curasonix
The Wound Cleaning Company

curason

User Manual

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Curason Wound Cleaning

Instructions for Use

Software V1.4

Manufacturer:
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Amtsgericht Lübeck HRB 15609 HL
Lübecker Straße 42
DE-23611 Bad Schwartau

Content

1. Safety Notice

1.1. General Safety

	- This IfU must be used only for the product Id: curason - The stated instructions must be followed
	- Fully charge the device before use to ensure continuous operation - Ensure full functionality of the device before use - Only use original sterile curasonix cleaning heads to ensure full functionality and safety

1.2. Safety during use

	- Inspect all components for damage before use. - The devices should be accepted only if the factory packaging and labeling arrive intact. Discard parts if the package is not sealed or destroyed. Do not use if packaging shows evidence of puncture(s), tampering, water contamination or other damage. Do not attempt to repair damaged parts. - [RK] is supplied pre-sterilized by plasma and intended for single use only. Do NOT re-sterilize. Re-sterilization may cause loss of function. - Do not use beyond the expiration date listed on the device (or its parts) outer label. - [HA] hand-apparatus shall be manually disinfected only (7.1), not automated. - In case an error occurs, stop current treatment and try to resolve error before proceeding
	- Dispose of single use parts after use following standard hospital waste disposal procedures

1.3. Electrical Safety

	- Ensure the connecting cable of the Charging Adapter does not come into contact with water. - Do not place or store the charger where it can fall into water or other liquid. - In case of any damage to the electrical parts, for e.g. damage to insulation on the cable of charging adapter, please return the part to the manufacturer. - Do not plug the charger into an incorrect voltage source outlet. Curason has been designed to charge with a specific voltage (100-240 volts @ 50-60Hz). Voltage converters and plug adapters do not guarantee voltage compatibility. Never force the plug into an outlet.

	- Ensure that the Curason charging adapter is detached from wall socket when not in use. - Ensure that any portable RF communication equipment or infrastructure is used no closer than 30 cm (12”) from Curason system and vice versa. - Precautions have to be taken if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas.

1.4. Mechanical Safety

	- Do not try to repair damaged parts. - Do not try to demount the component or force open the reusable or single use parts.
	- In case the device breaks, please return the device to the manufacturer.

1.5. Safety against risk of fire

	- Keep away from inflammable agents (e.g. cleaning fluids or anesthetic agents) - Use this product only for its intended use as described in this instruction - Do not use accessories other than those provided or recommended by the manufacturer. - Keep cord away from heated surfaces. - Do not insert any object into any opening of the appliance.

1.6. Chemical and Biological Safety

	- The [RK] is for Single Use only and must never be re-used. Risks of re-use may include patient infection due to lack of sterility. - If [RK] falls on the floor, discard it and do not use it again.
	- Check for the Sterile symbol on the Cleaning head [RK]’s packaging label. - Disinfect and clean the reusable Hand device before every use using the procedure explained in Section 4.

1.7. Patient and User Safety

	- Do not apply strong pressure while operating the device and cleaning the wound. Only apply with gentle pressure (weight of the device) to ensure contact to the wound bed. - Do not use device if orange LED indicator is active; immediately recharge the device - Do not use device if orange LED indicator blinks, resolve error state before commencing - Do not use device on patient while charging (hand apparatus placed in charging dock) - Antiseptic solutions of any kind must not be used immediately before or during treatment with curason. If antiseptic solutions are indicated, they can be applied after completion of the individual curason treatment session at the discretion of the physician in charge. - Always use mouth-nose protection in form of FFP2 masks for user and patients and potential present third parties. - User shall wear proper gowns and eye-protection during application
	- Inform the patient of possible adverse effects including discomfort, pain, and other possible risks. - Some patients may feel discomfort, pain and allergic reaction or other concerns. In such cases, interrupt, modify or discontinue the treatment according to your professional judgement. - Do not use the device further, if patient feels pain or burns due to ultrasound exposure. - Gloves must be worn while using and cleaning the device. - Device shall only be used by trained professional staff. - Room shall be ventilated with fresh air after each treatment - In the case of critical viral infections, e.g. HIV- and hepatitis patients (HBC, HCV) or critical bacterial infection (e.g. MSRA) precautionary measures are recommended to avoid cross-contamination between patients and users, i.e. operators of the device.

2. Glossary

IfU: abbreviation for Instruction for Use.

User: person handling equipment qualified/trained to use the device.

Patient: living being (person or animal) undergoing a medical, surgical or dental procedure.

Intended Use: use of for which a product, process or service in accordance with is intended according to the specifications, instructions and information provided by the manufacturer.

Single use part (SUP): Indicates a medical device part that is intended for one use, or for use on a single patient during a single procedure.

Reusable Part: Indicates a medical device part that is intended for more than one use, or for use on various patients.

Handheld: term referring to electrical equipment intended to be supported by the hand during normal use term referring to equipment that, once installed and placed into service, is intended to be supported by the hand.

Manufacturer: the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device, regardless of whether these operations are carried out by that person himself or on his behalf by a third party (MDD93/42/EEC)

[HA]: HA is the abbreviation for the German term “Handapparat”, which means “handheld device”. See chapter 5.2.1 for details.

