Cloud Cuddle®



CE UKCA

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Instructions for Use

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Scan the QR code to watch the instruction videos for the CloudCuddle Maxx.

I. PURPOSE OF THE DEVICE

The CloudCuddle Maxx is a CE marked Class I Medical device, designed as a mobile, inflatable bed tent. The product offers a safe rest and sleep environment for children and adults with special care needs.

1.1 Intended user

This medical device is intended for use by:

- Parents, care providers, or carers at home.
- Healthcare professionals such as nurses, care attendants, or therapists.

The patient/user: children and adults with special care needs, with:

- A maximum length of 193 cm
- A maximum weight of 100 kg
- An increased risk of falling, wandering, injury, or overstimulation.

1.2 Intended purpose

The CloudCuddle Maxx is an inflatable bed tent that transforms any standard single bed with a mattress into a safe and secure sleep and rest environment. This device helps prevent users from getting out of bed unintentionally or falling out of bed and provides a sense of comfort, safety and security.

1.3 Indications

The CloudCuddle Maxx is designed to promote sleep and safety in individuals with an increased risk of nighttime incidents or restlessness. Indications for use of the CloudCuddle Maxx include:

- Disorders and/or disabilities that may cause the user to roll out of bed or get out of bed unintentionally.
- To assist caregivers when there is an imminent risk of the user falling out of bed or getting out of bed unintentionally

1.4 Contraindications

Medical and physical contraindications

Do not use the CloudCuddle Max if one or several of the contra-indications below apply. Contact your attending physician or attending healthcare professional in that case.

- Known (hyper)sensitivity or allergy to one of the materials used: Organic cotton, polyester, polyamide, zinc, copper, stainless steel or nickel.
- Skin that is extremely sensitive to pressure or friction, with an increased risk of skin irritation.
- Increased risk of breathing problems in closed environments without adequate supervision.
- Known claustrophobia or a tendency to have panic attacks in enclosed spaces.
- Patients with an increased risk of suffocation. This device is not suitable for use if a healthcare professional has established that breathable materials are necessary to prevent breathing problems.
- Patients weighing more than 100 kg.
- Use for patients with multiple medical lines (e.g., IV line, tube) that cannot be safely routed through the medical access ports.

Behavioural and functional contraindications

- Patients who forcefully throw, launch or drop themselves against the side panels of the CloudCuddle Maxx.
  ATTENTION! Tipping hazard: If patients forcefully throw, launch or drop themselves against the side panels of the bed tent, this can cause the CloudCuddle Maxx to tip over. This is a serious safety risk and may cause injury to the patient.
- Severe behavioural issues with a risk of deliberate damage to materials.
- Increasingly aggressive, violent or self-destructive behaviour that is triggered or intensified by the use of the CloudCuddle Maxx.
- Use on electric adjustable beds without secure and stable attachment of the product.

Important warning

The CloudCuddle Maxx is an assistive device, but its suitability depends on the specific situation, diagnosis and needs of the patient. In some cases, an enclosed space may have a detrimental effect on the patient, e.g., in certain behavioural disorders or neurological conditions.

Immediately stop using the device if

- The patient's condition deteriorates during or after use of the CloudCuddle Maxx.

- Signs of panic, shortness of breath, resistance or other negative behaviour that can be linked to use of the CloudCuddle Maxx are observed.

In the above cases, immediately contact a physician or attending healthcare professional.

1.5 Description of the device

The CloudCuddle Maxx is an inflatable mobile bed tent, that was designed for children and adults with various disorders that result in increased care needs and safety risks while sleeping. These can include physical, cognitive or behavioural disorders, with or without additional medical care needs.

The device offers a secure, enclosed rest and sleep environment that can promote rest, security and protection against falling out of bed or uncontrolled movements. It helps reduce external stimuli, contributing to calmer and deeper sleep and significantly improving sleep quality and the patient's circadian rhythm.

The CloudCuddle Maxx is designed for installation in under 5 minutes on almost any single bed and care bed and is suited for children and adults weighing no more than 100 kg.

The system consists of an inflatable frame, breathable mesh windows, an integrated mattress cover with fasteners, and a removable sheet with a zip.

The CloudCuddle Maxx has medical access ports for medical lines, tubes or cables, so medical care can be administered safely and comfortably while the patient is in the CloudCuddle Maxx. The product has four access panels to facilitate administering emergency care and/or access in the event of calamities.

The accessibility set is an optional accessory for the CloudCuddle Maxx. The accessibility set is designed to adapt the use of the CloudCuddle Maxx to the needs of carers and patients. The set contains parts that promote patients' independence. If patients are capable, they can independently open or close the CloudCuddle Maxx from the inside. The set also promotes additional safety and security because of the Quick Release system, which is mounted on the outside of the bed tent. This prevents accidental opening of the CloudCuddle Maxx.

The expected lifespan of the CloudCuddle Maxx is 5 to 7 years with normal use and maintenance in accordance with this user manual.

1.6 Benefits of the CloudCuddle Maxx

- Safe, comfortable and sensory-friendly.
- Sturdy, protective and reliable.
- Prevents falling out of bed and nighttime agitation.
- Reduces the risk of injuries due to uncontrolled movements or self-harm.
- Inflatable, lightweight and easy to transport.
- Can be set up in under 5 minutes.
- Fits on virtually any single bed.
- Hygienic and washable.
- CE-certified Class I medical device

1.7 Applications

The CloudCuddle Maxx is suited for temporary use, depending on the user's situation and care needs.

Possible settings include:

- At home.
- Out of home or on holiday.
- Care institutions (long-term care, disability care, mental health care).
- Hospitals.
- Temporary care or respite care.
- Rehabilitation centres.
- Education institutions with a care function.

- Crisis houses or respite care.
- Hospice care.



The CloudCuddle Maxx is designed for use in-house. We recommend consulting with the manufacturer or a medical specialist in case of non-confirming use or use in a special setting.

1.8 Technical suitability

- User length: up to 193 cm
- User weight: up to 100 kg
- Minimum weight bed frame + mattress: at least 66 kg

II. PROCEDURE FOR USE OF THE CLOUDCUDDLE MAXX

2.1 Responsible use and safety warnings

The following procedure must be followed carefully for safe and responsible use of the CloudCuddle Maxx.

- Always consult a healthcare professional before using the CloudCuddle Maxx
  To check that it is suitable for use by the patient; always consult with a healthcare professional before using the CloudCuddle Maxx
- If necessary, obtain permission from the patient's legal representative
  For adults who are unable to give their consent themselves, please always consult with – and obtain the approval of – the patient's legal representative or attending healthcare provider before use of the CloudCuddle Maxx.
- Always read the entire instructions for use before using the CloudCuddle Maxx
  Make sure you are familiar with the installation, use, safety instructions, and contraindications of the CloudCuddle Maxx before using the device.
- Install the CloudCuddle Maxx in a safe and stable environment
  Always use the bed tent on a suitable bed and follow all the instructions carefully. Check the stability and sturdiness of the CloudCuddle Maxx daily.
- Additional instructional videos and training
  For parents and carers:
  Watch the instructional videos on the official website: www.cloudcuddle.com.
  These videos provide step-by-step instructions on how to set up, use, take down, and store your CloudCuddle Maxx.
  For healthcare professionals:
  Follow the required steps and instructions in the Human Protection Academy learning portal. This portal contains information about safe use in a professional healthcare context, including the device's application as part of a care plan, involuntary treatment (under compulsory treatment legislation and regulations), and observation during first use.

