English

EASY
EXCELLENCE

3D-SCANNERS
MILLING
PROSTHETIC PARTS
ORTHODONTICS

Instructions for use

CS.Nova / CS.Nova^{Pro}



www.cadstar.dental

CADstar

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1. Safety information

1.1 General safety instructions

Instructions for use of the intraoral scanner:

CS.Nova

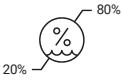
UDI-DI:	09120135441002
Basic UDI:	912013544NOVA9D
Instructions for use:	Version 1.00
Date:	31.05.2026

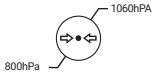
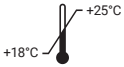
Please read these instructions for use carefully before using the product. Observe all warnings, precautions, and instructions to avoid risks to patients, users, and third parties.
The CS.Nova is a wireless intraoral scanner for digitally recording intraoral structures. Using optical triangulation and structured light projection, the device creates high-resolution 3D surface scans of the teeth and surrounding tissue. The data are used for further processing in the dental technology sector, in particular for the production of dental prostheses.

1.2 Symbols and graphical conventions

The following additional information highlights important information or draws attention to potential hazards for the user or the device.

No.:	Symbol	Meaning
1		Follow the instructions. To ensure safe operation of the device, the user must follow the instructions for use.
2		Follow the instructions for use
3		Caution
4		Medical device
5		Unique Device Identifier
6		Serial number

No.:	Symbol	Meaning
7		Batch number
8		Catalogue number
9		CADstar Technology GmbH, Grasslau 30, 5500 Bischofshofen, Austria
10		Indicates the date the device was manufactured. YYYY-MM-DD (year-month-day)
11		Laser product class 1 acc. IEC 60825-1:2014.
12		Application part type B
13		Maximum recommended sterilisation temperature
14		Built-in wireless connection: 5GHz WiFi, 2.4GHz Bluetooth
15		Indicates the side of the package that must face upwards.
16		Stack limit: 7 pieces
17		Store in a dry location
18		Fragile, handle with care
19		Fragile, handle with care
20		Maximum ambient humidity 20-80%

No.:	Symbol	Meaning
21		Permissible operating air pressure range: 800hPa-1060hPa Permissible storage and transport air pressure range: 620hPa-1200hPa
22		Ambient temperature: +15°C to +25°C Storage temperature: -10°C to +50°C
23		Do not dispose of this device in normal household waste. Ensure that the device is disposed of separately.
24	CE	CE marking
25	RoHS COMPLIANT	Complies with RoHS Directive 2011/65/EU
26	REACH COMPLIANT	Complies with REACH Regulation (EC) No. 1907/2006

1.3 Responsibilities of the user



The CS.Nova is intended exclusively for use by dentally trained professionals.

The user is responsible for assessing whether the CS.Nova is suitable for the specific patient case and clinical conditions.

The CS.Nova must be used exclusively in accordance with the instructions in these instructions for use. Deviations from the procedures described in them may lead to malfunctions and risks for patients and users.
Improper handling, modification or use contrary to the information in these instructions for use will result in the exclusion of any warranty or liability claims.

The user may not alter or modify the CS.Nova. Modifications to the device, software, or accessory components are prohibited and will result in loss of conformity and safety.

1.4 Instructions for safe use



Use the product only in accordance with these instructions for use. Failure to heed the warnings and safety information contained in these instructions for use may result in residual risks for users and patients. Please follow all instructions carefully to ensure the safe use of the CS.Nova.

Modifications to the device, software or accessories are prohibited and will void the warranty and result in the loss of CE conformity.

Observe the electromagnetic and physical environmental conditions specified in these instructions. The device must not be operated in close proximity to other devices to avoid malfunctions or electromagnetic interference.

Only accessories specified and approved by the manufacturer may be used. The only exceptions are notebooks that demonstrably meet the requirements of DIN EN IEC 62368-1. The use of cables or accessories other than those specified may adversely affect the electromagnetic compatibility (EMC) of the device and result in improper operation.

The device has been tested according to IEC 61000-3-2, Class A and IEC 61000-3-3 and is classified as CISPR 11, Class A according to the requirements of electromagnetic compatibility. Portable and mobile RF communication devices (e.g. mobile phones, radios) can interfere with the performance of the CS.Nova. Maintain a minimum distance of 30 cm between the CS.Nova and any portable or mobile RF transmitting equipment to avoid electromagnetic interference. When used in a residential setting, this device may not provide adequate protection from radio services. The user may need to take remedial action, such as moving or reorienting the device.

The CS.Nova uses WiFi and Bluetooth radio technology in the frequency ranges from 2.4 GHz to 2.4835 GHz and 5.15 GHz to 5.825 GHz. The transmission takes place on channels 1 – 13 (2.4 GHz band) and 36 – 165 (5 GHz band) with a typical bandwidth of 80 MHz.

Only place the device on a stable, level surface. Avoid placing the device on edges and stacking it. The housing of the CS.Nova is of robust construction and can withstand drops from a typical working height. Damage can still occur under extreme mechanical stress (e.g., fall from a great height, strong impact). In this case, do not continue using the device and have it checked by the manufacturer.

Only use the device when the tip has audibly and tangibly clicked into place. The device must not be operated if it is incorrectly seated. The tip can be damaged by excessive mechanical force. Damaged scan tips must not be used further, as their function and safety are no longer guaranteed.

Under special circumstances, the scan tip may heat up beyond the specified limit. When used in the mouth, this heat is effectively dissipated through the moist mucosal surfaces and does not cause any impairment or danger to the patient. Do not use the device if the handpiece becomes unusually hot. After a thermal event, check the device for visible damage before using it again.

The CS.Nova has been tested according to the EMC immunity test levels for professional healthcare facilities of IEC 60601-1-2:2014+AMD1:2020. No extended testing scope was found beyond that described in IEC 60601-1-2:2014+AMD1:2020. Despite comprehensive testing, unexpected software errors can occur. If the device or software does not respond as intended (e.g. freezing, error messages, data loss), cancel the application and restart the system. If the problem persists, contact the manufacturer's support. If the USB power adapter will not be used for an extended period of time, please disconnect it from the power source.

WARNING:	The use of this device directly next to other devices or stacked with other devices should be avoided, as this could result in faulty operation. If use in the manner described above is nevertheless necessary, this device and the other devices should be monitored to ensure that they are working properly.

WARNING:	The use of accessories, converters, and cables other than those specified or provided by the manufacturer of this device may result in increased electromagnetic interference emissions or reduced electromagnetic immunity of the device and may lead to faulty operation.

WARNING:	Portable RF communications equipment (including accessories such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part or lines of the CS Nova specified by the manufacturer. Failure to comply may result in a reduction in the performance characteristics of the device.

WARNING:	The scanner and scan tip can be damaged by excessive mechanical stress or by a fall. Do not use the scanner or scan tip if any damage is visible. Before each use, carefully check the scanner and scan tip for visible damage.

