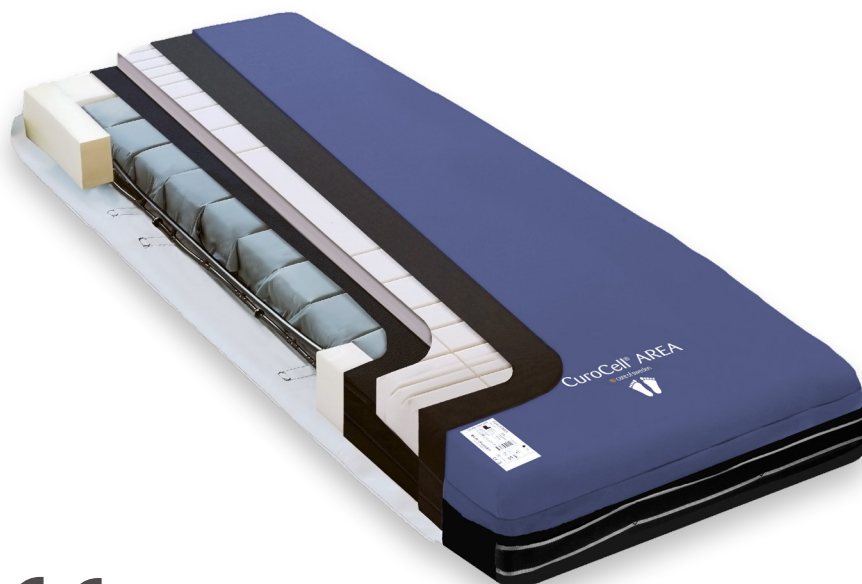


# *Clinical performance*

**CUROCELL® AREA ZONE**



## Product information - CuroCell® AREA Zone

Care of Sweden's mattresses are used in the prevention and as an aid in treatment of pressure ulcers. CuroCell® AREA Zone is an 18 cm full replacement mattress which combines foam with air for good pressure redistribution. It contains prefilled air cells that are divided into zones, which adapt automatically to the user and provides individual setting. The mattress also contains multiple layers of high quality High Resilience (HR) foam. The good quality means that the mattress is equipped with features such as large carrying capacity, long life and good comfort.

CuroCell® AREA Zone is developed to redistribute pressure, contribute to reduce shear forces and to improve the microclimate by supporting the reduction/transfer of moisture<sup>(2,3)</sup>, three important elements related to prevention or treatment of pressure ulcers<sup>(1)</sup>. The functionality of the CuroCell® AREA Zone is documented through external and internal testing and through user testimonials.

User reviews of the CuroCell® AREA Zone prove that the mattress is easy to work with and comfortable with a good capacity of pressure redistribution. On a scale of 1-5, healthcare nursing staff have given the mattress a score of 4.21 according to expectations.

Some of the most essential benefits with CuroCell® AREA Zone:

- Hybrid mattress
- Silent
- Cost effective
- Designed to reduce shear
- Easy to maintain
- Requires no adjustments

## Pressure redistributing hybrid mattress

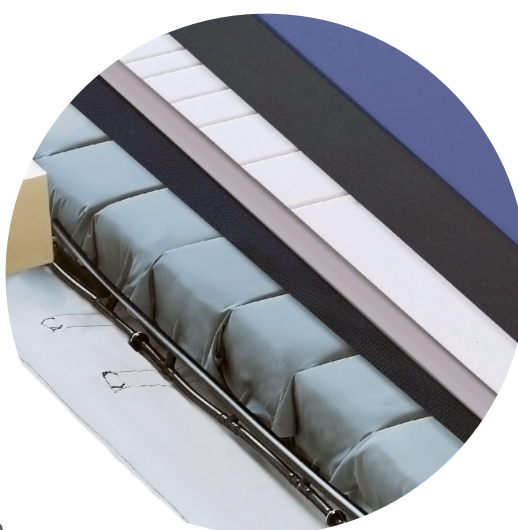
CuroCell® AREA Zone is used as an aid in the prevention and treatment of pressure ulcers up to category III<sup>(1)</sup>. Recommended user weight is up to 230kg<sup>(2)</sup>. The mattress is self-adjusting and non-powered. It is a flexible mattress replacement system that can be used in all kinds of healthcare settings, easy to use and handle.