In case of doubt, please contact us or check with a qualified healthcare provider

⚠ The instructional videos are a complement to the instructions for use. They do not in any way replace it. Always read the entire instructions for use of the CloudCuddle Maxx before using the device for the first time.

- Start with gradual habituation
  Let patients get used to their new sleep and rest environment by starting with a short, supervised nap session during the day after which you can gradually extend the time spent in the bed tent to the desired duration.
- Observe the patient's behaviour the first time you use the device
  Watch out for signs of stress, anxiety, panic or worsening behaviour. If patients remain restless or become even more restless, immediately get them out of the CloudCuddle Maxx and consider another solution.
- Check medical equipment
  If patients are dependent on medical lines or equipment, make sure they can be securely routed through the medical access ports without risk of kinks or obstruction.
- Responsible use of the accessibility set
  When using the accessibility set: Before using the accessibility set always check whether the patient/user of the CloudCuddle Maxx can safely open the bed tent independently from the inside or whether additional fixation is required.
- Supervision at all times
  The CloudCuddle Maxx is not a substitute for supervision. Always take patients' individual care needs into account and adapt your use of the device accordingly.
- If necessary, make sure that use of the CloudCuddle Maxx is part of an overall care plan
  In case of professional or long-term care, use of the CloudCuddle Maxx must be explicitly included in the individual care plan.
- If necessary, establish an escape protocol and align it with the patient's/client's specific needs
  In situations where there is a risk that the patient may have an anxiety attack or may try to get out of the CloudCuddle Maxx in an uncontrolled manner, an escape protocol must be drawn up prior to the first use of the device. This protocol must be tailored to the patient's/client's individual needs and must be discussed with all care providers and/or carers involved.
- Only use the hand pump supplied with the device
  Use of other pumps, such as electric pumps or compressors, is not permitted. This can cause damage to the product and/or give rise to unsafe situations.

2.2 Checklist for use

Preparation

- You have read the entire instructions for use.
- You have checked whether there are contraindications for use with the patient.
- Use only based on the advice of a medical professional, and in accordance with the care plan.

2.3 Training for care providers

Every care provider who uses the CloudCuddle Maxx must have received full instructions and training relating to the responsible and safe use of the device. This applies both in a home environment and in a professional care environment.

Before use, it is crucial that the care provider:

- Is aware of the organisation's internal protocols regarding restrictive freedom measures.
- Is aware of applicable national and international laws and regulations regarding the patient's freedom of movement, including the use of involuntary treatment, if applicable.
- Has reviewed the guidelines below and acts in accordance with them.
  - The instructions in these instructions for use.
  - The safety warnings and safety instructions in these instructions for use.



The CloudCuddle Maxx is not a substitute for supervision or care assessment. Incorrect use without the right training can result in dangerous situations or violations of the patient's rights. Training and compliance with the guidelines are therefore always mandatory.

2.4 Use as involuntary treatment

Depending on the situation and the way in which it is deployed, use of the CloudCuddle Maxx may be considered involuntary treatment in the sense of legislation and regulations on involuntary/compulsory treatment.



The CloudCuddle Maxx is not designed for restraint. The device is intended to offer patients a safe, secure and comfortable sleep environment, in which they can move around freely within a protected space.

The following conditions apply in the context of involuntary treatment:

- Apply legislation/regulations on involuntary/compulsory treatment
  Always adhere to applicable laws and regulations when using the CloudCuddle Maxx as part of involuntary treatment.
  Make sure any use as part of such treatment complies with local legal and ethical guidelines.
- Assessment by an authorised care provider
  Have an attending physician or healthcare provider assess whether use of the CloudCuddle Maxx as involuntary care is necessary and proportionate.
- Consent from the patient's legal representative
  Obtain explicit consent from the patient or – if they are unable to give this – from their legal representative for use of the CloudCuddle Maxx.
- Draw up an escape protocol
  If necessary, draw up an escape protocol that is tailored to the patient's individual needs. Involve all the relevant healthcare providers in the formulation of this protocol.
- Documenting use of the CloudCuddle Maxx in the patient file
  Record use of the CloudCuddle Maxx as involuntary treatment in the patient file, stating the reason for this use and including the assessment and care providers involved, in accordance with applicable local laws and regulations.

2.5 Installation

Only use the CloudCuddle Maxx on:

- A single bed and a care bed with a mattress with the following dimensions: 200 x 90 x 12-26 cm (L x W x H),
- A bed frame and mattress with a minimum combined weight of 66 kg.
- Care bed, only if the bed tent can be attached to the moving part of the bed base.

The CloudCuddle Maxx can be used on a care bed, subject to conditions, if the bed meets the below requirements and restrictions. Incorrect use can result in instability or dangerous situations.

A suitable care bed meets the following requirements:

- Bed rails can be lowered
  The bed rails must be lowered completely so the frame of the CloudCuddle Maxx has sufficient space next to the mattress. The

CloudCuddle Maxx may not be wedged between the frame and the bed rails.

- Adjustable head and foot incline can be blocked
  The head and foot incline must be completely blocked while using the CloudCuddle Maxx.
  These inclines may not be used in combination with the frame as this may cause damage, instability, or injury.
- Use in the lowest position
  Always use the CloudCuddle Maxx in the lowest position. The height of the bed frame during use may not exceed 50 cm from the floor, except when care is administered.

Do not use on

Do not use the CloudCuddle Maxx on the following bed types:

- Mattresses on the floor, double beds, bunk beds, beds without legs.
- Beds with fixed bed rails or a slatted bed base > 50 cm from the floor.
- Care beds with adjustable inclines unless:
  - The adjustable sections of the bed are completely and permanently locked.
  - The CloudCuddle Maxx remains locked during use in a flat position.

⚠ The CloudCuddle Maxx is not designed for use on an adjustable bed with the head and legs slightly elevated.

- Air beds:
  Because these are insufficiently stable, safe installation and attachment of the bed tent cannot be guaranteed.
- Pressure relieving mattresses with active systems, such as:
  - Low air loss mattresses.
  - Alternating pressure mattresses.

These mattress types are not compatible with the attachment system and frame of the CloudCuddle Maxx.

Requirements

- The CloudCuddle Maxx must cover the entire outer dimensions of the bed at all times, i.e.: 200 x 126 x 110-120 cm (L x W x H).
- The CloudCuddle Maxx must be installed away from walls, ceiling structures and other obstacles.
- Do not install it near sharp objects or heat sources.
- Prevent entrapment. The CloudCuddle Maxx may not be wedged in between bed rails.
- Make sure the CloudCuddle Maxx is attached correctly. Incorrect attachment can lead to instability or dangerous situations.
- Pay attention to the temperature restrictions: The frame of the CloudCuddle Maxx may never be exposed to temperatures above 50°C. Avoid storage in hot vehicles, near heating elements, or in direct sun on hot, sunny days.

2.6 How to set up

Always install the CloudCuddle Maxx carefully and according to the prescribed steps in the user manual. A correct installation is vital for the CloudCuddle Maxx's safe and stable use.

2.6.1 How to inflate the frame

Always use the hand pump supplied with the device to inflate the CloudCuddle Maxx.

- Set the pump to inflation setting 1.
- It takes 70 full strokes to fully inflate the frame.
- Please follow the instructions carefully: Setting up and taking down the CloudCuddle Maxx **(chapter 6)**.

