New as of: 2024-09

Dentsply Sirona

Primescan™ 2

Primescan™ 2 Cart
Single Use Sleeve Primescan™ 2

Instructions for use (valid for Canada, Australia and New Zealand)

English

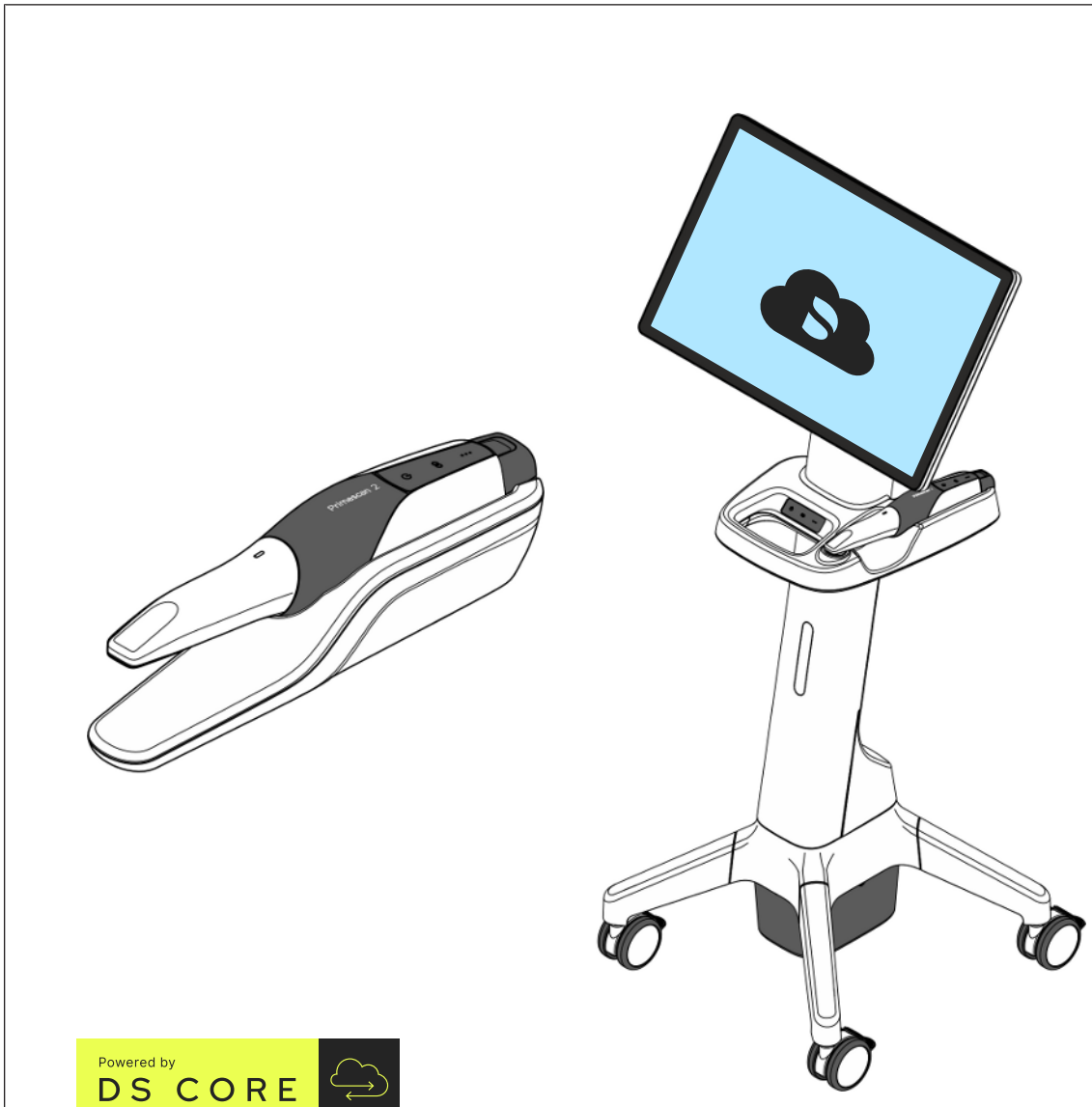


Table of contents

1 General data

1.1 Dear Customer,

Thank you for your purchase of this Primescan™ 2 system from Dentsply Sirona.

The Primescan™ 2 intraoral scanner makes it possible to create digital impressions for use in dentistry.

Improper use and handling can create hazards and cause damage. Please therefore read and follow these instructions for use carefully. Always keep them within easy reach.

Also observe the safety notices to prevent personal injury and material damage.

Your Primescan™ 2 team

1.2 Contact information

Dentsply Sirona Product service

Log in to register your units and make service requests:
https://dentsplysirona.service-pacemaker.com/

Manufacturer's address

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
E-Mail: contact@dentsplysirona.com
www.dentsplysirona.com

1.3 General information about these instructions for use

Observe the instructions for use.

Please familiarize yourself with the unit by reading through these instructions for use before putting it into operation. It is essential that you observe the specified safety information and warning notices.

Original language

Original language of this document: German

Store documents

Keep the instructions for use so that they are always at hand in case you or another user requires information at a later point in time. Save the instructions for use on the PC or print them out.

If you sell the unit, make sure that the instructions for use are included with it either as a hard copy or on an electronic storage device so that the new owner can familiarize himself with its functions and the warning and safety notices.

"Download Center" for technical documents

We have set up a "Download Center" for the technical documents at dentsplysirona.com/ifu. From here, you can download these instructions for use along with other documents. Please complete the online form if you would like a hard copy of the instructions for use or operator's manual. We would be happy to send you a printed copy, free of charge.

"Customer Support Portal"

You can obtain additional product information, tutorial videos and other self-help tips at the "Customer Support Portal" at www.dentsplysirona.com/csp.

Help

If you still need assistance, despite carefully reading this technical document and the information in the "Customer Support Portal", contact your dental depot.

1.3.1 Notes to the repository

Be sure to keep these instructions for use in an easily accessible place for later reference. In the event of a sale or transfer of the unit to another user, make sure that the new owner can get acquainted with the operation and the appropriate precautions and warnings.

1.4 General conventions and structure of the document

1.4.1 Structure of the document

1.4.1.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these operating instructions. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in minor or moderate bodily injury.

NOTICE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information on making work easier.

1.4.1.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Identifies an action sequence with prompt and result.
see “Formats and symbols used [→ 8]”	Identifies a reference to another text passage and specifies its page number.
• List	Identifies a list.
"Command / menu item"	Identifies commands, menu items or a quote.

1.5 Other relevant documents

For making acquisitions with the intraoral scanner, the DI Scan cloud-based scan application based on DS Core is required.

DI Scan and DS Core are described in separate documents/FAQ:

- DI Scan Operator's Manual (valid for Canada, Australia and New Zealand), REF 68 51 377, to be found at the online portal www.dentsplysirona.com/ifu.
- DS Core FAQ,
  can be found at the DS Core portal (www.dscore.com) in the *"Feedback & Support"* section.
  You must register at the DS Core portal with your DS Core login data.

Familiarize yourself with the software using these documents/FAQ before operation. It is essential that you comply with the specified warning and safety information.

1.6 Warranty and liability

Maintenance

In the interest of the safety and health of patients, users or third parties, it is necessary that maintenance work is carried out at fixed time intervals to ensure the operational safety and reliability of your product.

The operator must ensure that the maintenance work is conducted.

As a manufacturer of medical electrical equipment, we can consider ourselves responsible for the safety characteristics of the device only if maintenance and repairs are carried out only by us or by companies authorized explicitly by us for this purpose and if components are replaced with original spare parts in case of failure.

Exclusion of liability

If the operator does not meet the obligation to carry out such maintenance or error messages are ignored, Dentsply Sirona or its authorized dealer does not assume any liability for resulting damage.

1.7 Obligation to notify authorities

The operator or user must report all serious events related to medical devices to the manufacturer and the competent authority of the country in which they are established.

1.8 Legend

Manufacturer

Date of manufacture: YYYY-MM-DD (year-month-day)

Reference number

Serial number

Internal code for product identification.

Batch number

"Warning of optical radiation" symbol

Warning of injuries to eyes and skin in the vicinity of optical radiation.

ESD symbol: Warning of electrostatic discharge

Caution: Hot surface

Product disposal symbol (see "Disposal" [→ 111]).

Recycling symbol for the battery pack (see "Disposal of batteries (scanner and mobile display unit" [→ 112]).

The unit may contain an RF transmitter in the form of a WLAN card or a separate wireless module.

Radio approval for Australia/New Zealand.

Follow the instructions for use.

To ensure safe operation of the unit, the user must follow the instructions for use.

NOTICE! Observe instructions for use!

Electronic instructions for use

You can easily download the instructions for use from https://www.dentsplysirona.com/ifu.

This product is intended for single use only.

Type BF applied part according to IEC 60601-1

This product is a medical device.

This symbol indicates that this product does not contain any toxic or hazardous substances or components above the maximum concentration level set out in the Chinese standard SJ / T 11364-2014, and can be recycled following disposal and should not be carelessly discarded.

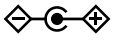
Unique Device Identifier (UDI)

Data matrix code (here: an example)

Content of the data matrix code:
+E27667548600/$+5001/16D20210819P

A B C D

A: Manufacturer code (here: E276)
B: Reference no. (here: 6754860)
C: Serial no. (here: 5001)
D: Manufacture date (YYYYMMDD)



Polarity of the DC connection of a direct current part:
The inner contact has positive polarity, the outer contact has negative polarity.

Labels electrical equipment intended for use indoors.

MET mark

MET certified product.

CE mark

Marking for CE conformity.

UL-recognized component

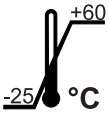
Symbols on the packaging

Take note of the following symbols on the packaging:

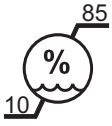
Up

Keep dry.

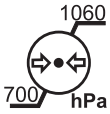
Fragile, handle with care.



Temperature during storage and transport.



Relative humidity during storage and transport



Air pressure during storage and transport.

Do not use if packaging is damaged.

Protect against direct sunlight.

Unit quantity in the packaging.

Packaging contains lithium-ion batteries.

Rx only

Federal law restricts this device to sale by or on the order of a dentist.

2 Safety instructions

2.1 Basic safety information

2.1.1 Prerequisites

NOTICE

Important information on building installation

In order to prevent the risk of an electric shock, this unit must only be connected to a supply mains with a ground wire.

The building installation must be performed by a qualified expert in compliance with the national regulations.

NOTICE

Restrictions regarding installation site

The unit is not intended for operation in areas subject to explosion hazards.

NOTICE

Do not damage the unit!

The components of the Primescan™ 2 system can be damaged if opened improperly.

It is expressly prohibited to open the components.

Opening the mobile display unit (optional) is permissible only if required for installation (see section "Installation and initial startup“ [→ 51]).

For the USA only

Federal Caution: Federal law restricts this device to sale by or on the order of a dentist.

2.1.2 Connecting the unit

Connection must be carried out according to section "Installation and commissioning" [→ 51].

When using the Primescan™ 2 Cart mobile display unit (optional), the following also apply

NOTICE

Damage to the unit

The unit may not be connected to a multiple socket or an extension cable.

➢ Connect the unit directly to the building power supply with the supplied power cable.

➢ Do not use non-medical technical devices in the patient environment.

2.1.3 General safety information

⚠ WARNING

Danger of contact with live parts

If the housing is damaged, there is a possibility of touching live parts inside the unit.

➢ Check all components of the Primescan™ 2 system for integrity before use. It may be used only with undamaged components.

➢ If the housing is damaged, the affected component must be taken out of operation until it has been professionally repaired.

⚠ WARNING

Temporary loss of functionality of a magnetically susceptible implanted medical device (magnetic safety mode)

A magnet with a magnetic field strength of less than 10 mT at the outer surface of the scanner is used in the back end of the device handle next to the battery pack.

➢ Ensure the back end of the scanner is kept at least 2 inches (approximately 5 cm) away from any implants or medical devices that can be adversely impacted by magnetic fields.
Examples of these types of devices include pacemakers, implantable cardioverter defibrillators, neurostimulators, stents, cerebrospinal fluid shunts, cochlear implants and insulin/infusion pumps.

⚠ CAUTION

Risk of injury

An evidently damaged scanner must no longer be used on patients until it is repaired.

If the Primescan™ 2 scanner is dropped accidentally, check whether the output window of the scanner (not the window for the disposable sleeve) is damaged. In case of damage, the Primescan™ 2 scanner may no longer be used on patients until it is repaired.

The Primescan™ 2 scanner must always be recalibrated if it is dropped.

⚠ CAUTION

Risk of injury

No system components are intended to be repaired by a technician except the Primescan™ 2 mobile display unit.

➢ In case of a defect, contact the Dentsply Sirona product service.

⚠ CAUTION

Risk of injury

Evidently damaged or contaminated disposable sleeves (e.g. due to dropping the unwrapped disposable sleeves) may no longer be used on the patient.

⚠ CAUTION

Restoration to be checked by trained personnel

Each restoration created must be checked for suitability by a trained person (e.g. dentist).

⚠ CAUTION

Risk group 2: Potentially hazardous optical radiation!

Direct radiation to the eye can be harmful for the eye.

➢ During operation, do not look directly at the light source for long periods.

⚠ CAUTION

Note on the prevention, recognition, and elimination of unintended electromagnetic effects:

Primescan™ 2 is Class B equipment (classified according to CISPR 11, IEC 60601-1-2:2014+AMD1:2020).

This unit may be used in professional facilities of the healthcare system.

IMPORTANT

The medical evaluation of the images (including the images from the caries diagnosis support) of the Primescan™ 2 may only be carried out by a licensed dentist.

IMPORTANT

When using caries diagnostic support, ensure that no additional light sources (treatment light, LED spotlight, or sunlight) shine directly into the patient's mouth.

IMPORTANT

Interruption of the mains power supply

The external plug-in adapters of the charger and the optional connection set have no power switch.

➢ Unplug the respective adapter from the socket to interrupt the mains power supply of the charger or the connection set.

IMPORTANT

Unused 5G frequencies

The 5G frequencies 28 GHz and 39 GHz are not currently used and are therefore not tested.

➢ Do not operate the unit near MRI units.

When using the Primescan™ 2 Cart mobile display unit (optional), the following also apply

⚠ CAUTION

Risk of toxic liquid escaping from a damaged display

There is a risk of injury if toxic liquid escapes from a damaged display.

- ➢ Do **not** touch the LED screen with sharp or pointed objects.
- ➢ If the LED monitor is damaged (e.g. the glass screen is broken), prevent any leaking liquid from coming into contact with your skin, mucous membranes (eyes, mouth), or foodstuffs and be careful not to inhale any escaping vapors.
- ➢ Rinse any parts of your body or items of clothing already contaminated by the liquid with ample amounts of water and soap.

⚠ CAUTION

Risk of damaging components

Components may be damaged if ventilation openings are covered.

- ➢ Ensure that the ventilation openings are not covered.

NOTICE

Danger posed by broken glass

Stress to the glass surface of the monitor from strong forces and impacts must be prevented, otherwise there is a risk of the glass breaking. Prevent impacts to the monitor, especially around the edges of the cover glass.

NOTICE

No manipulation of the installed software

To prevent disruption of the process reliability of the program, the installed software may not be manipulated.

NOTICE

Damage to the monitor

Avoid impermissible loads on the monitor, for example by leaning on the monitor or forcefully jerking the monitor to the end stops of the monitor joint.

IMPORTANT

The monitor of the mobile display unit is used only for displaying, e.g. during the exposure process.

The monitor is not suitable for diagnosing X-ray images.

IMPORTANT

The network connection and the charger interface of the mobile display unit carry low voltages.

- ➢ Do not touch the connection sockets.
- ➢ Mount the cover or the charger with wall holder at the charger interface.

Plug connections of external interfaces

⚠ CAUTION

Additional devices connected to external interfaces must be tested according to the relevant standards, e.g.:

EN 60601-1:2006 + Cor.:2010 + A1:2013,
IEC 60601-1 Edition 3.1:2012,
EN 61010-1:2010 based on IEC 61010-1:2010 + Cor.:2011,
IEC 62368-1:2018.

They must be installed outside of the patient area (a radius of 1.5 m around the patient).

⚠ CAUTION

Low voltages are applied to the sockets of the connection set for connecting external interfaces.

➢ Do not touch the pins of the connectors.

⚠ CAUTION

Tripping/falling hazard

There is a risk of tripping when laying the supply cable (cable between the optional connection set and the scanner).

➢ Lay the cable in such a way that there is no risk of tripping.
➢ Fix the supply cable so that it remains in place at all times.

NOTICE

The externally connected cables must not be subjected to tensile stress.

2.1.4 Portable use of the unit

⚠ CAUTION

Trip/fall hazard

When using the optional connection set, you may trip and fall over the supply cable (cable between the optional connection set and the scanner).

➢ Lay the cable so that there is no risk of tripping.
➢ Attach the cable so that it remains secured at all times.
➢ Ensure that the free cable ends are coiled.

The scanner can be moved from room to room in the camera holder for use in different treatment rooms. The scanner can be separated from the optional connection set for this purpose.

When using the Primescan™ 2 Cart mobile display unit (optional), the following also apply

⚠ CAUTION

Trip/fall hazard

When using the ☐Primescan™ 2 Cart mobile display unit, you can trip and fall over the supply cable.

➢ Lay the cable so that there is no risk of tripping.
➢ Attach the cable so that it remains secured at all times.
➢ Ensure that the free cable ends are coiled.

NOTICE

Tripping hazard posed by cable connection to USB port on the monitor

The connection of a USB cable to the USB port on the monitor can cause a tripping hazard that endangers its stability.

➢ Do not connect a USB cable to the USB port on the monitor.

NOTICE

The mobile display unit can fall over or slide away

For reasons of tipping stability, the mobile display unit must be held by one of the handles when being moved. Do not grasp the monitor to move the mobile display unit.

Obstacles on the floor could block its wheels, thus causing it to overturn. For this reason, pull the unit and avoid pushing it.

The monitor may be in the upper or swiveled down position when moving it.

All wheels of the unit have brakes that can be locked to ensure secure positioning. If the unit is on a steep incline or a slippery surface and lateral forces are acting on it, it may slide even though the wheel brakes are locked. Horizontal forces in the upper part of the unit (e.g. on the monitor) can cause the unit to tip over when the wheels are locked.

➢ For safe operation, ensure that the unit is standing on a flat, nonskid surface.

NOTICE

Damage to the monitor/monitor joint

Force acting on the monitor or monitor joint can cause damage to the monitor and monitor joint (and its stop) or cause the mobile display unit to topple.

➢ Do not rest on the monitor or the monitor joint.

NOTICE

Damage to the mobile display unit or the monitor

The mobile display unit and especially the monitor can be damaged if they collide with an object while being moved.

➢ When moving the mobile display unit, ensure that the monitor extends to both sides over the mobile stand.

The Primescan™ 2 Cart mobile display unit can be moved from room to room for use in different treatment rooms.

2.1.5 Stability of the unit

NOTICE

The unit could slip and fall off the table

Ensure that you place the holder with the scanner and the connection set (optional) on a flat surface. The standing surface of the scanner holder has nonskid feet that help prevent movement.

When using the Primescan™ 2 Cart mobile display unit (optional), the following also apply

NOTICE

The unit can fall over or slide away

All wheels of the unit have brakes that can be locked to ensure secure positioning. If the unit is on a steep incline or a slippery surface and lateral forces are acting on it, it may slide even though the wheel brakes are locked. Horizontal forces in the upper part of the unit (e.g. on the monitor) can cause the unit to tip over when the wheels are locked.

➢ For safe operation, ensure that the unit is standing on a flat, nonskid surface.

NOTICE

The unit can tip over

➢ Do not lean on the handle of the unit, as it could tip over.

2.1.6 Batteries and charger

⚠ CAUTION

Biological incompatibility

If a battery leaks, the leaked fluid must not come in contact with skin or eyes.

➢ In case of contact, wash the affected area with plenty of water and consult a physician.

⚠ CAUTION

The battery used in this unit can present a risk of fire or corrosive burn if handled improperly. Do not open, heat over 60 °C, short circuit, dismantle, immerse in liquids or burn, as it may leak or burst.

⚠ CAUTION

Do not expose the batteries to excessive heat or fire. Avoid storage in direct sunlight.

NOTICE

Non-rechargeable batteries may not be charged.

NOTICE

This charger is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or those who lack experience and/or knowledge.

Children should be supervised to ensure that they do not play with the charger.

IMPORTANT

Do not store loose batteries

Ensure that the batteries are always either in the charger or in the scanner.

For storage longer than 1 month, the scanner battery should be taken out of the scanner and stored in the charger.

When using the Primescan™ 2 Cart mobile display unit (optional), the following also apply

⚠ CAUTION

Electric shock from extra-low voltage

When the charger is installed on the mobile display unit, there is a risk for the patient if the user touches the inside of the charging slot and the patient simultaneously.

➢ Do not touch a charging slot and the patient at the same time.

2.1.7 Maintenance and repair

As manufacturers of dental instruments and laboratory equipment, we can assume responsibility for the safety properties of the unit only if the following points are observed:

- Maintenance and repair of this unit may only be performed only by Dentsply Sirona or by agencies authorized by Dentsply Sirona.
- Components which have failed and which could affect the safety of the unit must be replaced with original (OEM) spare parts.
- To ensure that EMC requirements are met, only original cables and original power supplies may be used.

Please request a certificate whenever you have such work performed. It should include:

- The type and scope of work.
- Any changes made in the rated parameters or working range.
- Date, company details and signature.

2.1.8 Modifications to the product

Modifications to this product which might affect the safety of the system owner, patients or other persons are prohibited by law!

2.1.9 Accessories

In order to ensure product safety, this device may be operated only with original Dentsply Sirona accessories or third-party accessories expressly approved by Dentsply Sirona. In particular, only the included power cable, power supply units and batteries may be used with the

unit. The user is responsible for any damage resulting from the use of non-approved accessories.

2.2 Connections and network connection

USB connection on the monitor of the Primescan™ 2 Cart mobile display unit (optional)

NOTICE

Do not connect any USB hubs

Use the USB interfaces of the monitor only for USB devices with no additional electrical interfaces (e.g. USB sticks).

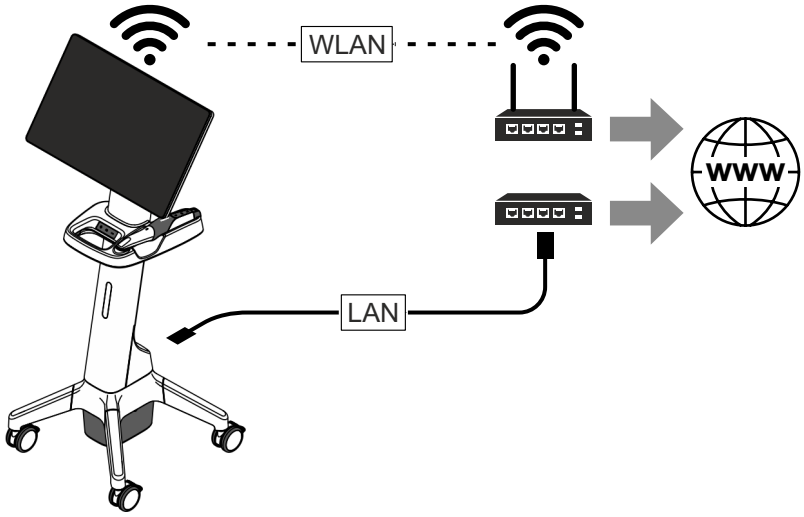
Battery charger interface of the Primescan™ 2 Cart mobile display unit (optional)

NOTICE

Use original accessories

Connect only the original Dentsply Sirona charger to the charger interface.

Network connection of the Primescan™ 2 Cart mobile display unit (optional)



NOTICE

Observe the following installation instructions

For connecting the Primescan™ 2 Cart mobile display unit to a network, the following installation rules apply:

The Primescan™ 2 Cart mobile display unit may be connected with the network only via WLAN or a connection via LAN cable on a hub/switch or permanently installed network connection.

