jewellery, nails, abrasive surfaces etc.
- Avoid contact with walls, door frames, door catches or locks etc.
- Do not transport in roll cages unless completely protected from the sharp edges of the cage.

6 Maintenance

6.1 Inspection

Check cushion (foam and cover) for strike-through (this may include fluid ingress, stains, rips or damage) after the release of each patient, after ending of the period of use or on a minimum monthly basis (depending on which occurs first) by a suitably qualified and competent person.

Check cushions

1. Unzip the cover completely.
2. Check for any staining on the interior foam.
3. Replace any stained items and dispose of as per local authority procedure.

6.2 Cleaning and care

IMPORTANT

All cleaning agents and disinfectants used must be effective, compatible with one another and must protect the materials they are used to clean. For further information on decontamination in Healthcare Environments, please refer to 'The National Institute for Clinical Excellence' guidelines on Infection Control www.nice.org.uk/CG139 and your local infection control policy.

IMPORTANT

The Platilon covers are not washable and need to be replaced in case of heavy soilage.

Cleaning black covers

(Removal of contaminants such as dust and organic matter)

1. Remove cover for laundering.
2. Launder the cover at the recommended temperature between 60 and 80 °C using a diluted detergent solution (instructions on label).

IMPORTANT

Washing at higher temperatures may cause shrinkage.

Drying black covers

1. Hang cover from a line or bar and drip dry in a clean environment.

IMPORTANT

- Tumble drying only for the ingress residence cover as this ensures that the fluorocarbon finish remains effective.
- Tumble dry setting must not exceed 80 °C.
- Do not tumble dry for longer than 10 minutes.
- Dry covers thoroughly before re-fitting to the Flotech product.

Disinfecting black covers

(Reducing the number of microorganisms)

Please contact your hygiene specialist in the event of contamination.

IMPORTANT

Ensure that any residual detergent has been removed prior to disinfection.

Light soilage

1. Wipe down the cover with a 0.1% Chlorine Solution (1,000 ppm).
2. Rinse the cover with clean water using a single use nonabrasive cloth.
3. Dry the cover thoroughly.

Heavy soilage

Where the cover is badly soiled, we recommend cleaning with a dilute cleaning detergent at 80 °C in the washing machine.

Large spillages of blood should be absorbed and removed with paper towels first.

1. Clean up all spillages of bodily fluids i.e. blood, urine, faeces, sputum, wound exudater and all other bodily secretions as soon as possible using a 1% Chlorine Solution (10,000 ppm).
2. Rinse the cover with clean water using a single use nonabrasive cloth, and dry thoroughly.
3. Dry the cover thoroughly.

IMPORTANT

1% Chlorine Solution used on a regular basis can diminish the life of the cover if not rinsed and dried properly.

- Do not use granules.

WARNING

- Remove contaminated foams from use.

CAUTION

- Keep clear of open heat sources.

IMPORTANT

- Do not use phenols, alcohols, bleaches, or other abrasive materials.

Replacing covers

1. Unzip the cover and remove it carefully from the foam core.
2. Place new cover onto the foam core.
3. Then close the zipper.

! IMPORTANT

- Ensure that the orientation label on the cover of the cushion matches the orientation printing on the foam core.
- Ensure that the corners are positioned correctly into the corners of the cover.

7 After-use

7.1 Storage

! IMPORTANT

- Store cushions in a dry environment.
- Store cushions within a protective cover/box.
- Store cushions in a flat state on clean, dry, off-flooring free from sharp edges to avoid any possible damage.
- Never store other items on top of a cushion.
- Do not store cushions next to radiators or other heating devices.

7.2 Re-use

The product is suitable for repeated use. The number of times it can be used depends on how often and in which way the product is used.

- Before reuse, clean the product thoroughly, see chapter 6.2 Cleaning and care, page 8.

7.3 Disposal

The disposal and recycling of used devices and packaging must comply with the applicable legal regulation.

- Ensure that the cushion is cleaned prior to disposal to avoid any risk of contamination.

8 Technical data

8.1 General data

Product	Total Height [mm]	Total Width [mm]	Total Depth [mm]	Nominal density range [kg/m³]	Nominal hardness range [N]	Minimum / maximum user weight [kg]	Product-weight [kg] [1)]
Flo-tech® Contour Visco medium	120	360 – 430	330 – 430	80 – 90	140 – 160	40 – 75	1.6
Flo-tech® Contour Visco firm	120	360 – 510	330 – 530	80 – 90	180 – 200	50 – 100	1.6
Flo-tech® Contour Visco very firm	120	360 – 510	330 – 530	80 – 90	240 – 260	80 – 125	1.6

[1)] Weights can vary depending on size of cushion ordered, average weights used as an indication.

Local requirements / certification available upon request from Invacare.

8.2 Material

Viscoelastic foam	Polyurethane foam components
HR foam	Polyurethane foam components
Black cover	Knitted polyamide, coated with an anti-microbial poly-urethan coating. Substrate treated with a flurocarbon to give water/stain resistance.
Platilon cover	Polyurethane Ether

All cushion components are Latex-Free.

8.3 Contour Visco Warranty

Warranty : 3 years

This warranty applies against manufacturing defects under normal use of the cushion. CAUTION : The warranty is only valid if the dealer has properly fulfilled this warranty certificate with date of sale, dealer stamp and cushion number.

N°

Sticker

Date of sale:

Vendor's stamp

ATTESTATION DE CONFORMITES TECHNIQUES
N° ESC 13-004/1

Ce document annule et remplace le document référencé ESC 13-004.