[RK]: RK is the abbreviation for the German term “Reinigungskopf”, which means “cleaning head”. See chapter 5.1.1 for details.

[CLA]: CLA is the abbreviation for the German term “Curason Ladeadapter”, which means “Curason charging adapter”. See chapter 5.2.2 for details.

[EP]: EP is the abbreviation of Essential Performance. The Curason systems does not obtain an EP, but it obtains a Clinical Function [CF] instead.

[CF]: CF is the abbreviation of Clinical Function. An active Curason device consisting of [HA] and attached [RK] providing the CF is identifiable by bristle vibration and lit GREEN LED indicator for the operator.

[BS]: BS is the abbreviation for Basic Safety. The BS will be assured by visual inspection of the enclosure integrity and the usage of certified, intrinsically safe components evaluated according to risk management.

3. Purpose

3.1. Description

curason is a non-invasive medical device that causes the mechanical disruption and removal of bacterially contaminated wound coverings through micro-streaming by vibration and generated ultrasound (indirectly), applied onto the wound surface. Ultrasound is the primary micro-cleaning process, supported by mechanical removal of wound coverings through vibration. To achieve a gentle cleansing of wounds, the hand-held medical device curason combines a mechanical removal of wound covering layers e.g. soft fibrin layers, sloth etc. and removal of microscopic coverings containing bacterial biofilm.
The contributing mechanism of ultrasound (US) application is the mechanical removal of a wound-embedded biofilm by producing micro-bubbles (degassing effect) and micro-streaming, thereby causing a local dispersion and removal of bacteria that can be rinsed out more effectively.
Rigid structure of wound coverings e.g. strong fibrin or necrotic tissue cannot be removed by using the curason. The curason is intended to be used on the wound surface only, without entering or damaging intact viable tissue structures.

!	No tissues or cells of animal origin or biological tissues have been used for design and production of the curason ultrasonic wound cleaner.

3.2. Intended Use

The medical device Curason Wound Cleaning System is a hand-held device aimed at mechanically gently removing contaminated wound coverings that might cause healing disturbances or infections.
The curason is not intended for healing purposes, but as an instrument for wound cleaning and removal of soft wound coverings. The curason shall only be used on wounds that can only heal by secondary intent.

3.3. Patient Population

Adults with septic chronic wounds and wounds healing by secondary intent (excluding burns and trauma wounds) that are considered suitable for wound bed conditioning with contact low-frequency ultrasound, e.g. patients with diabetic foot ulcers, chronic venous or arterial ulcers, or pressure ulcers, except pregnant women and burn wound patients.

3.4. Intended User

Intended users are physicians (e.g. surgeons) and trained specialists (e.g. examined wound nurses) who attend patients with chronic wounds and wounds healing by secondary intent.

3.5. Application

Application type:
• single-use sterile cleaning head (applied part)
• reusable handheld device (re-processing instructions see chapter 7)
• reusable charger (re-processing instructions see chapter 7)

Environment:
To be used in medical treatment rooms of in- and out-patient healthcare facilities.

Frequency of Use:
The frequency of application, similar to other wound bed preparation and non-surgical debridement methods, is at the sole discretion of the physician in charge and based, among other aspects, on the presentation of the patient, the specific diagnosis/es, diagnostic findings, pathophysiologic reasoning, and personal experience.
Typical frequencies of application range from every few days over once a week to on demand.
If a treatment session extends over 15 minutes duration, a new cleaning head (RK) has to be used every 15 minutes. It is at the sole discretion of the trained wound expert to decide if the wound cleaning requires more than 15 minutes application. The cleaning head is a single-patient, single-use disposable.

- Gloves must be worn while using or cleaning the device.
- Device may only be used by trained professional staff
- Device shall not be used in surgical operation rooms and environments
- The [RK] is for Single Use only and must never be re-used. Risks of re-use may include patient infection due to lack of sterility
- Sterile gloves must be worn while set-up and application of the device
- Sterile sleeve must be used to fully cover the hand-apparatus
- Protective gowns (mask and eye-protection) for operator and protective handling must be utilized

The usage of Curason in vehicles is excluded.

Potential side-effects caused by the removal of wound coverings and bacteria contaminated wound debris can be e.g. pain and mild local bleeding. However a very gentle application shall be performed in such way that bleedings are not common or cause pain for the patient.

	- Do not apply strong pressure while operating the device and cleaning the wound. Gently move the cleaning head over the wound surface. In case pressure is too strong, the vibration sound will be hearable slowed down or interrupted.
	- In case wounds are very sensitive, user shall be skilled to apply local anesthetic prior to treatment. In case extreme pain occurs, treatment shall be aborted.
	- During application the wound bed and the wound edges shall be frequently rinsed with sterile saline solution (from a bottle) to remove contaminated debris. To apply the rinsing solution, use your free hand or ask for assistance. After each application the wound and wound edges must be thoroughly rinsed and cleaned before wound will be closed with dressings etc.