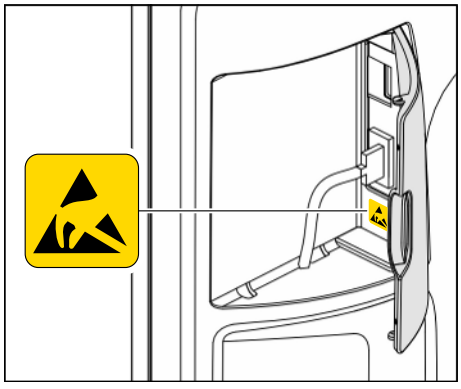
The hub/switch must:

- be **permanently installed** in the same room in which the mobile display unit is operated.
- be grounded via an **additional protective conductor**.

Cross-section of the protective conductor	laid in a protected installation	2.5 mm^2
	laid in an unprotected installation	4 mm^2

2.3 Safety labels

Plug connections of external interfaces of the Primescan™ 2 Cart mobile display unit (optional)



⚠ WARNING

Risk of electric shock

Low voltages are applied to the sockets for connecting external interfaces. In order to maintain electrical safety, the rear covers of the monitor must be closed while the mobile display unit is in operation.

➢ Do not touch the pins of the sockets.

➢ When using the unit on the patient, please note that the covers on the rear side of the monitor must remain closed and no voltage sources may be accessible. The cover on the monitor may be opened if both USB sockets are in use or locked.

➢ The mobile display unit must not be operated inside of the patient area (within a radius of 1.5 m surrounding the patient) if the cover is not closed.

⚠ CAUTION

Adaptation of mobile display unit to external components

Additional devices connected to external interfaces must be tested according to the relevant standards, e.g.:

EN 60601-1:2006 + Cor.:2010 + A1:2013,
IEC 60601-1 Edition 3.1:2012,
EN 61010-1:2010 based on IEC 61010-1:2010 + Cor.:2011,
IEC 62368-1:2018

NOTICE

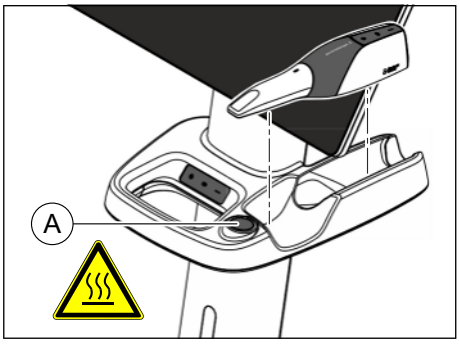
Risk of damage to the plugs/cables

The externally connected plugs/cables may be damaged, if they are subjected to tensile stress or if the plug connections do not snap in.

➢ Do not pull on the cables.

➢ Make sure that the plug connections snap in.

Heater plate of the Primescan™ 2 Cart mobile display unit (optional)

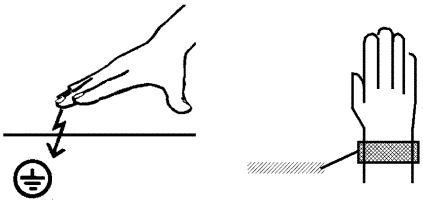


⚠ CAUTION

Risk of burns due to hot surface

➢ Do not touch the heater plate (A).

2.4 Electrostatic discharge



ESD (**E**lectro**S**tatic **D**ischarge)

Electrostatic discharge from a person can damage electronic components when the components are touched. Damaged components usually have to be replaced. Repairs must be performed by qualified personnel. The required service documents are provided to qualified personnel.

Measures to protect against ESD include:

- Procedures to avoid electrostatic charging via
  - air conditioning
  - air humidification
  - conductive floor coverings
  - non-synthetic clothing
- Discharging the electrostatic charges from your own body through contact with
  - a metallic unit casing
  - a larger metallic object
  - any other metal part grounded with the protective ground wire
- wearing an antistatic band that creates a connection between the body and a protective ground wire

Areas at risk are indicated on the unit by the ESD warning label.

2.5 Radiotelephones

Mobile RF communication equipment, including accessories, should not be used within a short distance of the unit. Non-compliance can lead to a reduction in the performance features of the unit.

2.6 Cybersecurity

If Dentsply Sirona detects a security vulnerability in the Primescan™ 2 devices, Dentsply Sirona will provide an updated firmware with

necessary mitigations and you will be notified in DS Core when the new firmware is available.

If you suspect a cybersecurity attack on the Primescan™ 2 has taken place, please report the incident using the contact information in chapter "Contact information" [→ 6].

If the device will no longer be maintained (i.e., there will be no further firmware updates), you will be informed in DS Core.

The Software Bill of Materials (SBOM) can be requested using the contact information in chapter "Contact information" [→ 6].

3 Product description

3.1 Intended use

⚠ CAUTION

The unit may be operated only by medically trained and qualified personnel.

The intraoral scanner records and generates digital images and impression data for dental use.

Primescan™ 2 Cart is intended to be used as an accessory for an intraoral scanner.

Single Use Sleeve is intended to be used as an accessory of an intraoral scanner.

Areas of application

This unit must not be used for any other purpose. If the unit is used for any purpose other than the one mentioned above, it may be damaged.

Intended use also includes compliance with these instructions for use and the relevant maintenance instructions.

⚠ CAUTION

Follow the instructions

If the instructions for operating the unit described in this document are not observed, the intended protection of the user may be impaired.

For the USA only

⚠ CAUTION

Rx only

Federal Caution: Federal law restricts this device to sale by or on the order of a dentist.

3.2 Indication/contraindication

Indications for use

Primescan™ 2 can be used by dental professionals to acquire images and 3D data.

These can be used as an input into the design and production of dental restorations, some prosthodontic appliances, and orthodontic appliances as well as for supporting treatment planning and monitoring, and patient communication.

Data acquired by Primescan™ 2 can be used as a diagnostic aid for detection of caries on visible tooth surfaces, proximal caries, and tooth cracks.

Contraindications

There are no contraindications.

3.3 Patient population

The intended patient population includes children, adolescents and adults and patients of all age and ethnic groups relevant for dental treatment.

3.4 Transportation and storage conditions

In the original transport packaging, the unit withstands the following environmental conditions during transport and storage:

Temperature	-25 °C to 60 °C (-13 °F to 140 °F)
Relative humidity	10% to 85%
Air pressure	700 hPa to 1060 hPa

3.4.1 Storage of the disposable sleeve by the customer

The Primescan™ 2 disposable sleeve must be stored at the specified operating conditions (see "Operating conditions" [→ 27]).

3.5 Operating conditions

The unit can be operated in the following environmental conditions:

Ambient temperature	18 °C to 28 °C (64.4 °F to 82.4 °F)
Relative humidity	30% to 75% No condensation
Air pressure	700 hPa to 1060 hPa
Operating altitude	≤ 3000 m

3.6 Technical data

3.6.1 Scanner

Type designation	Primescan™ 2
Type of protection against electric shock	Protection class II equipment
Type of protection against electric shock	Type BF applied part 
Degree of protection against ingress of water	IP20
Pollution degree	2
Installation category	II
Operating mode	Continuous operation

Power supply for wireless operation

Battery:	
Nominal voltage	3.6 V DC
Nominal capacity	3000 mAh

Power supply connection set (optional)

Power supply unit, mains side:	
Nominal voltage	100 - 240 V AC / 50 - 60 Hz
Nominal current	1.7 A
Power supply unit, output side:	
Nominal voltage	12 V DC
Rated power	60 W

Data connection

Wireless:	
WLAN	5 GHz Wi-Fi
Bluetooth	Bluetooth Low Energy 5 (2.4 GHz)
Optional connection:	
Ethernet	1000 Mbit/s (Standard 1000BASE-T)

LEDs / wavelengths

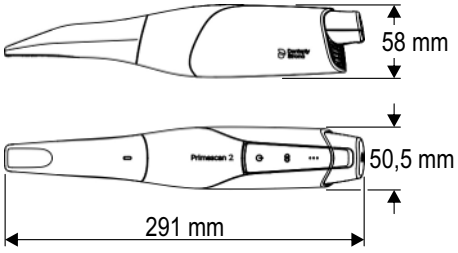
Color 2D:	White LEDs
3D:	450 nm
Fluorescence:	405 nm

Near infrared mode:	850 nm

Optical system / sensor

Optical system:	Multiple lens system with protective glass
Sensor type:	CMOS
Image size:	13.8 x 13.8 mm (at 8.5 mm working distance)
Depth of focus for 2D (caries detection):	20 mm

Dimensions and weight



Scanner dimensions W x H x D	
in mm	291 x 58 x 50.5
in inches	$11^{1}/_{2}$ x $2^{1}/_{4}$ x 2
Weight (operational with battery and disposable sleeve)	542 g (1.2 lbs)

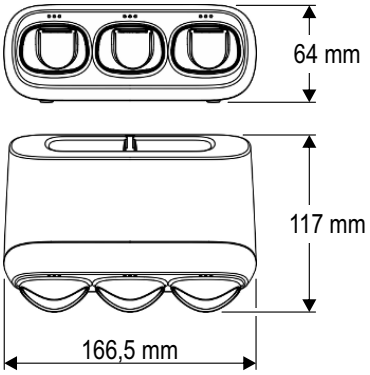
3.6.2 Charger

Type designation	Charger Primescan™ 2
Environment for use	Use outside the patient environment or attached to the mobile display unit.
Connection, input side	10-14VDC / 3.0A / 36W
Output per charging slot	4.2V DC / max. 2.5A
Battery type	Lithium-ion battery
Number of charging slots	3 Only the supplied batteries described above can be charged in the charger.

Power supply when using the supplied power plug for the charger

Power adapter charger, mains side:	
Nominal voltage	100-240VAC / 50-60Hz
Nominal current	1.7A
Power adapter charger, output side:	
Nominal voltage	12VDC
Nominal power output	60W

Dimensions and weight



Dimensions of charger WxHxD	
in mm	166.5x64x117
in inches	$6^1/_2$x$2^1/_2$x$4^1/_2$
Weight (without battery)	520g (1.15lbs)

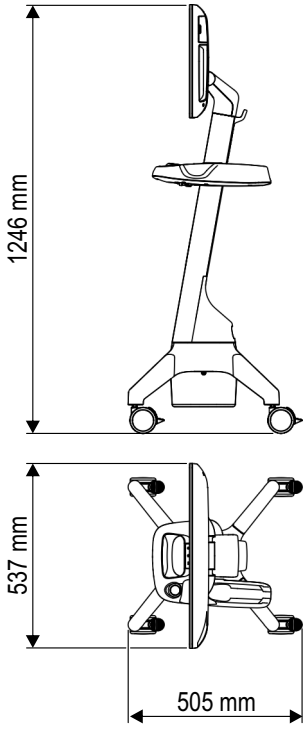
3.6.3 Mobile display unit (optional)

Type designation	Primescan™ 2 Cart
Nominal line voltage	100-240 VAC / 50-60 Hz
Nominal power output	175 W
Type of protection against electric shock	Protection class I unit
Degree of protection against ingress of water	Ordinary device (without protection against ingress of water)
Degree of contamination	2
Installation category	II
Operating mode	Continuous operation

Power supply for wireless operation

Battery:	
Nominal voltage	25.2 VDC
Nominal capacity	12 Ah

Dimensions and weight



Dimensions of mobile stand with monitor W x H x D	
in mm	537 x 1246 x 505
in inches	$21^{1}/_{4}$ x $49^{1}/_{8}$ x 20
Weight	
Weight of the mobile display unit incl. safe working load	24.9 kg (54.9 lbs)
Weight of mobile display unit (without scanner and charger)	
Gross weight	23.6 kg (52.0 lbs)
Weight without monitor and battery	15.0 kg (33.1 lbs)
Weight of accessories (scanner and charger)	1.3 kg (2.9 lbs)
Weight of monitor	6.4 kg (14.1 lbs)
Weight of battery	2.2 kg (4.9 lbs)

3.7 Major components

IMPORTANT

Use of short forms

In the interest of better legibility, the short forms provided for the component designations are used in the further course of the document.

The Primescan™ 2 medical device includes the following main components:

- Primescan™ 2, short: (intraoral) scanner
- Cradle Primescan™ 2, short: scanner holder
- Protective sleeve
- Battery Primescan™ 2, short: battery
- Charger Primescan™ 2, short: charger
- Power supply unit for charger
- Calibration Set Primescan™ 2, short: calibration set

Sleeves (accessories)

- Single Use Sleeve Primescan™ 2, short: disposable sleeve

Connection Set optional Primescan™ 2

The Connection Set optional Primescan™ 2 (short: connection set) for use in cable operation includes the following main components:

- Coupling Box Primescan™ 2, short: coupling box
- Cable adapter
- Network cable
- Power supply unit

Primescan™ 2 Cart mobile display unit (optional accessory)

The Primescan™ 2 Cart mobile display unit (short: mobile display unit) is an optional accessory for the Primescan™ 2 medical device and includes the following main components:

- Mobile stand
- All-in-one touch computer (also called AIO monitor below)
- Scanner holder
- Battery
- Network cable
- Power cable

The Primescan™ 2 Cart mobile display unit is designed for use within the patient environment.

3.8 Technical description

Intraoral scanner for precise optical impressions in the mouth

- High-resolution, heated intraoral scanner (3D scanner) with removable disposable sleeve and integrated image processing for wireless or cable operation,
- Scanner holder,
- Battery and charger.

High-resolution intraoral scanner with control and image processing electronics

• Image acquisition:	2D and 3D data acquisition takes place inside the scanner handpiece.
• Image data transfer:	The image data acquired are transmitted wirelessly (via 5 GHz Wi-Fi) or by cable via the optional coupling box or the optional mobile display unit.

No water or air connection required.

Connection Set optional Primescan™ 2 (only when using the scanner without a mobile display unit)

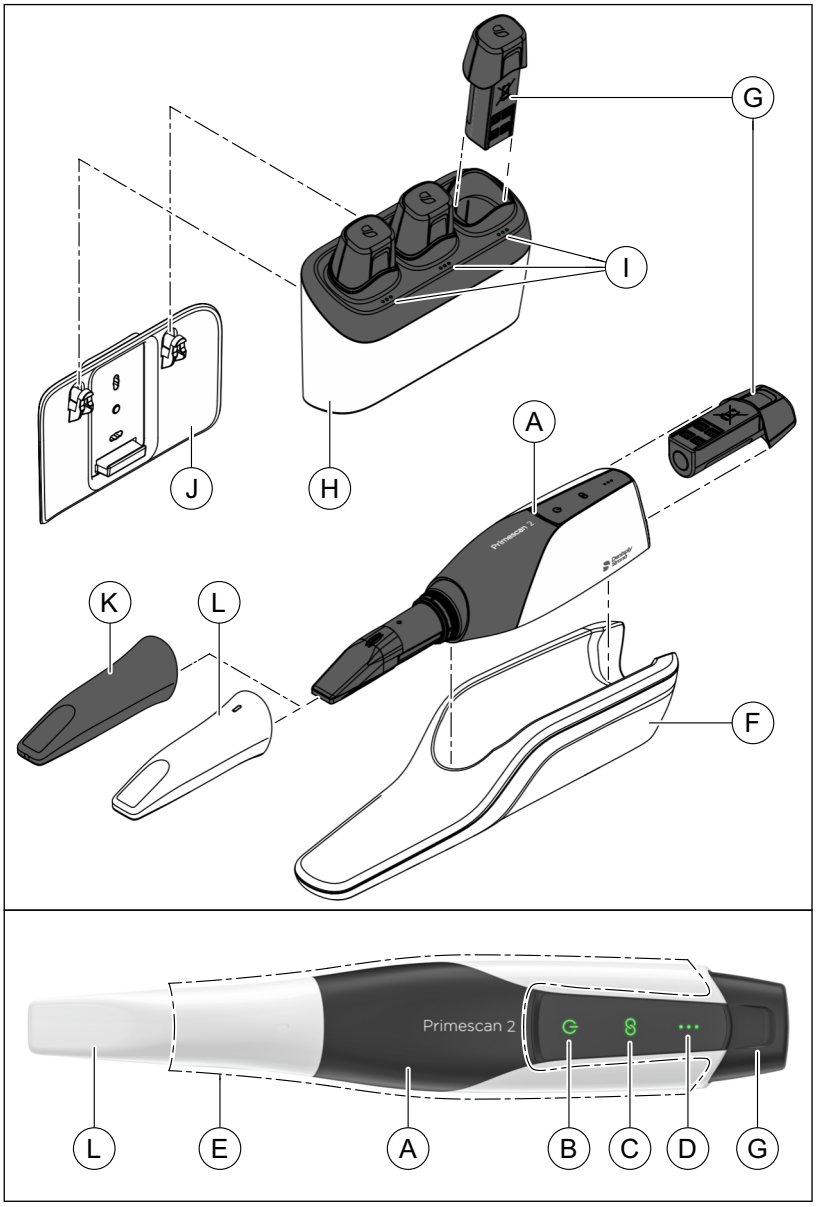
- Connection set with cable adapter and coupling box for cable operation.

Primescan™ 2 Cart mobile display unit (optional)

- Digital, mobile display unit for wireless or cable operation,
- All-in-one touch computer with 21.5 inch display (also called AIO monitor below), 1920 x 1080 pixel (16:9),
- Mobile stand with smooth moving / adjustable wheels,
- Scanner holder,
- Heater to ensure fog-free scanner view,
- Cloud-based software for creating and managing images,
- Battery and power cable,
- USB A port,
- Integrated foot input key,
- Optional charger for the batteries for the intraoral scanner.

3.9 Operation and functional elements

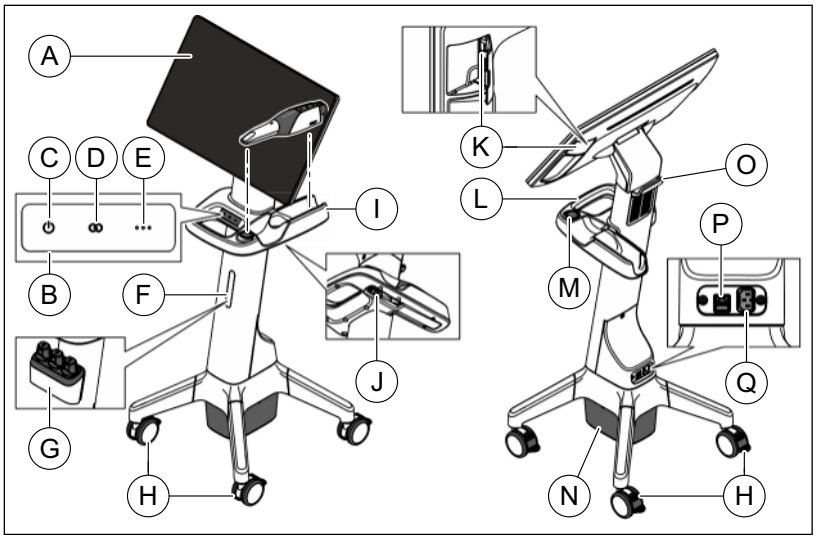
3.9.1 Scanner and charger



A	Primescan™ 2 scanner	G	Battery
B	ON/OFF button Operating status display	H	Charger
C	Connect key Connection status display	I	Charger status displays
D	Battery charge level display	J	Wall holder for charger

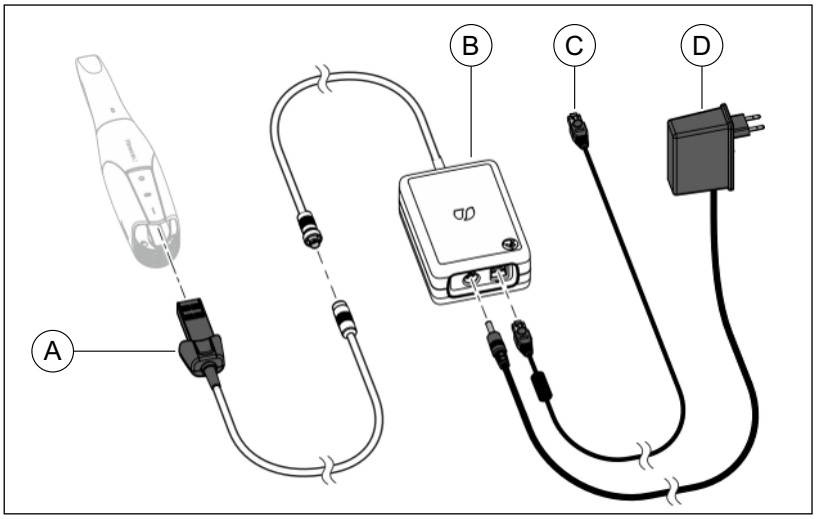
E	Area for tapping the scanner housing (acquisition mode)	K	Protective sleeve
F	Scanner holder	L	Disposable sleeve

3.9.2 Mobile display unit (optional)



Primescan™ 2 Cart mobile display unit		I	Scanner holder
A	All-in-one touch computer or AIO monitor	J	Scanner connection for cable operation
B	Control panel	K	USB connection
C	ON/OFF button / Operating status display (display unit)	L	Handle
D	Connect display (display unit)	M	Heater plate
E	Battery status display (display unit)	N	Battery cover / Foot control
F	Charger interface cover	O	Monitor interface cover / Handle / Cable holder
G	Charger with wall holder at the charger interface	P	Network connection
H	Wheels with brakes	Q	Power connection

3.9.3 Connection set (optional) for cable operation



A	Cable adapter	C	Network cable
B	Coupling box	D	Power supply unit

⚠ CAUTION

Only use the power supply unit and power cable supplied by Dentsply Sirona for operating the connection set.

3.9.4 Operating status

Operating status of the Primescan™ 2 scanner

LED display		Description
	not lit	The scanner is switched off.
	flashes blue	• The scanner is in the start process. • The scanner is in the switch-off process. • After a cooling process, the scanner is again ready to be switched on.
	lights up green	The scanner is switched on and ready for operation.
	flashes white	The scanner firmware is being updated. During the firmware update, the battery or cable adapter may not be disconnected from the scanner.

LED display		Description
	flashes light orange	The scanner is in cooling mode. The scanner cannot be switched on again during cooling. At the end of the cooling process, the color changes to blue and the scanner can be switched on again.
	lights up light orange	• The start process failed. • There is a problem with the scanner or the battery.

Operating status of the Primescan™ 2 Cart mobile display unit (optional)

LED display		Description
	not lit	The mobile display unit is switched off.
	flashes blue	The mobile display unit is in the start process.
	lights up green	The mobile display unit is switched on and operational.
	lights up light orange	An error has occurred in the mobile display unit.

3.9.5 Battery charge level

Battery charge level of the Primescan™ 2 scanner

LED display		Description
	All 3 LED light up green	Battery charge level: high
	2 LED light up green	Battery charge level: medium
	1 LED lights up green	Battery charge level: low
	1 LED flashes green	Battery charge level: very low Replace the battery promptly with a full one.

IMPORTANT
Battery is not fully charged On delivery, the battery is not fully charged. Put the battery in the charger before the first use to reach full capacity.

Battery charge level of the Primescan™ 2 Cart mobile display unit (optional)

LED display		Description
	All 3 LED light up green	Battery charge level: high
	2 LED light up green	Battery charge level: medium
	1 LED lights up green	Battery charge level: low
	1 LED flashes green	Battery charge level: very low Connect the mobile display unit to the power supply promptly.

IMPORTANT
Battery is not fully charged On delivery, the battery is not fully charged. Connect the unit to the mains with the power cable to achieve the full capacity of the battery.

3.9.6 Network connection status

Network connection of the Primescan™ 2 scanner

LED display		Description
	flashes blue twice	The scanner is in search mode: Bluetooth is active, but the scanner is not yet connected to a network.
	lights up green	The scanner is connected to the network.
	lights up light orange	Connection error: The scanner cannot find the network.

Network connection of the Primescan™ 2 Cart mobile display unit (optional)

LED display		Description
	flashes blue twice	The mobile display unit is in search mode: Bluetooth is active, but the mobile display unit is not yet connected to a network.
	lights up green	The mobile display unit is connected to the network.
	lights up light orange	Connection error: The mobile display unit cannot find the network.

3.10 Certification

CE marking

This product is compliant with EU Medical Device Regulation 2017/745 including all amendments.

This product bears the CE mark in accordance with the provisions of Directive 2014/53/EU (RED).