WARNING:	Under certain operating conditions, the temperature of the scanner tip may briefly exceed slightly the permissible limit for the surface temperature of 43 °C. During testing under worst-case conditions, a maximum temperature of 44 °C was recorded. The scanner tip is intended for intraoral use. Upon contact with the moist mucous membrane of the oral cavity, heat is quickly dissipated by the natural cooling effect of the tissue. Please note: • Avoid prolonged, continuous contact between the scanner tip and dry or sensitive tissue. • Stop using the device if the patient reports discomfort or a sensation of warmth. • Use the device only for its intended use within the oral cavity.

1.5 Hygiene and infection control



The product contains components that need to be cleaned and disinfected or sterilised (e.g. attachments).

Note the maximum number of permitted reuses for recyclable parts. Improper processing can lead to infections or malfunctions. Contaminated or damaged components must not be reused. Attachments that show visible cracks, deformations or discolourations must no longer be used.

1.6 Safety during maintenance and operation

The CS.Nova is powered by a replaceable lithium-ion battery specifically designed for this device. Please note the following technical specifications and safety instructions:

- Battery type: Lithium-ion battery (3.7 V DC, 2600 mAh / 9.62 Wh)
- Maximum discharge current: 15 A
- Operating life: approx. 2 years under normal use or 500 charging cycles
- Charger: Use only with the CS.Nova charging station (Item 79506) or the original USB charger.
- Safety features: integrated overcurrent, overcharge and temperature protection

Maintaining basic safety

To maintain basic safety with regard to electromagnetic compatibility over the entire expected lifespan of the device, the following points must be observed:

- Battery maintenance instructions
- Visual inspections of the cables and system components for damage
- Place the device on a stable surface, avoid impacts/falls, and prevent damage to the housing or sharp edges.
- Keep ventilation openings clear, do not cover, operate only in specified environmental conditions, watch for unusual heating
- Operation only as described in the IFU, by trained personnel, no unauthorised accessories or modifications

Note: Use only original batteries from CADstar Technology GmbH.
The use of unauthorised batteries can lead to malfunctions or safety risks.



Use only power supplies that are certified according to IEC 60601-1 for medical electrical equipment. Power supplies conforming to IEC 60950-1 or IEC 62368-1 (e.g., from IT or consumer electronics) are not permitted,
as they do not meet the specific requirements for medical safety.

Battery maintenance and service life

The battery must not be opened or repaired by the user,
however, it may be replaced, charged and stored by the user. Please observe the following instructions to ensure safe use and a long service life:

- Use only the chargers and batteries supplied by the manufacturer
- Service life: The battery is designed for at least 500 charging cycles or approximately 2 years of operation
- Charging temperature: +10 °C to +40 °C
- Charging temperature: dry +10 °C to +40 °C Keep the charge level between 20% and 80%
- Visual inspection: Do not use damaged, swollen, or leaking batteries.
- Cleaning: Never immerse the battery in liquids or treat it with disinfectants – only wipe it dry.
- Disposal: Dispose of batteries at the end of their service life via the manufacturer or an approved collection point (see section 8.2.2)
- If you experience a noticeable decrease in capacity or error messages, please contact the CADstar Service department.

2. Intended use

2.1 Intended purpose

The CS.Nova intraoral scanner is a non-invasive medical device for the digital recording of intraoral topographical structures. It is used to record three-dimensional surface data of the teeth and surrounding tissue in the oral cavity. The collected data will be used exclusively for dental technical purposes, in particular for the production of dental prostheses.

This product is not intended for direct diagnosis, therapy, or decision-making regarding medical treatment.

2.2 Additional Information

The recorded data are intended exclusively for dental technical purposes, in particular for:

- Production of dental prostheses (e.g. crowns, bridges, inlays, onlays, veneers)
- Planning of implant-supported dentures (e.g., individual abutments, implant templates)
- Orthodontic modelling
- Digital fabrication of models in the dental laboratory

Note: This product is not intended for diagnosis or therapeutic decision-making. It does not replace a clinical examination.

2.3 Indications

The CS.Nova intraoral scanner is designed for the digital recording of intraoral topographical structures. The 3D data obtained are used exclusively for dental applications, in particular for the planning and production of dental prostheses.

The system is suitable for:

- Custom individual abutments
- Inlays, onlays and veneers
- Individual crowns
- Implant-supported bridges with up to 3 units
- Conventional bridges with up to 5 units
- Implant drilling templates
- Models for the production of dental appliances

The device can also be used for scanning the entire dental arch. However, various factors (intraoral environment, user experience and laboratory workflow) can influence
the final results.

2.4 Contraindications

The use of the CS.Nova intraoral scanner is contraindicated in the following cases:

- in clinical situations with more than three consecutive edentulous areas in the jaw, a stable optical reference structure for capture is lacking
- when capturing internal tooth structures (e.g., root canals or subgingival areas), the scanner is designed for capturing superficial intraoral geometries

2.5 Intended users

The CS.Nova intraoral scanner is intended exclusively for use by dental professionals.
These include:

- Registered dentists
- Orthodontists
- Oral and maxillofacial surgeons

The application requires that staff have knowledge of digital impression taking and intraoral scanning procedures.

This product is not intended for non-professional users. Safe and correct use requires adherence to the instructions for use, especially regarding:

- the correct integration of the accessories
- compliance with hygiene standards
- the systematic execution of the scanning process
- as well as the appropriate interpretation and use of the digitally generated 3D data

2.6 Intended patient group

The product is intended for use on adult patients during dental examinations and treatments. This device is not suitable for people with epilepsy.

3. Product description

3.1 Overview

The CS.Nova is a compact, portable intraoral scanner for the digital capture of intraoral structures. The system consists of an optical unit for image capture, a data processing unit, and software for displaying and further processing the scan data. The scanner is designed for use in the dental treatment room and can be operated via a cable or wireless connection to an evaluation station (e.g. PC or laptop). The CS.Nova connects locally to the computer via WiFi and processes all data exclusively in the CS.Nova software installed on the PC, without an automatic internet connection; always use a current, manufacturer-supported operating system to ensure data security.

3.2 System components

The CS.Nova system consists of the following main components in its standard version:

Nr.:	Item	Product image	CS. Nova Classic package	CS. Nova Pro package	Description	Item number
1	CS.Nova		1	1	Intraoral scanner	79500 (Classic) 79502 (Pro)
2	Calibration station		1	1	For calibration of the CS.Nova	79505
3	Holder		1	1	Scanner tray	79507
4	Battery		1	3	Battery for the Intraoral scanner	79508 (1x) 79509 (3x)
5	Battery charging station		0	1	For fast charging of up to 3 batteries at the same time	79506
6	Scan Tip		2	4	Scanner attachment to protect the patient from contamination	79510 (1x) 79511 (3x)
7	USB adapter (USB-C -> USB-C)		1	1	To connect the battery directly to a USB charger	79516

Nr.:	Item	Product image	CS. Nova Classic package	CS. Nova Pro package	Description	Item number
8	WiFi dongle		1	1	WiFi dongle for communication with the intraoral scanner	79515
9	USB-C charger		1	1	USB-C charger	79513
10	USB-C charging cable		2	2	Connection cable	79514
11	Instructions		1	1	IFU for the intraoral scanner	-

3.3 Initial setup of the CS.Nova

3.3.1 Unpacking

Packaging and contents
The scanner is packaged in a single unit containing two separate boxes:

- Box 1: Scanner including instructions for use (IFU)
- Box 2: Accessories

Procedure after delivery:
Check the delivery for completeness using the delivery note and the instructions for use. Examine the device and accessories for visible damage.