3.6. Indications

Contaminated and/or infected non-vital wound coverings and bacteria contaminations, mainly at the extremities or torso. Application at mucous membranes or at the head or neck and wounds other than second intent wounds as well as burn wounds and large surface traumatic wounds shall be excluded.

3.7. Contraindications

For pregnant women, neonates, infants and children the clinical evidence for treatments with low-frequency ultrasound is limited. Therefore, the curason shall not be used in these patient groups. Cancer where the tumor is at or close to the treatment site. The device shall not be used on mucous membranes (e.g. mouth) or at the head or neck of a patient or on burn wounds or on wounds other than wounds healing by secondary intent. Burn wounds and large surface traumatic wounds shall be excluded.

4. Curason and Components

4.1. Single Use Parts

4.1.2. Cleaning Head [RK]

Cleaning Head (Reinigungskopf [RK]) is a disposable single-use sterile part packed as SUP, intended for contact with the wound bed. Its function is to carry the main activity, i.e., the cleaning of the wound when connected to the Handheld Device. Cleaning Head consists of a brush with bristles at the lateral end that when moved at the wounds help in disruption and removal of the bacterial tissue layers. The bend profile accounts for easy and effective application.

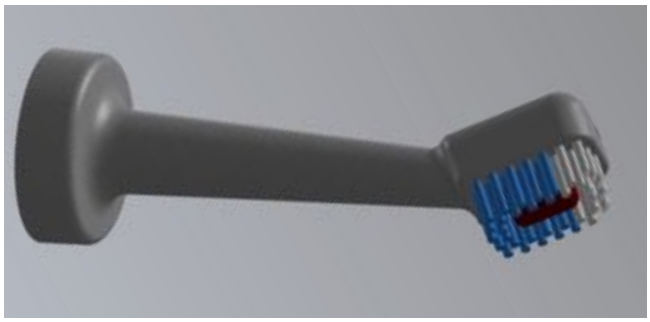


Figure 1: Model of cleaning head [RK]

4.2. Reusable Parts

4.2.1. Handheld Device [HA]

Handheld Device (Handapparat [HA]) is the curason's reusable part and not intended for direct patient contact. It consists of the electronics and software part that drives the device. It's carries the functioning of the device when connected to the correct Cleaning Head. Along with driving the system, it consists of RFID that ensure recognition of the correct [RK] and eliminates the risk of attaching the wrong or reused [RK].

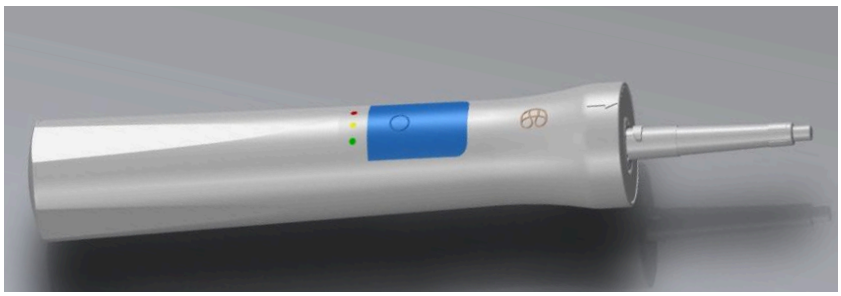


Figure 2: Model of handheld device [HA]

4.2.2. Charging Adapter

[HA] consists of a permanent battery. Charging Adapter provides wireless charging to the device.

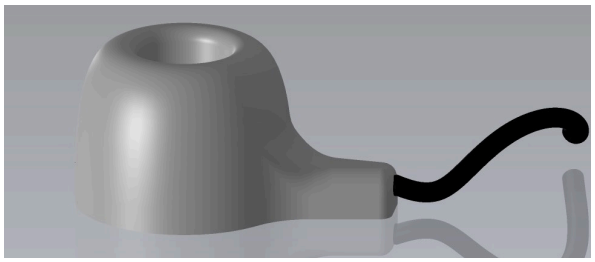


Figure 3: Model of charging adapter [CLA]

5. System Setup Instructions

5.1. Attaching the Cleaning Head [RK] to Handheld device [HA]

Before attaching a new Cleaning Head RK to the hand-apparatus, make sure the hand-apparatus is fully cleanied (refer to chapter 7) and can be properly covered with the sterile sleeve (refer to chapter 6.2).
Remove the Cleaning Head and the Handheld device from the packaging. Check the package seal before use and notice the label stating the date of expiry.
Align the brush bristles to the front of the [HA]. Insert the [RK] to the [HA] by pressing it down firmly until it clicks indicating it is attached. The markings on the device show the attachment. (as shown in Figure 4). Try to rotate the [RK] gently. It should be fixed and allow no rotation.

⚠	- Do not touch the [RK] or sterile sleeve (see chapter 6.2) with the hand or glove that had contact to non-sterile surfaces.

Figure 4: Curason system (handheld device and cleaning head attached)

5.2. Charging and re-charging the device

Remove the Charging Adapter [CLA] from the packaging. Check the package seal before use and notice the label stating the date of expiry.
Plug the wall socket adapter to the mains socket. Place the [HA] device to the [CLA].
Notice the charging LED will illuminate. The possible LED colors are red, yellow or green showing the battery charging state (Please see the section 7.3 for the LED modes).