2.6.2 Checking frame pressure

The CloudCuddle Maxx is sufficiently inflated when:

- The frame feels sturdy, retains its shape and can no longer be squeezed.
- The mesh is visibly taut and does not hang loosely.

⚠ Never use an electric pump. This can lead to overpressure, damage to the material, or even explosion of the frame.

2.6.3 Valve and 3 tube clamps

The air circuit of the CloudCuddle Maxx must be correctly closed to ensure the device's stability and safety. Follow these instructions for checking and using the valve and 3 tube clamps:

- Check that the knurled nut on the valve is securely fastened. Make sure the cord is not trapped and check that you do not hear a hissing sound.
- Close the valve cap and place the valve cover on the valve.
- After inflation: close the 3 tube clamps at the top of the frame. This maintains pressure in the air chambers.
- Only open the 3 tube clamps when you need to add air.
- Close the 3 tube clamps immediately after adding air to avoid loss of pressure.

⚠ Incorrect use of the valves or 3 tube clamps can lead to pressure loss, instability of the frame, and unsafe use.

2.6.4 First use (stabilisation period)

After assembly, leave the CloudCuddle Maxx to stand for at least 3 hours before first use. After this time, you must carry out a full check. Check the following:

- Stability of the frame
  The frame must feel solid, retain its shape and can no longer be squeezed.
- Air pressure
  Check whether the air chambers are fully inflated and the tube clamps at the top of the frame are closed to avoid loss of pressure.
- Zips
  Make sure that all zips close smoothly and are fully closed, including the zip of the frame cover, the removable sheet, and the medical access ports.
- Attachment to the mattress
  Check whether the tensioning straps have been securely and correctly fastened around the mattress and, if applicable, to the bed frame or bed legs. Make sure the buckles are securely fastened and cannot come undone.

2.7 Attaching the bed tent and safety

All fastenings and security devices of the CloudCuddle Maxx must be correctly and completely applied for safe use of the device. Check the following points before you use the device.

2.7.1 Frame and pressure

- The frame has been fully inflated. It can no longer be squeezed.
- The 3 tube clamps at the top have been closed to retain pressure in the air chambers.

2.7.2 Tensioning straps and attachment

- Fasten the tensioning straps around the mattress and, if possible, to the legs of the bed frame.
- The buckles must be securely fastened and cannot come undone.
- If available, also use the four additional tensioning straps to attach the bed tent to the head and footboard.
- Use on a care bed: only fasten the tensioning straps to the moving part of the bed base.
- Hospital bed: make sure the brakes are engaged.

2.7.3 Sheet and zips

- Always use the CloudCuddle Maxx with a zipped-in sheet. Without this sheet, the patient may end up entrapped between the mattress cover and the bed frame.
- Check whether the following zips are correctly zipped and close without jamming or sticking:
  - Zip of the frame cover.
  - Zip of the zipped-in sheet.
  - Zips of the mesh on all four sides.
  - Zips of the medical access ports.

2.7.4 Medical access ports

- The aim of the medical access ports is to provide secure access for medical lines such as IV lines or tubes, without opening the CloudCuddle Maxx **(photo 1)**.
- Check that all three access ports are closed and that the zip pullers are laid flat (so they cannot be opened). Use of the three access ports must always be assessed and approved by a medical professional.
- Each opening has a zip with a lockable zip puller that can be laid flat to prevent unwanted opening.
- Lines must never be routed through the mesh or other parts of the cover. Ensure flow is not impeded. Check lines for kinks.
- Close the zip as much as possible after inserting the line.



Photo 1

Only to be used after consultation with a medical professional and in line with the care plan.

2.7.5 Use with hoists

Use of hoists in combination with the CloudCuddle Maxx

- Active hoists
  Active hoists can always be safely used in combination with the CloudCuddle Maxx.
- Passive hoists – seated transfers
  Passive hoists may be used when the patient is lifted out of or into the CloudCuddle Maxx in a seated position.
- Passive hoists – supine transfers
  When carrying out a supine transfer with a passive hoist, the CloudCuddle frame must be laid completely flat on the bed by deflating the air chambers. This prevents entrapment and ensures a safe and stable transfer.

2.7.6 Access for emergency care and calamities

- The product has four access panels to facilitate administering emergency care and/or access in the event of calamities **(photo 2)**.
- The head and foot end have additional openings for acute medical care **(photo 3)**.
- These panels provide direct access to the patient without having to take down the entire bed tent.
- The openings can be secured with snap buckles **(photo 4)**.
- CPR. A visual marking on the relevant panel indicates that this panel can be opened quickly to provide immediate access for resuscitation in emergency situations **(photo 5)**.
- Emergency care for the patient: Use the quick-release function to unzip the panels completely.

Users in a professional setting: include the use of the CloudCuddle Maxx in the organisation's existing contingency plan or emergency protocol.



Photo 2



Photo 3



Photo 4



Photo 5

2.7.7 General safety requirements

- Check the product for damage or defects of the frame, cover, zips, or other parts.
- In case of doubt or damage: do not use the CloudCuddle Maxx and immediately contact the supplier or manufacturer.
- When used in combination with a care bed, the bed base must be lowered to its lowest position for use of the CloudCuddle Maxx, except when care is administered.
- Never leave a patient in the CloudCuddle Maxx without supervision or monitoring.
- Please bear in mind that the mesh may hinder external camera observation. It is not possible to install a camera inside the CloudCuddle Maxx.
- Keep pets away from the CloudCuddle Maxx to avoid damage.
- **NEVER** use any aid, such as a zip tie or padlock, to close the zippers of the panels.
- The product is solely intended for use as set out in the user manual. Use in combination with other products, medical devices or accessories is not permitted, unless these are explicitly listed in the user manual. Combining the CloudCuddle Maxx with non-approved products may give rise to safety risks. The manufacturer has solely validated the device's performance and safety for the combinations and applications listed in the user manual. Any other form of combined use is not approved by the manufacturer and is thus not permitted.

2.8 While using the CloudCuddle Maxx

It is extremely important that the CloudCuddle Maxx is used responsibly and that its use is tailored to the patient's current condition and needs. Take the following guidelines into account:

Prior to each use, review the checklist with "Key points to check before use" **(page 23)**, before leaving the patient in the bed tent unsupervised.

- Observe the patient carefully
  Check that the CloudCuddle Maxx meets the patient's physical and emotional needs during use. Observe the patient's comfort, attitude, and behaviour.
- Re-assess use of the CloudCuddle Maxx if the patient's condition changes
  Re-assess use of the CloudCuddle Maxx every time the patient's mental, physical or behavioural condition changes.
- Stop using the CloudCuddle Maxx if the patient feels claustrophobic
  If the patient suffers from claustrophobia or experiences symptoms of claustrophobia during use, immediately get the patient out of the CloudCuddle Maxx.
- Stop using the CloudCuddle Maxx in the event of danger
  Immediately get the patient out of the CloudCuddle Maxx when you observe:
  – A risk of self-harm or harm to others.
  – Signs of anxiety, aggression or extreme restlessness.
  – That the bed tips over or may tip over.

⚠ Use of the CloudCuddle Maxx requires continuous observation and careful professional consideration. In case of doubt: consult a physician or attending care provider.

2.9 Incidents and feedback

To guarantee the quality and safety of the CloudCuddle Maxx, we ask you to take the following into account:

Report incidents, damage or defects

Immediately report any safety incident, damage or defect to

Human Protection B.V.
Droogdokkeneiland 4
5026 SR Tilburg, The Netherlands
info@cloudcuddle.com
+31 (0)13 303 30 30

Do not use the CloudCuddle Maxx in case of

- Visible damage to the inflatable frame (such as leaks, tears or the tubes cannot be fully inflated).
- Zips that jam or stick.
- Damage or wear of the mesh or cover.
- Doubts about the product's safety.