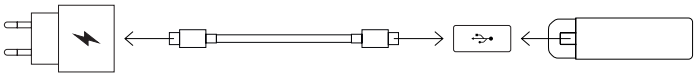
Procedure in the event of defects

Note: If any damage to the packaging, the device or the accessories is found upon delivery, please contact your dealer.

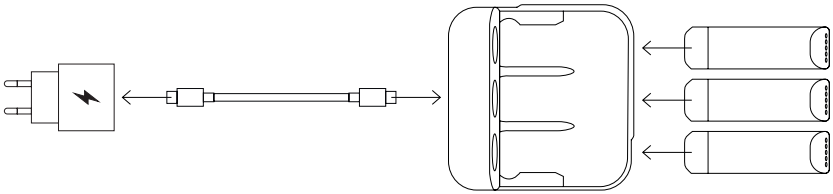
3.3.2 Preparation for commissioning

The batteries required for operation are included in the scope of delivery. The batteries must be charged before the scanner can be used. The batteries are shipped in "shipping mode", which is only deactivated after the initial charging. The batteries are only ready for use after this initial charge. There are two ways the batteries can be charged:

1) Charge the battery directly using the supplied USB charger, USB charging cable and USB adapter.

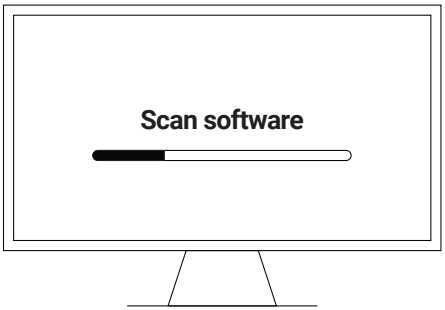


2) Charge the batteries using the supplied USB charger and Battery charging station.



3.3.3 Software installation

If you purchase an intraoral scanner without a notebook/laptop, the scanning software must first be installed. If the notebook/laptop was purchased directly from CADstar, the software is already pre-installed and set up. If you have any questions, please contact us or your local dealer. If you obtained the device from another source, please install the CS. Nova Software. You can request this software through your local dealer. After downloading the software, run the installation. This requires administrative rights on the notebook/laptop. After the installation is complete, restart your notebook/laptop.

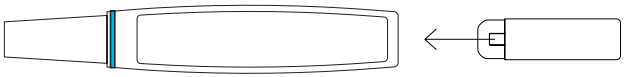


3.3.4 Scanner operation

The following describes all the functions that are possible with the CS.Nova.

Switching on

The device switches on automatically as soon as a battery is inserted. A magnet holds it in the battery compartment. The startup process takes approximately 15 seconds. Once the system has started successfully, the Home menu is displayed.



Note: If the scanner has already been connected to the notebook/laptop, it will automatically reconnect.

Switching off

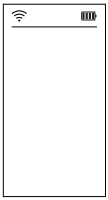
To switch off the device, simply remove the battery.

Standby

The scanner automatically switches to power-save mode after 10 seconds of inactivity. In this state, energy consumption is reduced to a minimum. As soon as the scanner is moved or the display is touched, the device automatically returns to standard mode and is immediately ready for use again.

Screen description

The symbol for the WiFi signal strength is located in the top left corner.
The current battery level is displayed in the upper right corner.



Scanning

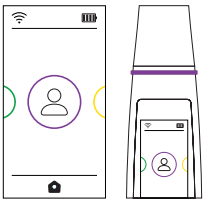
A new case can be started using the symbol with the person and the plus sign ("New case").

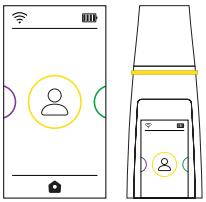


Case selection (only in the Pro version)

It is possible to select a patient case previously defined in the software. This is done via the person icon. Swiping left or right allows you to navigate between the available cases.
For easier identification, the LED ring and the circle around the person symbol indicate the assigned case colour and the case name below.

Additionally, a new case can be added at any time under "New case".
In addition, an empty case can be scanned, which can then be assigned to a patient.





Settings

The scanner has a compact settings menu where various device configurations can be made:

- WiFi settings
- Display brightness
- Touch test
- Device information



Touch gestures

The scanner supports multiple touch gestures to make operation easier.

Always active:

- Swipe from bottom to top: Return to the previous screen or the home screen

During scanning:

- Tap the middle area: Start scan (play symbol) or pause (pause symbol)
- Swipe from top to bottom: Rotate view 180°
- Swipe from left to right: Switch to photo mode
    - Tap the area with the photo icon: Take a photo
    - Swipe from right to left: Switch to UV camera
    - Swipe from left to right: Switch to RGB camera

- Swipe from right to left: Open the menu for computer software control
    - Swipe from top to bottom: Confirm scan
    - Swipe from left to right: Zoom out
    - Swipe from right to left: Zoom in

After scanning:

- Swipe from bottom to top: Delete current scan (confirmation required)
    - Swipe from left to right: Cancel
    - Swipe from right to left: Confirm

After the scan confirmation:

- Swipe from left to right or vice versa: Switch between different scans (lower jaw, upper jaw, occlusion)
- Tap symbols with a green circle: Display previously confirmed scans (the symbol in the circle indicates the lower jaw, upper jaw, occlusion).
    - Swipe from left to right: Switch to photo mode
    - Swipe from right to left: Open the menu for computer software control
    - Swipe from top to bottom: Delete current scan (confirmation required)

- Tap symbols with a blue circle: Start a new scan (the symbol in the circle indicates lower jaw, upper jaw, occlusion)

3.3.5 Connecting to the notebook

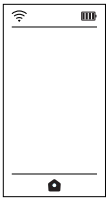
To start the scanner, please insert a charged battery correctly and wait until the device has fully booted up and the main menu appears on the display. Next, activate the WiFi function on your notebook and search for the hotspot network provided by the scanner. The name of the hotspot includes the serial number of the device. If the hotspot network is not found, go to the scanner's settings and enable WiFi and the hotspot network connection. If the hotspot is displayed in the WiFi menu of the notebook/laptop, you will need the WiFi password. This information is displayed in the software or can be read from the device menu. After entering the password, confirm it, and the connection to your intraoral scanner will be established. The scanner and the notebook retain the last connection settings. This step can be skipped on a restart. To return to the WiFi settings, please swipe right to the menu and go to the WiFi settings submenu.



->

To update the scanner, initiate the update via the scanner software. Please ensure that the update process is not interrupted to guarantee a complete and secure installation. After the update is complete, the scanner may restart automatically. Finally, check via the device menu that the current software version has been successfully installed.

Note: All further information can be found in the scanner software description.



->

3.3.6 WiFi settings

Once you are in the Home menu, you have several options for connecting the scanner to a PC or laptop. The simplest and most reliable option is to use the included WiFi dongle.

Note: When purchasing a complete scanning system (scanner and notebook/laptop), the scanner is already pre-configured.