NOTICE

CE mark for connected products

Products that are connected to this unit must also bear the CE mark.

Compliance

Anyone creating or changing a medical electrical system in accordance with standard IEC 60601-1:2005 + A1:2012 (+A2:2020) chapter 16 through a combination with other devices is responsible for ensuring that the requirements of this standard are met to the full extent in order to ensure the safety of patients, operators and the environment. The combination with a PC is such a creation of a medical electrical system.

The modules meet the requirements of the Federal Communications Commission (Part 15 of the FCC Rules).

FCC ID (Primescan™ 2): 2AD7W-6802040

FCC ID (Primescan™ 2 Cart): PD9AX210NG

Industry Canada

The modules meet the requirements of Industry Canada (RSS210).

IC ID (Primescan™ 2): 12730A-6802040

IC ID (Primescan™ 2 Cart): 1000M-AX210NG

3.11 FCC and IC compliance

FCC compliance statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Changes or modifications not expressly approved by the manufacturer could void the user’s authority to operate the equipment.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

Note: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows:
Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

IC declaration (for Canada only)

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) This device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

3.12 Electromagnetic compatibility

The following information must be observed to ensure safe operation regarding EMC aspects.

Primescan™ 2 complies with the requirements for electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014+AMD1:2020.

Primescan™ 2 is hereinafter referred to as "UNIT".

3.12.1 Electromagnetic emission

The UNIT is intended for operation in the electromagnetic environment specified below.

The customer or user of the UNIT should make sure that it is used in such an environment.

Emission measurement	Conformity	Electromagnetic environment - guidelines
RF emissions according to **CISPR 11**	Group 1	The UNIT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to **CISPR 11**	Class B	The UNIT is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply also providing electricity to buildings used for residential purposes.
Harmonics according to **IEC 61000-3-2**	Class A	
Voltage fluctuations / flicker according to **IEC 61000-3-3**	Conform	

3.12.2 Interference immunity

The UNIT is intended for operation in the electromagnetic environment specified below.

The customer or user of the UNIT should make sure that it is used in such an environment.

Interference immunity tests	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) according to **IEC 61000-4-2**	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/burst according to **IEC 61000-4-4**	± 1 kV for input and output lines ± 2 kV for power supply lines	± 1 kV for input and output lines ± 2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to **IEC 61000-4-5**	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and variations of the power supply according to **IEC 61000-4-11**	0% U_T for ½ period (100% dip of U_T) 0% U_T for 1 period (100% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) 0% U_T for 5 sec. (100% dip of U_T	0% U_T for ½ period (100% dip of U_T) 0% U_T for 1 period (100% dip of U_T) 70% U_T for 25 periods (30% dip of U_T) 0% U_T for 5 sec. (100% dip of U_T	The quality of the line power supply should be that of a typical commercial or hospital environment.
Proximity magnetic fields **IEC 61000-4-39**	30 kHz 8 A/m 134.2 kHz 65 A/m 13.56 MHz 7.5 A/m	30 kHz 8 A/m 134.2 kHz 65 A/m 13.56 MHz 7.5 A/m	Keep a distance of 1 m from units expected to have magnet field interference.
Magnetic field of power frequencies (50/60 Hz) according to **IEC 61000-4-8**	30 A/m	30 A/m	Magnetic fields of power frequencies should be at levels of a typical commercial or hospital environment.
Remark: U_T is the alternating supply voltage prior to application of the test level.			
			Portable and mobile radio equipment must not be used within the recommended working clearance from the UNIT and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance:

Interference immunity tests	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF interference **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz 6 V_{eff} in ISM frequency bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 V_{eff} 6 V_{eff}	d= [1.2] √P
Radiated RF interference **IEC 61000-4-3**	3 V/m 80 MHz to 800 MHz 3 V/m 800 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 3 V/m	d= [1.2] √P at 80 MHz to 800 MHz d= [2.3] √P at 800 MHz to 2.7 GHz with P as the power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as recommended safety distance in meters (m). According to an on-site survey[1], the field strength of stationary radio transmitters is lower than the compliance level in all frequency ranges[2]. Interference is possible in the vicinity of equipment bearing the following graphic symbol. 

Immunity to interference against high-frequency electromagnetic fields in the immediate vicinity of wireless communication devices IEC 61000-4-3			
Test frequency (MHz)	**Modulation**	**Required immunity test level (V/m)**	**Maintained immunity test level (V/m)**
385	Pulse	27	27
450	FM	28	28
660 680 700	Pulse	28	28
710 745 780	Pulse	9	9
810 870 930	Pulse	28	28
1720 1845 1970	Pulse	28	28
2450	Pulse	28	28

Immunity to interference against high-frequency electromagnetic fields in the immediate vicinity of wireless communication devices IEC 61000-4-3			
Test frequency (MHz)	**Modulation**	**Required immunity test level (V/m)**	**Maintained immunity test level (V/m)**
3300 3750 4200	Pulse	28	28
4400 4700 5000	Pulse	28	28
5240 5500 5785	Pulse	9	9
5925	Pulse	28	28

Remark 1
The higher frequency range applies at 80 MHz and 800 MHz.

Remark 2
These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. Field strengths from fixed transmitters, such as base stations for wireless telephones and land mobile radios, amateur radio, AM/FM radio and TV broadcasts, cannot be predicted theoretically with accuracy. A site survey is recommended to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location in which the UNIT is used exceeds the applicable RF compliance level specified above, the UNIT should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the UNIT.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Remark 3
Frequency band n260 (28 GHz), n261 (39 GHz):

These frequencies are not used for 5G mobile communication and are therefore not considered to cause interference. Thus, no additional tests are required for these frequency bands.

3.12.3 Working clearances

Recommended working clearances between portable and mobile RF communication devices and the UNIT

The UNIT is intended for operation in an electromagnetic environment where radiated RF interference is checked. The customer or the user of the UNIT can help prevent electromagnetic interference by duly observing the minimum distances between portable and mobile RF communication devices (transmitters) and the UNIT – depending on the maximum output power of the communication device as specified below.

Power rating of the transmitter [W]	Working clearance according to transmission frequency [m]			
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	2.3 GHz to 6 GHz
	d= [1.2] √P	d= [1.2] √P	d= [2.3] √P	d= [4.6] √P
0.01	0.12	0.12	0.23	0.46
0.1	0.38	0.38	0.73	1.46
1	1.2	1.2	2.3	4.6
10	3.8	3.8	7.3	7.3
100	12	12	23	46

The recommended working clearance d in meters (m) can be determined for transmitters whose maximum power rating is not specified in the above table, using the equation that belongs to the corresponding column, wherein P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Remark 1

An additional factor of 10/3 is applied when calculating the recommended working clearance between transmitters in the 80 MHz to 2.3 GHz frequency range in order to reduce the probability that a mobile/portable communication device unintentionally brought into the patient area could lead to interference.

An additional factor of 6.6 was added to calculate the frequencies from 2.3 GHz to 6 GHz.

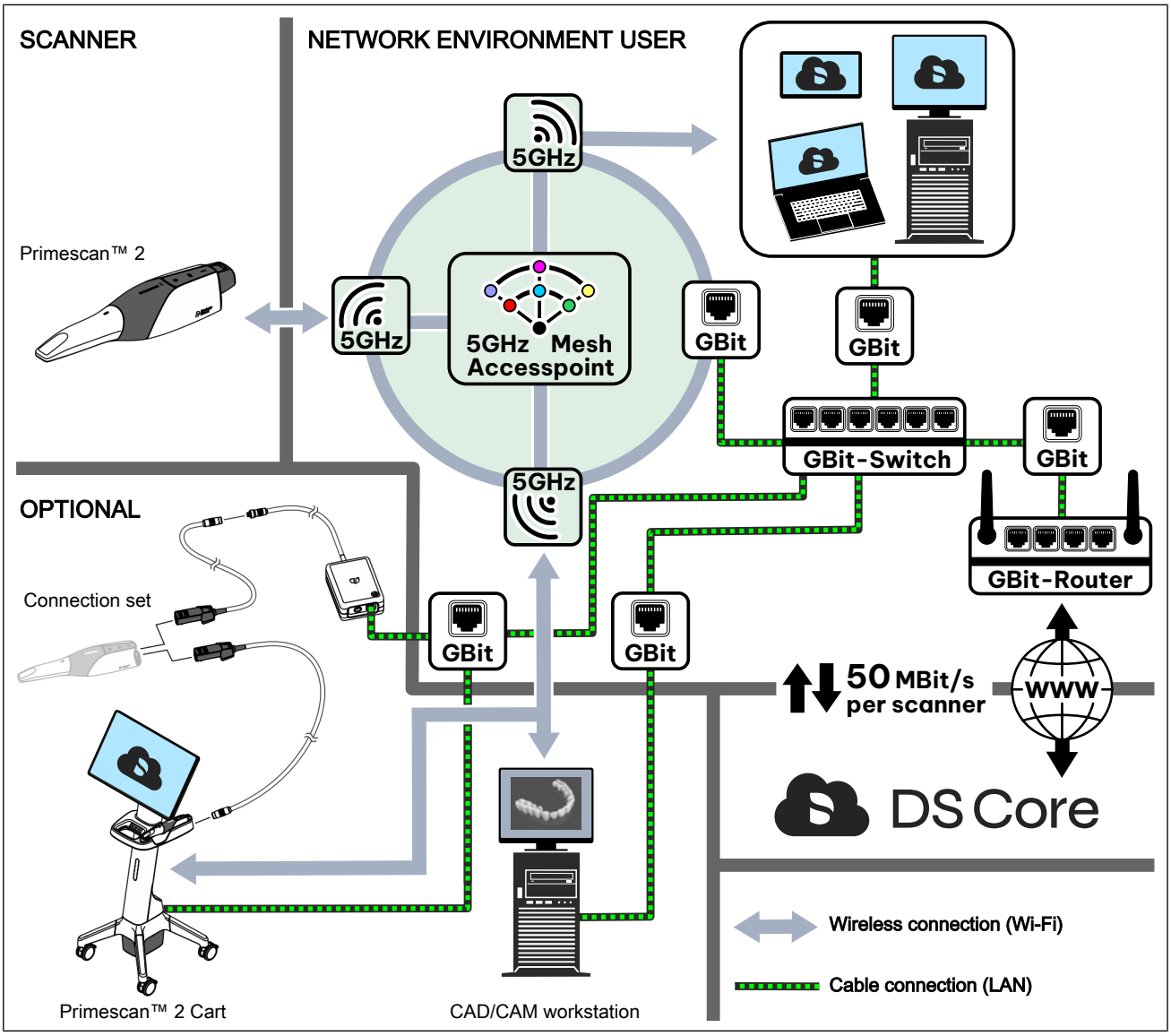
Remark 2

These guidelines may not apply in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4 Installation requirements

4.1 Network infrastructure requirements

Network topology



Network requirements

Wi-Fi band:	5 GHz
Wi-Fi standard:	Wi-Fi 5 (802.11 ac), Wi-Fi 6 (802.11 ax) or higher
Wi-Fi roaming:	802.11r/k/v
Upload / download:	min. 50 MBit/s per scanner
Encryption:	WPA2 with preshared key
Recommended IP assignment:	DHCP
Latency:	max. 100 ms
Jitter:	max. 5 ms
Distance from the scanner to the Wi-Fi access point:	max. 5 m, not obscured by walls
Connection to Wi-Fi access points:	Gigabit Ethernet, e.g.: 1000BASE-T with cable category 5 or higher
LAN standard (for optional, cabled system components):	Gigabit Ethernet, e.g.: 1000BASE-T with cable category 5 or higher

IMPORTANT

When operating the intraoral scanner in your network environment, we strongly recommend analyzing the IT network.
Security measures such as up-to-date virus protection and firewall settings are also strongly recommended for your network. If necessary, have experts advise you on securing your system and network.
The risk for patients, users and third parties must be assessed and if necessary, corresponding safety measures should be taken.
When changes are made (update or upgrade of connected IT equipment and expansion and removal of additional participants in the network) this process must be repeated.

IMPORTANT

To ensure data transmission with the above requirements, other Wi-Fi participants (third-party SSIDs) at the access point used by the scanner must have a signal strength of less than -85 dB.
Follow the local regulations on interrupting radio operation in case of conflicts with privileged participants (e.g. weather radar) by avoiding the radio channels 118–128 when configuring the Wi-Fi access point.

IMPORTANT

Restrict physical access to the IT infrastructure of your practice or clinic and the cloud platform to employees and personnel who actually need access to it.
Ensure that access data are stored safely and not shared with third parties. Dentsply Sirona or its partners will not ask you for access data.

It is not necessary to prioritize data transmission in the router settings if the required bandwidth of 50 Mbit (upload and download) does not decrease when operating other devices in the same network.

The data integrity of the data exchanged with the intraoral scanner via WiFi is guaranteed by the CCMP (Counter Mode with Cipher Block Chaining Message Authentication Code Protocol) implemented in the WPA2 standard.

Dentsply Sirona has successfully conducted performance tests concerning the electronic interfaces Wi-Fi and Ethernet under the above stated network infrastructure requirements. When these requirements are met, the system will work as intended.

Required communication ports

The following ports must be enabled for the practice network to ensure all functions of the unit.

Port (TCP/ UDP)	Description
123	Synchronization of time with a public time server (NTP)
68	When using DHCP
546	
53	Standard port for the domain name system (DNS)
443	Standard port for encrypted internet access (https) Sending and receiving data

4.2 Bluetooth radio interface

Bluetooth

Transmission standard:	Bluetooth Low Energy 5
Frequency band:	2.4 GHz
Maximum range:	< 3 m
Communication profile:	Generic ATTribute profile (GATT profile)
Encryption:	Standard Bluetooth encryption

Bluetooth QoS

Data latency:	Not relevant for this function
Throughput:	Not relevant for this function
Signal priorities:	Not relevant for this function

5 Installation and commissioning

The unit/system can be installed and operated either by you as the user or by qualified personnel.

5.1 Transport

Dentsply Sirona units are carefully checked prior to shipment. Please perform an incoming inspection immediately after delivery.

1. Check the delivery note to ensure that the consignment is complete.
2. Check whether the product shows any visible signs of damage.

NOTICE

Damage during transport

If the unit was damaged during transport, please contact your shipping agent.

NOTICE

Damage due to extreme temperatures

After transporting or storing the system under extreme temperatures, it is recommended to wait 12 hours before putting the system into operation.

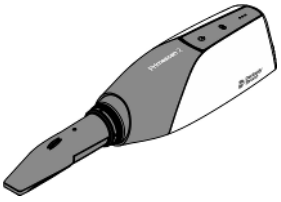
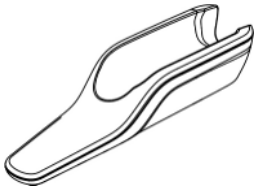
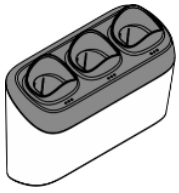
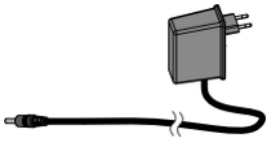
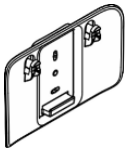
If return shipment is required, please use the original packaging for shipment.

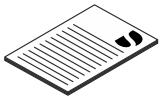
When using the Primescan™ 2 Cart mobile display unit (optional), the following should also be noted

To prevent damage to the AIO monitor, the AIO monitor and battery must be removed when transporting the unit.

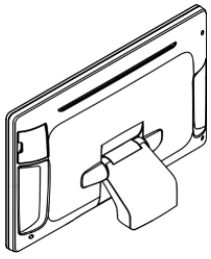
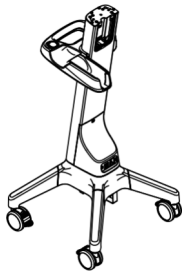
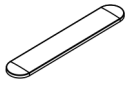
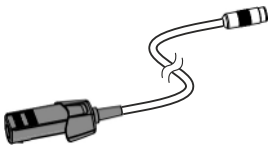
5.2 Scope of supply

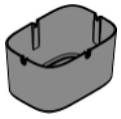
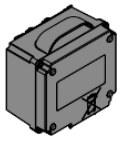
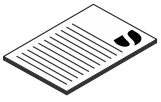
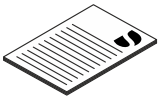
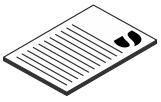
Primescan™ 2 scope of delivery

	1x	Primescan™ 2 scanner
	1x	Scanner holder
	1x	Protective sleeve (black)
	3x	Battery
	1x	Charger
	1x	Plug-in power supply with angled connection (for charger)
	1x	Wall holder
	1x	S3 screw set (for wall holder) consisting of: 2x particle board screw 3 x 30 Z1 2x A 3.2 washer 2x S3 screw anchor
	1x	Calibration set

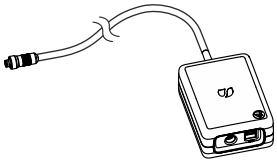
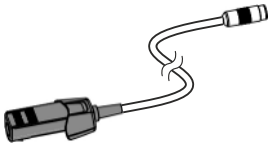
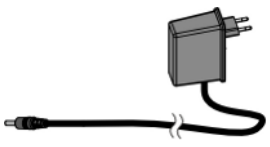
	1x	Package with disposable sleeves
	1x	Cleaning swabs
	1x	Quick start guide

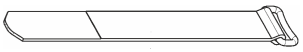
Scope of delivery of the Primescan™ 2 Cart mobile display unit (optional accessory)

	1x	AIO monitor
	1x	Mobile stand
	1x	Monitor interface cover
	1x	Charger interface cover
	1x	M6x16 screw with washer (for AIO monitor)
	4x	M4 x 10 screw with washer (for monitor interface cover)
	1x	Cable adapter
	1x	Network cable

	1x	Power cable (in selected version)
	1x	Charger connection cable
	1x	Battery cover
	1x	Battery (separate package)
	1x	TX30 offset screwdriver
	1x	TX20 offset screwdriver
	1x	Unpacking slip
	1x	Quick installation guide
	1x	Instruction sheet

Scope of delivery of connection set (optional accessory)

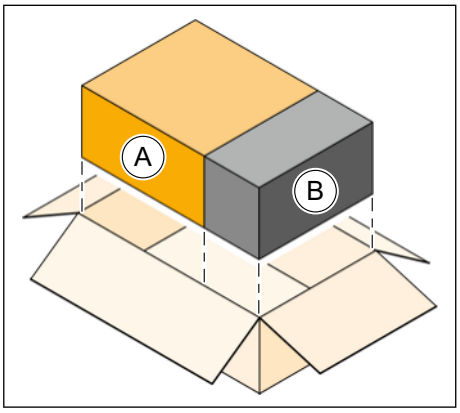
	1x	Coupling box
	1x	Cable adapter
	1x	Power supply unit (for coupling box)

	1x	Network cable
	3x	Hook-and-loop strap

5.3 Unpacking

5.3.1 Packaging concept

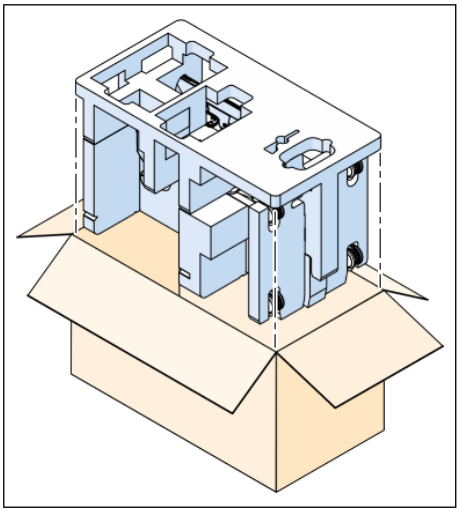
Scanner



The scanner (A) with accessories is delivered with one set of disposable sleeves (B) in a common outer packaging.

The box (A) for the scanner is in an aluminum bag.

Mobile display unit (optional)



The optional mobile display unit is delivered in a separate outer packaging on a pallet. This contains the mobile stand, the AIO monitor, the cover parts and accessories.

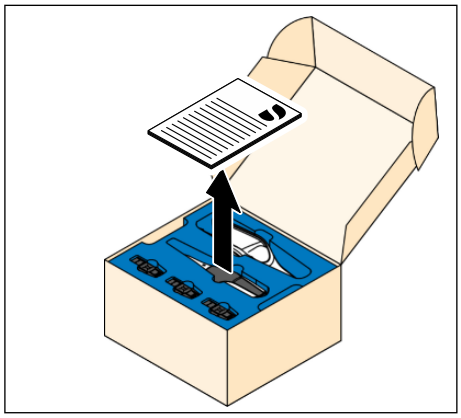
5.3.2 Unpacking the scanner

Outer packaging

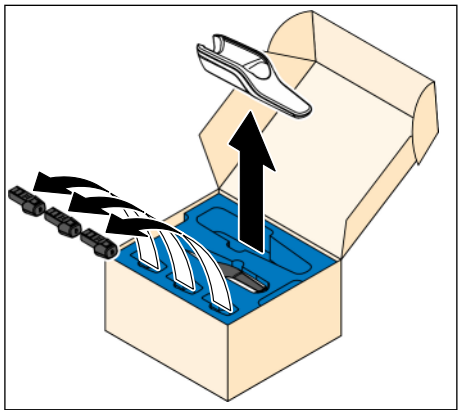
➢ Open the outer packaging and take out the two boxes.

Box 1 in the aluminum bag: scanner

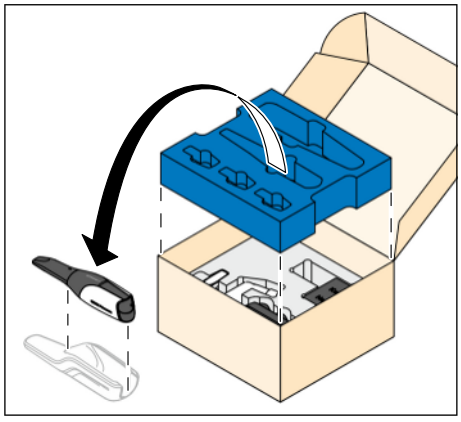
1. Take the box out of the aluminum bag.
2. Open the box at the top.



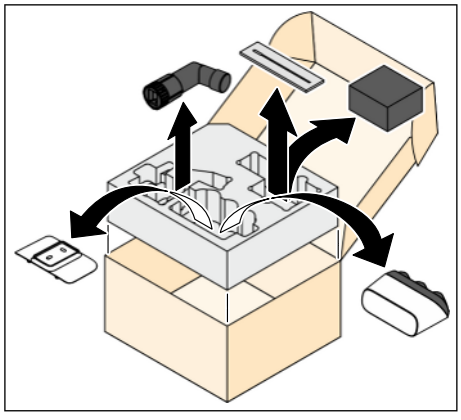
3. Take the quick start guide out of the upper box insert.



4. Take the scanner holder and the 3 batteries out of the upper box insert.



5. Take the scanner out of the upper box insert and set it down in the scanner holder.
6. Lift the upper box insert out of the box.

