



General User/ Safety Guide

HARVEST STATIC CUSHION RANGE

STATIC CUSHIONS



www.harvesthealthcare.co.uk



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WARNINGS & CAUTIONS

READ THIS INSTRUCTION MANUAL CAREFULLY.



PLEASE NOTE IN PARTICULAR THAT THE SAFETY INSTRUCTIONS MUST BE OBSERVED.



WARNING

Please refer to the information in this booklet as a guideline only.

Harvest Healthcare Ltd recommend that prior to using this product, a full risk assessment must be completed by a qualified professional, in order to determine that the correct product is suitable for each individual.

Do not use this product for / whilst lifting the patient. This will damage the product and could put the patient at risk.

Ensure that this product is used the correct way up.

Facial contact with the cover may cause suffocation.

Do not allow sharp objects to penetrate the cover material.

Do not expose this product to open flames and heat source.

Harvest Healthcare advise against smoking whilst the cushion is in use, to prevent the accidental ignition of associated items which may be flammable, such as chair or external fabric.

Cushions should be checked regularly to ensure they remain 'fit for purpose', clinically Effective and pose no risk of infection to either the patient or the carer.

Harvest Healthcare Ltd recommend that a thorough inspection of both the interior (foam core) and exterior (cover) of the cushion is carried out weekly, or each time a new patient is placed on the cushion.

Visual checks should be carried out daily to identify any significant signs of damage or infection risk.

If any signs of contamination are identified on the cover, the cushion should be withdrawn from use immediately and the cover replaced.

If the foam and/or the cover are showing signs of contamination or excessive wear the cushion should be removed from use immediately and the entire cushion replaced.

This system is intended for use as part of a pressure ulcer prevention program; do not rely solely on this device to achieve the result. The medical professional is responsible for applying best medical judgment when using this system.

Select the correct cushion for the occupant's weight and therapy required.

Only use the correct size of cushion for the chair. If the cushion has a strap to hold it in place this must be used and securely fastened.

Do not use with hot water bottles or electric blankets.

OVERVIEW



WARNING

Do not allow sharp objects to puncture the cushion material.

The Cushion should be cleaned between patient uses.

Do not use bleach, chlorine releasing agents in concentrations over 1000 ppm, solvents or alcohol-based cleansers, e.g. Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline as these will destroy the cushion material.

Suitable for continuous use.

Do not modify the cushion in any way.

Not for use in an outdoor environment.

Store the cushion in a clean and dry environment, out of direct sunlight.

Do not use this cushion for lifting the patient. This will damage the cushion and could put the patient at risk.

This product is fire rated. The cushion material is tested to BS7175:1989 Crib 5. Use of this product should be subject to a risk assessment in which all hazards are considered.

SYMBOLS USED



Wash at
80°C (cover only
- remove foam)



Tumble dry
on Low



Do Not
Dry Clean



Do Not Bleach



Do Not Iron



CE Mark in accordance with the Medical
Device Directive (93/42 EEC).
UKCA to supersede CE Mark.



Do Not Use
Phenols



No
Smoking



This symbol indicates general hazards. There is a danger to life and health.

OVERVIEW

CUSHION RANGE OVERVIEW

CUSHION	WIDTH / DEPTH (MM)	THICKNESS (MM)	MAX PATIENT WEIGHT (KG)	RISK LEVEL	BRADEN SCALE SCORE	WATERLOW SCORE
COMMUNITY MODULAR FOAM HFC121	430	95	95	Medium	13 - 14	5 - 10
COMMUNITY MODULAR FOAM HFC116 (LARGE)	500	95	108	Medium	13 - 14	5 - 10
PRIME COMFORT VISCO TOP HFC129	430	95	127	High	13 - 14	5 - 10
PRIME COMFORT VISCO TOP HFC123	510	76	139	High	13 - 14	5 - 10
PRIME COMFORT PLUS VISCO TOP HFC129.01	430	75	158	High	10 - 12	15 - 20
REFLECT HFC130	430	100	127	High	10 - 12	15 - 20
REFLECT EXTRA HFC130.EX (LARGE)	510	100	254	High	10 - 12	15 - 20

All Harvest Healthcare static cushion covers are PU - stitched.

Prime Comfort Visco Top cover is stitched with flap.

They are all non-slip base and have a Crib 5 fire rating.

GENERAL INFORMATION

INSTRUCTIONS FOR USE

Check that the safe working load of the cushion is suitable for the intended user.

Do not exceed the maximum patient weight of the cushion (see page 6).

Ensure the Risk Factor is suitable for the intended user. To help prevent pressure damage it is important that patients reposition themselves, or are repositioned regularly.

Cushions are delivered in plastic covers for protection; these covers must be removed before use. Avoid using any additional covers/padding between the patient and the support surface, as this may affect its pressure reducing qualities.

Ensure that this product is used the correct way up and on a suitable chair.

PERFORMANCE CHARACTERISTICS/CUSHION INSPECTION RECOMMENDATIONS

Cushions should be checked regularly to ensure they remain 'fit for purpose', clinically effective and pose no risk of infection to either the patient or the carer.

Harvest Healthcare Ltd recommend that a thorough inspection of both the interior (foam core) and exterior (cover) of the cushion is carried out weekly, or each time a new patient is placed on the cushion. Visual checks should be carried out daily to identify any significant signs of damage or infection risk.