The mattress' design contributes to reduce shear forces and with the built-in sloped heel function it also helps to reduce pressure on the heels.

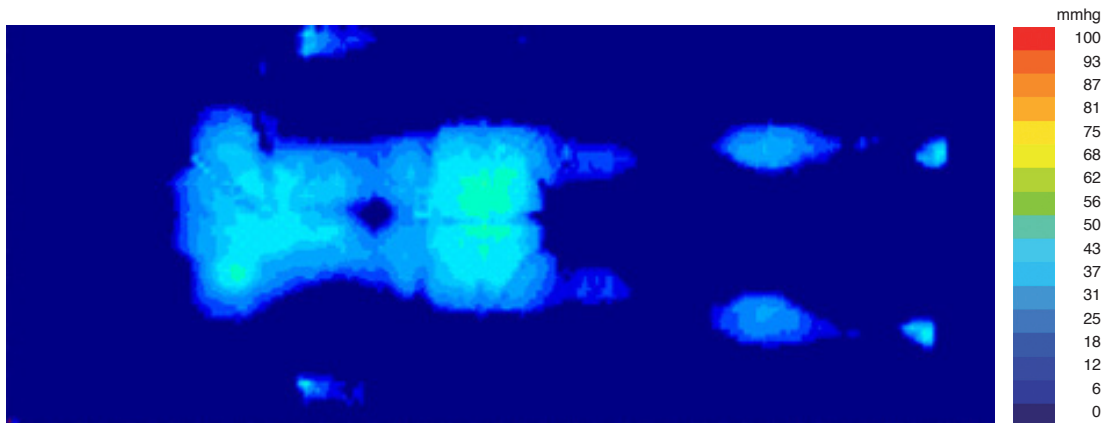
CuroCell® AREA Zone has good pressure redistribution properties. When tested, the mattress' capacity of pressure redistribution (PAI) it is reported that 100% of the pressure on the mattress is below the threshold of 30mmHg (load 80kg).

Care of Sweden's mattresses are supplied with a four way stretch hygiene cover which conforms to relevant standards for hygiene, quality and safety<sup>(4)(5)</sup>.

All covers are manufactured from modern, recyclable materials and are vapour permeable<sup>(3)</sup>, which contributes to reduce the risk of skin maceration.



## 1. Pressure redistribution



Example of pressure mapping (Xensor). CuroCell® AREA Zone with Evac cover.  
(Describes the characteristics of the device. It cannot directly predict clinical outcome).

## Examination of the pressure relief capability and the shear force

(Berlin Cert)

CuroCell® AREA Zone have received the highest rating for “High Pressure Relief” in tests carried out by Berlin Cert and have been given a test rating which is 32% better than the reference mattress used for a user weight of 80kg.

### Pressure Area Index (PAI)

Pressure	Patient weight of 80kg	Patient weight of 230kg
Below 30mmHg	100%	40%
Below 20mmHg	94%	24%
Below 10mmHg	55%	14%

PAI (Pressure Area Index) is a way to evaluate reactive products. Measuring the interface pressure (IP) across the support surface, below certain thresholds. These thresholds can be selected upon clinical relevance, capillary, arterial and venous pressure, 30, 20 and 10mmHg.

Ex: A PAI of 100 % below 30mmHg means that the whole body is experienced pressure reduction below the 30mmHg threshold. The higher the PAI, the better the pressure reduction provided.

## 2. Microclimate

Moisture increases the risk of skin maceration and therefore microclimate is important in prevention of pressure ulcers. It is important that the skin is dry and the mattress is comfortable. The design of CuroCell® AREA Zone improves the microclimate by increasing the ventilation in the cutting areas between the zones in the mattress.