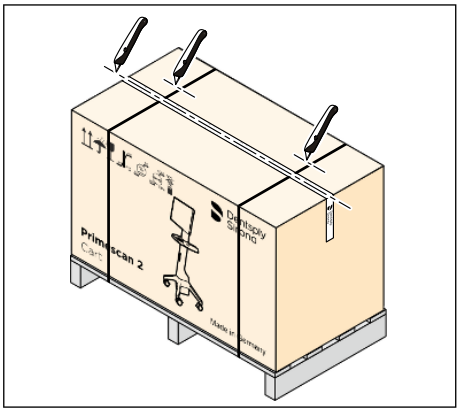


7. Take the accessories out of the upper box insert.

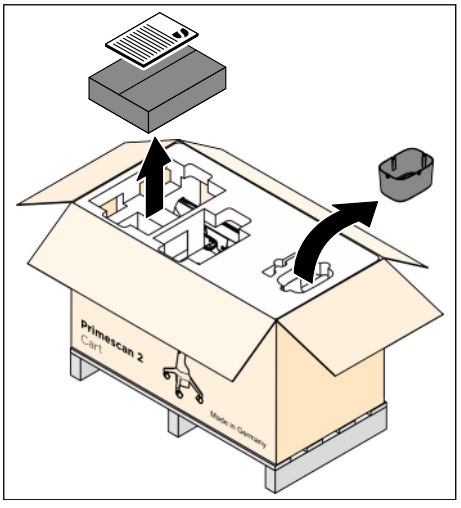
Box 2: Disposable sleeves

1. Open the box.
2. Take the disposable sleeves out.

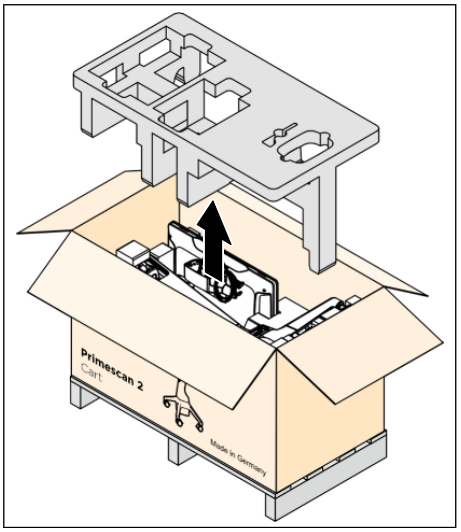
5.3.3 Unpacking the mobile display unit (optional)



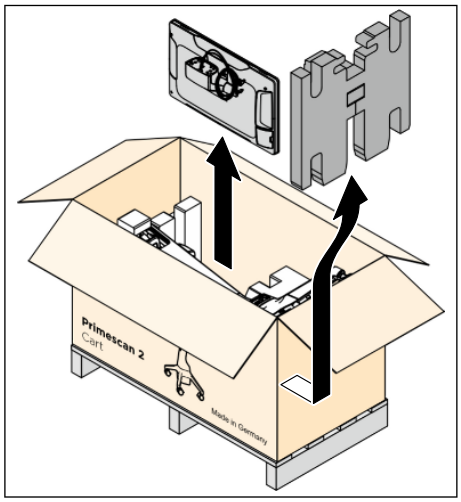
1. Open the box at the top.



2. Take the charger cover and the accessories box with the quick installation guide out of the upper part of the packaging.

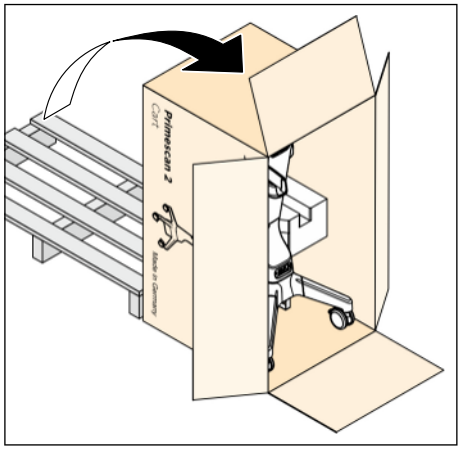


3. Lift the upper part of the packaging out of the box.

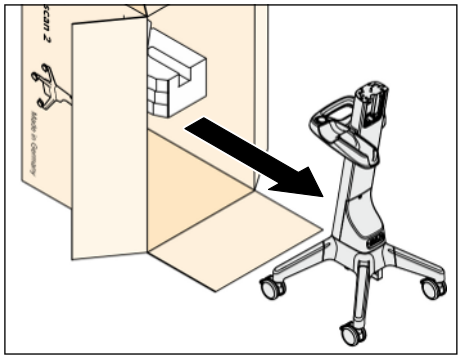


4. First push the clamping part aside out of the battery compartment of the mobile stand and then lift it off.
5. Take the bag with the AIO monitor out of the lower part of the packaging.

IMPORTANT
Place the bag with the AIO monitor carefully onto a level surface with the monitor facing down so that it is not damaged.



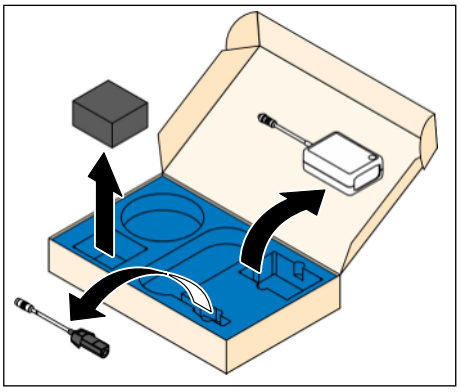
6. Rotate the packing box 90° to an upright position so the wheels of the mobile stand face the floor.



7. Take the mobile stand out of the lower part of the packaging.

5.3.4 Unpacking the connection set (optional)

1. Open the box at the top.



2. Take all parts of the connection set out of the box insert.

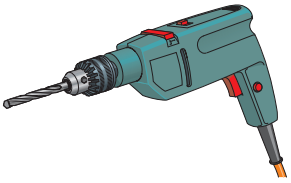
5.3.5 Disposal of packaging materials

The packaging must be disposed of in compliance with the relevant national regulations. Observe the regulations applicable in your country.

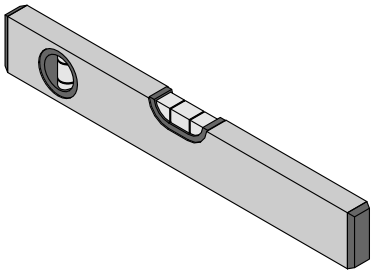
5.4 Installation

5.4.1 Installing the wall holder for charger

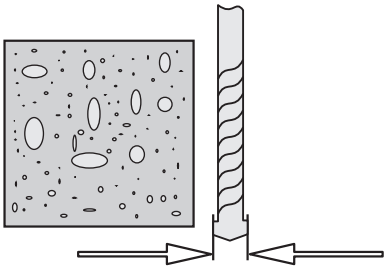
Required tools



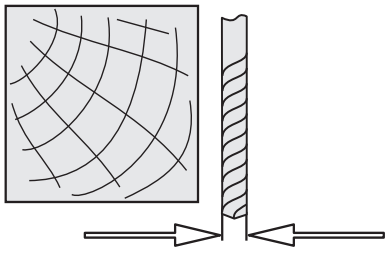
- Drill or hammer drill, depending on the underground



- Spirit level



- Masonry drill bit 5 mm

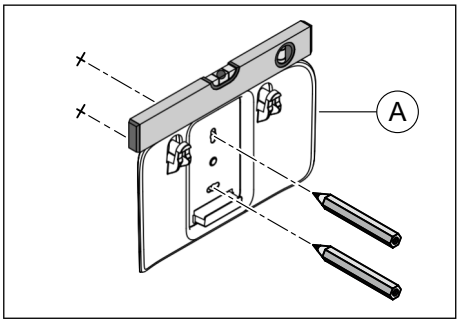


- Wood drill bit 2 mm

Mounting the wall holder for charger

IMPORTANT
Ensure that in the area of the wall holder mounting site there are no cables above or below the plaster.

1. Find a suitable place for mounting the wall holder of the charger. Note the limited length of the power supply cable. It must be possible to plug the power supply unit of the charger into a nearby socket.



2. Hold the wall holder (A) at the desired mounting site and align it horizontally using a spirit level.
3. Mark the two drilling holes on the wall with a pen.
4. Set the wall holder down.
5. Drill the two holes depending on the type of attachment:
   - For mounting with the supplied S3 screw anchors, use a ⌀5mm masonry drill bit to drill holes at least 35 mm deep.
   - For a wooden wall use a ⌀2mm wood drill bit to drill holes at least 15 mm deep.
6. **For fastening with screw anchors:** Insert the anchors in the drill holes.
7. Fasten the wall holder firmly to the wall with two screws with washers.

5.4.2 Installation of charger and scanner (cordless)

⚠ WARNING

Hazard for patient and user

If you do not use freely accessible sockets, there is a risk of injury to patients and users.

➢ Use only sockets that are freely accessible at all times. This ensures that power can be disconnected quickly.

⚠ CAUTION

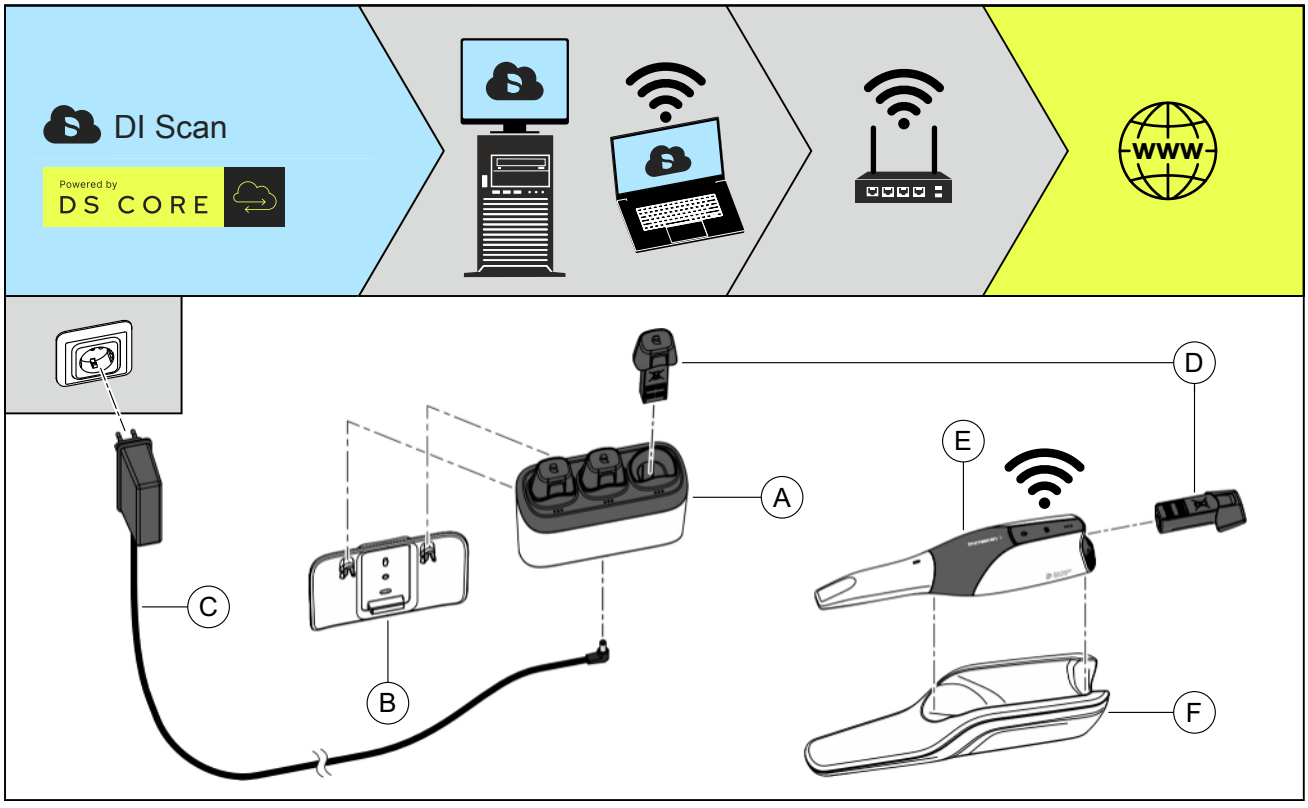
Placing the scanner holder

The scanner holder must be placed on a flat, horizontal surface inside or outside of the patient environment.

NOTICE

The Primescan™ 2 scanner is a high-precision optoelectronic scanning instrument for non-contact impression taking which requires careful handling. Incorrect handling (impacts, dropping) leads to failure of the scanner.

➢ Always store the sensitive scanner in its holder!



1. Insert the charger (A) into the wall holder (B) from above or place it on a flat surface outside the patient area.
2. Plug in the power supply (C) of the charger.

IMPORTANT

Do not mix up the power plugs

Use the power supply unit with angled plug supplied with the charger. The power supply unit of the optional connection set has a straight plug and should not be used for the charger.

3. Plug the power supply unit (C) into the socket.
4. Charge the battery (D):
   Remove the protective strip on the battery contacts and insert the battery into one of the charging slots on the charger.
   Up to three batteries can be charged simultaneously.
   The charge level is displayed on an LED display on the respective charging slot (see the table in section "Using batteries, charger and cable adapter" [→ 78]).
5. Take the charged battery out of the charger and put it carefully into the scanner (E).
   The battery is held in the scanner magnetically.
   When the battery is inserted, the charge level is continuously displayed on the scanner.
6. Place the scanner in the scanner holder (F).

Integration into the practice network (onboarding)

Follow the directions in the section "Integration into the practice network (onboarding)" [→ 74] to connect the scanner with the practice network and make the unit available in your DS Core environment.

5.4.3 Installation of mobile display unit (optional)

⚠ WARNING

Hazard for patient and user

If you do not use freely accessible sockets, there is a risk of injury to patients and users.

➢ Use only sockets that are freely accessible at all times. This ensures that power can be disconnected quickly.

⚠ CAUTION

Trip/fall hazard

When using the mobile display unit, there may be a trip/fall hazard.

➢ Lay the cable so that there is no risk of tripping.
➢ Fasten the supply cable so that it remains secured at all times.
➢ Hang cables that are too long in loops on the cable holder at the back of the mobile display unit.

⚠ CAUTION

Use only the power cable and network cable supplied by Dentsply Sirona for operating the mobile display unit.

⚠ CAUTION

Risk of fire or chemical burns

Improper handling of the battery used in this unit can lead to a risk of fire or chemical burn.

➢ Do not dismantle the battery, allow it to heat up above 60 °C or burn it.
➢ The battery must be replaced only by a spare part provided by the manufacturer. Use of other batteries can lead to a risk of fire or explosion.

⚠ CAUTION

Connect only the supplied charger to the charger interface of the mobile display unit.

IMPORTANT

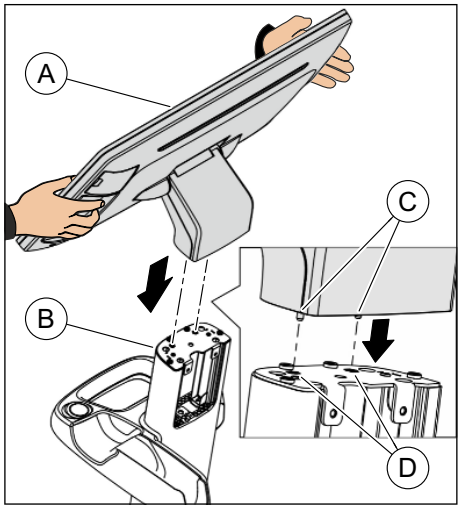
The charger interface has low voltage. Mount the charger with wall holder on the charger interface or attach the cover to the charger interface to prevent the user or patient from touching the charger interface.

Required tools (included in scope of delivery)

- Torx® TX30 offset screwdriver
- Torx® TX20 offset screwdriver

Installing the AIO monitor

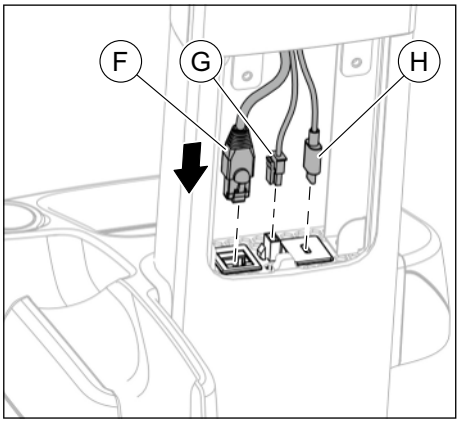
✓ The mobile stand, AIO monitor, mounting material and tools are unpacked.



1. Set the AIO monitor (A) on the mobile stand (B).
Make sure that the two guide bolts (C) of the AIO monitor are completely inserted into the drill holes (D) of the mobile stand.
Make sure not to pinch the connection cable of the AIO monitor.

↳ The AIO monitor is held by the guide bolts on the mobile stand. It does not need to be held by hand for the remaining assembly.

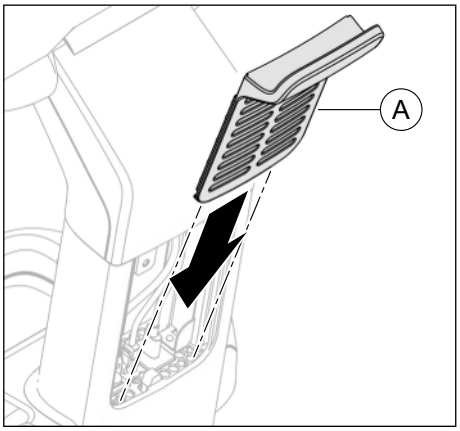
2. Screw the AIO monitor firmly onto the mobile stand using the included M6x16 screw (E).
Use the included Torx TX30 offset screwdriver.



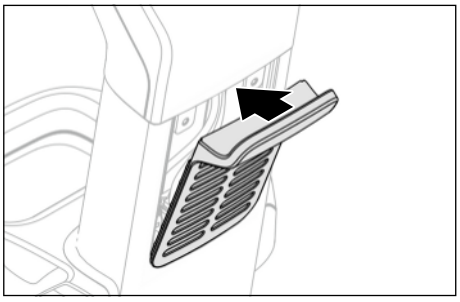
3. Connect the following cables of the AIO monitor to the respective connections on the mobile stand:
   - Network cable (F)
   - Power supply (G)
   - USB cable (H)

Attach the monitor interface cover

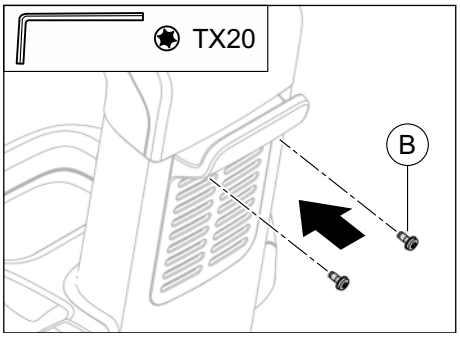
✓ The AIO monitor is installed and the cables are connected to the mobile stand.



1. Set the cover (A) with the two flaps onto the lower edge of the recess of the mobile stand.



2. Flip the cover (A) up on the mobile stand.

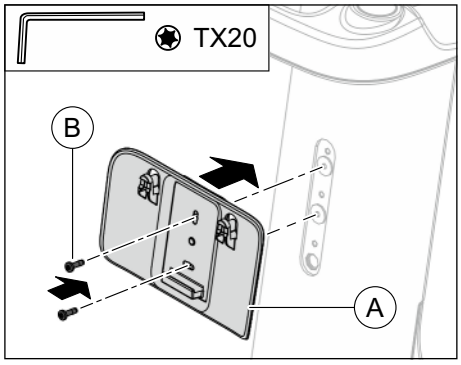


3. Screw the cover (A) firmly onto the mobile stand using the two included M4x10 screws (B) and washers.
   Use the included Torx TX20 offset screwdriver.

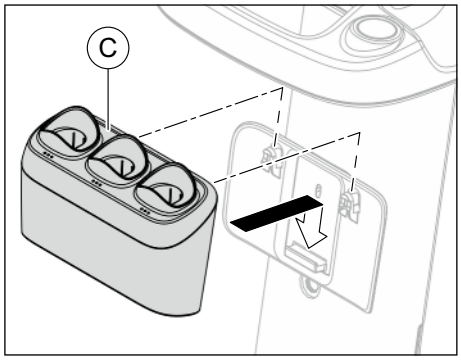
Installing charger or cover at the charger interface

As an alternative to wall installation, you can also install the charger for the scanner batteries directly on the mobile display unit. There is a charger interface on the front of the mobile display unit for this.

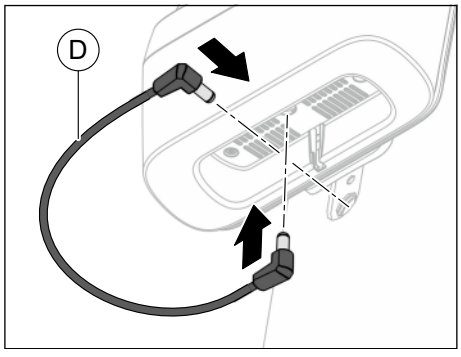
Close the charger interface with the included cover if it is not used.



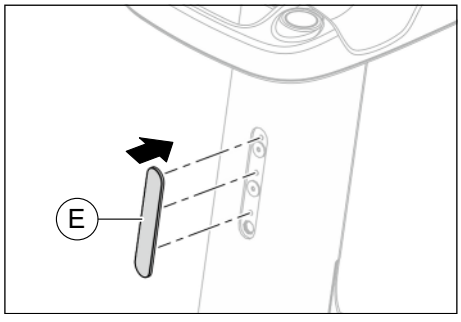
1. Place the wall holder (A) for the charger at the charger interface so that the two drill holes of the wall holder align with the drill holes at the interface.
2. Screw the wall holder firmly onto the interface using the two enclosed screws (B).
   Use the enclosed Torx TX20 offset screwdriver.



3. Insert the charger (C) into the wall holder.



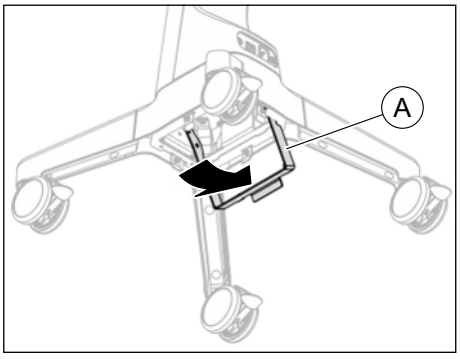
4. Connect the power connection of the charger to the power connection of the charger interface. Use the included power cable (D) with angled plugs.



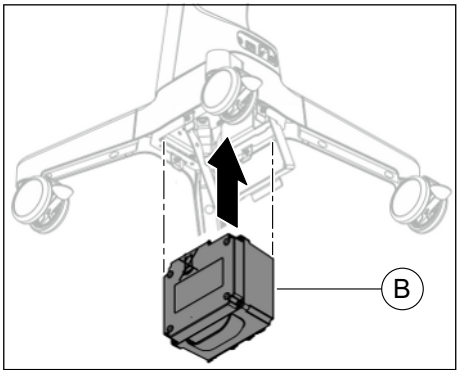
or

➢ Close the charger interface with the included cover (E).

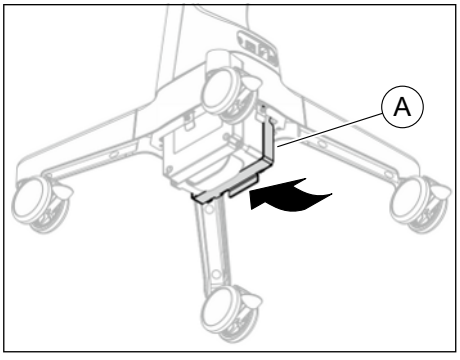
Inserting the battery



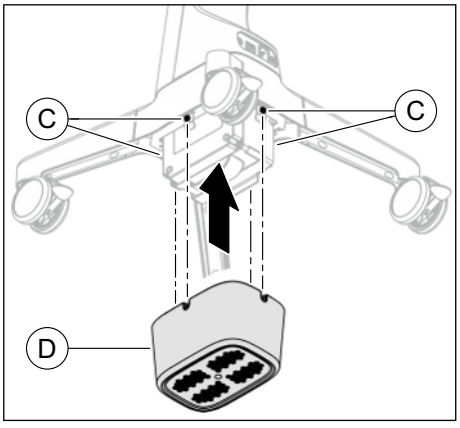
1. Swivel the attachment bracket (A) to the side until it clicks into place.



2. Insert the battery (B) from below with the electrical connection facing upward into the battery compartment as far as it will go.
   ↳ The battery is held in the battery compartment by the guide bolts. It does not need to be held by hand for the remaining assembly.