Leave the device charging until the LED shows up green indication battery fully charged. The device is ready to use.

Charge the device for min. 3 hours before the initial use.

Figure 5: Handheld device inserted into charging adapter

5.3. Changing the head after single use

Remove the used [RK] after the application by pulling the [RK] from the [HA]. Dispose the used [RK] using standard hospital disposal procedures. Insert a new head by following the instructions in section 2.1.

6. Operation and Monitoring Instructions

6.1. User Interface

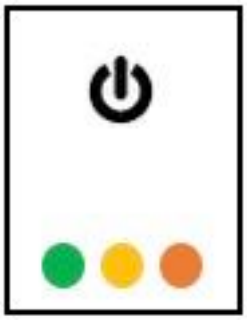


Figure 6: User interface

LED Behaviour	Definition
No LEDs	Passive Mode
Green, steady	Active Mode
Green, intermittent	Complete battery charge
Yellow, steady	Medium battery charge
Orange, steady	Low battery charge
Orange, intermittent	Error state

	Do not touch any sterile parts of the curason or sterile sleeve with the glove or hand that was in contact with the hand-apparatus body or non-sterile surfaces and objects.
	If the HA is in the CLA and the green LED starts flashing, the battery is charged to saturation. To protect the HA, the CLA switches off the charging current intermittently. The green LED switches off completely when the charging current has been shut off completely.
	In case an error occurs, stop current treatment and try to resolve error before proceeding

6.2. Application

Switch the fully charged device on by pressing the push button ⏻ present on the handheld device (as shown in the figure).

!	Check correct functionality (vibration, LED etc.) before use.
⚠	Only use the [HA] on the patient if you have previously protected the [HA] with a sterile protective sleeve to cover the surfaces of the [HA]. Examples of usable sterile protective sleeves for e.g. „SonoGuard Ultrasound Sleeve, sterile, 25 cm length, code US.10.140.025 by Promecon GmbH“ can be found in Chapter 7.

To prevent contamination of the hand-apparatus [HA] and sterile part of the curason [RK] Cleaning Head, always use a sterile protective sleeve before starting application (refer to list of suitable sleeves in chapter 7).

To do this, wear sterile gloves and connect the [RK] to [HA]. Then take the sterile sleeve and simply pull the sterile sleeve from the rear end of the hand-apparatus [HA] to the top end of the hand-apparatus [HA].

When placed in position connect the cleaning head [RK] and slide the sterile sleeve over the [RK] until the [RK] is halfway covered by the sterile sleeve. Now use the sterile fixation tape and fixate the open end to the [RK] shaft in such way that the tape (coming with the sterile sleeve) will be glued / fixed to the [RK] shaft and the sterile sleeve, holding them closely together. Make sure no openings or gaps are between the sterile sleeve and the [RK] shaft.
Make sure that during this process the surface of the [HA] or the hand that was touching the HA surface does not get into direct or indirect contact with the outer surfaces of the sterile parts (SonoGuard Ultrasound Sleeve, sterile, 25 cm length, code US.10.140.025 by Promecon GmbH)

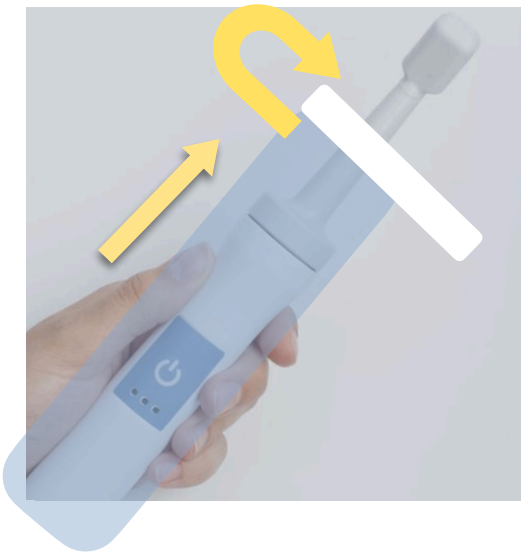


Figure 7: curason with sterile sleeve protection and fixation position

See following page with single steps:

Step 1: prepare articles:

Step 2: unpack sterile sleeve:

Step 3: put HA into sleeve:

Step 4: pull sleeve over HA:

Step 5: connect RK to HA:

Step 6: wrap sleeve around RK shaft:

Step 7: fixate sleeve with adhesive band:

Step 8: keep prepared HA in sterile field:

After the sterile sleeve was applied correctly, place the [HA] and [RK] onto a sterile surface, cloth or plate within the working field.

In case the sterile sleeve covering the hand-apparatus was in contact with non-sterile surfaces or objects before application, please exchange the sterile sleeve following the above described procedure and dispose off the [RK] cleaning head.