Option 1: Hotspot with WiFi dongle

Connect the WiFi dongle to the PC/laptop and start the scanner software. A direct connection to the scanner's hotspot can be established via the WiFi dongle. After a short connection time, the intraoral scanner should be connected to the PC/laptop and the software and device should display a connection status.

Option 2: Scanner hotspot with internal WiFi

Start the scanner software. Suggestion: The built-in WiFi connection allows a direct connection to the scanner's hotspot. After a short connection time, the intraoral scanner should be connected to the PC/laptop and the software and device should display a connection status.

Attention: A high WiFi standard is required here to achieve the maximum performance of the intraoral scanner . Next-generation dual-band (600Mbit/s on 2.4GHz and 1300Mbit/s on 5GHz) according to the 802.11ac standard.

Option 3: Company WiFi

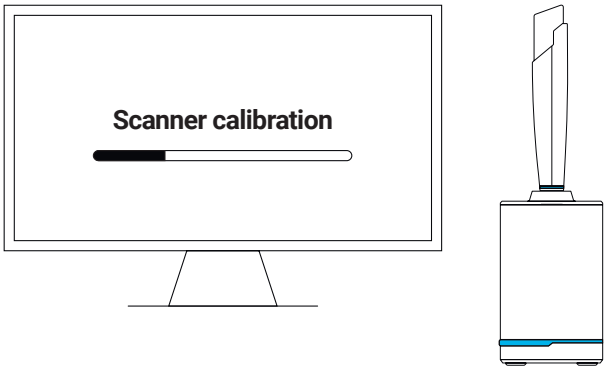
Since this function requires many settings and possibly structural changes for smooth operation, please contact our support team for this version.
The scanner's menu allows you to switch the operating mode from WiFi hotspot to WiFi connection. The access data for the company network can then be transferred to the scanner via the software. Once the connection is established, the scanner can be used anywhere where there is a sufficiently good WiFi connection.

Attention: A high WiFi standard is required here to achieve the maximum performance of the intraoral scanner: Dual-band (600Mbit/s on 2.4GHz and 1300Mbit/s on 5GHz) of the next generation according to the 802.11ac standard.

3.3.7 Integration into IT networks

When integrating the CS.Nova into an IT network (e.g., clinic WiFi), care must be taken to consider potential risks to patients, users, or third parties.
The operator should ensure that the IT network is suitable, assess potential risks, and take appropriate measures.
After changes to the IT network (e.g., adjustments to the network configuration, connection or removal of devices, as well as software updates or upgrades), the suitability of the network should be re-evaluated.

3.3.8 Calibration of the CS.Nova scanner



The first step is to calibrate the CS.Nova scanner. To do this, connect the calibration station to the USB-C charger. Next, press the USB pairing button and pair the station with your notebook or laptop. Now turn on the scanner and establish a WiFi connection to the same notebook or laptop. Once the connection is established, insert the scanner into the calibration station as shown in the illustration. Next, open the CS.Nova software, go to the calibration menu and start the process. The calibration process is automatic and is completed after about one minute, so the scanner is immediately ready for use.

Important:	To achieve the specified scan accuracy, it is recommended to calibrate the scanner once a week.

Note:	It is recommended to perform calibration before scanning if increased accuracy is required.

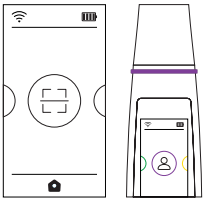
Note:	The calibration station features automatic scanner detection. This enables automatic calibration to start when the scanner is inserted.

3.3.9 Select/create project

There are several ways to start a scan with the scanner:

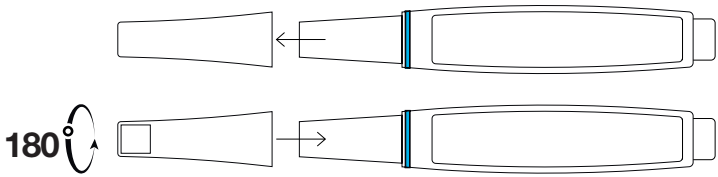
(1) You can start a free scan and assign it to a project later on your PC or laptop
(2) You can select an existing project and assign the scan directly to that project.
(3) You can select a project already assigned to the scanner and start the scan immediately.

For better orientation, the respective project colour is displayed on the scanner's LED ring.



3.3.10 Scan tip

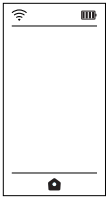
The scan tip is the only part of the scanner that should have direct contact with the patient. Use only a freshly sterilised scan tip for each patient. The scan tip is automatically detected by the scanner, and the orientation can also be detected automatically. Use the tip so that the scanner display always faces upwards and only the tip is rotated.



Important: The scan tip can and must be sterilised before scanning a new patient. Please refer to the cleaning section in the operating instructions.

3.3.11 Scanning & scanning strategies

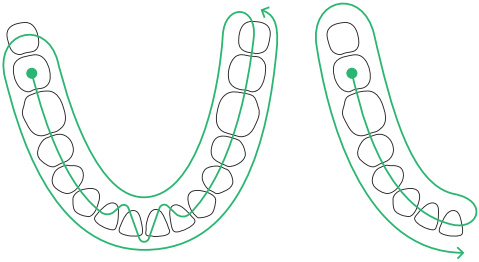
When the scan process starts, the display shows the current scan progress (2). By tapping the icons, you can either cancel, pause or complete the scan. (3) Swiping to the left confirms the scan. (1) Swiping to the right will make the software functions available.



->

Scanning method

The best scanning method is to start with a molar, as it contains a lot of detail that is easier to recognise. Swing back and forth at angles of between 35 and 55 degrees so that the surfaces overlap. If the overlaps are too small, the alignment may fail.



Scan path

To ensure good data acquisition from all surfaces, the recommended scan path consists of 3 passes: occlusal, lingual and buccal. The occlusal pass is always performed first, as it contains the most 3D structures, thus facilitating scanning. The first pass should be started at the first molar (if antagonist) or during the preparation (to scan the gingiva before it retracts after retraction). Give the scanner the opportunity to scan the starting point extensively.

Wait 3 to 5 clicks before moving the scanner smoothly and slowly less than 5 mm away from the teeth. Special care must be taken during scanning to protect soft tissues, e.g., tongue, lips and cheeks. If these are also scanned, it can lead to delays or the cancellation of the scanning process. Therefore, the simplest second pass depends on the jaw:

- Since soft tissue is only present on one side of the upper jaw (buccal), the second pass should be performed buccally. This pushes the soft tissue away, preventing it from interfering with the further scanning process.
- The tongue makes it more difficult to scan the lower jaw. The cheek can be gently pushed back with a finger or a mirror. Therefore, the second pass is a lingual pass, in which the tongue is pushed back.
- The third pass captures the side opposite the second pass. Try to avoid the soft tissue here as well. Since the scanner has already captured the other sides of the teeth on the second pass, the system uses the generated data to avoid adding soft tissue to the scanned teeth. The recommended scan paths are summarised.

3.3.12 Controlling the PC/Laptop

Swiping from top to bottom activates the computer controls. You have the choice between (1) “Mouse”, which is similar to a touchpad, and (2) “3D”, which allows you to control the 3D model.