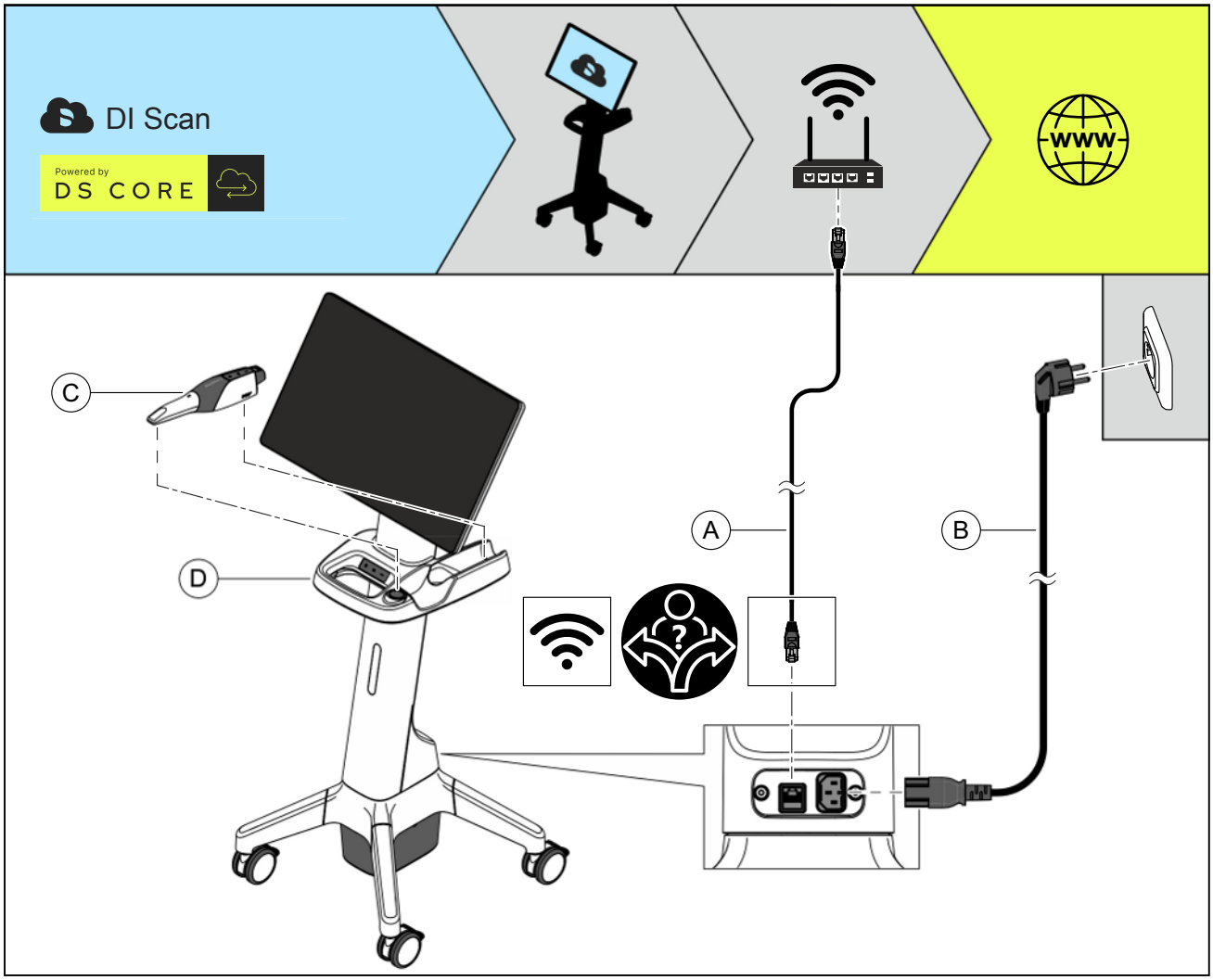


3. Swivel the attachment bracket (A) back down until it clicks into place.



4. Loosen the four pre-mounted M4 x 10 screws (C) on the battery compartment (approx. 5 rotations).
   Use the enclosed Torx TX20 offset screwdriver.
5. Slide the enclosed battery cover (D) onto the four pre-mounted screws (C).
6. Screw the battery cover (D) on firmly with the four pre-mounted screws (C).
   Use the enclosed Torx TX20 offset screwdriver.

Connecting the cable



1. Ensure that the mobile display unit is switched off.
2. **Only for cable operation:** Connect the mobile display unit with a network connection of the practice network using the network cable (A).
3. Connect the mobile display unit to a network socket using the network cable (B).
   ↳ The battery of the mobile display unit will be charged.
4. Check the plug connections of the power supply and the mobile display unit.
5. Place the scanner (C) into the scanner holder of the mobile display unit.

Integration into the practice network (onboarding)

Follow the directions in the section "Integration into the practice network (onboarding)" [→ 74] to connect the mobile display unit with the practice network and make the unit available in your DS Core environment.

5.4.4 Installation in wired operating mode (optional)

⚠ WARNING

Hazard for patient and user

If you do not use freely accessible sockets, there is a risk of injury to patients and users.

➢ Use only sockets that are freely accessible at all times. This ensures that power can be disconnected quickly.

⚠ CAUTION

Tripping/falling hazard

With wired operation, there may be a risk of tripping.

➢ Lay the cable in such a way that there is no risk of tripping.

➢ Fix the supply cable so that it remains in place at all times.

⚠ CAUTION

Only use the power supply unit and power cable supplied by Dentsply Sirona for operating the connection set.

⚠ CAUTION

Use only the power cable and network cable supplied by Dentsply Sirona for operating the mobile display unit.

NOTICE

The Primescan™ 2 scanner is a high-precision optoelectronic scanning instrument for non-contact impression taking which requires careful handling. Incorrect handling (impacts, dropping) leads to failure of the scanner.

➢ Always store the sensitive scanner in its holder!

NOTICE

Risk of damage from pulling on the scanner cable

If you pull on the cable itself in order to unplug it or to check the plug connection, you will damage the cable.

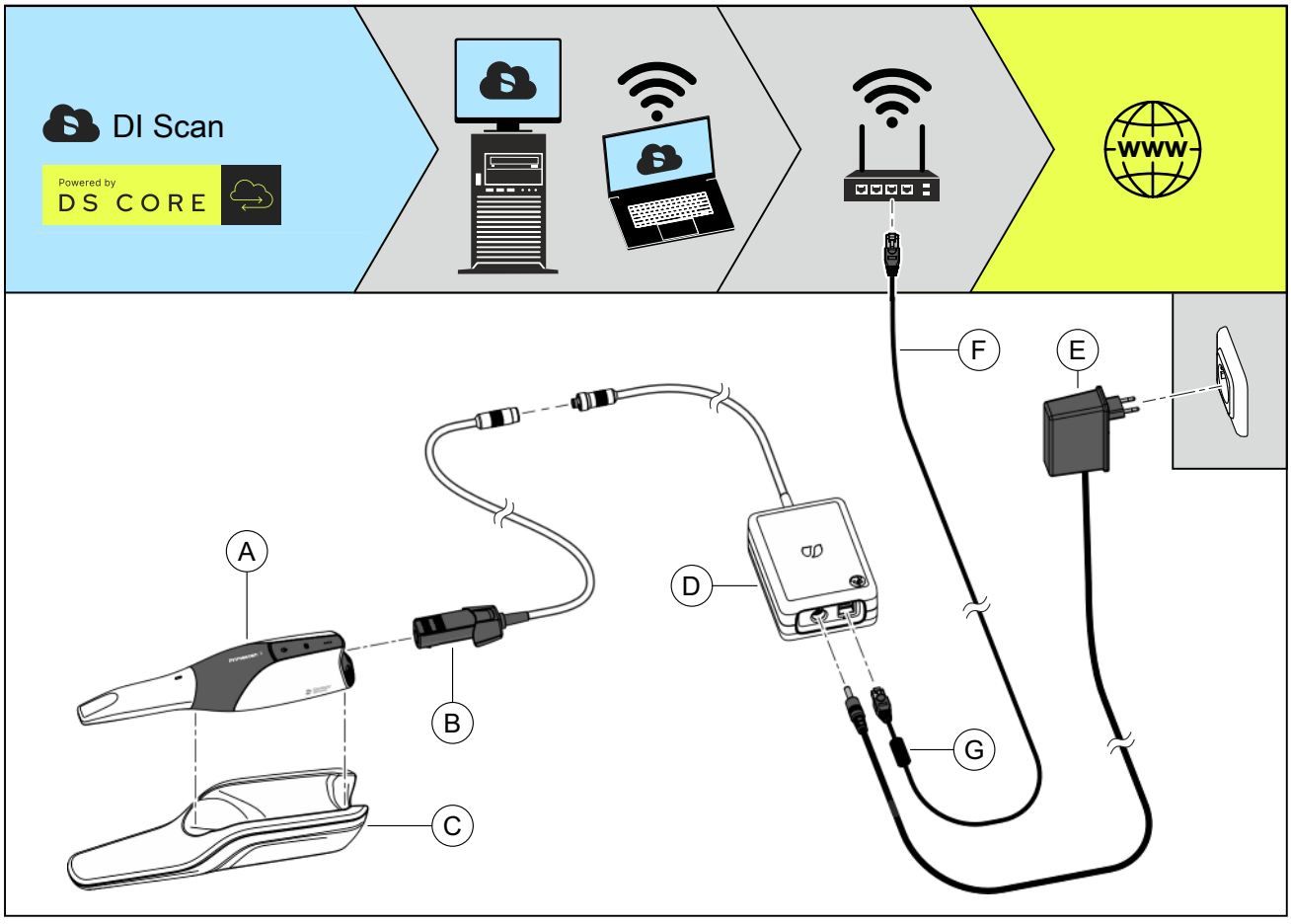
➢ Never pull on the cable.

When using the connection set (optional)

⚠ CAUTION

Placing the scanner holder

The scanner holder must be placed on a flat, horizontal surface inside or outside of the patient environment.



1. Guide the cable adapter (B) carefully into the scanner (A) until it clicks audibly into place.
2. Place the scanner (A) into the scanner holder (C).
3. Connect the plug of the cable adapter (B) to the connection of the coupling box (D).
4. Connect the coupling box (D) to a network connection of the practice network using the network cable (F).
   Ensure that the cable side with the ferrite core (G) is connected to the coupling box.
5. Plug in the power supply (E) to the coupling box (D).

IMPORTANT

Do not mix up the power plugs

Use the power plug with straight plug supplied with the connection set. The power plug of the charger has an angled plug and should not be used for the coupling box.

6. Plug the power supply unit (E) into a network socket.
7. Check the plug connections to the mains connection and the scanner. The scanner always remains connected.
   ↳ As soon as the scanner is installed in cable operation, it automatically switches on.
   The scanner is continuously ready for use in cable operation and does not need to be switched on manually.

Integrating the scanner into the practice network (onboarding)

Follow the directions in the section "Integration into the practice network (onboarding)" [→ 74] to connect the scanner with the practice network and make the unit available in your DS Core environment.

When using the Primescan™ 2 Cart mobile display unit (optional)

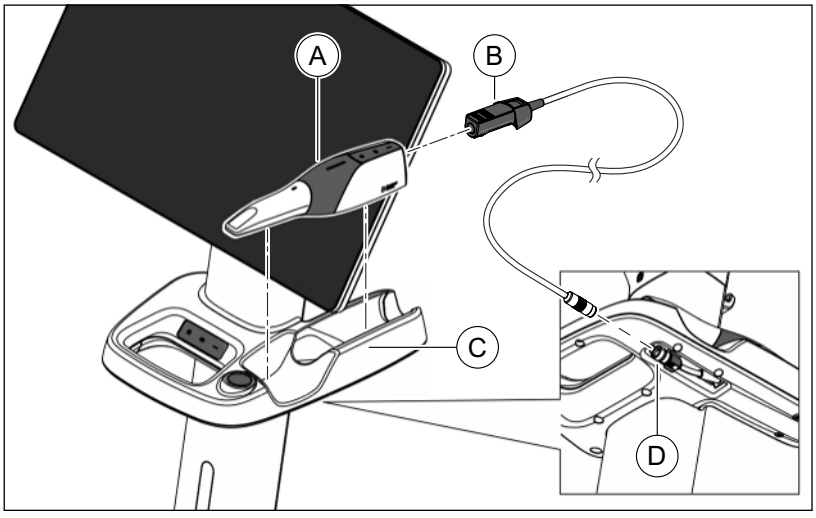
NOTICE

Risk of damage from pulling on the scanner cable

If the mobile display unit is moved by pulling on the scanner cable, there is a risk of damage to the cable, scanner and display unit.

➢ Never pull on the scanner cable to move the mobile display unit.

➢ Always hold the mobile display unit by the handle to move it.



1. Ensure that the mobile display unit is switched off.
2. Guide the cable adapter (B) carefully into the scanner (A) until it clicks audibly into place.
3. Place the scanner (A) into the scanner holder of the mobile display unit (C).
4. Connect the plug of the cable adapter (B) to the coupling connection (D) of the mobile display unit.
5. Check the plug connections on the scanner. The scanner always remains connected.
   ↳ As soon as the scanner is installed in cable operation, it automatically switches on.
   The scanner is continuously ready for use in cable operation and does not need to be switched on manually.

Integrating the mobile display unit into the practice network (onboarding)

Follow the directions in the section "Integration into the practice network (onboarding)" [→ 74] to connect the mobile display unit with the practice network and make the unit available in your DS Core environment.

5.5 Initial startup

5.5.1 Switching the units on

NOTICE

Do not put the unit into operation at low temperatures!

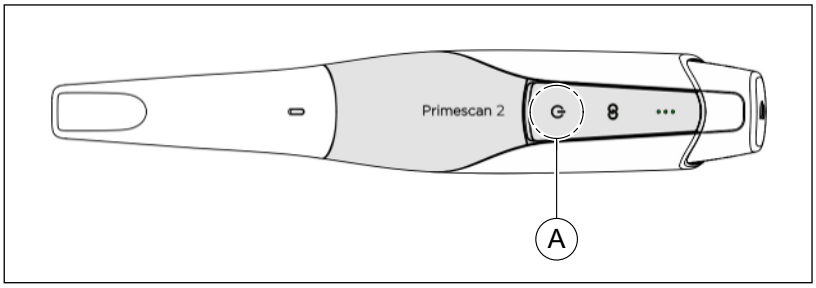
If you move the unit to the operating site from a cold environment, condensation may form and result in a short circuit.

✓ Install the unit at room temperature.

➢ Wait until the unit has reached room temperature and is absolutely dry (for at least one hour)

The unit is dry and can be put into operation.

Using the Primescan™ 2 intraoral scanner without a cable



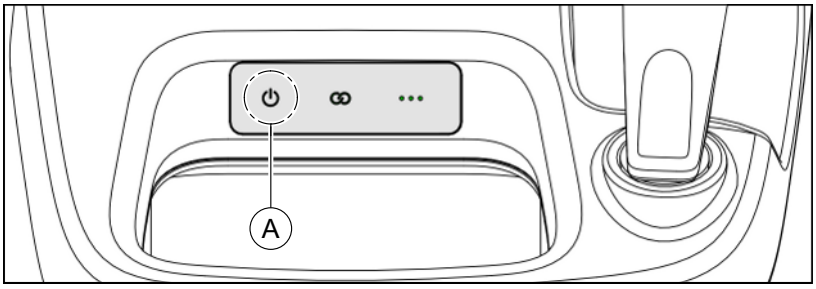
✓ A charged battery is in the scanner. The charge level of the battery is displayed continuously on the scanner.

➢ Switch the scanner on by pressing the ON/OFF button (A).

Using the Primescan™ 2 intraoral scanner with a cable

➢ The scanner is continuously switched on in cable operation as long as it is connected to the mobile display unit or connection set.

Primescan™ 2 Cart mobile display unit



✓ Before switching it on, you can display the battery charge level by pressing the ON/OFF button briefly.

➢ Switch the mobile display unit on by pressing and holding (approx. 1 sec) the ON/OFF button (A).

5.5.2 Integrating units into DS Core (onboarding)

Powered by DS CORE

The unit can be used only in connection with the DS Core cloud platform. You must have a DS Core account for this.

IMPORTANT

Further information on DS Core

Find information on using the cloud platform DS Core in the FAQ on the DS Core portal www.dscore.com in the *"Feedback & Support"* section.

To make the unit available in the DS Core environment, it must first be integrated into DS Core via the practice network.

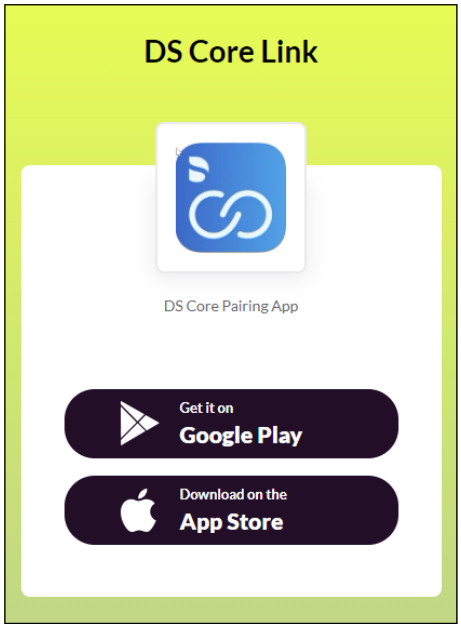
The DS Core Link application for Android and iOS aids you in this procedure. Following the following steps:

✓ You have the credentials for your DS Core access at hand.

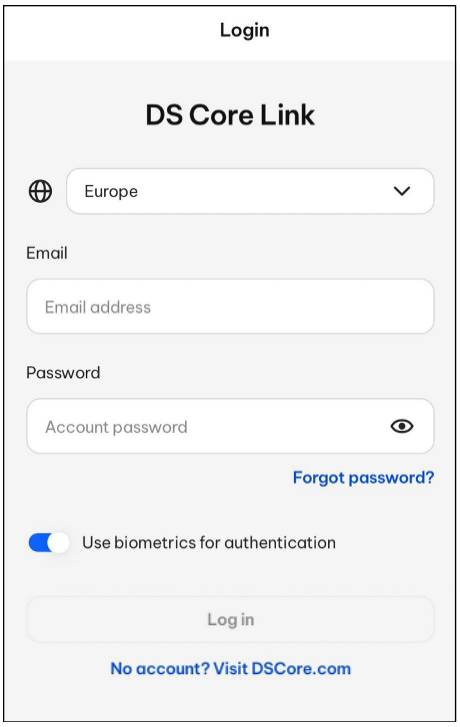
✓ You have a mobile end device with the Android operating system (Android 13 or higher) or with iOS operating system (iOS 14 or higher) and an integrated camera at hand.

✓ The mobile end device is connected to the internet.

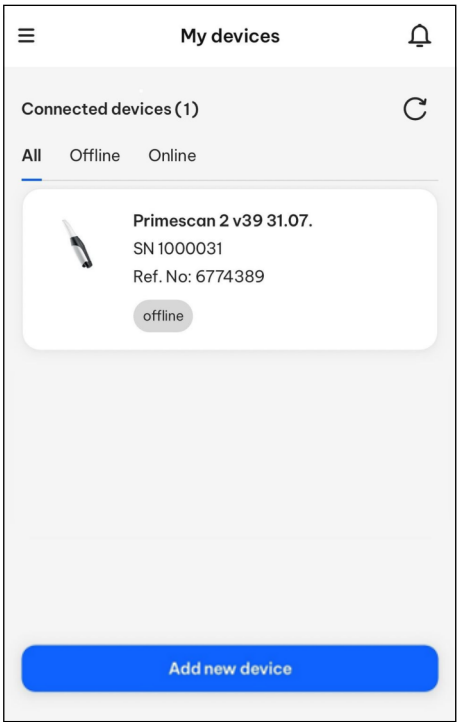
1. Scan the QR code displayed at the left with your mobile end device. Use the integrated scan function for QR codes or a suitable app for this.



   ↳ You will be taken to a selection page for your operating system.
2. Select the operating system of your mobile end device.
   ↳ You will be taken to the corresponding DS Core Link download page.
3. Install DS Core Link.
4. Start DS Core Link.
   ↳ A login window first appears when starting.



5. Select your region.
6. Enter the login data for your DS Core account.
7. Complete entry by clicking on the *"Log in"* button.



8. Click on the *"Add new device"* button.
9. Switch the unit on by pressing and holding the ON/OFF button for approx. 3 seconds.
   ↳ The booting process is completed when the ON/OFF button lights up green.
10. At the initial start, the unit automatically switches to onboarding mode after approx. 3 minutes.

or

➢ Switch to onboarding mode manually by pressing and holding the Connect key for approx. 10 seconds.
   ↳ The Connect key flashes blue when the unit is in onboarding mode.

11. Follow the instructions for onboarding in the app.
12. The unit is now available in your DS Core environment.

IMPORTANT

Repeat this procedure in the following cases:

- Your WiFi access data have changed.

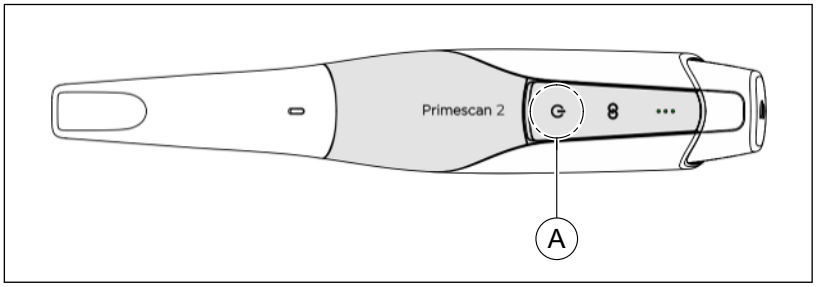
- You wish to reconnect the unit with your practice network or your DS Core access.

IMPORTANT

At initial startup or after mechanical or thermal stress, e.g. due to transport, the user should calibrate the unit as per section "Calibrating the scanner" [→ 99].

5.5.3 Switching the units off

Using the Primescan™ 2 intraoral scanner without a cable



✓ The scanner is not in acquisition mode.

➢ Switch the scanner off by pressing the ON/OFF button (A).

IMPORTANT

Do not remove the battery when the unit is switched on.

IMPORTANT

Emergency shutdown

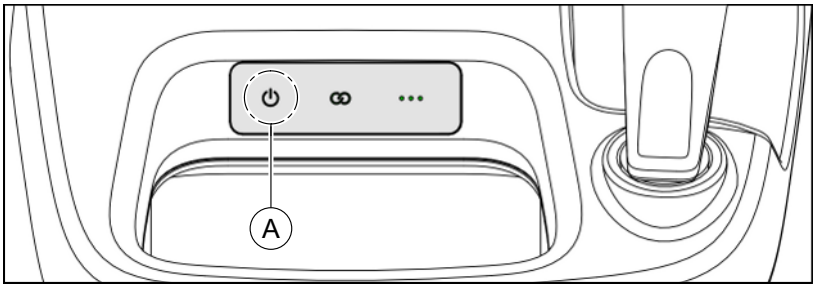
The scanner has an emergency shutdown mechanism.
Use the emergency shutdown mechanism only if the system cannot be switched off by pressing the ON/OFF button.

➢ Press and hold the ON/OFF button for > 5 sec. to trigger the emergency shutdown mechanism.

Using the Primescan™ 2 intraoral scanner with a cable

The scanner is continuously switched on in cable operation as long as it is connected to the mobile display unit or connection set.

Primescan™ 2 Cart mobile display unit



➢ Switch the mobile display unit off via the corresponding software function.
You can find further information about the software in the user manual.

or

➢ Switch the mobile display unit off by pressing and holding (approx. 1 sec.) the ON/OFF button (A).

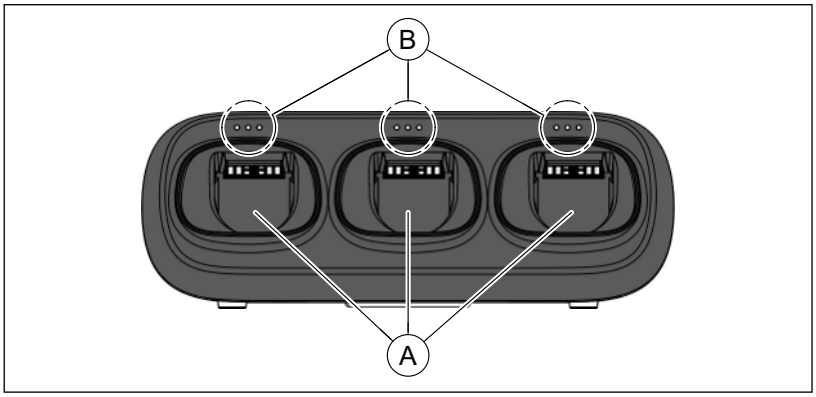
IMPORTANT

Emergency shutdown

The mobile display unit has an emergency shutdown mechanism. Use the emergency shutdown mechanism only if the system cannot be switched off by holding the ON/OFF button (approx. 1 sec.).