Switching on of the [HA]:

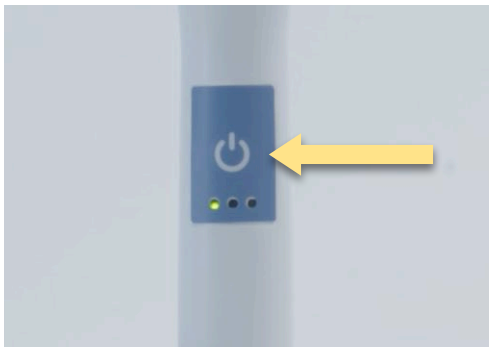


Figure 7: Switching on curason

The sterile sleeve covering the [HA] is transparent and allows good vision to the control pad of the [HA].
Hold the device in a suitable position, for e.g. a ‘pen holding’ position and move the bristles on the wound surface in a smooth movement with gentle but sufficient pressure to remove the bacterial layers and remove soft wound coverings on the wound. In case you apply too much pressure the vibration will hearably be slowed and comes to a stop at extreme pressure. For all wounds the movement of the device should be from the center of the wound towards the periphery of the wound. During application always take care to frequently apply an adequate amount of sterile saline solution to the area treated with curason to keep the wound wet. Repeat this as needed during the treatment session. Saline solution is required for the acoustic coupling between the tissue and the cleaning head and rinsing of the wound to remove detached wound coverings.

!	Please note the process explained during the mandatory training provided to the users

Ensure to switch the device off by pressing the push button again after completing the application. Ensure no LEDs are illuminated.

⚠	- The hand-apparatus [HA] cannot be steam or thermally sterilized and might be damaged during such procedure. - The hand-apparatus [HA] cannot be cleaned in an ultrasonic bath, therefore requires manual cleaning
!	After attachment of a new cleaning head [RK] and switching on, the cleaning head has a lifetime of 15 minutes. In that timeframe, the device can be switched off and on again (e.g. for patient repositioning or application of sterile saline solution). After 15 minutes, the attached cleaning head needs to be disposed off according to hospital hazardous waste disposal guidelines.
⚠	Antiseptic solutions of any kind must not be used immediately before or during treatment with curason. If antiseptic solutions are indicated, they can be applied after completion of the individual curason treatment session at the discretion of the physician or wound expert in charge.

6.3. Operating Modes

The device shows different operating modes indicated by the LEDs present on the device and visible through a transparent window located at the [HA].
The following four **modes** can be distinguished:

- Until initially pressed ⏻, the device is in the **PASSIVE mode**, therefore **all LEDs** are **OFF**.
- When switch is initially pressed and a new [RK] has been mounted to [HA] before, the device is in **ACTIVE mode**, therefore the **GREEN LED** is always **ON** in this state to show-up to operator that the wound cleaning procedure can be started:

• If the battery is in **full** charge state, the **YELLOW** and **ORANGE LEDs** are OFF.
You can operate the pending and following cleaning application.

Figure 8: Device in full charge state

• If the battery is in **medium** charge state, the **YELLOW LED** is **ON**.
You can operate the pending cleaning application. After regular termination and switching off the device, you have to attach the device to the [CLA] for charging before beginning a new wound cleaning application.

Figure 9: Device in medium charge state

• If the battery is in **low** charge state, the **Orange LED** is **ON**.

⚠	Do not use device on patient while charging (hand apparatus placed in charging dock)

No new treatment should be started, current cleaning application should be terminated. After switching off the device, you have to attach the device to the [CLA] for charging before beginning a new wound cleaning application.

Figure 10: Device in minimum charge state

By pressing ⏻ again, the device goes back to the **PASSIVE mode**.

- When attached to a powered-up [CLA], the device is in **CHARGE mode**, now displaying the state of the running battery charging process:

• If the battery is in **low** charge state, the **ORANGE LED** is **ON.**
Keep the [HA] attached to powered [CLA].

• If the battery is in **medium** charge state, the **YELLOW LED** is **ON.**
Keep the [HA] attached to powered [CLA].

• If the battery is in **full** charge state, the **GREEN LED** is **ON.**
Now you can detach the [HA] from [CLA] to commence the wound cleaning application.

- When an exceptional condition occurs to Curason [HA] or [CLA] setup, the device is in **ERROR mode**, therefore the **ORANGE LED** is **BLINKING** in this state to show-up to operator that the wound cleaning procedure cannot be started:

⚠	In case an error occurs, stop current treatment and try to resolve error before proceeding

• When [RK] has been removed **or** the same one **or** a wrong head inserted, the device can be considered in this mode. Use a new and correct [RK] and activate the device again.

• In all other cases or situations, contact a representative of curasonix GmbH for further steps with regards to section 0.

After a period of max. 3 seconds, the device ERROR mode falls automatically back to the **PASSIVE mode** again.

6.4. LED at Wall Socket Adapter connected to Charging Adapter

The Wall Socket Adapter attached to [CLA] shows a LED on the front side indicating the following:

- LED is OFF -> The adapter is not powered on.
- LED is ON -> The adapter is powered on and working. It can now be used to charge the [HA] device placed in the Charging Adapter.

Figure 11: Wall plug (example for US variant)

!	The wall plug shall be mounted in a way, that it can be unplugged easily in case of failure or error.

7. Cleaning and Disinfecting

The [RK] is a SUP and is not meant to be cleaned and reused. In case the [RK] falls down to the floor, it needs to be disposed off according to standard hospital disposable methods.