3.4 Controls and displays

The CS.Nova system's scanning software offers an intuitive user interface for precise digital recording of tooth and jaw structures in the oral cavity. It efficiently supports dental professionals during the intraoral scanning process and enables the structured processing of the data obtained for diagnostic or dental technical purposes.
To optimise the workflow, the intraoral scanner has several integrated display elements that ensure easy handling and clear status feedback:

Display 1: Display

The integrated display is the central display and control panel of the device. It enables:

- Live-View: Direct viewing of the scanning process on the scanner without an external monitor
- Mouse control: Touchpad-like control of a connected PC or laptop
- 3D control: Interactive rotation and viewing of 3D models directly via the display

Display 2: LED colour ring

The surrounding LED ring indicates the current status of the device from a greater distance. Features:

- RED: Error calibration instructions
- Blue: Connection status
- Pastel colour: Lavender, mandarin, lemon, candy and mint:
  these are project-specific colours according to software assignment

Display 3: LED battery level

Visual feedback on the battery charge level and any error messages during operation.
To ensure uninterrupted operation of the CS.Nova throughout the entire scanning process, make sure the battery is fully charged before each use.

Charging states

LED 1	LED 2	LED 3	LED 4	LED 5	Info
○	○	○	○	○	0%
●	○	○	○	○	0 - 20%
●	●	○	○	○	20 - 40%
●	●	●	○	○	40 - 60%
●	●	●	●	○	60 - 80%
●	●	●	●	●	80 - 100%

Display of errors:

LED 1	LED 2	LED 3	LED 4	LED 5	Info
●	○	○	○	●	Battery power too low
○	○	●	○	○	Battery defective

If the battery displays an error message, it must no longer be used. For questions or further information, please contact your local dealer.

3.5 Mode of operation

The device uses optical scanning technology (structured light or confocal imaging) to create a precise 3D model of the intraoral structures. The collected data are:

- visualised in real time
- processed as a 3D model
- and exported for transfer to dental laboratories or CAD/CAM systems

Radiation warning

The device emits optical radiation in the form of structured light as well as laser radiation with wavelengths of 455 nm and 520 nm. The radiation is guided within a closed optical system in the scanner head and attenuated by optical components. Under normal operating conditions, no hazardous radiation is accessible to the user.

4. Repair, maintenance and calibration

4.1 General information

The CS.Nova is a precision medical device and requires regular maintenance to ensure safe and reliable operation.

- Only use cleaning and reprocessing methods approved by the manufacturer.
- Clean the device after each patient contact, especially the reusable tips.
- Always observe the maximum number of permissible reuses of 100 sterilisation cycles for the scan tips.

4.2 Cleaning and disinfection (reprocessing)

These cleaning products have been tested by us and classified as safe.

Cleaning agent	Manufacturer	pH value	Effectiveness / Info
Minutenwipes	Alpro Medical GmbH	7.5 - 8.5	Bactericidal Yeasticidal Limited virucidal Plus
Pursept A Xpress Disinfectant wipes	Merz Dental GmbH	3.5	Bactericidal, yeasticidal (including TB), inactivation of adenoviruses
FD 366 Sensitive Wipes	DÜRR DENTAL SE	6.5 - 7.5	Bacteria1) and yeasts, TB bacteria, enveloped viruses including HBV, HCV, HIV, coronaviruses, noroviruses
FD 366 Surface sanitisers	DÜRR DENTAL SE	6.5 - 7.5	Bacteria1) and yeasts, TB bacteria, enveloped viruses including HBV, HCV, HIV, coronaviruses, noroviruses
CaviCide	Kerr Italia srl	11 - 12.49	*TUBERCULOCIDE Mycobacterium tuberculosis var: bovis (BCG)3 BACTERICIDE Methicillin-resistant Staphylococcus aureus (MRSA)9 Pseudomonas aeruginosa4 Salmonella enterica9 Staphylococcus aureus4 Vancomycin-resistant Enterococcus faecalis (VRE)9 2 minutes Staphylococcus aureus with reduced susceptibility to vancomycin9 Enterococcus hirae4 Escherichia coli4 Proteus mirabilis4 VIRUCIDE SARS-associated human coronavirus (SARS-CoV-1)5 SARS-associated human coronavirus 2 (SARS-CoV-2) (COVID-19 virus)10 Human coronavirus5 Hepatitis B virus (HBV)5 Hepatitis C virus (HCV)5 Human immunodeficiency virus (HIV-1)5 Herpes simplex virus types 1 and 25 Influenza A2 virus5 Modified vaccinia virus Ankara (MVA)6 FUNGICIDE AND LEVUROCIDE Candida albicans7 Trichophyton mentagrophytes9
Meliseptol	B. Braun SE	n.a	bactericidal/yeasticidal, tuberculocidal, mycobactericidal, limited virucidal (including HBV, HCV, HIV), rotaviruses, adenoviruses. Noroviruses
Meliseptol® Wipes sensitive	B. Braun SE	approx. 7	tuberculocidal, mycobactericidal, limited virucidal (including HBV, HCV, HIV), rotaviruses, avian influenza viruses, polyomaviruses, noroviruses
FD312	DÜRR DENTAL SE	9 - 10	Bacteria and yeasts, enveloped viruses including HBV, HCV, HIV, coronaviruses, noroviruses

4.2.1 CS.Nova handpiece

The CS.Nova handpiece is a highly sensitive optical device that must be handled with extreme care. Protect the camera windows from scratches and clean them only with a lint-free cloth if you notice any blurring during recording.

- The handpiece may only be disinfected by wiping.
- Before use, check that the front glass is free of dust and streaks.
- Make sure that no liquid enters the ventilation openings.

Attention: If glass chips, deformations or other defects are visible on the scanner, the scanner must no longer be used.

4.2.2 Scan tip

Due to direct patient contact, the scan tips are subject to more stringent cleaning requirements.
The scan tip must be prepared according to the prescribed cleaning and disinfection steps before sterilisation. Sterilisation is carried out using a validated steam sterilisation process in accordance with the steriliser manufacturer's instructions. Damaged scan tips must not be used.

- The scan tip is autoclavable. Please adhere to the applicable regulations for cleaning instruments.
- If any dirt is visible inside the scan tip, especially on the mirror, clean it with a soft cloth or cotton swab.
- If you limit the autoclave cycle to 4 minutes at 134°C, you can autoclave the scan tips up to 100 times.
- Please dispose of the scan tip after 100 cleaning cycles or if it is damaged or worn.

Attention:	Prepare before first use The reusable sleeve must be prepared before first use.

Attention:	Prevent cross-contamination Avoid the transmission of germs between patients. Never use the scanner without a reusable sleeve. The reusable sleeve must always be properly cleaned and disinfected.

Attention:	Visual inspection after processing Attachments that show visible cracks, deformations or discolourations must no longer be used.

Attention:	In the steam steriliser, the scan tip must be positioned so that no water droplets can accumulate on the mirror surface; the mirror surface must be oriented downwards.

4.3 Calibration

Why calibrate?