In all the above cases, stop using the product immediately and contact us.

Feedback and user experiences

Your feedback helps us to further improve the CloudCuddle Maxx. Do you have comments or suggestions? Do you want to share your experience? Let us know through www.cloudcuddle.com.

III. PARTS OF THE CLOUDCUDDLE MAXX

The CloudCuddle Maxx consists of the following parts:

1. Pull cord (optional from the accessibility kit)
2. Snap buckles / quick release (4x male + 4x female optional from the accessibility kit)
3. Cover
4. Frame
5. 4 white tensioning straps with belt buckles
6. Zipped in sheet
7. Valve cap with lockable cover
8. 2 white stabilising straps
9. 3 medical access ports
10. CPR (Cardiopulmonale resuscitation) + 2x quick Release)
11. Mesh
12. 4 access panels (12a front and back, 12b head and foot end)
13. 3 tube clamps
14. 3 snap button fasteners
15. 4 black tension straps
16. 4 white tensioning straps with snap buckles





3.1 Cover

The cover protects the frame and provides limited visibility, air circulation, and medical accessibility, with transparent mesh and special openings **(photo 6)**.

Properties

- Transparent mesh.
- 3 medical access ports.
- Mounting points for the Quick Release system.
- Can be opened on all four sides, additional openings with a zip at the head and foot end for emergency care or calamities.

Material composition

- Blue cover: 100% Polyamide (PA).
- Mesh: 100% polyester (PES).
- White socks: 100% polyester (PES).
- Weight: 6.6 kg (excl. frame, incl. a sheet).

3.2 Inflatable frame

A sturdy, lightweight frame with several air chambers, specially designed for stability and protection **(photo 7)**.

- The air chambers are interconnected.
- After inflating the frame, the connections must be closed with the 3 tube clamps.
- Weight: 1.9 kg

3.3 Sheet

The device is supplied with a sheet that is zipped into the cover. The sheet can be replaced with another CloudCuddle Maxx sheet **(photo 8)**.

- Dimensions: 196 x 86 cm (L x W).
- Composition: 100% organic cotton (ORGCO).
- Weight: 0.4 kg



Photo 6

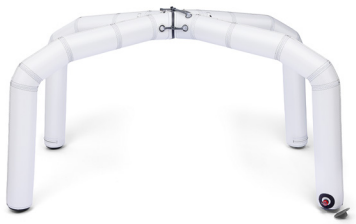


Photo 7



Photo 8

3.4 Pump

Hand pump, exclusively intended for inflating the CloudCuddle Maxx frame **(photo 9)**.

- Weight: 1.1 kg

3.5 Bag

A sturdy bag for the secure transport and storage of the CloudCuddle Maxx **(photo 10)**.

- Material: 65% polyester (PES), 35% cotton (CO).
- Weight: 0.5 kg

3.6 Accessibility set

Set for adapted access and safety **(photo 11).**

- 4 snap buckles to secure the zippers on the panels along the long sides.
- When using the snap buckles, attach the rings to the respective loops. Push the two sides of the snap buckles together to fasten them. You will hear a click when the snap buckle is closed. Always check that the snap buckles are securely locked after fastening them. The snap buckles are an additional safety measure, to prevent the patient from opening the CloudCuddle Maxx.
- A pull cord on the inside when the snap buckles are not used.



Photo 9



Photo 10



Photo 11

3.7 Incontinence sheet

The CloudCuddle Maxx incontinence sheet is an optional accessory. This replaceable sheet is secured with a zip, just like the standard sheet. In case of incontinence, it can be used as an alternative to the standard sheet. The sheet comes with its own instructions for use.

3.8 Stabilising straps

There are tensioning straps on the 4 white socks of the cover of the CloudCuddle Maxx. The bottom tensioning straps and buckles are used to fasten the CloudCuddle Maxx to the bed frame.

There are additional tensioning straps with a belt buckle at the top of the 4 socks. These can be attached individually to the head and foot ends of the bed as additional reinforcement. If the CloudCuddle Maxx cannot be fastened to the head and foot end of the bed, you can use the stabilising straps.

3.9 Top mattresses

You can use a top mattress in the CloudCuddle Maxx. Use of additional materials in the CloudCuddle Maxx may however increase the risk of shifting, suffocation, or entrapment. Always check that the use of a top mattress is suitable and safe for the user.

Before use, always check the care plan and assess whether the user is able, both physically and cognitively, to move themself or push away the top mattress in an emergency. The guideline is that the weight of the top mattress may not exceed 10% of the user's body weight.

Some top mattresses have a detachable cover that can be opened by the user. This can increase the risk of entrapment or suffocation. The user also has access to the contents of the top mattress as a result.

A top mattress is never fixed in place in the CloudCuddle Maxx. As a result, it may shift, especially with users who suffer from nighttime agitation or lie awake at night. Among these patient groups, there is an increased risk that the user may end up under the top mattress. Active monitoring is essential to ensure safe use of the top mattress.

Check daily that:

- The top mattress is in good condition.
- Any zips on the top mattress are zipped up.
- The top mattress is correctly positioned and has not shifted.
- The top mattress is still suited for use given the risk and current condition of the user.

The top mattress can be removed at any time. The CloudCuddle Maxx can always be used without a top mattress.

3.9.1 Technical data

Any top mattress used in the CloudCuddle Maxx must at least meet the following requirements:

- The top mattress has a solid core, and is not inflated (such as airbeds or alternating pressure systems).
- Dimensions: 200 x 90 x 2.5-5 cm (L x W x H).
- The mattress has no sharp or hard edges that might damage the cover or mesh of the CloudCuddle Maxx.

CAUTION

Do not use top mattresses, inlays, mats or other materials that do not meet the above specifications. This can lead to instability, shifting, entrapment or suffocation and is always a serious safety risk.

IV. TECHNICAL SPECIFICATIONS

4.1 Dimensions

- Outer dimensions: 200 x 126 x 110-120 cm (L x W x H).
- Inner dimensions: 200 x 90 x 90-100 cm (L x W x H).
- Internal height: 90 cm

4.1.1 Weight

- Total weight CloudCuddle Maxx: 11 kg

4.1.2 Maximum load

- Maximum weight of patient: 100 kg
- Maximum length of patient: 193 cm



Photo 12



Photo 13

4.2 Supplied parts, optional accessories, and spare parts

Supplied parts

The CloudCuddle Maxx is supplied as a complete set with the following parts:

Item code	Description
CCM01.01	CloudCuddle Maxx Cover
CCM01.02	CloudCuddle Maxx Frame
CCM01.03	CloudCuddle Maxx Sheet
CCM01.04	CloudCuddle Maxx Pump
CCM01.05	CloudCuddle Maxx Bag
CCM01.06	Accessibility set (quick release system pull cord)

CCM01.08	Stabilising straps set

Optional accessories

The following accessory is available as an option:

Item code	Description
CCM01.07	CloudCuddle Maxx Incontinence sheet

Spare parts

All of the above parts are also available separately as spare parts. The following reserve parts can also be ordered separately.

Item code	Description
CCVEN	CloudCuddle Valve cap frame red
CCSLA	CloudCuddle Repair set tubes frame

Is there a part missing? Does a part (snap buckle, valve cap, bag, or cover) need to be replaced?
Private individuals can order replacement parts through our online store at www.cloudcuddle.com.