According to ISO 17664-1, Annex C, the [HA] is considered a non-critical product but is not intended to come into contact with the patient and additionally shielded by a sterile sleeve during preparation and application for further safety.

To prevent germ transmission, the [HA] must be used on the patient fully covered with a sterile protective cover. See chapter 6.2 for more information on how to apply the sterile sleeve.

Recommended examples of sterile protective sleeves are (according to FB 010b Risk and Hazard Analysis referencing ISO 10993):
Promeceon GmbH, Kreuslerstrasse 10, 20095 Hamburg, Germany, SonoGuard Ultrasound Sleeve, sterile, code US.10.140.025, size 25 cm x 14 cm

[HA] and [CLA] can be cleaned and disinfected by scrubbing and wiping the surface. Protective gowning must be worn while cleaning and disinfecting the device. Please follow the cleaning and disinfection instructions in chapter 7.1.

7.1 Cleaning and Disinfection Instructions

Instructions for cleaning and disinfecting the hand-apparatus [HA]

Initial treatment at the point of use:
Before and after each application the hand-apparatus [HA] requires to be cleaned and disinfected.

Therefore the protective sterile sleeve and the cleaning head [RK] need to be removed and safely disposed off. The cleaning and disinfection must be performed in a clean environment and in a clean and sterile container. The used and potentially contaminated hand-apparatus [HA] must be transported to the processing location in a closed or covered container to prevent contamination risk.

Preparation before cleaning:
Make sure the cleaning head [RK] and the sterile sleeve are removed from the hand-apparatus [HA]. Make sure that the [HA] can be placed on a clean or sterile surface during the cleaning process. Always wear an eye-protection, mask and protective clothing such as gown and gloves during cleaning.

Cleaning and disinfection method:
Manual cleaning and disinfection with wipe and sponge inside a sterile container.
Scrub the device with a new and clean soft medical single-use sponge and single-use wipe containing active peracetic acid detergent (≥2000ppm ie Clinell™ Sporicidal Wipes) 3 times within a minimum of 5 minutes until all surface was repeatedly cleaned and there is no visual contamination remaining. Make sure all surfaces and edges have been repeatedly wiped and soaked with the detergent. Let the detergent reside for a total of 15 minutes on the surface of the [HA]. After the residence time of 15 minutes rinse the [HA] with cold clean water as required (clean tab water or clean desalted water).

Drying:
Take the hand-apparatus from the container and dry it with a sterile lint-free cloth from all visible liquid adhesions. Place the hand-apparatus [HA] on a sterile lint-free cloth and cover it totally in this sterile cloth. Drying should be completed after 10-15 minutes.

Packaging:
In case the hand-apparatus [HA] is cleaned and disinfected before application, keep the [HA] totally covered inside the sterile cloth on a metal tray. If the tray is not sterile, do not take the tray directly to the patient site.

Storage:
In case the hand-apparatus [HA] was cleaned and disinfected after an application, it can be taken from the cloth and placed inside the charger [CLA] for re-charging. Prior to the next application the [HA] must be cleaned and disinfected following these instructions.

Additional information: The charger needs to be surface cleaned at least once a week with the detergent (Stabimed© ultra by B.Braun) following these instructions.

Manufacturer contact: curasonix GmbH, Lübecker Str. 42, 23611 Bad Schwartau, Germany

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

8. Storage

The device can be easily stored for a maximum of 2 years (shelf life of the device) at temperatures from 15°C to 25°C) under normal conditions (see section 13).
The cleaning head can be stored for a maximum of 18 months at temperatures from 15°C to 25°C (see section 13)

9. Troubleshooting

⚠	- In case an error occurs, stop current treatment and try to resolve error before proceeding - Do not try to repair damaged parts. - Do not try to demount the component or force open the reusable or single use parts.

- If no cleaning head attached, the device signals that before switching to active mode, a new cleaning head needs to be attached.
- If a cleaning head is attached, the RFID system is not working properly. Try to attach a new cleaning head. If the error persists, please contact the manufacturer
- If in charging station, there could be an error with the charging system. Try to re-insert the device. If problem persists, please contact the manufacturer.

10. Maintenance, Repair and Warranty

Neither the device nor any parts are meant to be repaired and must be returned to the manufacturer in case of error.
The hand-apparatus has a shelf life of 2 years, it must be returned to the manufacturer after 2 years from the date of use.

11. Disposal

The [RK] is a SUP and can be disposed off according to standard hospital disposable methods. The [HA] and the [CLA] must be returned back to the manufacturer after use or in case of error or complaint. The device must be disposed of according to local disposal regulations or to be sent back to the following address:

curasonix GmbH
Lübecker Straße 42
DE-23611 Bad Schwartau
Germany

12. Accessories

The device shall be used with the following accessories e.g. sterile sleeves (see Chapter 7) and sterile physiologic saline solution (NaCl 0.9%).