- The optical accuracy of the CS.Nova can be affected by temperature, mechanical stress or transport
- Regular calibration ensures that scan results are precise and reproducible.

Calibration process

For optimum functionality, we recommend calibrating the scanner at least once a week.

Attention:	Calibration ensures the accuracy of the scan.

5. Safety instructions

5.1 General information

Read the safety instructions carefully and heed all warnings preceded by the words WARNING and CAUTION. To avoid injuries or property damage, the safety instructions must be strictly followed. All instructions and precautions in these safety instructions must be followed to ensure the proper functioning of the CS.Nova and personal safety. The CS.Nova may only be used by dental professionals. Any use outside the intended purpose described in Chapter 2 may result in injury or damage.

5.2 Procedure in the event of serious incidents

Any serious incident involving the device must be reported to the manufacturer and the relevant national authority.

AUSTRIA

AGES Medical Market Surveillance

Traisengasse 5
A-1200 Vienna
Tel. national: 050 555-36111
Tel. international: +43 (0)50 555-36111
Email: basg@basg.gv.at

5.3 Using the system

If you have stored the device in a cold environment, allow it to reach ambient temperature before use and wait for at least 2 hours. Check the device for any visible damage before each use. If there is any visible damage, the device must not be used any further. Handle the scan tips with extreme care. Contaminated or damaged scan tips must not be reused.
Avoid any contact of the device with liquids. Place the device only on stable, dry and clean surfaces.

Additionally, the following should be noted:

- Do not place any objects on the device and do not block the ventilation openings.
- Perform calibration, cleaning, and disinfection exclusively in accordance with these instructions for use.

5.4 Training

- Before using the device on a patient, the specialist staff must be trained in its operation.
- The contents of these instructions for use must be fully understood and followed.
- Before each use, ensure that the camera display is working correctly.

5.5 Device failure

- If the device malfunctions, remove it from the mouth immediately and switch it off.
- Then check the device or contact the manufacturer.

5.6 Hygiene rules

- Always wear clean gloves when touching or changing the scan tip.
- The device and tip must be hygienically cleaned before each use.

5.7 Electrical safety

The scanner is designed in accordance with applicable electromagnetic compatibility (EMC) standards with regard to both incoming and outgoing radiation.
Should any problems such as connection interruptions or unintentional operation occur, please contact support and reduce parallel wireless connections if possible.

5.8 Eye safety

Bright light sources are used for three-dimensional scanning of the oral cavity. The device contains internal laser radiation sources with wavelengths of 455 nm and 520 nm. The laser radiation generated in the device is limited by optical elements so that the radiation accessible to the user does not exceed the limits of laser class 1 according to IEC 60825-1:2014. The laser is completely enclosed in the scanner head and is inaccessible to the user.
The laser radiation is guided within a completely closed optical beam path in the scanner. This beam path includes optical components such as objectives, lenses, mirrors and scattering elements (patterns) that attenuate the radiation. This optical beam path serves to selectively reduce and distribute the laser radiation.

Caution:	The scanner must not be used on patients with epilepsy, as the light emission occurs at a frequency of 15-60 Hz.
Caution:	To avoid eye damage, never look directly into the scanner opening when the light is switched on.
Caution:	If the device shows visible damage, it must not be used. Contact the manufacturer.

5.9 Danger of explosion

When used as intended, there is no risk of explosion, as the device does not contain any explosive substances or explosive mixtures. The device must not be used in potentially explosive atmospheres or in areas containing flammable gases, vapours or dusts.

Caution:	Use the device only in accordance with the manufacturer's instructions.
Caution:	Do not use the device in potentially explosive atmospheres or in areas with flammable gases, vapours or dusts.

5.10 Cybersecurity

The CS.Nova must not be operated in open or unsecured WiFi networks. Regular software updates are necessary for secure operation. Furthermore, the use of up-to-date antivirus software and active firewalls is required to ensure the integrity of the data and systems.
In the event of cyber incidents:

- Turn off the device immediately and contact support.
- Gather as much information as possible (time, behaviour) for analysis.

Caution:	Since the CS.Nova is an IoT device with a Linux operating system, regular security updates are essential to ensure effective protection against cyberattacks.

5.11 Remaining residual risks

The following remaining residual risks were identified:

Technical residual risks

- Software errors: Despite extensive testing, unexpected bugs can still occur
- Battery wear: Over time, the capacity decreases, and the device shuts off sooner

Electrical/Mechanical residual risks

- Fall damage: The casing is robust, however damage is possible under extreme mechanical stress.

Optical / radiation-related residual risks

- Laser / LED: Despite IEC 60825-1:2014, a residual risk remains if users look directly into the light source.

Hygienic residual risks

- Cross contamination: If cleaning or sterilisation is not carried out according to IFU

Usability residual risks

- Misuse by the user (e.g., incorrect placement of the scanner in the mouth, incomplete scan).
- Ignoring warnings in the IFU (e.g., using damaged tips)

Organisational residual risks

- Unauthorised accessories

5.12 Transport

It is recommended to keep the original packaging. The scanner must be properly packaged and transported securely. The original packaging is best suited for this. The consignment is only considered to be properly packed if all parts are securely packed and there are no loose parts or parts flying around.

5.13 Storage

The scanner and batteries may only be stored under the following conditions.

Storage conditions CS.Nova + accessories:

- -10°C to +50°C
- No direct sunlight
- 20-80% relative air humidity (non-condensing):
- No chemicals in the air

Battery storage conditions:

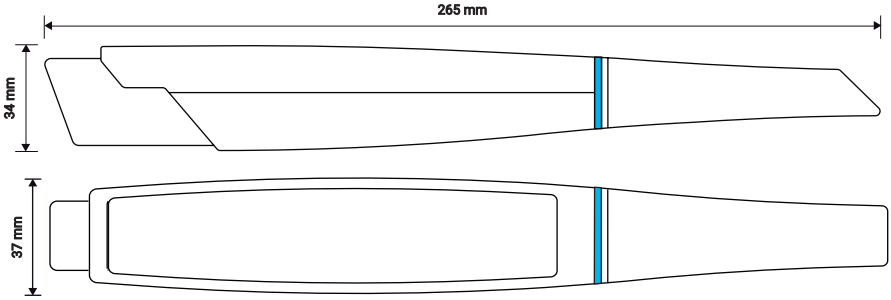
- the maximum storage temperature is between -5°C and +45°C.
- the optimum storage temperature is between +15°C and +25°C
- a cool, dry area protected from direct sunlight
- no chemicals in the air
- maximum charge level for storage 20% - 80%
- optimum charge level for storage 50% - 65%

Caution: Improper storage of batteries can lead to an increased risk of fire.