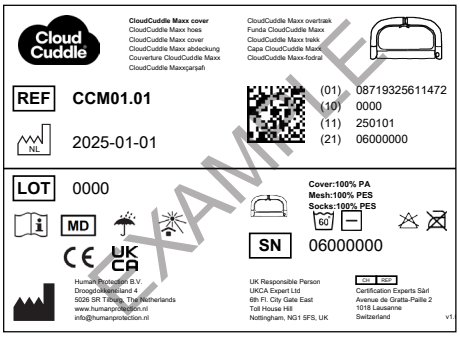
Care professionals can order replacement parts through Human Protection. Contact us through the usual channels or by email to info@humanprotection.nl.

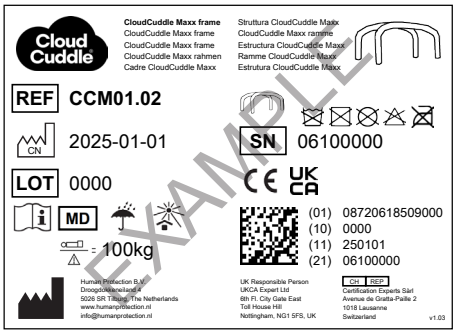
V. LABELS

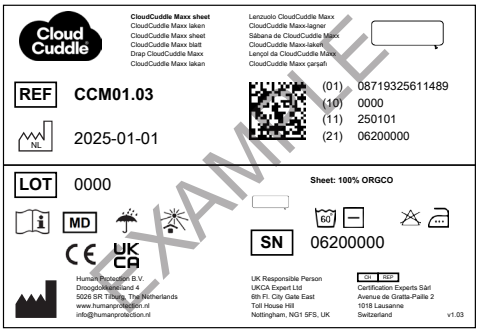
5.1 Manufacturer and representatives

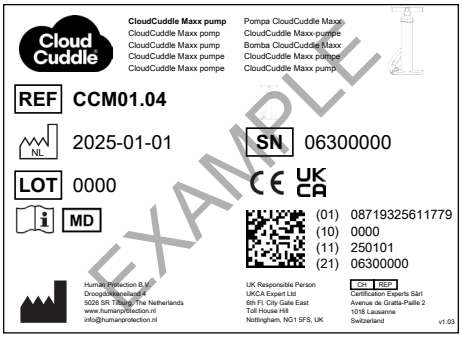
	Human Protection B.V. Droogdokkeneiland 4 5026 SR Tilburg, Netherlands www.humanprotection.nl info@humanprotection.nl	**UK Responsible person:** UKCA Expert Ltd 6th Fl. City Gate East, Toll House Hill, Nottingham, NG1 5FS, UK	**CH Responsible Person:** Certification Experts Sàrl Avenue de Gratta-Paille 1018 Lausanne Switzerland

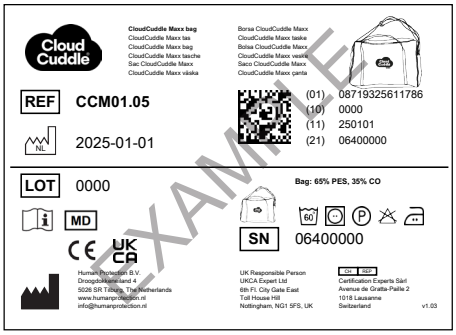
5.2 Labels by part











5.3 QR code

The QR code of the CloudCuddle Maxx can be found at the head end of the product and is attached in the centre of the cover, on the outside. This QR code can be used for retrieving the digital instructions for use (IFU) and instructions videos in an online environment **(photo 14)**.



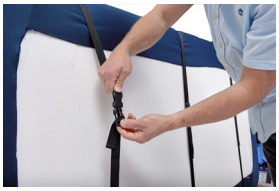
Photo 14

5.4 Explanation of symbols

Symbol	Meaning	Symbol	Meaning
	Warning		Medical device
	Manufacturer		Please refer to the manual for instructions for use
	Country of manufacture incl. incl. production date		Keep dry
	Catalogue number		Keep away from sunlight and keep away from heat
	Serial number		Batch number

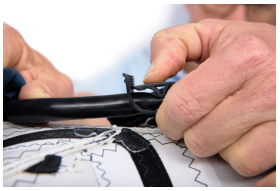
6.1 Setting up the CloudCuddle Maxx

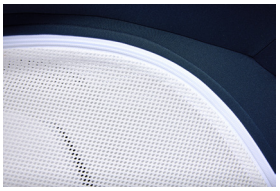
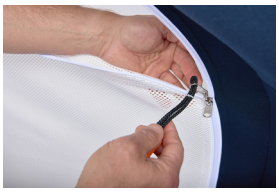
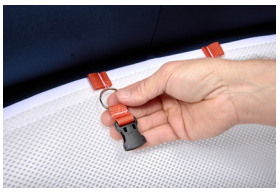
The CloudCuddle Maxx can be easily set up by following the instructions below.

Step	Instruction	Photo
1	Open the bag and take out the CloudCuddle Maxx.	 Photo 15  Photo 16
2	Lay the CloudCuddle Maxx on the mattress.	 Photo 17  Photo 18
3	Roll out the CloudCuddle Maxx over the mattress.	 Photo 19  Photo 20
4	Fold open the CloudCuddle Maxx.	 Photo 21  Photo 22
5	Slide the cover with the zipped sheet over the mattress. Make sure that the corners fit snugly around the mattress.	 Photo 23  Photo 24
6	Tilt the mattress and secure the four tensioning straps under the mattress by tightening the buckles.	 Photo 25  Photo 26

Step	Instruction	Photo
7	Tighten the straps until taut by pulling the loose ends.	 Photo 27  Photo 28
8	Check that all four tensioning straps are securely fastened.	 Photo 29  Photo 30
9	Put the mattress back down on the bed frame.	 Photo 31  Photo 32
10	Check that the 3 tube clamps at the top are open.	 Photo 33  Photo 34
11	Take the pump that was supplied with the device and select inflation setting 1.	 Photo 35  Photo 36
12	Open the valve cap and firmly tighten the rear knurled nut to close the valve. Make sure the cord is not trapped and check that you do not hear a hissing sound.	 Photo 37  Photo 38

Step	Instruction	Photo
13	Connect the supplied hose to the pump and turn it until it is locked in place.	 Photo 39  Photo 40
14	Connect the other end of the hose to the CloudCuddle Maxx and lock it in place.	 Photo 41
15	Inflate the CloudCuddle Maxx. It takes 70 full strokes.	 Photo 44  Photo 45
16	Check that the CloudCuddle Maxx is fully inflated as follows: - The frame feels solid and retains its shape - The frame cannot be squeezed - The mesh is visibly taut and does not hang loosely	 Photo 46
17	Close the valve cap and place the valve cover on the valve. Check again that the cord is not trapped to prevent the frame from deflating.	 Photo 47  Photo 48  Photo 49  Photo 50