➢ Press and hold the ON/OFF button for > 5 sec. to trigger the emergency shutdown mechanism.

5.5.4 Using the batteries, charger and cable adapter



Operating the charger

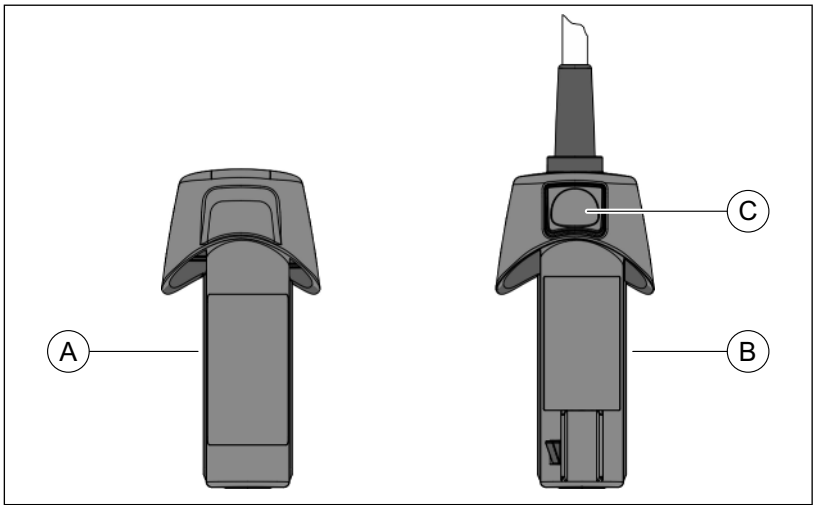
Put the battery to be charged in a free charging slot (A) on the charger. Up to three batteries can be charged simultaneously. The status display (B) on the charging slot shows information on the charge level of the respective battery.

Take the charged battery out to use it or keep it in the charger device until needed.

Charger status displays

LED display		Description
	1 LED flashes green	Battery is charging. Battery charge level: low
	1 LED lights up green 1 LED flashes green	Battery is charging. Battery charge level: medium
	2 LED light up green 1 LED flashes green	Battery is charging. Battery charge level: high
	3 LED light up green	The battery is fully charged.

LED display		Description
	No LED is lit	Charging error: • Check whether the battery is inserted completely into the charging slot. • Check the charging slot for foreign bodies. • Battery is defective: Contact service.
	On all charging slots: No LED is lit	Charger error: • Disconnect the charger from the mains and let it cool down. • Charger is defective: Contact service.



Use of the batteries

The batteries may be stored only in the charger or when inserted in the scanner.

The batteries are rotation proof and can be inserted into the charger or the scanner only in one direction. When inserted completely in the scanner, the batteries are held in place by a magnet.

Using the cable adapter

The cable adapter (B) is rotation proof and can be inserted into the scanner only in one direction. When inserted completely in the scanner, the cable adapter clicks mechanically into position.

Press the unlock button (C) to unlock it and take the cable adapter out of the scanner.

6 Operation

6.1 Basics

The scanner acquires images that are moved during the ongoing measurement in spatial relation to each other (registration).

During the acquisition and then during the ongoing registration process, a distinctive sound can be heard.
If the registration cannot be conducted, the acquisition flow is suspended. You are informed of this by means of a sound. This sound is different from the sound emitted during successful acquisition. You can configure the volume and type of sound (melody) in the software.

IMPORTANT

Registration error

Should a registration error occur, you must return to an already recorded point.
First practice this procedure on the model and then on intraoral areas.

➢ Move the scanner to a position where a successful acquisition was made. A point in the occlusal area that has already been scanned is best.

↳ You will be able to hear the sound for registered acquisitions.

➢ Continue the acquisition.

6.2 Software for acquisition

Powered by DS CORE

For making acquisitions, the cloud-based DI Scan scan application based on DS Core is available. The software can be run on any digital end device with internet browser, internet connection and connection to the practice network.

The Primescan™ 2 intraoral scanner can be used with DI Scan software version 1.0 or higher.

Optionally, Dentsply Sirona offers the Primescan™ 2 Cart mobile display unit that is optimally coordinated for operation with the Primescan™ 2 intraoral scanner.

IMPORTANT

Further information on DS Core

Find information on using the cloud platform DS Core in the FAQ on the DS Core portal www.dscore.com in the *"Feedback & Support"* section.

IMPORTANT

Further information on DI Scan

Information on using the DI Scan scan application can be found in the DI Scan Operator's Manual (REF 6822725).

6.3 Optical impressions with the scanner

⚠ WARNING

Risk of injury for those diagnosed with epilepsy

For persons who have been diagnosed with epilepsy, there is a risk of epileptic shock due to the flashing light of the scanner.

➢ Ensure that no direct/indirect or diffuse light from the scanner reaches the eyes of patients who have been diagnosed with epilepsy.

➢ Dentists and dental assistants who have been diagnosed with epilepsy cannot work with the scanner.

⚠ CAUTION

1st degree burns

The ventilation slots of the scanner must not be obstructed.

⚠ CAUTION

Unintended damage after use

After use, store the scanner including holder and connection set outside the patient environment to avoid unintended damage.

⚠ CAUTION

After each use

Reprocess the scanner after each patient.

➢ Follow the instructions for cleaning and disinfecting in the "Cleaning and disinfecting" [→ 94] section to prevent cross-contamination among patients.

⚠ CAUTION

Prevent cross-contamination

The scanner may not be put in the patient's mouth without the disposable sleeve.

⚠ CAUTION

Prevent cross-contamination

Germs can be transmitted to uncontaminated persons via the hands, materials or objects.

➢ For hygiene reasons, wear a new set of disposable gloves for each patient while using the scanner.

⚠ CAUTION

Hot tip of the scanner sleeve!

When switched on, the tip of the scanner sleeve is continuously preheated. The surface temperature of the sleeve can be up to 48 °C when the scanner is in the holder and up to 58 °C when the scanner is deposited in the mobile display unit. This may cause an unpleasant heat sensation on brief contact with skin or mucous membrane in the course of the intended use. These temperatures will not damage the skin or mucous membranes. The temperature sensitivity in the mouth is considerably lower than it is on other skin surfaces. The scanner does not exert pressure on the oral mucosa. Brief contact at temperatures up to 58 °C is therefore classified as non-critical for the patient. If this temperature is unpleasant for the patient, you can wait briefly after taking the scanner from the holder before starting the scan.

⚠ CAUTION

Hot housing surface

While scanning, the housing of the scanner heats up. After a longer period of continuous use, the surface temperature of the scanner can reach up to 54 °C in some areas. This may cause an unpleasant heat sensation on contact with skin. In this case, the scanner can be placed in the holder to cool off. These temperatures will not damage the skin. Temperatures up to 54 °C are therefore classified as non-critical for the patient and the user.

⚠ CAUTION

Potentially hazardous optical radiation

The scanner transmits potentially hazardous optical radiation which may cause harm to the eyes.

➢ During operation, do not look directly at the scanner for long periods.

NOTICE

Possible damage during transport

Use the original packaging of the scanner to transport it. Ensure that the components are properly stowed in the original packaging.

NOTICE

Image brightness

The image brightness during the acquisition is controlled automatically, so that there is always optimum image brightness, largely independent of the distance between the scanner and the tooth.

The surroundings of the tooth to be scanned should be as dimly illuminated as possible. Avoid any type of external light. Switch off the operating light.

IMPORTANT

Do not use cotton rolls in the scan area

Do not use any cotton rolls in the vicinity of the scan area, as they can reduce the precision of the scan and create image interference.

IMPORTANT

Potential switch-off procedure

In the case of several repeated scans of the image fields without model calculation, the scanner can deviate from the calibrated temperature range. In this case, a warning message appears and you need to take a scanning break prior to completing the exposures. Please pause your scan for about as long as the remaining scan would need. The potential switch-off procedure is innocuous for your scanner and is not a malfunction.

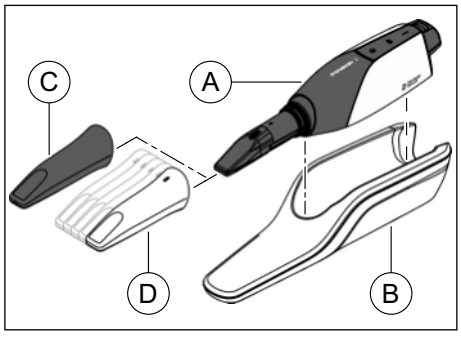
IMPORTANT

Heating up the scanner

The internal scanner heating ensures that condensation does not form during scanning. In cable-free operation (with battery), the heating starts only after the scanner is switched on (ON/OFF button pressed). In cable operation, heating starts immediately after connecting the scanner to the coupling box and connecting the coupling box to the mains using the power supply unit.
The scanner is fog-free after around 5 minutes. This is generally the case by the time navigation in the scan application starts.

Preparing the acquisition

Powered by DS CORE



- ✓ You are logged into DS Core.
- ✓ The scanner is integrated in your DS Core environment.
- ✓ You have selected the patient in DS Core and opened the patient file.

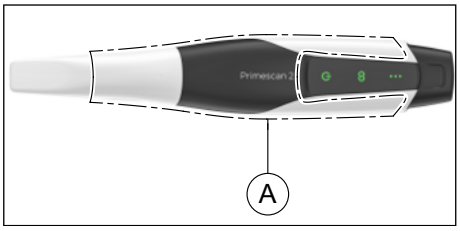
1. Take the scanner (A) out of its holder (B).
2. Take the black protective sleeve (C) off the scanner.
3. Put a new disposable sleeve (D) on the scanner.
   Do this very carefully. Slide the sleeve carefully onto the tube until it clicks into place.
4. Switch on the scanner (see "Switching on the unit" [→ 74]).
5. Return the scanner to the holder if necessary until you start acquisition.

Scan

Powered by DS CORE

- ✓ The patient's teeth have been blow dried.
- ✓ The scanner is ready and switched on.

1. Start the DI Scan scan application from DS Core.
2. Select the scanner that you wish to use for the acquisition in DS Core.
   ↳ The scanner is ready for acquisition.
3. Take the scanner out of its holder.



- As soon as you move the scanner, a live image appears that can be used for orientation in the patient's mouth.

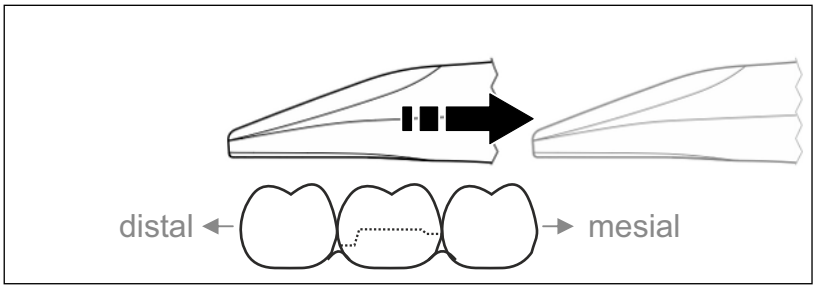
4. Activate the acquisition mode. To do this, tap your finger on the scanner housing (A).
5. Scan the jaw, following the instructions in the following section "Guiding the scanner" [→ 84].
   - As soon as the scanner is guided over a tooth or the gums, data acquisition begins. During the continuous data acquisition, a color 3D model is generated automatically on the monitor.
   - If the automatic data flow is interrupted during acquisition, move the scanner to any area that has already been scanned. Data acquisition will be continued.
6. To stop data acquisition, deactivate the acquisition mode. Tap your finger on the scanner housing (A) again.
7. Place the scanner in the scanner holder.
8. Finish the acquisition process in the scan application to transfer the scanned data to DS Core.
   - The scanner switches off automatically.
     Alternatively, you can switch it off manually by pressing the ON/OFF button.
     In cable operation, the scanner cannot be switched off, it remains continuously switched on.

6.4 Scanner guide

Divide the acquisition into four consecutive sequences:

1. Occlusal
2. Buccal
3. Lingual
4. Proximal

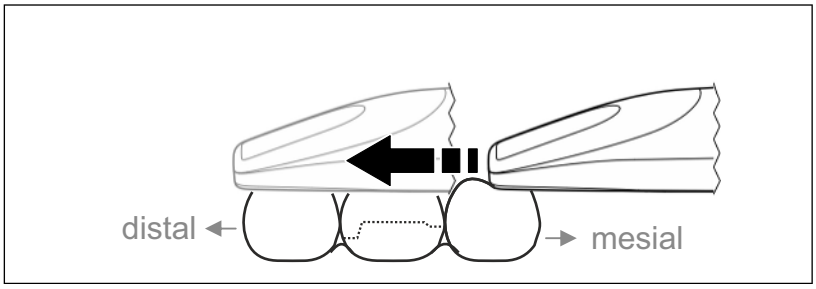
6.4.1 Occlusal scan



Important: Note the distance of the scanner window to the surface to be measured.
The distance must be between 0 - 20 mm (optimal: 2 mm). The scanner should not rest on the teeth or gums.

1. Move the scanner to the starting position. For this purpose, the scanner is in the occlusal view of the tooth closest to the prepared tooth in distal direction.
2. Scan in mesial direction. To do so, move the scanner in occlusal direction from the distal tooth over the prepared tooth to the mesial tooth.

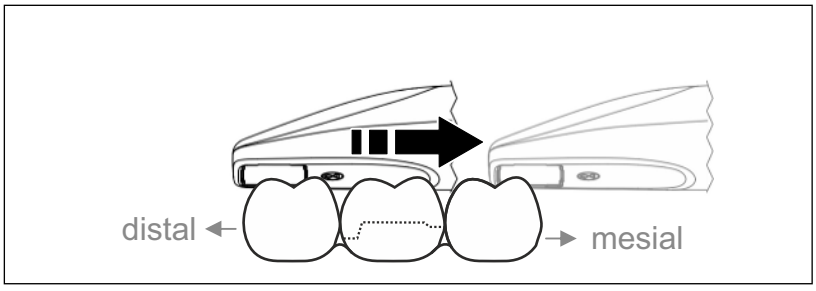
6.4.2 Buccal scan



✓ The scanner is on the adjacent tooth located mesial to the preparation.

1. Rotate the scanner 20° in buccal direction.
2. Guide the scanner over the entire distance in buccal to distal direction over the prepared tooth.

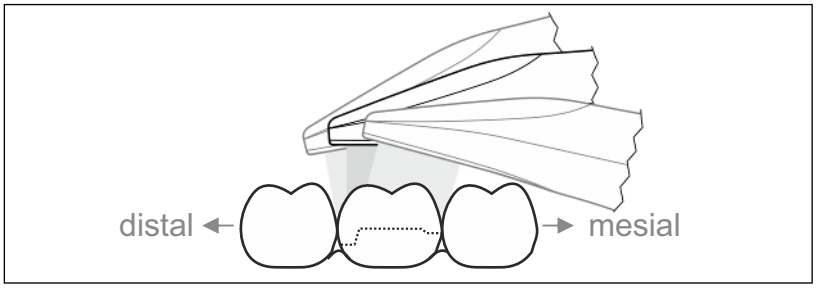
6.4.3 Lingual scan



✓ The scanner is on the distal tooth adjacent to the preparation.

1. Rotate the scanner to maximum 20° in lingual direction.
2. Guide the scanner over the entire distance in lingual to mesial direction over the prepared tooth.

6.4.4 Approximal surface scan



Scan the approximal surfaces of the prepared tooth.

➢ Move the scanner in the occlusal direction to the prepared tooth. Acquire the approximal surfaces in the distal and mesial direction.

6.4.5 Single and multiple buccal registration

The buccal registration establishes the arrangement of jaw images.

✓ The jaw with the preparation is scanned.

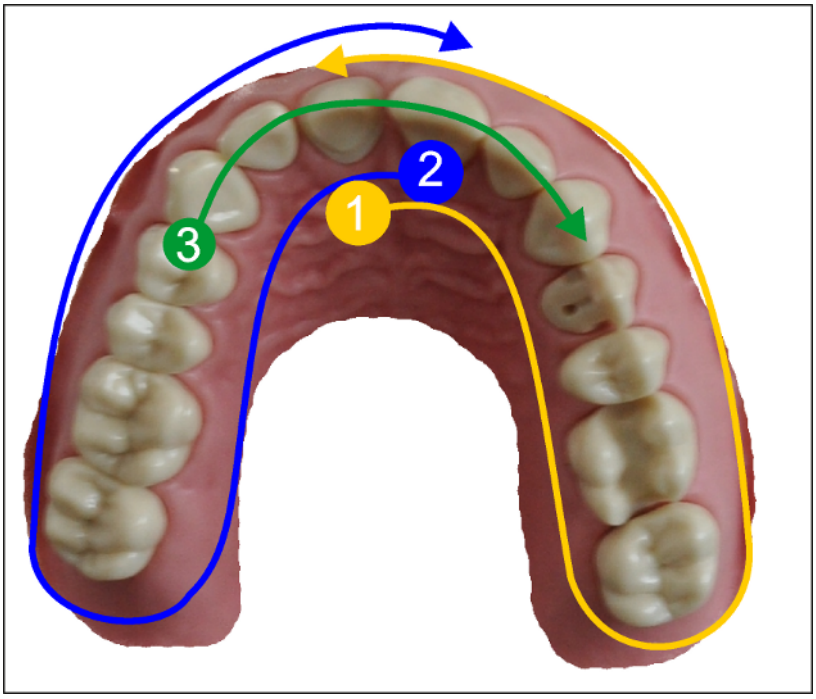
1. Scan the occlusal, buccal and lingual view of the antagonist (see section “Occlusal scan" [→ 84], “Buccal scan” [→ 85] and “Lingual scan” [→ 85]).
2. Perform a buccal scan of the bite block prior to completing the registration. This buccal scan should be carried out near the preparation. To acquire sufficient geometry, capture the teeth of the upper and lower jaw as well as 5 mm of the respective gingival areas.
3. Please complete a buccal scan on both sides for a full jaw scan. For this, use the scanner to complete a buccal scan in each case over the premolars of both quadrants.

Tip: If there are multiple or long-span restorations over several quadrants, we recommend generating several buccal exposures close to the restoration.

6.4.6 Square and full jaw scan

You can use different scanning procedures for scanning a quadrant or a full jaw. Find two procedures as follows to help you start should such help be necessary.

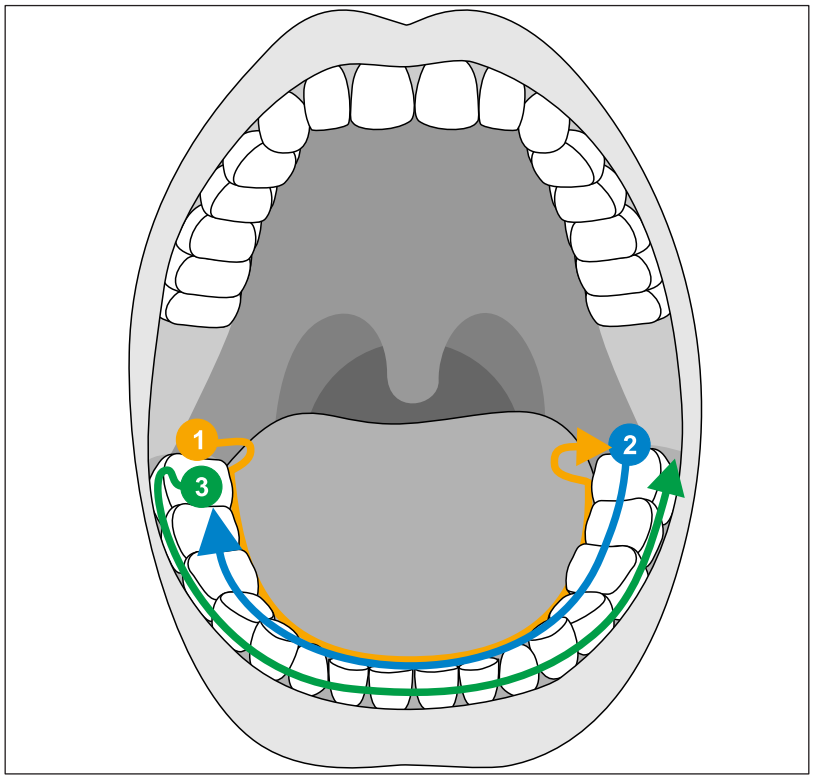
Procedure 1



1. Start with the oral surface of the anterior teeth and move the scanner in the oral direction along the quadrant. Move the scanner over the distal tooth to the vestibular side and track the first quadrant to the anterior teeth. Gently tilt the scanner approx. 30° in the coronal-apical direction.

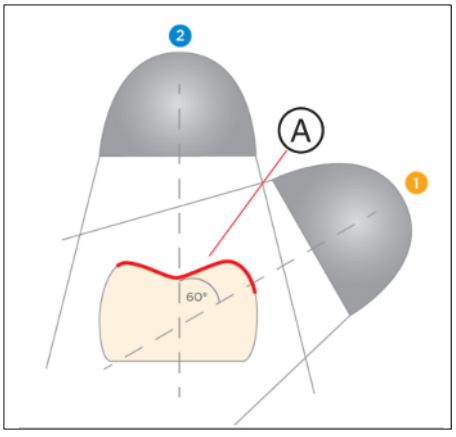
2. Move the scanner as shown below (1) for the second quadrant.
3. Then scan the anterior teeth from cuspid to cuspid in the coronal-apical direction. Ensure that both the labial surface and the oral surfaces are visible.
   Extend this third scan to locations where you can view scan holes.

Procedure 2

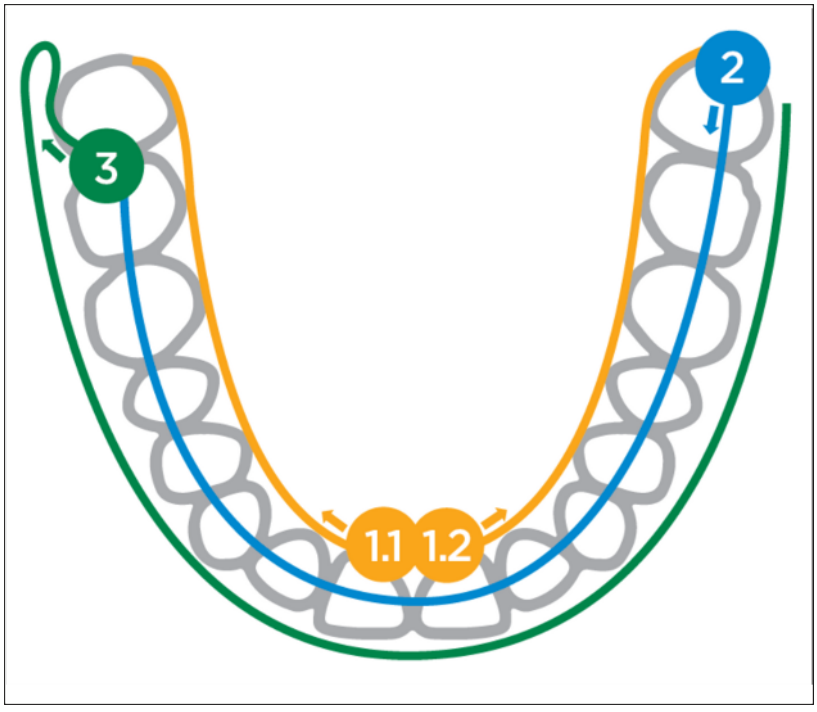


1. Start occlusally on the distal tooth, tilt the scanner approx. 60° in an oral direction and move it orally along the dental arch up to the opposite distal tooth.
2. Guide the scanner occlusally from the distal tooth across the entire dental arch back to the other side.
3. To complete the scan, tilt the scanner approx. 60° in a buccal direction and move it buccally along the entire dental arch.