6. Technical data

6.1 Device specifications including accessories

6.1.1 Device specifications CS.Nova



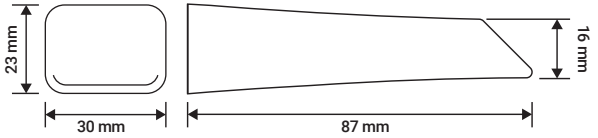
General device properties	
Characteristic	**Value / Description**
Product name	CS.Nova
Product type	Portable, battery-operated medical device
Device category	Class I, Rule 13, Annex VIII
Protection class	Class II according to IEC 60601-1
Supply	9V 1A (USBC PD Standard)
Operating time with CS.Nova Battery	approx. 60–90 minutes (depending on the application)
Communication interface	WiFi 5Ghz IEEE 802.11ax 2x2 5 GHz 802.11ax (80 MHz) 5 GHz: 36-68, 96-165 channels
Dimensions	265 × 37 × 34 mm (L × W × H)
Weight	Scanner: 225 g;

Optical properties	
Characteristic	**Value / Description**
Scanning method	Structured light, single-frame reconstruction
Light source	White LEDs 5600K UV LEDs 405nm Laser green 520nm Laser blue 455nm
Resolution	3x 1 MPix
Field of vision	approx. 28 x 16 mm on the mirror
Scan area scan tip	approx. 17 x 15 mm at tip outlet
Distance between scan tip and surface (working distance)	0 to 25 mm accurate range; 25 to 45 mm imprecise range
Scan speed	approx. 100 mm/s (80% superposition)

Safety, EMC and classification	
Characteristic	**Value / Description**
Protection class according to IEC 60601-1	Device in protection class III, operated with 9 V DC (battery)
EMC behaviour	CISPR 11 Class A, Group 1
Laser/Light classification	Laser product class 1
Material in patient contact	BPA-free plastic, polycarbonate
Reusability of the tips	Up to 100 cycles with validated reprocessing
Labelling	CE marking in accordance with MDR; UDI present

Operating, storage and transport conditions	
Characteristic	**Value / Description**
Operating conditions Temperature	15°C - 25°C
Operating conditions: Humidity	20-80% relative air humidity (non-condensing):
Operating conditions: air pressure	800–1,060 hPa
Operating conditions Contamination level:	II
Storage conditions/transport conditions: Temperature	-10° to +50°C
Storage conditions/transport conditions: Humidity	20-80% relative air humidity (non-condensing):
Storage conditions/transport conditions: Air pressure	620–1,200 hPa
Storage conditions / Transport conditions / Contamination level	II

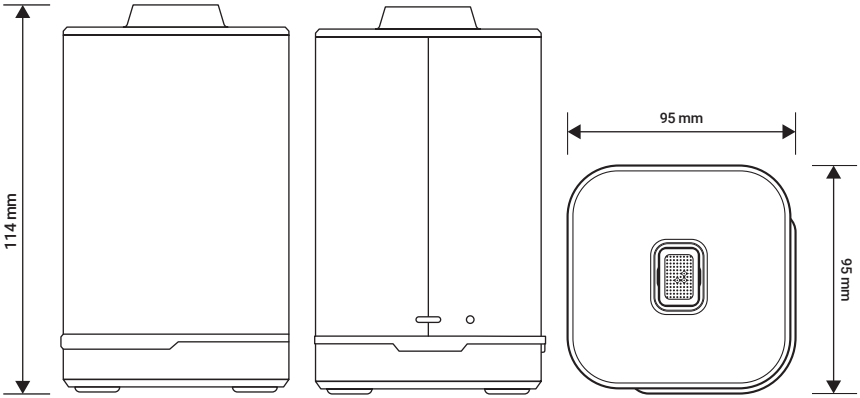
6.1.2 Device specifications Scan Tip



General device properties	
Characteristic	**Value / Description**
Product name	Scan Tip
Product type	Accessories for the medical device acc. Item 2 (2)
Device category	Class I, Rule 5, Annex VIII
Dimensions	23 × 30 × 87 mm (L × B × H)
Weight	8 g

Optical properties	
Characteristic	**Value / Description**
Scan area scan	approx. 17 mm x 15 mm at tip outlet

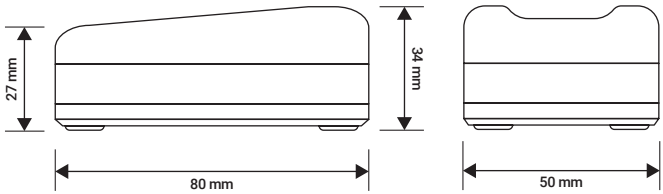
6.1.3 Device specifications Calibration station



General device properties	
Characteristic	**Value / Description**
Product name	Calibration station
Product type	Accessories for the medical device acc. Item 2 (2)
Device category	N/A
Protection class	Class II according to IEC 60601-1
Supply	USB-C PD 9 V DC Typical performance: 18 W
Communication interface	Bluetooth & USBC
Dimensions	95 × 95 × 144 mm (L × W × H)
Weight	1120 g

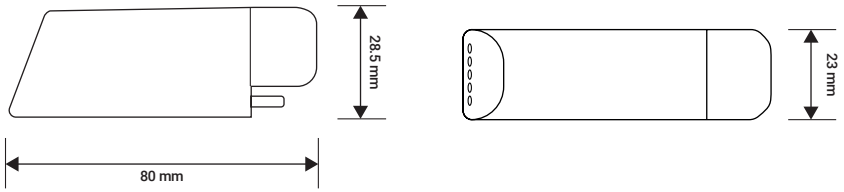
Safety, EMC and classification	
Characteristic	**Value / Description**
Protection class according to IEC 60601-1	Device in protection class III, operated with 9 V DC
EMC behaviour	CISPR 11 Class A, Group 1

6.1.4 Device specifications Holder



General device properties	
Characteristic	**Value / Description**
Product name	Holder
Product type	Component of the medical device - ergonomic storage device for the safe storage of the scanner
Device category	N/A
Protection class	Class II according to IEC 60601-1
Dimensions	80 × 50 × 34 mm (L × W × H)
Weight	490 g

6.1.5 Device specifications Battery

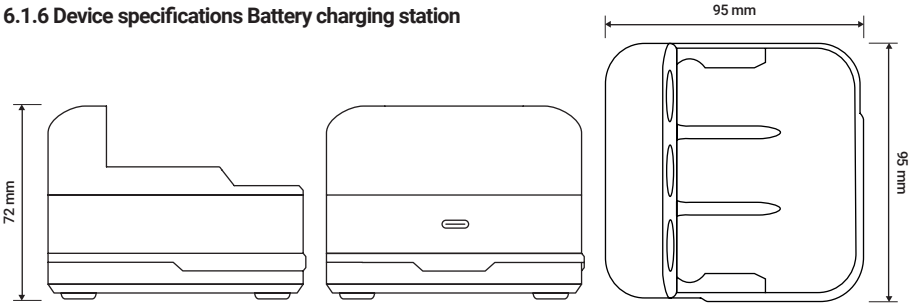


General device properties	
Characteristic	**Value / Description**
Product name	Battery
Product type	Component of the medical device - rechargeable lithium-ion battery for operating the scanner
Device category	N/A
Protection class	Class II according to IEC 60601-1
Supply	USBC In:5V 3A USBC Out: 5V 9V 2A
Communication interface	USBC (PD Standard)
Dimensions	80 × 28.5 × 23 mm (L × W × H)
Weight	66 g

Safety, EMC and classification	
Characteristic	**Value / Description**
Protection class according to IEC 60601-1	Device in protection class II
EMC behaviour	CISPR 11 Class A, Group 1