Step	Instruction	Photo
18	Close the 3 tube clamps at the top of the CloudCuddle Maxx to ensure the air connection between the tubes is closed.	 Photo 51  Photo 52
19	Zip up the cover around the tubes and fasten the snap button fasteners at the top of the cover.	 Photo 53  Photo 54
20A	Use the tensioning straps to secure the CloudCuddle Maxx at the corners around the legs of the bed frame. Fasten the buckles securely and pull the tensioning straps until taut. If possible: also attach the CloudCuddle Maxx to the head and/or footboard of the bed with the additional tensioning straps. Fasten the buckles and tighten the straps until taut.	 Photo 55  Photo 56  Photo 57
20B	**ATTENTION!** If the CloudCuddle Maxx is used on a care bed, always make sure to attach the tensioning straps to the moving part of the bed base. Fasten the buckles and tighten the straps until taut. Lowered the care bed to its lowest position (max 50cm) when using the CloudCuddle Maxx, except when care is administered, and activate the locking function. Next, engage the bed brakes.	 Photo 58  Photo 59
21	Check that the 3 medical access ports are closed and that the zip pull is laying flat on the zip to stop it from opening.	 Photo 60

Step	Instruction	Photo
22	When zipping up the CloudCuddle Maxx, check that all zips close smoothly and do not stick. If one or more zips do not close securely or stick, do not use the CloudCuddle Maxx and contact us immediately.	 Photo 61
23	Accessibility set additional freedom of movement pull cord on the inside. Loop the black cord through the opening of the zip puller on the inside of the CloudCuddle Maxx. Loop the orange section through the black cord and tighten it. Removal of the pull cord on the inside is considered a measure that restricts patients' freedom of movement. This may only be done after approval by a medical professional.	 Photo 62  Photo 63
24	Accessibility set additional safety Quick Release System Mount the keyrings on the CloudCuddle Maxx.	 Photo 64  Photo 65
25	If you leave the snap buckles open after zipping up the CloudCuddle Maxx, the device can be opened from the inside using the pull cord. When the snap buckles are fastened, the CloudCuddle Maxx cannot be opened from the inside out, even if the pull cord is in place. Closure of the snap buckles restricts patients' freedom of movement. This may only be done after approval by a medical professional.	 Photo 66

6.1.1 Checkpoints after installation

Check the following points after setting it up:

- The tensioning straps have been correctly attached:
  - Under the mattress.
  - Around the bed legs and bed frame.
  - Care bed: tensioning straps are attached to the moving part of the bed base.
- The frame is fully inflated and can no longer be squeezed by hand.
- The CloudCuddle Maxx must be installed away from walls and obstacles.
- The CloudCuddle Maxx is capable of expanding to its full outer dimensions. The outer dimensions of the CloudCuddle Maxx are: 200 x 126 x 110-120 cm (L x W x H). The height must be measured from the top of the mattress to the top of the frame.
- The CloudCuddle Maxx is not wedged in between bed rails.
- The CloudCuddle Maxx is installed on a mattress with the following dimensions: 200 x 90 x 12-26 cm (L x W x H).
- The CloudCuddle Maxx is installed on a bed frame and a mattress with a minimum weight of at least 66 kg.
- The sheet and mesh are visibly taut. There are no visible folds.
- The 3 tube clamps at the top of the frame are closed.
- The 3 snap button fasteners at the top are closed.
- Care bed: Correctly attached to the movable bed base.
- Care bed: Use in the lowest position (max 50 cm), except when care is administered.
- Locking function of the bed frame is activated.
- Bed brakes of the hospital bed are engaged.
- No visible defects of the frame, cover or parts.
- All zipper pullers are correctly positioned and functioning properly.
- The 3 medical access ports are closed except if an access port is used for medical lines.
- The zipper pulls of the medical access openings lie flat and are therefore restrained.
- Check that the 3 medical access ports are closed and that the zip pull is laying flat on the zip to stop it from opening.
- Use of the pull cord on the inside: do not use the Quick Release system.
- Check that the valve is properly closed:
  - The knurled nut must be securely tightened.
  - The red valve cap must be securely tightened
  - You may not hear any air hissing. This may cause the frame to gradually deflate, and compromise the patient's safety.
  - The valve cap is connected with a cord to avoid losing it.
  - Check that this cord did not become trapped while securing the knurled nut. This may cause the frame to deflate.
- Never place objects or loose materials in the CloudCuddle Maxx. This may impact the device's performance.

For the daily inspection of the CloudCuddle Maxx, we refer to the document "CloudCuddle Maxx Inspection Points".

6.2 Taking down the CloudCuddle Maxx

The CloudCuddle Maxx can be easily taken down by following the instructions below.

Step	Instruction	Photo
1	Open the 3 snap button fasteners at the top of the cover.	 Photo 67
2	Open the 3 tube clamps to establish an air connection.	 Photo 68
3	Unscrew the knurled nut to open the valve and deflate the CloudCuddle Maxx. You may hear a hissing sound, followed by a pop. This is normal.	 Photo 69  Photo 70
4	Loosen the tensioning straps on the bed frame by releasing the buckles.	 Photo 71  Photo 72
5	Tilt the mattress and undo the four tensioning straps under the mattress by opening the buckles.	 Photo 73  Photo 74
6	Lay the CloudCuddle Maxx on the bed frame and place the inflatable frame in the centre of the mattress.	 Photo 75  Photo 76

Step	Instruction	Photo
7	Remove the CloudCuddle Maxx from the mattress by popping the corners off the mattress and folding them inwards. Place all the materials, such as the tensioning straps, buckles and tubes in the mattress cover. Work from the outside in.	 Photo 77  Photo 78
8	Roll up the CloudCuddle Maxx. Always roll towards the valve to express as much residual air from the frame as possible.	 Photo 79
9	Fold the CloudCuddle Maxx and store it in the bag. Place the pump and the CloudCuddle Maxx in the bag supplied with the product.	 Photo 80  Photo 81

7.1 Washing instructions

The CloudCuddle Maxx can be used in home settings as well as in hospitals and healthcare institutions.
The way the CloudCuddle Maxx must be cleaned, disinfected, and maintained depends on the setting in which it is used. Following these washing instructions helps to maintain the lifespan, hygiene, quality, and safety of the CloudCuddle Maxx.

7.1.1 Hospitals and healthcare institutions

- Full cleaning and disinfection may only be performed by Human Protection B.V. or an approved service partner of Human Protection.
- Users and healthcare workers may not clean or disinfect internal parts.

7.1.2 Private individuals home setting

- In a home setting, users may clean and maintain the CloudCuddle Maxx in accordance with the instructions in **chapter 7.3**.
- Specific guidelines apply for the washing of the cover, the cleaning of the inflatable frame, and the inspection of the parts for soiling.

7.2 Cleaning, disinfection and maintenance for hospitals and healthcare institutions

- After each extended period of use, the CloudCuddle Maxx must undergo professional cleaning, disinfection, and inspection at Human Protection B.V. or an approved service partner of Human Protection.
- This procedure consists of:
  - Cleaning and disinfecting the cover, sheet, and fasteners.
  - Cleaning and disinfecting the inflatable frame.
  - Inspecting the product's general condition.
  - Release for reuse.

The product may only be released for reuse after all steps in the process have been completed and after it has passed the full quality control.

7.2.1 Extended use changeover interval

- The CloudCuddle Maxx can be used for an extended period for one user.
- A changeover must be respected after 60 days.
- This means that, after each 60-day period, the CloudCuddle Maxx must always undergo professional cleaning, disinfection, and inspection by Human Protection B.V. or an approved service partner of Human Protection.

7.2.2 Surface cleaning during continued use

When the CloudCuddle Maxx is used by the same user for an extended period, surface cleaning may be performed by healthcare professionals.