6.4.7 Scan strategy for edentulous cases



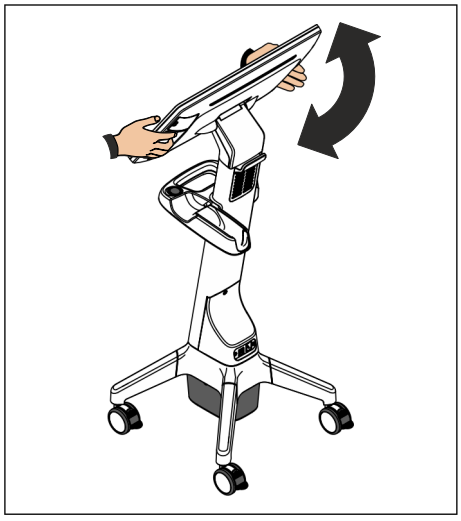
Use the same scan strategy as for a full jaw scan, but split the first run-through. It is important to have overlapping data (A) so that the run-throughs can be joined together.



1. Start from occlusal in the incisal area and tilt the scanner approx. 60° in oral direction and move it orally along the dental arch to the distal area. Repeat this on the opposite side. Make sure that 1.1 and 1.2 overlap at the starting point.
2. Guide the scanner in occlusal direction from the distal area across the entire dental arch back to the other side.
3. To complete the scan, tilt the scanner approx. 60° in buccal direction and move it in buccal direction along the entire dental arch.

6.5 Work with the AIO monitor of the mobile display unit (optional)

6.5.1 Adjusting the position of the AIO monitor



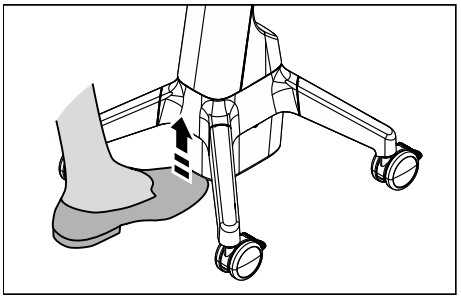
You can tilt the AIO monitor to a position convenient for you.

To move the AIO monitor, there are recesses shaped to fit the fingers on the rear side. To adjust the AIO monitor, always grasp these recesses at the sides with both hands. Grasping with one hand or grasping the top/bottom of the monitor is not intended.

IMPORTANT

Always use both recesses when adjusting the monitor position. This allows you to avoid possible impairment of the adjustment mechanism and maintain the minimum distance from the radio antennas at the upper edge of the AIO monitor.

6.5.2 Operating the foot control



Press the battery cover upward with the tip of the foot to trigger the foot control.

6.5.3 Multi-touch gestures

You can use the multi-touch gestures with and without a glove.

The following gestures can be made:

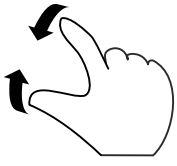
Edit a 3D model with multi-touch

You can edit the 3D model using multi-touch gestures.

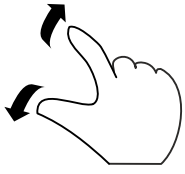
➢ Complete a rotary movement using 2 fingers.
↳ The object is rotated in the plane.

➢ Drag with 1 finger.
↳ The model is rotated out of its current plane.

➢ Drag with 2 fingers in the same direction.
↳ The model is dragged.



➢ Move 2 fingers together.
↳ The object is scaled down.



➢ Move 2 fingers apart.
↳ The object is enlarged.

7 Reprocessing

⚠ CAUTION

After each use

Reprocess the scanner after each patient.

➢ Follow the instructions for cleaning and disinfecting in the "Cleaning and disinfecting" [→ 94] section to prevent cross-contamination among patients.

7.1 Required materials

NOTICE

Approved cleaning agents and disinfectants

Use only cleaning and disinfecting agents which have been approved by Dentsply Sirona!

⚠ CAUTION

Handling cleaning agents and disinfectants

For general handling of the cleaning agents and disinfectants, see the respective safety data sheets or manufacturers' specifications.

7.1.1 Cleaning agents

- Isopropanol, concentration: 70%; (not valid for Australia and New Zealand)
- FD 366 sensitive (Dürr Dental); (valid only for Australia and New Zealand)
- CaviCide™ (Metrex); (not valid for Australia and New Zealand)

7.1.2 Wipe disinfectants (virucidal limited)

- Isopropanol, concentration: 70%; (not valid for Australia and New Zealand)
- FD 366 sensitive (Dürr Dental); (valid only for Australia and New Zealand)
- CaviCide™ (Metrex); (not valid for Australia and New Zealand)

7.1.3 Other materials

- Lint-free, colorless cleaning cloths (clean and dry)

7.2 Components of the scanner

⚠ CAUTION

Risk of cross-contamination

Without the disposable sleeve, the scanner may not be used in the patient's mouth. Cross-contamination may occur if used without a disposable sleeve.

➢ Always put a disposable sleeve on the scanner.

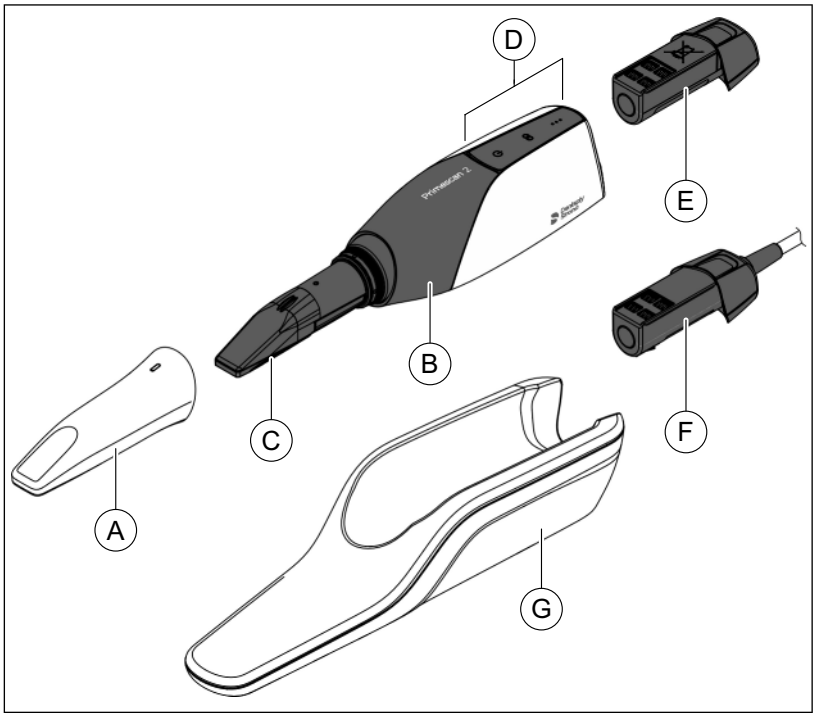
⚠ CAUTION

Risk of injury

The window of the optic tube is made of sapphire crystal and is fragile.

➢ Use the scanner with care so that the window does not crack.

➢ If the window has been broken, the scanner may no longer be used on patients.



A	Disposable sleeve with plastic window	E	Battery
B	Scanner body	F	Cable adapter
C	Scanner head (optic tube with prism and window made of sapphire crystal)	G	Scanner holder
D	Control elements		

7.3 Cleaning and disinfection

⚠ CAUTION

Risk of infection

There is a risk of infection if the scanner is not regularly disinfected.

➢ Immediately after using the scanner, carry out cleaning and disinfection of the scanner.
Follow all reprocessing instructions in the following sections.

⚠ CAUTION

Risk of cross-contamination

Reprocessing the disposable sleeves for multiple use is not permissible. The disposable sleeves may not be reused.

NOTICE

Country-specific requirements

Observe the country-specific requirements.

NOTICE

Visual inspection after reprocessing

Inspect all parts after the cleaning and disinfection process. If parts have visible damage after this process, they must be replaced. Signs of visible damage may include discoloration, corrosion, cracks, and other forms of damage.

Conducting reprocessing

NOTICE

Hygiene processes

Observe the following hygiene processes.

The required steps for reprocessing are described below.

Reprocessing involves the following steps:

- cleaning
- Disinfection

Conduct reprocessing after each patient.

For cleaning and disinfection, **all steps** of the following sub-section must be conducted in sequence.

7.3.1 Cleaning and disinfecting the scanner holder

Follow **all** of the following steps:

Cleaning the scanner holder

1. Use a new lint-free cloth (see "Other materials" [→ 92]).
2. Moisten the cloth thoroughly with cleaning agent (see "Cleaning agent" [→ 92]).
3. Thoroughly wipe down the scanner holder and clean it for at least 1 minute until there is no more visible contamination.

4. Check under good lighting (min. 500 lux) whether the product is visibly clean.
5. If there is visible contamination, repeat the process with a new, thoroughly moistened, lint-free cloth.
6. Dispose of the used cloth.

Disinfection of the scanner holder

1. Use a new lint-free cloth (see "Other materials" [→ 92]).
2. Moisten the cloth thoroughly with disinfectant (see "Wipe disinfectant" [→ 92]).
3. Wipe down the entire scanner holder thoroughly.
4. Ensure that all areas of the scanner holder are thoroughly moistened with disinfectant.
5. Maintain the required reaction time according to the instructions for use of the disinfectant **(at least 5 minutes for isopropanol, at least 3 minutes for CaviCide™)**.
   If necessary, use another thoroughly moistened, lint-free cloth.
6. Dispose of the used cloth.
7. Use a new, clean, lint-free cloth to wipe the entire scanner holder dry after the reaction time to remove the remaining disinfectant.
8. Dispose of the used cloth.

7.3.2 Cleaning and disinfecting the scanner

IMPORTANT
The Primescan™ 2 scanner is a highly sensitive optical device and must therefore be handled with the utmost care.

IMPORTANT
Clean and disinfect the scanner only when the battery/cable adapter is inserted.

Follow **all** of the following steps:

Cleaning the scanner

1. Use a new lint-free cloth (see "Other materials" [→ 92]).
2. Moisten the cloth thoroughly with cleaning agent (see "Cleaning agent" [→ 92]).
3. Thoroughly wipe down the entire scanner body including the protruding part of the battery / cable adapter and clean it for at least 1 minute until there is no more visible contamination.
4. Check under good lighting (min. 500 lux) whether the product is visibly clean.
5. If there is visible contamination, repeat the process with a new, thoroughly moistened, lint-free cloth.
6. Dispose of the used cloth.
7. Detach the disposable sleeve and dispose of it according to country-specific regulations.

Disinfecting the scanner

1. Use a new lint-free cloth (see "Other materials" [→ 92]).

2. Moisten the cloth thoroughly with cleaning agent (see "Cleaning agent" [→ 92]).
3. Thoroughly wipe down the entire scanner body except the optical window.
4. Wipe down the protruding part of the battery / cable adapter thoroughly.
5. Ensure that all areas except the window on the scanner head are thoroughly moistened with disinfectant.
6. Maintain the required reaction time according to the instructions for use of the disinfectant **(at least 5 minutes for isopropanol, at least 3 minutes for CaviCide™)**.
   If necessary, use another thoroughly moistened, lint-free cloth.
7. Dispose of the used cloth.
8. Use a new, clean, lint-free cloth to wipe the entire scanner including the optical window dry after the reaction time to remove the remaining disinfectant.
9. Dispose of the used cloth.
10. After reprocessing, put the black protective sleeve on the scanner.

7.3.3 Cleaning and disinfecting the mobile display unit

⚠ CAUTION

Risk of infection

There is a risk of infection if surfaces are not regularly disinfected.

➢ Immediately after using the scanner, carry out cleaning and wipe disinfection of the non-critical contact surfaces of the Primescan™ 2 Cart mobile display unit.
Follow all reprocessing instructions in this section.

NOTICE

Malfunction or failure of the mobile display unit

Do not clean and disinfect using spray or a wet cloth. This can lead to malfunction or failure of the electronic components of the mobile display unit.

IMPORTANT

On a heated heater plate, the cleaning and disinfecting agents evaporate and are thus ineffective.

Allow the heater plate of the mobile display unit to cool down before conducting reprocessing.

Follow **all** of the following steps:

Cleaning the scanner holder, heater plate, operating panel, handle and AIO monitor

✓ The heater plate of the mobile display unit has cooled down.
The cooling times was at least 8 minutes.

1. Use a new lint-free cloth (see "Other materials" [→ 92]).
2. Moisten the cloth thoroughly with cleaning agent (see "Cleaning agent" [→ 92]).

3. Thoroughly wipe down the scanner holder and the heater plate of the mobile display unit and clean them for at least 1 minute until there is no more visible contamination.
4. Thoroughly wipe down the operating panel and handle of the mobile display unit and clean them for at least 1 minute until there is no more visible contamination.
5. Thoroughly wipe down the entire screen of the AIO monitor and the handles on the back of the monitor and clean them for at least 1 minute until there is no more visible contamination.
6. Check under good lighting (min. 500 lux) whether the product is visibly clean.
7. If there is visible contamination, repeat the processes with a new, thoroughly moistened, lint-free cloth.
8. Dispose of the used cloth.

Disinfecting the scanner holder, heater plate, operating panel, handle and AIO monitor

✓ The heater plate of the mobile display unit has cooled down. The cooling times was at least 8 minutes.

1. Use a new lint-free cloth (see "Other materials" [→ 92]).
2. Moisten the cloth thoroughly with disinfectant (see "Wipe disinfectant" [→ 92]).
3. Wipe down the scanner holder and heater plate of the mobile display unit thoroughly.
4. Wipe down the operating panel and handle of the mobile display unit thoroughly.
5. Wipe down the entire screen of the AIO monitor and the handles on the back of the monitor thoroughly.
6. Ensure that all areas are thoroughly moistened with disinfectant.
7. Maintain the required reaction time according to the instructions for use of the disinfectant **(at least 5 minutes for isopropanol, at least 3 minutes for CaviCide™)**.
   If necessary, use another thoroughly moistened, lint-free cloth.
8. Dispose of the used cloth.
9. Use a new, clean, lint-free cloth to wipe all areas dry after the reaction time to remove the remaining disinfectant.
10. Dispose of the used cloth.

8 Maintenance

⚠ WARNING

Danger of contact with live parts

If the housing is damaged, there is a possibility of touching live parts inside the unit.

➢ Check all components of the Primescan™ 2 system for integrity before use. It may be used only with undamaged components.

➢ If the housing is damaged, the affected component must be taken out of operation until it has been professionally repaired.

NOTICE

Regular inspection

Some countries have legal regulations that require regular safety inspections of electrical devices or systems by the operator.

Dentsply Sirona would like to draw your attention to the fact that a repeat inspection according to IEC 62353 must be carried out for the Primescan™ 2 intraoral scanner in combination with the connection set and for the optional Primescan™ 2 Cart mobile display unit at least every three years. In addition, this repeat inspection must also be performed following every repair or if the unit is retrofitted with components such as a cable adapter or coupling box.

NOTICE

Maintenance performed by trained technical personnel is recommended on at least an annual basis.

NOTICE

Inspection

Unless otherwise specified in these instructions for use, check all components of the unit for proper functioning on a regular basis and carry out a visual inspection for damage and wear. Replace damaged components if necessary.

NOTICE

Replacing components

A component can be replaced in accordance with the "Installation and commissioning" section.

NOTICE

Service and maintenance work on the unit is not permissible during use on a patient or in the patient environment.

8.1 Calibration of the scanner

Use a calibrated scanner

NOTICE

Use calibration set only with a clean, dry Primescan™ 2 scanner

In order to achieve optimal results, the Primescan™ 2 scanner must be clean, disinfected and dry before the calibration.

➢ Make sure that the Primescan™ 2 scanner is clean, disinfected and dry.

➢ Put a new disposable sleeve on before calibration.

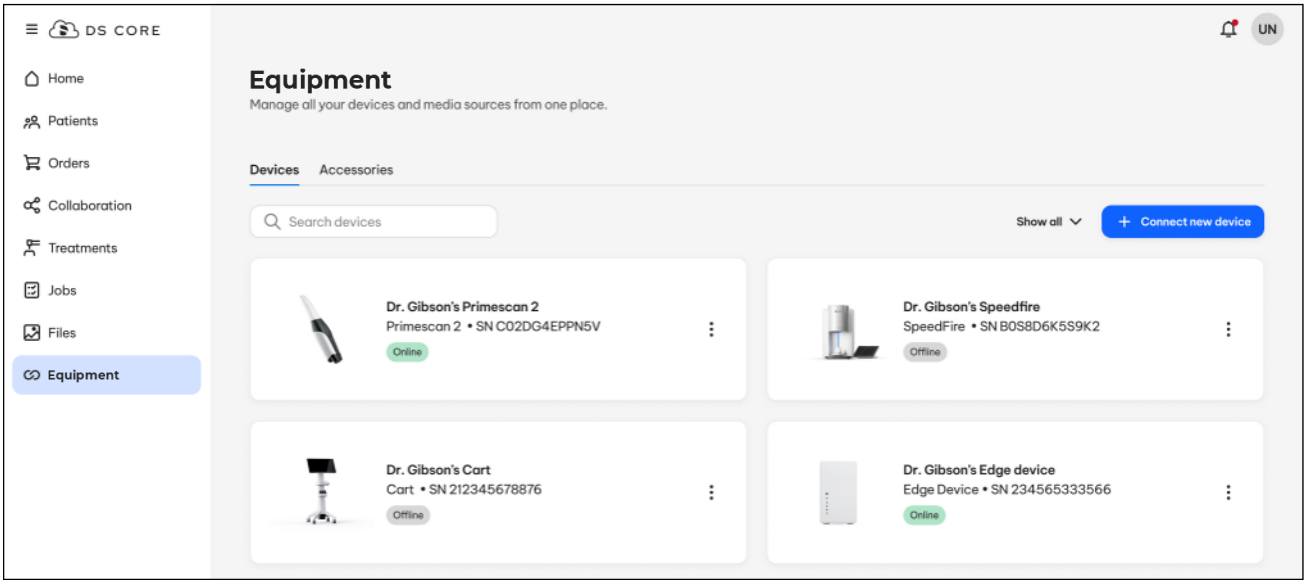
To ensure the quality of the Primescan™ 2 measuring process used, the unit must be calibrated after every new installation and following the events listed below. The calibration set supplied is available for the calibration process.

In order to achieve optimal results, the scanner must be warmed up before calibration.

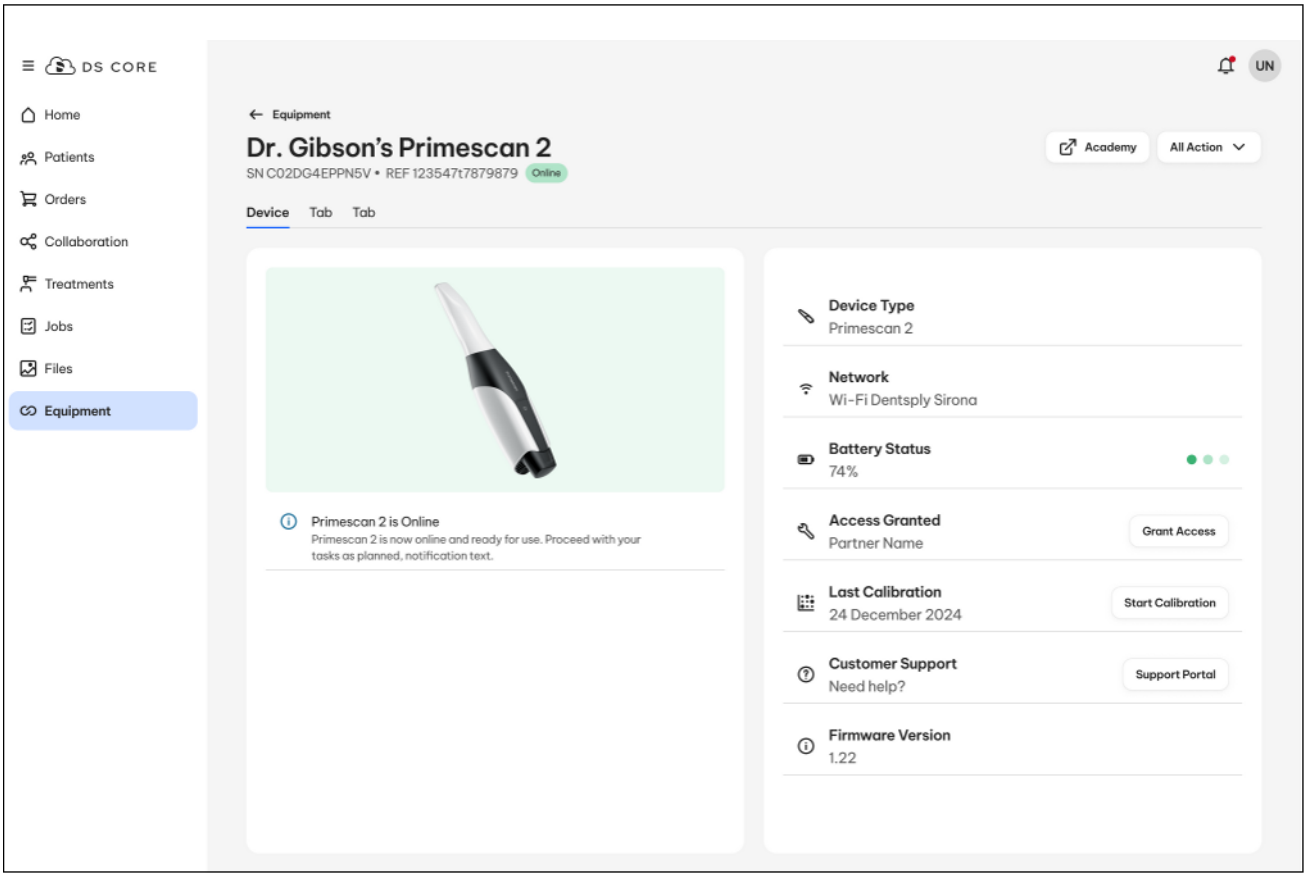
Recalibrate the scanner in the following cases:

- After transport (jolts) or at initial start-up.
- After storage in unheated or non-airconditioned rooms (temperature differences exceeding 30 °C / 54 °F).
- If the temperature difference exceeds 15 °C / 27 °F between the last calibration and operation.
- In general, carrying out a calibration is the correct process in the event of errors in the acquisition process (such as poor image quality or the lack of a 3D preview). In many cases, the error can be corrected by doing so.
- As the system may have unwittingly been exposed to jolts, it should be calibrated once a month.

Starting the calibration process from the DS Core device management



1. In DS Core, click on the *"Equipment"* entry in the left column.
   ↳ The device management is displayed.



2. Click on the scanner that you wish to calibrate.
   ↳ The detailed view of the scanner is displayed.
3. Click on the *"Start 3D calibration"* button.

↳ The calibration application will be loaded.

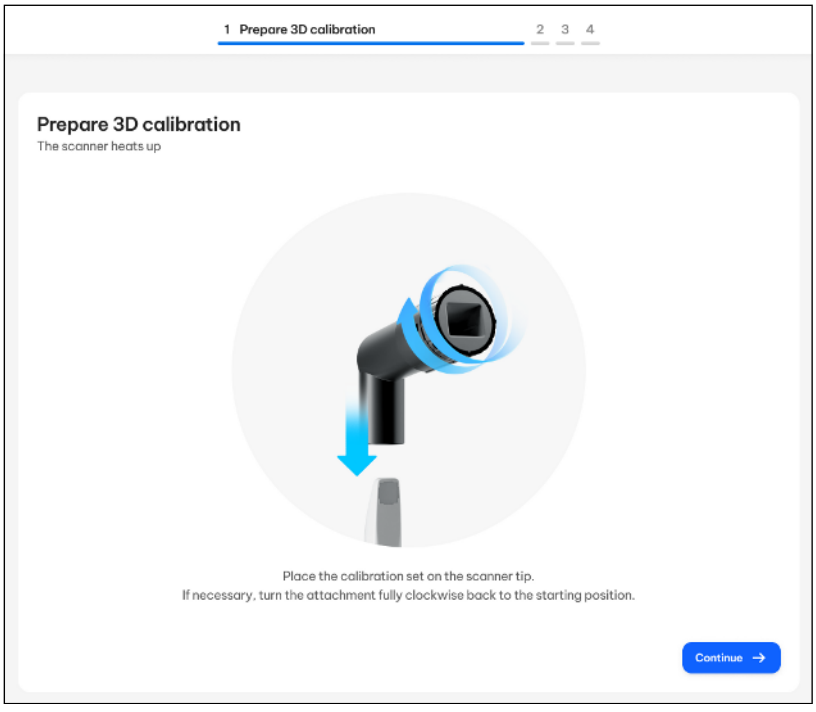
Calibrate scanner

When you start calibration, you are guided through the entire process with step-by-step instructions on the monitor. To give you an overview of this process, the steps of the calibration process are summarized below.