Operating, storage and transport conditions	
Characteristic	**Value / Description**
Operating conditions Temperature	15°C - 25°C
Operating conditions: Humidity	20-80% relative air humidity (non-condensing):
Operating conditions: air pressure	800–1,060 hPa
Operating conditions Contamination level:	II
Storage conditions/transport conditions: Temperature	-10°C to +50°C
Storage conditions/transport conditions: Humidity	20-80% relative air humidity (non-condensing):
Storage conditions/transport conditions: Air pressure	620–1,200 hPa
Storage conditions / Transport conditions / Contamination level	II

6.1.6 Device specifications Battery charging station



General device properties	
Characteristic	**Value / Description**
Product name	Battery charging station
Product type	Component of the medical device - technical charging unit that enables the simultaneous charging of up to three batteries
Device category	N/A
Protection class	Class II according to IEC 60601-1
Supply	Input: USB-C PD 9 V, 15 V, 20 V Typical performance: 15–45 W
Power output	Output: USB-C 3× 5 V / 3 A Typical performance: 0–45 W
Dimensions	95 × 95 × 72 mm (L × W × H)
Weight	600 g

Safety, EMC and classification	
Characteristic	**Value / Description**
Protection class according to IEC 60601-1	Device in protection class III, operated with 20 V DC
EMC behaviour	CISPR 11 Class A, Group 1

Safety, EMC and classification	
Characteristic	**Value / Description**
Operating conditions Temperature	15°C–25°C
Operating conditions: Humidity	20-80% relative air humidity (non-condensing):
Operating conditions: air pressure	800–1,060 hPa
Operating conditions Contamination level:	II
Storage conditions/transport conditions: Temperature	-10°C to +50°C
Storage conditions/transport conditions: Humidity	20-80% relative air humidity (non-condensing):
Storage conditions/transport conditions: Air pressure	620–1,200 hPa
Storage conditions / Transport conditions / Contamination level	II

6.2 Compatible systems / software

Minimum system requirements

- CPU: Intel Core i7-14700K
- RAM: 16GB DDR4
- SSD 500GB
- Graphics: Nvidia RTX 2060 (8GB GDDR6)

Recommended system requirements

- CPU: Intel Core-i9 11900k
- RAM: 32GB DDR4
- SSD 1TB
- Graphics: Nvidia RTX 2070 TI (12GB GDDR6)

Recommended software

- Windows 11

6.3 Potential problems and recommended measures

Problem	Possible cause	Solution
The device cannot be switched on	Battery empty / not properly connected	Insert a charged battery and try again.
No connection to the computer	WiFi connection problems Network problems	Reconnect Check the firewall settings
The scanner does not respond	Software crashed / Device frozen	Restart the application, and if necessary, restart the device.
Poor scan quality	Lens soiled Mirror soiled Calibration faulty	Clean lens Clean mirror Recalibrate scanner
Scans are not displayed	Lens soiled Mirror soiled Bad calibration Software crashed / Device frozen Unsupported graphics card	Clean lens Clean mirror Recalibrate scanner Restart the device Check graphics card
Scans are not saved	Insufficient storage space / incorrect file path	Check memory, adjust path
Software does not start	Driver missing / Software not up to date	Update driver, check software version

6.4 Technical support

For technical problems or questions, please contact your local dealer first. Should they be unable to resolve your issue completely, please contact our technical support.

Support address	support@cadstar.dental
Telephone	+43 (0)6462-32880
Website	www.cadstar.dental

7. Conformity and standards

7.1 CE marking

The product bears the CE marking and complies with the requirements of Regulation (EU) 2017/745 on medical devices (MDR).

7.2 EU Declaration of Conformity

The EU Declaration of Conformity is available on request and confirms compliance with all applicable requirements of the MDR.

7.3 Applied standards and guidelines

- EMC requirements:
  CISPR 11:2015 +AMD1:2016+AMD2:2019
  EN IEC 61000-4-2: 2009-12 / EN IEC 61000 4-3:2021-11 / EN IEC 61000-4-8:2010-11
- EN IEC 60601-1-2:2014 / IEC 60601-1-2:2014 / AMD1:2020 Safety of electrical medical devices
- EN ISO 10993-1:2020 Biological assessment
- EN IEC 60825-1:2014 + A11:2021 Laser safety
- EN ISO 14971:2019 + A11:2021 Application of risk management
- EN ISO 20417:2021 Requirements for information for users
- DIN EN ISO 13485:2016 + A11:2021 Quality management systems
- EN IEC 62304:2006 + A1:2015 Medical device software
- EN ISO 15223-1:2021 Medical devices – Symbols in labelling
- EN 62366-1:2015 + AC:2015 + A1:2020 Serviceability
- Ordinance (EU) 2017/745 (MDR)
- RoHS 2015/863/EU
- REACH 1907/2006/EC

8. Disposal information

8.1 Electronic components

The CS.Nova system contains electronic components and must not be disposed of with household waste. Dispose of the device in accordance with Directive 2012/19/EU (WEEE) on waste electrical and electronic equipment.
We feel responsible for our products from the initial idea to their disposal. For this reason, we offer you a way to take back our old electrical and electronic equipment. If you would like to take advantage of this offer, please proceed as follows.

Austria

To arrange for the return of the electrical appliance, please submit a disposal order to CAD-star Technology GmbH. You have the following options for this:

Contact:	Tel: +43 (0) 6462 / 328 80 Fax: +43 (0) 6462 / 60 11-1 Email: support@cadstar.dental
Return address:	CADstar Technology GmbH Grasslau 30, 5500 Bischofshofen Austria

8.2 Accessories and consumables

Consumables (e.g. tips) must also be disposed of via the appropriate recycling route after hygienic processing.

8.2.1 Disposal of packaging

The packaging must be disposed of according to country-specific regulations. Please observe the regulations applicable in your country.

8.2.2 Battery disposal

Defective batteries or batteries that have reached the end of their service life must be recycled. Recycling is carried out by the company CADstar Technology GmbH. In order to ensure environmentally sound recycling/disposal, the batteries must not be disposed of with household waste.

Austria

To arrange for the return of the electrical appliance, please submit a disposal order to CAD-star Technology GmbH. You have the following options for this:

Contact:	Tel: +43 (0) 6462 / 328 80 Fax: +43 (0) 6462 / 60 11-1 Email: support@cadstar.dental
Return address:	CADstar Technology GmbH Grasslau 30, 5500 Bischofshofen Austria

9. Changes and updates to the instructions for use

Please note that these instructions for use may be updated regularly to provide current information and guidance. We strongly recommend that all users consult the latest version of these instructions to ensure they are always up-to-date with the latest instructions and safety guidelines. The updated instructions for use can be obtained via the homepage or by contacting our support team. Your safety and the best possible user experience are our highest priority, which is why regularly reviewing these instructions for use is of great importance.

10. Manufacturer of the medical device

Company name: CADstar Technology GmbH
Registered office: Grasslau 30, 5500 Bischofshofen, Austria
Telephone: +43 (0) 6462-32880

Information, data requests and complaints can be found at:
support@cadstar.dental

Managing director: Georg Dick
Legal form GmbH
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