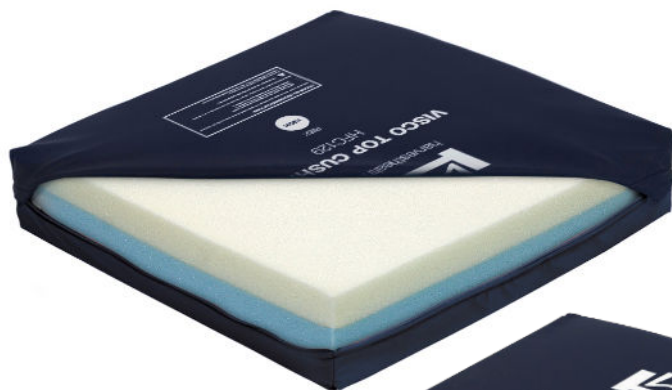




General User/ Safety Guide

HARVEST STATIC CUSHION RANGE

STATIC CUSHIONS



www.harvesthealthcare.co.uk

UK
CA



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If any signs of contamination are identified on the cover, the cushion should be withdrawn from use immediately and the cover replaced.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

WARNINGS & CAUTIONS



WARNING

Do not allow sharp objects to puncture the cushion material.

The Cushion and 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 conforms to BS7176 Low Hazard. Use of this product should be subject to a risk assessment in which all hazards are considered.

GENERAL INFORMATION

INSTRUCTIONS FOR USE

Check whether the cushion is suitable and large enough for the chair.

Place the cushion flat on the chair, ensuring that the non-slip material of the cushion cover is in contact with the chair's surface.

Verify that the safe working load of the cushion is appropriate for the intended user. **Do not exceed the maximum patient weight specified for the cushion, which is printed on the cover or can be found on page () of this IFU.**

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

Cushions are delivered in protective plastic covers; these covers must be removed before use. Dispose of the protective plastic covers safely and in an environmentally friendly manner.

Note that using any additional covers or padding between the patient and the support surface may compromise the cushion's pressure-reducing properties.

INTENDED PURPOSE

Harvest Healthcare static cushions are designed for patients at risk of pressure injuries or those who have already developed them. The foam surface redistributes pressure, aiming to reduce capillary closure in the sacral area. The cushion range overview (see page --) provides information for identifying the most appropriate static cushion for an individual patient, including ranges for patient risk levels and maximum patient weights.

These guidelines are intended to aid in selecting an appropriate cushion; however, all individuals should be risk-assessed by a trained professional, as individual circumstances may influence cushion choices.

Never use a cushion with a lower risk category than that assigned to the service user by a trained professional.

Never exceed the maximum patient weight for a cushion.

Misuse of the cushion could lead to the development of pressure injuries.

INTENDED USER / CARER

1 DEFINITION OF INTENDED USERS /CARERS

OPERATOR

An operator is any natural or legal person who uses the cushion or on whose instruction it is used (e.g. nursing homes, specialised retailers, health insurance companies, medical suppliers).

USER / CARE PERSONNEL

Users are persons who as a result of their vocational training, experience or briefing are authorised to use the mattress.

Furthermore, the user/ care personnel can recognise and avoid potential dangers and assess the clinical condition of the service user.

PATIENT / OCCUPANT / SERVICE USER

The person in need of care, handicapped or infirm who is at risk of a pressure ulcer.

GENERAL INFORMATION

QUALIFIED PERSONNEL

Qualified personnel are employees of the operator who as a result of their vocational training or briefing are entitled to deliver, assemble, disassemble and transport the product.

2 NON-COMPLIANT USE

All uses deviating from the intended purpose, which may also be hazardous as a result. This includes for example:

- Operation by persons who have not been instructed in its use.
- Using the mattress with non-approved parts/accessories.
- Using the mattress if any of the components are damaged or faulty.

3 SAFE USE

The length, width and height of the cushion should be checked to ensure that these dimensions are suitable for the size of chair being used.

3.1 PERFORMANCE CHARACTERISTICS/CUSHION INSPECTION RECOMMENDATIONS

Pressure-relieving 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 recommends that a thorough inspection of both the interior (foam core) and exterior (cover) of the cushion is conducted 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 cover show signs of contamination or excessive wear, the cushion should be removed from use immediately, and the entire cushion replaced.

Signs of excessive wear may include, but are not limited to, thinning, discoloration, 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.

3.2 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.

3.3 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.

GENERAL INFORMATION

3.4 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.

3.5 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.

SYMBOLS USED



WASH at
80°C



TUMBLE DRY
ON LOW



DO NOT
DRY CLEAN



DO NOT
BLEACH



Do Not Iron



Max. Patient
Weight



Do not use
Sharp Items



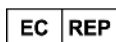
Do Not Use
Phenols



No
Smoking



Manufacturer



EU Representative



LOT Number



Medical Device



Date of
Manufacture &
Country of Origin



Product
Number



Unique Device
Identification



Instruction for
Use



Date of
Manufacture &
Country of Origin



CE Mark



UKCA Mark



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

OVERVIEW

CUSHION RANGE OVERVIEW

CUSHION	WIDTH X LENGTH(MM)	THICKNESS (MM)	MAX PATIENT WEIGHT (KG)	RISK LEVEL
COMMUNITY MODULAR FOAM HFC121	430 x 430	95	95	Medium
COMMUNITY MODULAR FOAM HFC116 (LARGE)	500 x 500	95	108	Medium
PRIME COMFORT VISCO TOP HFC129	430 x 430	95	127	High
PRIME COMFORT VISCO TOP HFC123	510 x 510	76	139	High
PRIME COMFORT VISCO TOP EXTRA HFC129.EX	520 x 520	80	190	High
PRIME COMFORT PLUS VISCO TOP HFC129.01	430 x 430	75	158	High
REFLECT HFC130	430 x 430	100	127	High
WHEELCHAIR CUSHION 13" HFC133.13	300 x 330	50	115	Low - Medium
WHEELCHAIR CUSHION 15" HFC133.15	380 x 380	50	115	Low - Medium
WHEELCHAIR CUSHION 18" HFC133.18	460 x 460	50	115	Low - Medium

All Harvest Healthcare static cushion covers have stitched seams which are covered with a flap.

Prime Comfort Plus Visco Top has welded seams which are covered with a flap. They all have a non-slip base and have a Crib 5 fire rating.

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.

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



Serial No:

DOCUMENT REFERENCE: 003030C - Static Cushions Manual - Dec. 2024



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