If any signs of contamination are identified on the cover, the mattress should be withdrawn from use immediately and the cover replaced. If the foam and/or the cover are showing signs of contamination or excessive wear the mattress should be removed from use immediately and the entire mattress replaced. Signs of excessive wear may include, but are not restricted to, thinning, discolouration, tearing, fraying, misshaping and fluid ingress.



Facial contact with any covering material such as that used on this product can cause suffocation and a Risk Assessment should be done prior to the use of this product.

CUSHION CLEANING AND CARE

Cushions are fully encased in a protective waterproof, multi-stretch, PU cover to prevent fluid ingress from damaging the foam core. The cushion cover should be cleaned regularly in accordance with your organisation's disinfection protocol.

For full cleaning procedures for our cushions see page 8.

MOVING, HANDLING AND STORAGE

Where possible, cushions should be stacked flat.

Store cushions in a temperate, dry environment. Do not expose to high humidity or heat.

Do not drag or pull cushions by the cover.

CLEANING & CARE



WARNING

Eye protection, gloves and protective clothing should be worn when carrying out cleaning and disinfection procedures.

When disinfecting the system, Harvest Healthcare Ltd recommends the following guidelines which have been developed to comply with recognised infection control procedures. These procedures are also to be used to prevent cross infection when transferring the system between patients.

CUSHION COVER

During general use the cushion can be cleaned by wiping with a mild detergent solution.

Where necessary the cushion cover can be removed for laundering or sterilisation. Where there is staining or body fluids on the cushion, wash thoroughly with soap and water, then wipe with a sodium hypochlorite solution diluted to 1000ppm before laundering.

After removing the inner foam, cushion covers may be laundered as follows:

- 1** Pre wash Cold 10 minutes
- 2** Main Wash 80°C 10 minutes
- 3** Followed by cold rinses and extraction.
- 4** Tumble dry at maximum 60°C for 2 minutes
- 5** Cool tumble dry for 2 minutes



Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline, as these will damage the cover materials.



Do not iron.



Ensure the cushion is thoroughly dried before use or placing in storage.



HYPERCARBONATE AND PHENOL-BASED SOLUTIONS SHOULD NOT BE USED AS THESE WILL DAMAGE THE CUSHION COVER

DISPOSAL

If contaminated, please dispose of as clinical waste.

If not contaminated dispose of as household waste at your local approved facility.

Note:

Please report any serious incident related to this device to Harvest Healthcare.

Full contact details can be found at the end of this document.

GUARANTEES & WARRANTIES

WARRANTY

Foam Inner

All Harvest Healthcare static foam cushions are covered by warranty for a period of 3 years. Damage through incorrect use will invalidate this warranty.

Cushion Cover

All Harvest Healthcare Ltd cushion covers are covered by warranty for a period of 12 months. Damage through incorrect use and penetration by sharp instruments will invalidate this warranty.

GUARANTEE

Harvest Healthcare Ltd guarantees to repair or replace all goods issued to its customers which are found to be defective whilst still under their applicable warranty period. All warranties are subject to our standard terms and conditions of sale which can be found on our website or by request to Harvest Healthcare Ltd.

If this device malfunctions and a serious incident occurs please contact Harvest Healthcare Ltd or your competent authority. A member of our service team will be happy to help you and offer advice.

Email: sales@harvesthealthcare.co.uk

Telephone: **01709 377172**

DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

Declaration of Conformity Annex VII EU Directive 93/42/EEC
UKCA to supersede CE Conformity Mark

We, as company: Harvest Healthcare Ltd
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham, S60 1BW

Authorised Representative: European Healthcare & Device Solutions Ltd.
Stratton House, Bishopstown Road, Cork T12 Y9TC, Ireland
SRN: TBC

Confirm on our own behalf that the medical product:

Please see the Static Cushions list on the next page.

Risk Class: I

SRN: TBC

complies with all applicable requirements in Appendix I of the EU directive 93/42E EC
The following compliance evaluation process was applied: Annex VII
EU legislation for this type of product covers all safety, health and environmental requirements.

Modifying this product without consultation with Harvest Healthcare Ltd will invalidate this declaration of conformity.

This declaration of conformity is issued under the sole responsibility of Harvest Healthcare.

Notified Body: TBC



Product Development and Quality Manager
Rotherham, 28.01.2021

This document is valid for 4 years after the date of the signature.

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Here is the list of the Static Cushions.

Community Modular Foam	HFC121	UDI: 5060517530303
Community Modular Foam (Large)	HFC116	UDI: 5060517530310
Prime Comfort Plus Vico Top	HFC129.01	UDI: 5060517532147
Prime Comfort Visco Top	HFC129	UDI: 5060517530341
Prime Comfort Visco Top (Large)	HFC123	UDI: 5060517530358
Reflect	HFC130	UDI: 5060517530402
Reflect Extra	HFC130.EX	UDI: 5060517531065

ALSO AVAILABLE...

HH20 - ACTIVE SYSTEM

This one-piece alternating cushion has been developed to provide maximum patient comfort whilst achieving optimum pressure relief, whilst seated.

The Active Seat System provides relief/pressure reduction during periods out of bed. This inexpensive system provides relief and comfort for those at risk of developing a pressure ulcer as well as assisting in the healing of existing problem areas.

It is compatible with all of Harvest Healthcare's pumps.

Please note that this is a cushion only, pumps are available separately.

For more information, please contact
a member of the sales team on
01709 377 172



LOW	MED	HIGH	V HIGH
PRESSURE RELIEF RISK			

Serial No:

DOCUMENT REFERENCE: CUSHIONS/MANUAL - Oct. 2021



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