### Determination of water vapour and water resistance

(IFP Research AB)

Penetration of water vapour was determined in accordance with SS-EN 15496:2004.

This is the ability to transport the vapour through the material (NB not liquid). The results showed 345 g/m<sup>2</sup>/24h.

Water resistance was determined according to SS-EN 20 811:1992. This test shows the material water resistance which is important for the material hygienic skills.

The result showed >10 m (98 kPa).

## 3. Hygiene

Hygiene is an important part for mattresses used in the healthcare sector and CuroCell® AREA Zone meets these hygienic standards.

Covers can be washed in 95 °C and tumbled dried. When necessary the foam is easy to clean by wiping. The covers are waterproof and vapour permeable and are tested according to the following hygiene standards:

- **SS-EN ISO 15496:2004 "water vapour permeability of textiles"**
- **ISO 16603 "resistance of penetration by blood and body fluids"**
- **ISO 16604 "resistance of penetration by blood-borne pathogens"**
- **EN 14126 "health care textiles-Bacteria penetration-Wet"**

## 4. Flame retardancy

In all healthcare environments it is important to use products which meet the flame retardancy requirements. CuroCell® AREA Zone is tested and meets the requirements in accordance with EN 597-1 and EN 597-2.

## 5. Clinical Report

(Care of Sweden 2017)

According to results from a real-world evaluation of CuroCell® AREA Zone, the mattress works well in the prevention of pressure ulcers. The aim of the evaluation was to evaluate how the mattress works in the prevention of pressure ulcers for patients undergoing emergency hip surgery. At the beginning of the project, each mattress was replaced by an CuroCell® AREA Zone. All patients were assessed according to the Modified Norton scale and skin assessments were performed on a daily basis. After six months of using the CuroCell® AREA Zone, the pressure ulcer results were improved.

### Hospital Acquired Pressure Ulcers 1 February 2016 – 31 July 2016

Total hip fracture patients	187
Number of PU (pressure ulcers)	13
Proportion of hospital acquired PU	$13/187 = 7.0 \%$

### Hospital Acquired Pressure Ulcers 1 February 2017 – 31 July 2017

Total hip fracture patients	177
Number of PU (pressure ulcers)	9
Proportion of hospital acquired PU	$9/177 = 5.1 \%^*$

\*Of the amount of hospital acquired pressure ulcers two of them occurred due to medical devices (plaster) which produces the true result of  $7/177 = 4\%$

### Hospital Acquired Pressure Ulcers 1 February 2018 – 31 Dec. 2018

Number of PU (pressure ulcers)	10
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Note! No pressure ulcers have occurred on heels.

## 6. Customer evaluations

Care of Sweden's customer survey of users and employees, show:

### Patient's review (scale 1-5)

Comfort	4.52
Turn/move on the mattress	4.03

### Staff review (scale 1-5)

To work with the patient	4.39
To clean, embed/handle the mattress	4.50
To understand attached instructions/user manual	4.56
How well has the mattress fulfilled your expectations	4.21



## A few words from our customers

*"Great to work with, easier to move the patient on this mattress compared to an air mattress"*

*"The CPR function is better, you don't need to deflate the mattress"*

*"Easier to clean and pack, not so unwieldy"*

*"More suitable to the bed compared to an air mattress, quick to inflate"*

*"The staff were gladly surprised how easy it was to work with"*

*"Very good features when doing any nursing work"*

*"The patient experiences the mattress very comfortable and sleeps well on it"*

*"The patient experienced very good comfort"*

*"The mattress has great advantages compared to air mattresses"*

*"It is easier to handle, you avoid the sound from the pump"*



## References

1. EPUAP/NPIAP/PPPIA, Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. Emily Haesler (Ed.), 2019, Editor. 2019, European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance.
2. Examination of the pressure relief capability, Berlincert 2012.
3. SS-EN ISO 15496: 2004, DIN 53.122.
4. CDC (2003), Guidelines for Environmental Infection Control in Health-Care facilities, updated 2019
5. SS 876 00 20:2017, Healthcare textiles - Mattresses - Specifications and requirements.

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