Demandeur : **INVACARE**

Route de St Roch
37 230 FONDETTES

Le(s) produit(s) ci-dessous référencé(s):

Coussin Technique FLO-TECH Contour visco medium Pmax 75 Kg

équipé(s) de : ou constitué(s) de :

¤ Mousse viscoélastique Medium
¤ Mousse PU
¤ Housse Dartex
* Housse Platilon

remplit(remplissent) les exigences des normes ou règlements techniques particuliers actuellement en vigueur :

Selon le protocole de la commission d'Evaluation des Produits et Prestations relatifs aux coussins, matelas et surmatelas d'aides à la prévention des escarres suivant l'avis du 22 décembre 2009.

suivant les observations et résultats d'essais consignés dans le(s) rapport(s) d'essais FCBA:

Pour les tests matériaux : n° M367130869, M367130827, M367130828, M37130829, M367130830, P116902/DE1, M367130874, M367130875, M367130876, M367130877, M367130878, M367130879, M367130850, M367130851, M367130852, M367130853, M367130854, M367130855, M367130856, M367130857, M367130858, , M367140034, M36740035, M367140036, M367140037

Pour les tests feu : n° 367130709, 367130710

Pour les mesures de répartition de pression : n° M367130870, M367130871, M367130873

Toute modification majeure apportée au produit présenté et testé entraîne la nullité de la présente ATTESTATION DE CONFORMITE. Les modifications éventuelles doivent être notifiées par écrit dans les plus brefs délais au LABORATOIRE ESSAIS & MESURES du FCBA qui décidera de la suite à donner.

La présente ATTESTATION DE CONFORMITE ne concerne que le(s) produit(s) soumis à l'examen par le demandeur. Elle ne peut en aucun cas caractériser une constance de qualité de fabrication. Le FCBA ne peut s'assurer ni garantir que le produit n'a fait l'objet d'aucune modification et qu'il demeure fabriqué et commercialisé sous les caractéristiques d'origine.

Paris, le 24 Janvier 2014

Suivi du dossier

Responsable de section

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Fax : +33 (0)1 43 40 85 65
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ATTESTATION DE CONFORMITE TECHNIQUE
N° ESC 13-003/1

Ce document annule et remplace le document référencé ESC 13-003.

Demandeur : **INVACARE**

Route de St Roch
37230 FONDETTES

Le(s) produit(s) ci-dessous référencé(s):

Coussin Technique FLO-TECH Contour visco Firm Pmax 100 Kg

équipé(s) de : ou constitué(s) de :

¤ Mousse viscoélastique Firm
¤ Mousse PU
¤ Housse Dartex
* Housse Platilon

remplit(remplissent) les exigences des normes ou règlements techniques particuliers actuellement en vigueur :

Selon le protocole de la commission d'Evaluation des Produits et Prestations relatifs aux coussins, matelas et surmatelas d'aides à la prévention des escarres suivant l'avis du 22 décembre 2009.

suivant les observations et résultats d'essais consignés dans le(s) rapport(s) d'essais FCBA:

Pour les tests matériaux : n° M367130859, M367130827, M367130828, M37130829, M367130830, P116902/DE1, M367130874, M367130875, M367130876, M367130877, M367130878, M367130879, M367132832, M367130833, M367130834, M367130835, M367130836, M367130837, M367130838, M367130839, M367130840, M367140034, M36740035, M367140036, M367140037

Pour les tests feu : n° 367130705, 367130706

Pour les mesures de répartition de pression : n° M367100860, M367100861, M367100863

Toute modification majeure apportée au produit présenté et testé entraîne la nullité de la présente ATTESTATION DE CONFORMITE. Les modifications éventuelles doivent être notifiées par écrit dans les plus brefs délais au LABORATOIRE ESSAIS & MESURES du FCBA qui décidera de la suite à donner.

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Paris, le 24 Janvier 2014

Suivi du dossier

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ATTESTATION DE CONFORMITES TECHNIQUES
N° ESC 13-002/1

Ce document annule et remplace le document référencé ESC 13-002.

Demandeur : **INVACARE**

Route de St Roch
37230 FONDETTES

Le(s) produit(s) ci-dessous référencé(s):

Coussin Technique FLO-TECH Contour visco Very Firm Pmax 125 Kg

équipé(s) de : ou constitué(s) de :

¤ Mousse viscoélastique Very Firm
¤ Mousse PU
¤ Housse Dartex
* Housse Platilon

remplit(remplissent) les exigences des normes ou règlements techniques particuliers actuellement en vigueur :

Selon le protocole de la commission d'Evaluation des Produits et Prestations relatifs aux coussins, matelas et surmatelas d'aides à la prévention des escarres suivant l'avis du 22 décembre 2009.

suivant les observations et résultats d'essais consignés dans le(s) rapport(s) d'essais FCBA:

Pour les tests matériaux : n° M367130864, M367130827, M367130828, M37130829, M367130830, P116902/DE1, M367130874, M367130875, M367130876, M367130877, M367130878, M367130879, M367132841, M367130842, M367130843, M367130844, M367130845, M367130846, M367130847, M367130848, M367130849, , M367140034, M36740035, M367140036, M367140037

Pour les tests feu : n° 367130707, 367130708

Pour les mesures de répartition de pression : n° M367100865, M367100866, M367100868

Toute modification majeure apportée au produit présenté et testé entraîne la nullité de la présente ATTESTATION DE CONFORMITE. Les modifications éventuelles doivent être notifiées par écrit dans les plus brefs délais au LABORATOIRE ESSAIS & MESURES du FCBA qui décidera de la suite à donner.

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Paris, le 24 janvier 2014

Suivi du dossier

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Making Life's Experiences Possible™

Yes, you can.