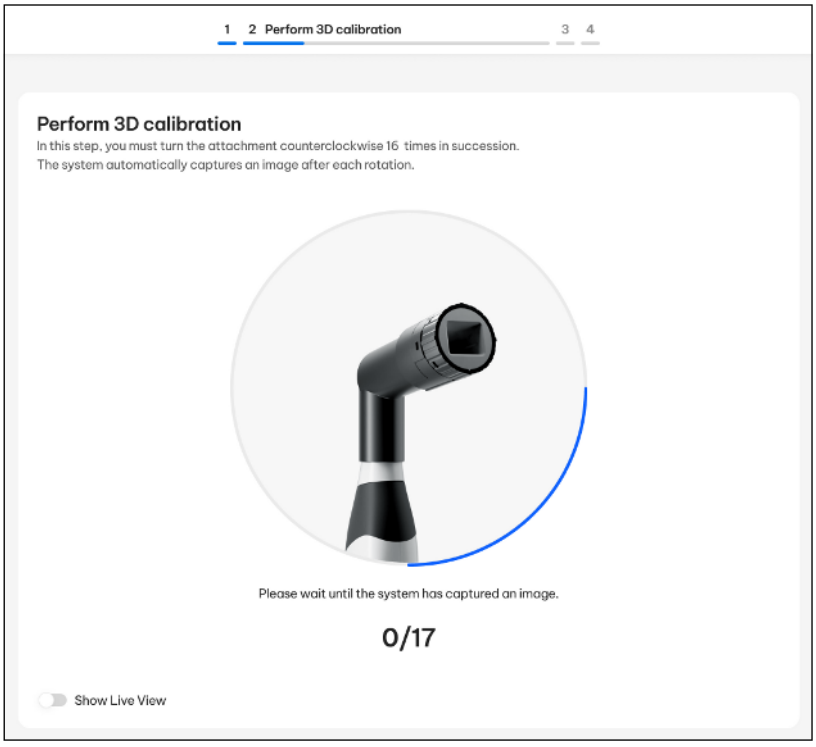
Show Live View

Tip: During calibration, you can show or hide the live view of the scanner at any time using the *"Show Live View"* switch.

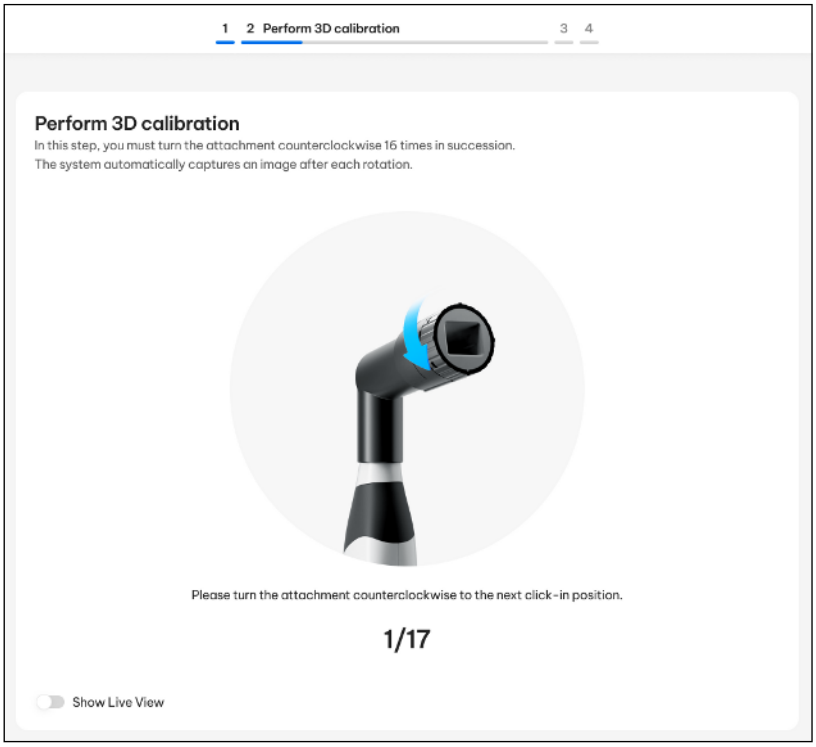
1. Remove the protective cap from the calibration set.
2. Mount the calibration set on the tip of the scanner until it locks into place.



3. Secure the scanner in the calibration set using one hand. Ensure that the external calibration set screw is fully screwed in clockwise until it gently locks into place.
   ↳ In the meantime, a progress bar indicates that the scanner is warming up.
   ↳ When the scanner is warmed up, the *"Continue"* button appears.
4. Click on the *"Continue"* button to start the measuring process.

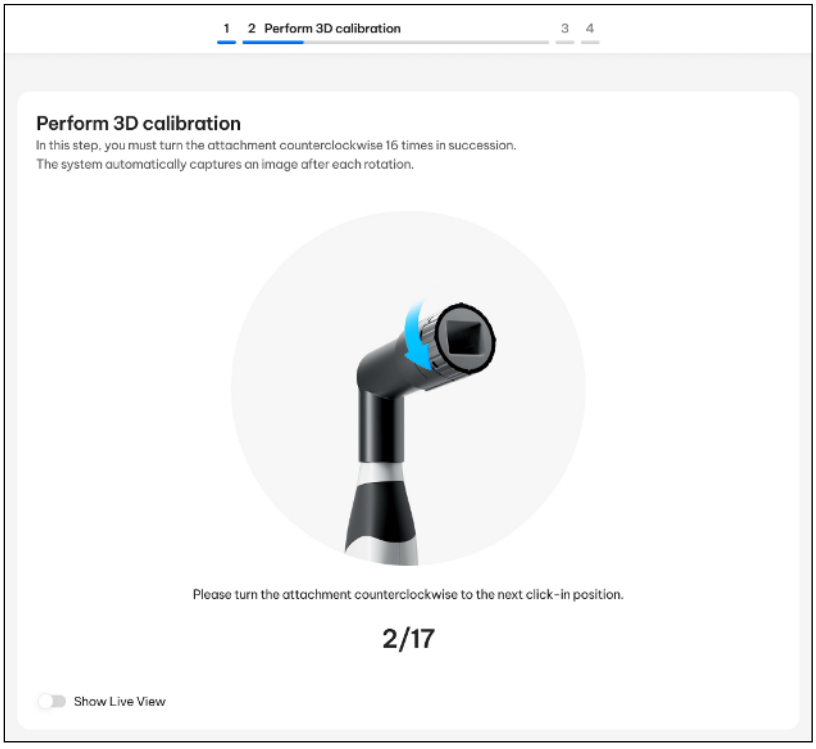


5. Wait while the system acquires a first image.



↳ After the acquisition is made, you will be prompted to turn the screw of the calibration set to the next latching position.

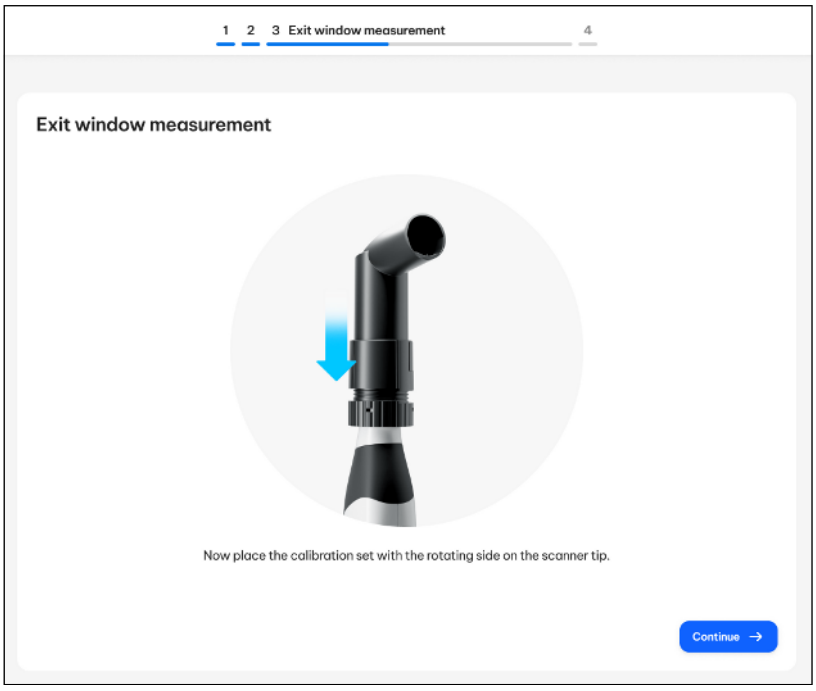
6. Turn the screw counterclockwise until you reach the next latching position.
7. Hold the scanner still and wait until the next image is acquired.



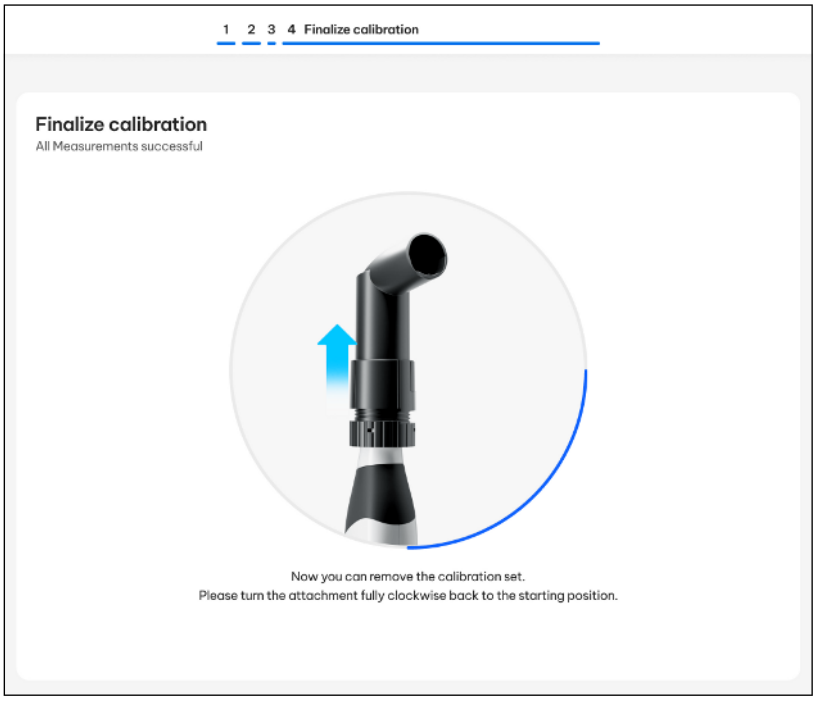
- ↳ After the acquisition is made, you will be prompted to turn the screw of the calibration set to the next latching position.

8. Execute steps 6 and 7 a total of 16 times.
   - ↳ The software provides information on the progress of the calibration and informs you once the procedure is complete.
   - ↳ You will be prompted to measure the position of the exit window.

Measuring the position of the exit window



1. Take the calibration set off the tip of the scanner.
2. Mount the bottom side of the calibration set on the tip of the scanner.
3. Click on the *"Continue"* button.
   - The calibration process is continued.
   - When measuring is finished, a message is displayed that calibration is completed.
   - The calibration application calculates the data for scanner calibration in the background.

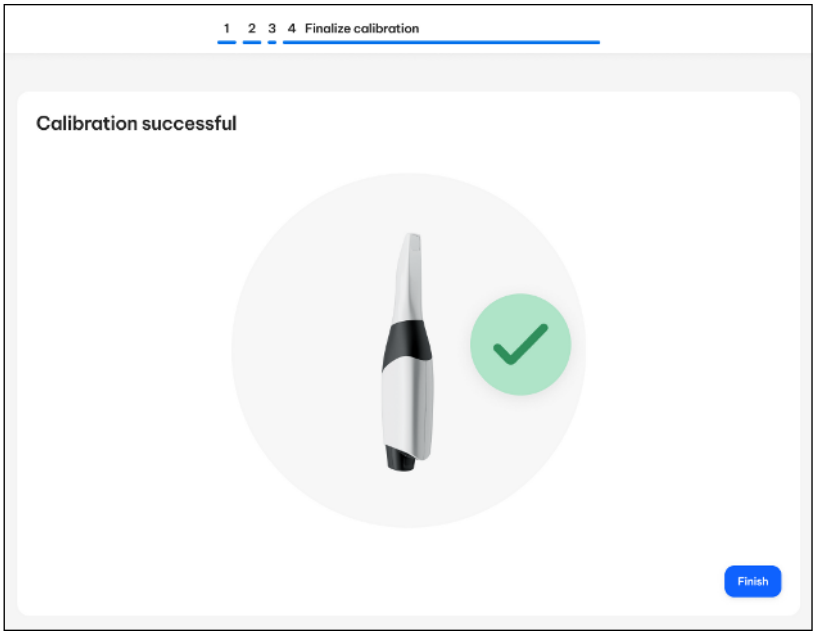


4. Take the calibration set off the tip of the scanner.
5. Turn the screw of the calibration set clockwise back to its original position.
6. Wait until the calculations are complete.

IMPORTANT
The calculations may take several minutes.

End calibration

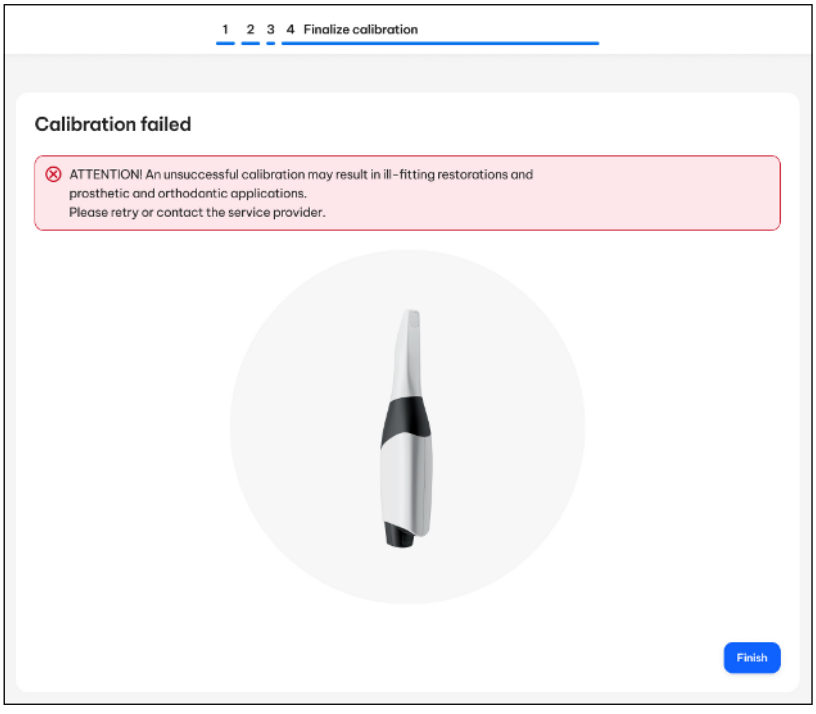
✓ The software indicates that the calibration was completed successfully.



➢ Click on the *"Finish"* button to finish the calibration process.
↳ The scanner is calibrated.

Error message during calibration

The software indicates if an error occurred during calibration. Repeat the calibration process if it was faulty.



1. Click on the *"Finish"* button.

2. Restart the calibration process.

8.2 Charge scanner battery (optional)

NOTICE

Information on charging cycles

Under normal operating conditions, the battery is sufficient for up to 60 minutes of wireless operation. Full charging requires approx. 2.5 hours.
Depending on usage and ambient conditions, the capacity of the battery may be reduced over time due to the battery technology.

For full charging, it is sufficient to put the battery in the charger and connect the charger to the power supply.

NOTICE

Reduced battery service life

If the battery is not charged over a long period of time, this significantly reduces its service life.

➢ Always recharge the battery fully immediately after use.

8.3 Charging the battery of the mobile display unit (optional)

NOTICE

Information on buffer cycles

The battery of the mobile display unit is designed for fully cable-free use for one working day. Approx. 3 - 5 hours are required for full charging, depending on the degree of use of the mobile display unit during the charging process.
Depending on usage behavior and ambient conditions, the capacity of the battery declines due to the nature of the battery technology used.

The battery is permanently charged during operation on mains power supply.

For full charging, it is sufficient to connect the mobile display unit to the mains power supply. The mobile display unit does not have to be switched on for the charging process.

NOTICE

Reduced battery service life

If the battery is not charged over a long period of time, this significantly reduces its service life.

➢ Always recharge the battery fully after buffer operation.

8.4 Replace battery of the mobile display unit (optional)

NOTICE

Damage to the battery or unit

The battery of the unit is not hot-plug capable and may not be exchanged during operation.

➢ Switch the unit off and disconnect the power plug before replacing the battery.

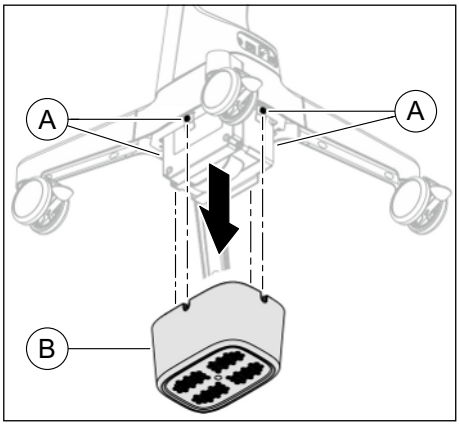
IMPORTANT

Battery replacement by the user

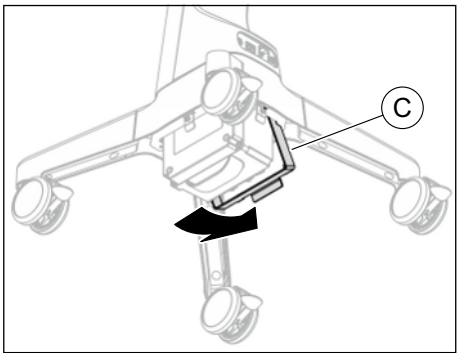
Users are authorized to replace the battery of the mobile display unit on their own.

Spare batteries for the mobile display unit can be obtained from your dealer or through your service organization.

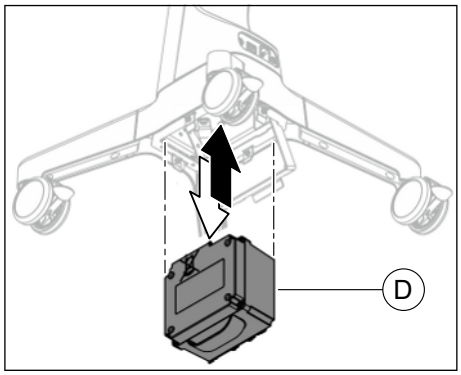
✓ The power plug of the mobile display unit is not connected.



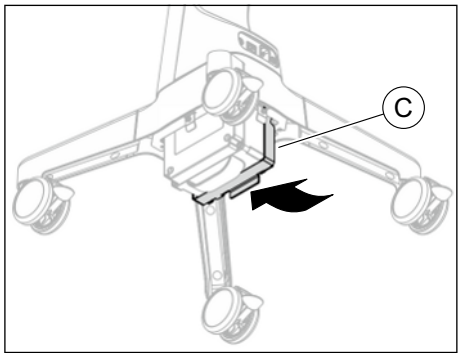
1. Loosen the four M4 x 10 screws (A) on the battery compartment (approx. 5 rotations).
   Use the enclosed Torx TX20 offset screwdriver.
2. Pull the battery cover (B) downwards to detach it from the four screws (A).



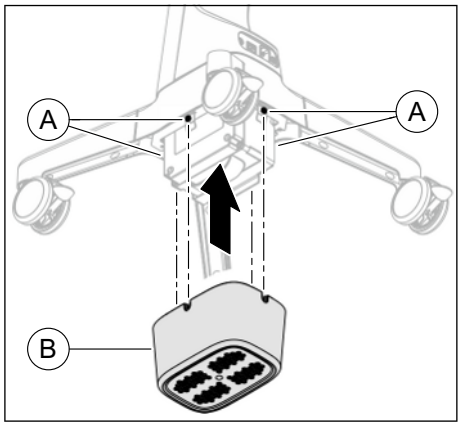
3. Swivel the attachment bracket (C) to the side until it clicks into place.
   Hold the battery firmly so it does not fall out of the battery compartment.



4. Pull the old battery (D) down out of the battery compartment and take it out of the unit.
5. Insert the new battery (D) into the battery compartment from below as far as it will go.
   ↳ The battery is held in the battery compartment by the guide bolts. It does not need to be held by hand for the remaining assembly.



6. Swivel the attachment bracket (C) back down until it clicks into place.



7. Slide the battery cover (B) onto the four pre-mounted screws (A).
8. Screw the battery cover (B) on firmly with the four pre-mounted screws (A).
   Use the enclosed Torx TX20 offset screwdriver.

9 Troubleshooting

9.1 Reset scanner to factory settings

If necessary, you can reset the scanner to the condition as delivered. To do this, proceed as follows:

➢ Press and hold down the ON/OFF button and the connect button on the scanner simultaneously for at least 10 seconds.
  ↳ The scanner is reset to the condition as delivered.
  ↳ The scanner is put in onboarding mode.

IMPORTANT
Wi-Fi access data are deleted When the unit is reset, the Wi-Fi access data stored in the unit are deleted. To operate the unit again, onboarding must be repeated, see "Integrate units into DS Core (onboarding)" [→ 74].

10 Dismantling and disposal

IMPORTANT

Operators of units with storage functions for customer and patient data are responsible for deleting all personal data before disposing of the equipment.

In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This is indicated by the printed icon of the "crossed out trash can".

Disposal procedure

We feel responsible for our products from the first idea to their disposal. For this reason, we give you an option to return our old electronic and electrical devices.

If you wish to dispose of your equipment, please proceed as follows:

In Germany

To initiate return of the electrical equipment, please send a disposal request to enretec GmbH. You have the following options for this:

- Tel.: +49 800 805 432 1
- Email: services@enretec.de

You can arrange the transport to enretec GmbH yourself or commission enretec GmbH with the organization.

Prepare the device for transport in accordance with the "Important regulations for the return of old electrical equipment". Available online at (www.enretec.de).

In accordance with the national disposal regulations regarding old electrical and electronic devices (ElektroG), we as the manufacturer assume the costs for disposing of the electrical and electronic devices in question that were purchased from us on or after August 13, 2005. Disassembly, transport and packaging costs shall be borne by the owner/operator.

By using this return option, we jointly ensure that any substances harmful to the environment and health contained in the devices are disposed of in compliance with the law and that the equipment is recycled in the best possible way.

If your unit is movable, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

⚠ WARNING

Before disassembling and disposing of the device, all parts must be properly prepared (cleaned, disinfected, sterilized).

Other countries

IMPORTANT
Please observe the disposal regulations applicable in your country.

For country-specific information on disposal, contact your local dental dealer.

10.1 Disposal of batteries (scanner and mobile display unit)

Batteries must be sent for recycling when they are defective or reach the end of their service life. For country-specific information on disposal, contact your local dental specialty trader.

The batteries are marked with the adjacent symbol. Dispose of discharged batteries immediately. Keep out of the reach of children. Do not dismantle or set on fire. Disposal of batteries with domestic refuse is not compatible with the objectives of environmentally sound recycling/ disposal.

10.2 Disposal of sleeves

Dispose of the disposable sleeves according to the country-specific regulations.

Also observe the regulations on infectious waste.

10.3 Data security at disposal

No patient data are stored in the unit.

Your Wi-Fi access data are stored in the unit. Delete the access data before disposing of the unit. Reset the unit to factory settings, see "Reset the unit to factory settings" [→ 110].

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We reserve the right to make any alterations which may be required due to technical improvements.

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