- Clean the outside of the cover with a soft, slightly damp cloth and a mild detergent (pH 6-8).
- Never use chlorine, alcohol, ammonia, abrasive or corrosive substances for this interim cleaning.
- Check that the cover is completely dry before reusing the device.
  - In case of extreme soiling, always contact Human Protection for professional cleaning, disinfection and inspection.

7.2.3 Maintenance and inspection

- Maintenance and functional inspections may only be performed by Human Protection B.V. or an approved service partner of Human Protection.
- The CloudCuddle Maxx may not be used in case of visible damage, leakage or defects; please notify Human Protection B.V. immediately in that case.
- All maintenance, cleaning and changeovers are registered in the service and maintenance system of Human Protection B.V.

7.2.4 Reuse

The CloudCuddle Maxx is suitable for reuse by several users, provided that the device is fully cleaned, disinfected and certified by Human Protection B.V. or an approved service partner of Human Protection before use by a new user. Reuse may only occur after this

professional treatment and inspection, and never directly within hospitals or institutions.

7.2.5 Use by healthcare professionals

When the CloudCuddle Maxx is used in a professional care setting, it must be used according to the applicable protocols, guidelines, and responsibilities of the healthcare professional or healthcare institution.

The decision to use it and its application (e.g., in situations where intensive care or restriction of the patient's freedom of movement are required) is the responsibility of the healthcare professional or the institution.

Human Protection B.V. merely provides the user manual and technical instructions. The clinical assessment, indication, and actual application are not the manufacturer's responsibility.

7.3 Cleaning in a home setting

The CloudCuddle Maxx is suited for use in a home setting and can be easily cleaned. The sheet, cover, and inflatable frame must all be cleaned in a different way. Follow the washing instructions below to guarantee hygiene, quality, and safety in a home setting.

- The sheet can be unzipped and washed separately.
- The inflatable frame may not be machine washed **(chapter 7.5.1)**.
- Both the sheet and the cover can be washed at 60°C.
- Always close all zips and buckles before machine washing.
- Always wash the bag separately to prevent colour bleeds.
- **ATTENTION!** The CloudCuddle Maxx fits in a washing machine with a load capacity of at least 10 kg

7.4 How to wash the sheet

To wash the sheet, follow the washing instructions on the label. The sheet must be fully unzipped and removed from the frame before washing.

There is no need to deflate the CloudCuddle Maxx or remove it completely from the mattress while unzipping or zipping the sheet.

To ensure maximum safety, all fabrics of the CloudCuddle Maxx must be tightly stretched. You may thus need some space or slack when unzipping or zipping the sheet. It may therefore be necessary to release the buckles from the bed frame and pop the corners partly off the mattress.

After zipping the sheet, make sure that the cover is correctly positioned around the corners and that the buckles are securely fastened to the bed frame.

7.4.1 Unzipping the sheet

Step	Instruction	Photo
1	Release the buckles from the bed frame and pop the cover off the mattress in the corners. This reduces tension on the zip and makes it easier to unzip the sheet.	 Photo 82  Photo 83

Step	Instruction	Photo
2	Put your hand through the opening next to the valve and unzip the sheet partly.	 Photo 84
3	Push the zip puller of the zip slider upwards so that the sheet can be unzipped from inside the CloudCuddle Maxx.	 Photo 85
4	Unzip the sheet and remove it from the CloudCuddle Maxx.	 Photo 86
5	**ATTENTION!** Always use the CloudCuddle Maxx in combination with a CloudCuddle Maxx sheet. The CloudCuddle Maxx may not be used without the zipped sheet.	

7.4.2 Zipping the sheet

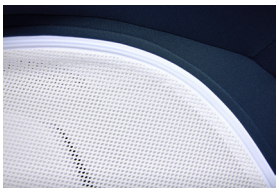
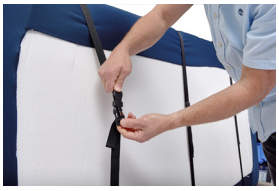
Step	Instruction	Photo
1	Release the buckles of the tensioning straps in the corners of the bed frame and pop the corners off the mattress.	 Photo 87  Photo 88
2	Check that the zip slider and zip pull of the cover are positioned at the top of the mattress.	 Photo 89

Step	Instruction	Photo
3	Slide the zip of the cover into the zip slider of the sheet and zip the sheet to the cover.	 Photo 90  Photo 91
4	After zipping in the sheet, make sure the zip puller is laid flat against the zip.	 Photo 92
5	Zip the cover tightly around the tubes and close the 3 snap button fasteners at the top of the cover.	 Photo 93
6	Place the cover around the mattress and attach all the tensioning straps to the mattress and legs of the bed frame.	 Photo 94  Photo 95
7	Follow the procedure for assembly and use the checklist (**chapter 6.1.1**, after set-up)	

7.5 How to wash the cover

To wash the cover, the inflatable frame must first be removed from the cover. **ATTENTION!** Do not machine wash the frame. The cover, and the 2 sheets, can be machine washed. Always check the load capacity of the washing machine because of the size of the frame. In most cases, you will need a washing machine with a load capacity of at least 10 kg.

Step	Instruction	Photo
1	Open the 3 snap button fasteners at the top of the cover.	 Photo 96

Step	Instruction	Photo
2	Open the 3 tube clamps to establish an air connection.	 Photo 97
3	Close all zips properly.	 Photo 98
4	Unscrew the knurled nut to open the valve and deflate the CloudCuddle Maxx. You may hear a hissing sound, followed by a pop. This is normal.	 Photo 99  Photo 100
5	Loosen the tensioning straps on the bed frame by releasing the buckles.	 Photo 101  Photo 102
6	Tilt the mattress and undo the four tensioning straps by opening the buckles.	 Photo 103  Photo 104
7	Lay the CloudCuddle Maxx on the bed frame and place the inflatable frame in the centre of the mattress.	 Photo 105  Photo 106

Step	Instruction	Photo
8	Starting from the top, unzip the legs completely to expose the inflatable frame. Remove the frame from the cover.	 Photo 107  Photo 108  Photo 109
9	Close the zips of the legs of the cover.	 Photo 110
10	Remove the CloudCuddle Maxx from the mattress by popping the corners off the mattress and folding them inwards. Place all the materials, such as the tensioning straps, buckles and leg sections in the mattress cover. Make sure all zips and buckles are closed to protect the cover.	 Photo 111  Photo 112
11	Place the cover in the washing machine. We recommend washing the cover at a low temperature. If necessary, it can also be washed at up to 60°C. Attention: do not machine wash the frame!	 Photo 113
12	Do not tumble dry the cover. Air-dry the cover to maintain its quality. We recommend air-drying the sheet to extend its lifespan.	

7.5.1 Cleaning and disinfecting the inflatable frame

- Clean the inflatable frame with a soft, slightly damp cloth and lukewarm water.
- For disinfection, wipe down the frame with a cloth moistened with (max.) 70% alcohol (ethanol or isopropyl alcohol).
- Avoid prolonged contact with alcohol or other solvents to prevent hardening, discolouration, or damage of the material.
- After disinfection, wipe down the frame lightly with a clean, moist cloth to remove any residue. Dry thoroughly with a soft, dry cloth.
- Never immerse the frame in water. Do not use running water or a high-pressure cleaner to clean it.
- Do not use chlorine, ammonia, abrasive or corrosive substances.
- Always check before assembly that the frame is completely dry and without damage.
- Also check that all the zips of the frame are fully closed before assembly of the frame cover or before use of the device.