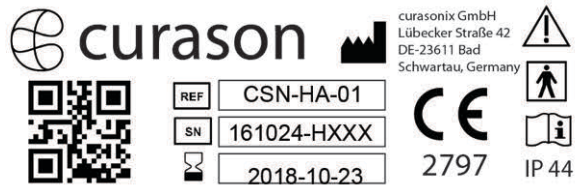
⚠	Only steril saline solitions shall be used for application
⚠	Antiseptic solutions of any kind must not be used immediately before or during treatment with Curason. If antiseptic solutions are indicated, they can be applied after completion of the individual Curason treatment session at the discretion of the physician in charge.

13. Technical Specifications

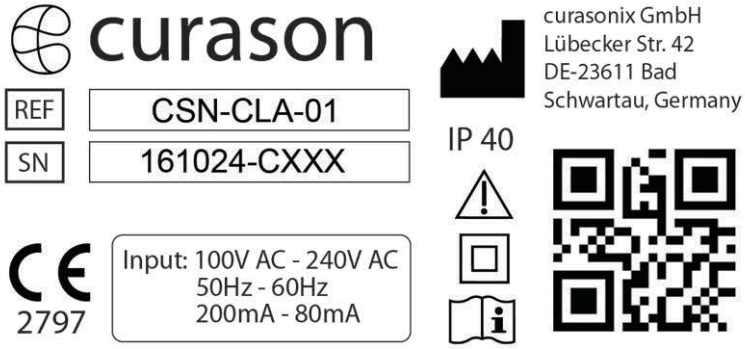
Operating Mode	Handheld
Weight of the Device	[RK]: 25g, [HA]: 140g, [CLA]: 175g
Dimensions (L x W x H)	[HA]: 214 mm x 33 mm x 33 mm [RK]: 100 mm x 34 mm x 34 mm [CLA]: 120 mm x 80 mm x 64 mm
Supply Voltage for the Charging Adapter	100 V – 240 V AC, 50 Hz – 60 Hz
Current Consumption	≤ 200 mA @ 100VAC ≤ 80 mA @ 240VAC
IEC Protection Class	II
Protection by enclosure	IP 44
Applied part classification	BF
Parts to be treated as applied part	Cleaning Head [RK] attached to handheld device [HA]
Over-Voltage category / Pollution Degree	II / 2
Admissible operating ambient temperature	15 °C - 40 °C
Admissible storage / transport ambient temperature	15 °C – 25 °C / 1 °C – 70 °C
Maximum relative humidity during operation	20 %rH – 80 %rH
Maximum relative humidity during storage / transport	35 %rH – 50 %rH / 10 %rH – 93 %rH
Lowest air pressure during operation	700 hPa – 1060 hPa
Lowest air pressure during storage / transport	700 hPa – 1060 hPa / 500 hPa – 1060 hPa
Battery	Built-in 3,7 V LiIon cell in [HA], not replaceable
Shelf Life	to be returned to the manufacturer after 2 years, cleaning head to be disposed after 18 months
Electromagnetic compliance info	Emission: Class B, group 1 Immunity: Home healthcare environment (ESD compliance level: ±8kV air discharge)
Transmit frequencies	Wireless charging: 100 kHz ± 10 kHz [CLA] [HA] intermittent Ultrasound power transfer: 54 kHz ± 2 kHz [HA] [RK] intermittent RFID communication: 13.56 MHz [HA] [RK] intermittent, amplitude shift keying, Rx bandwidth: 700 kHz