WARNING! Improper cleaning or exposure to aggressive chemicals may cause material damage or leakage or may affect device safety. Always follow the above cleaning instructions to guarantee the lifespan and safety of the CloudCuddle Maxx.

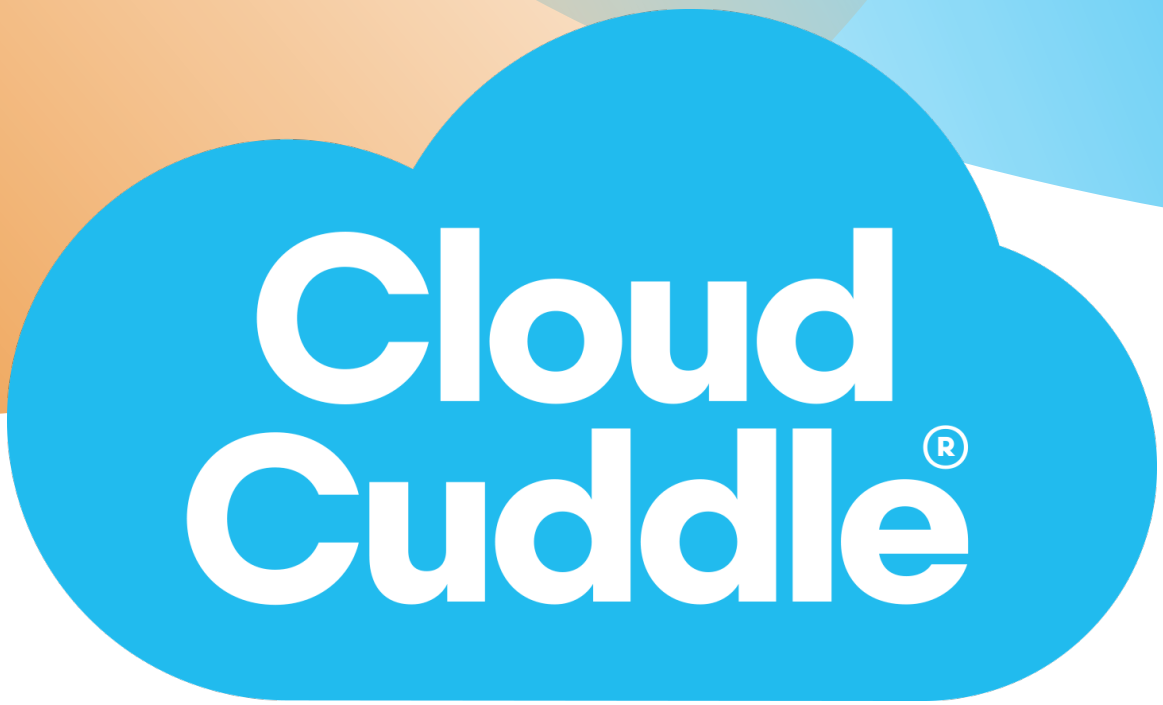
7.5.2 Replacing the frame

Step	Instruction	Photo
1	Lay the CloudCuddle Maxx on the mattress. Fold open the cover and release all the buckles.	 Photo 114  Photo 115
2	Unzip all the leg sections, starting from the top.	 Photo 116
3	Position the heart of the frame in the centre of the unzipped cover with the tubes and snap button fasteners facing up. Make sure that the four tubes are positioned on the blue legs with the seams facing up.	 Photo 117
4	Fold the 3 snap button fasteners over the heart of the frame and fasten them.	 Photo 118
5	Now insert the remaining legs into the right sections one by one. Push the frame firmly into the sock and zip up the leg.	 Photo 119
6	**TIP!** Inflate the frame slightly so its shape is visible. This prevents twisting of the legs.	
7	Now insert the remaining legs into the right sections one by one. Push the frame firmly into the sock and zip up the leg.	
8	After you have checked everything, deflate the frame again and follow the instructions for setting up the CloudCuddle Maxx (**chapter 6**) to ensure that it can be used safely and correctly next time you use it.	

VIII. PROBLEM SOLVING

Use the checklist below to solve common issues. Please follow the instructions carefully to ensure safe use of the CloudCuddle Maxx.

1. Deflating frame or hissing sound
   Does the CloudCuddle Maxx gradually deflate or do you hear a hissing sound? Check that the knurled nut is securely fastened. Check that the cord is not trapped between the nut. No air should escape from the knurled nut and the red valve cap. Contact us if the loss of pressure/air persists.
2. Tubes won't inflate or deflate
   Does one of the tubes not inflate while pumping or deflate while taking down the bed tent? Check that the tube clamps at the top of the CloudCuddle Maxx are open. Do you find it difficult to express the air from a tube even though the tube clamps are open? Roll the tube towards the middle to express the air. Contact us if the pressure loss persists.
3. Zip is difficult to open or close
   There are several reasons why this may happen:
   - Fabric, bedding or other material is stuck in the zip.
   You can fix this by pulling back the zip puller gently. Pull the zip in the opposite direction until the zip comes unstuck. Check that the zip, zip puller, and fabric of the cover are still intact and there is no wear or damage.
   - Check the teeth of the zip to see whether any are broken. Are the teeth broken or bent? Don't use the CloudCuddle Maxx in that case and contact us.
   Did the zip separate after closing?
   - The zip slider is damaged. As a result, the zip teeth are not properly aligned when the zip is closed. Please contact us in case of damage or wear.
   - Avoid this issue by always opening the zip with the zip puller.
   - Never pull open the access panel. This damages the slider. The zip cannot be securely closed because it is misaligned.
4. Unintentional opening from the inside out
   Can the CloudCuddle Maxx be opened from the inside out, from the foot and/or head end? Close the snap buckles on the outside.
   Can the CloudCuddle Maxx be opened from the inside through the side panels? Did you not use the snap buckles (Quick Release system)?
   Mount the snap buckles and contact us. The inner lining may be damaged.
5. Does the CloudCuddle Maxx not fit in the bag?
   Roll up the CloudCuddle again to remove any residual air in the frame and try again.
6. Pump hose comes undone
   Did the pump hose come undone from the valve while inflating the frame? Turn the hose until you hear it lock.
7. Legs bend when the patient lies against the mesh
   Do the legs bend when the patient lies against the mesh? Add air by further inflating the CloudCuddle Maxx. The frame is sufficiently inflated if you cannot squeeze the legs.
8. Zips or snap buckles do not work properly
   Is one of the zips sticky or do the snap buckles not work properly? Don't use the CloudCuddle Maxx and please contact us in that case.
9. Damage or defect
   Is something damaged or broken? Don't use the CloudCuddle Maxx and please contact us for advice, repairs or a replacement.
10. One of the zips has come undone
    Has one of the zips come off one side of the track or come undone? Don't use the CloudCuddle Maxx and contact us about a repair.
11. Frame does not fit snugly or legs are twisted/deformed after insertion into the cover.
    Are the frame legs twisted or does the frame appear to be distorted? In that case, the frame has probably not been inserted into the cover correctly. Follow the instructions in **chapter 6** of the manual to correctly set up the frame. Focus on the correct position of the legs in the white socks.
12. The legs of the CloudCuddle Maxx appear crooked or unstable
    Do the legs of the frame appear crooked or does the CloudCuddle Maxx look unstable? Check that the legs are not wedged between the head and/or foot end of the bed. Make sure that all legs are not wedged in between anything and are correctly positioned for stable placement of the frame. Did this not solve the problem? Don't use the CloudCuddle Maxx in that case and contact us.


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