14. Abbreviations and Symbols

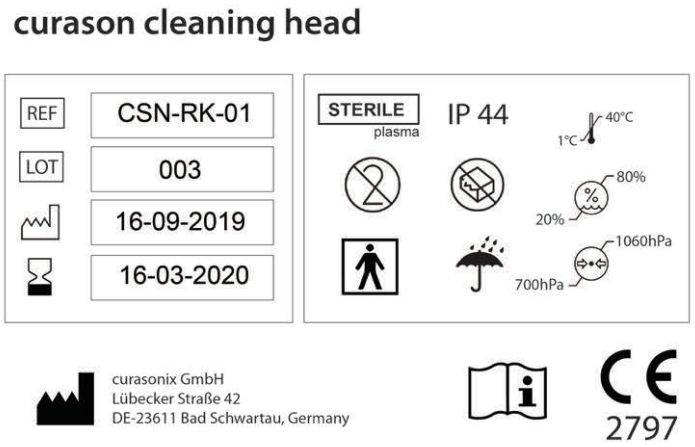
14.1. Product marking



Label 1: Hand-apparatus

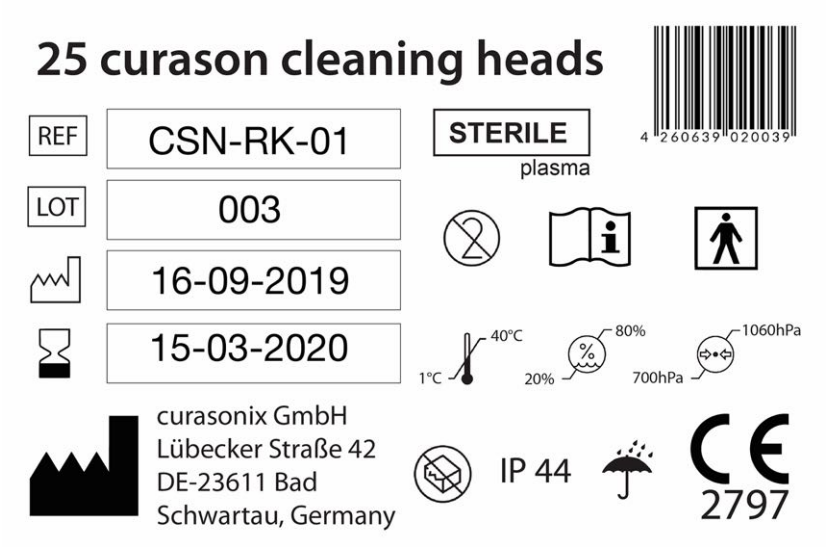


Label 2: Charger

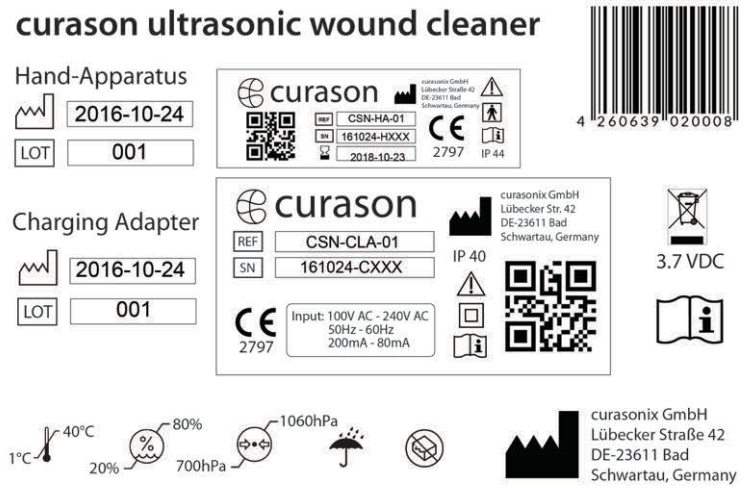


Label 3: Cleaning head

14.2. Packaging marking



Label 4: Cleaning heads packaging



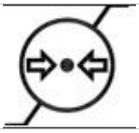
Label 5: Hand-apparatus and Charger

14.3. Caution symbols

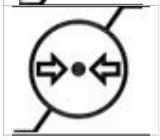
	Caution Statement that alerts the user to the possibility of a problem with the device associated with its use or misuse
	Warning Statement, that alerts the user to the possibility of serious adverse reactions.
	Note, Guidance for application of the curason device.
	Consult IfU

14.4. Product label and laser marking symbols

	Use by / Date of expiration [HA],[CLA]
	Manufacturer (including manufacturer address next to symbol) [HA],[CLA]
	Date of Manufacture [HA],[CLA],[RK]
STERILE	Sterile [RK]
	Keep dry [HA],[CLA],[RK]
	Do not use if package is damaged [HA],[CLA],[RK]
	Temperature limits (lower+upper) [HA],[CLA],[RK]
	Humidity limits (lower + upper) [HA],[CLA],[RK]

	Atmospheric pressure limits (lower + upper) [HA],[CLA],[RK]
	Lot number/ Batch number [HA],[CLA],[RK]
	Catalogue number [HA],[CLA],[RK]
	Serial Number [HA],[CLA] Production date followed by identifier x (C=CLA,H=HA) with running number index (y)
	Do not reuse [RK]
	Type BF Applied Part [HA]
	CLASS II equipment [CLA]
	Consult IfU
	Caution Statement that alerts the user to the possibility of a problem with the device associated with its use or misuse
 2797	CE Mark and number of Notified Body [HA],[CLA]
IP44	IP classification of protection by enclosure: Splashing of water and ingress of objects >1mm. [HA]
IP40	IP classification of protection by enclosure: Ingress of objects >1mm. [CLA]

14.5. Packaging symbols curason ultrasonic wound cleaner and charger

	Use by / Date of expiration [HA],[CLA],[RK]
	Manufacturer (including manufacturer address next to symbol) [HA],[CLA],[RK]
	Date of Manufacture [HA],[CLA],[RK]
	Lot number/ Batch number [HA],[CLA],[RK]
	Catalogue number [HA],[CLA],[RK]
	Serial Number [HA],[CLA],[RK]
	CLASS II equipment [CLA]
	Type BF Applied Part [HA]
	Keep dry [HA],[CLA],[RK]
	Do not use if package is damaged [HA],[CLA],[RK]
	Temperature limits (lower+upper) [HA],[CLA],[RK]
	Humidity limits (lower + upper) [HA],[CLA],[RK]
	Atmospheric pressure limits (lower + upper) [HA],[CLA],[RK]

	Not for general waste [HA],[CLA]
 2797	CE Mark and number of Notified Body [HA],[CLA],[RK]
IP44	IP classification of protection by enclosure: Splashing of water and ingress of objects >1mm. [HA],[RK]
IP40	IP classification of protection by enclosure: Ingress of objects >1mm. [CLA]

14.6. Device symbol

	On/Off, toggling on and off by pressing the push button. [HA]
	Alignment of [RK] to [HA]

CE 2797