

New as of:

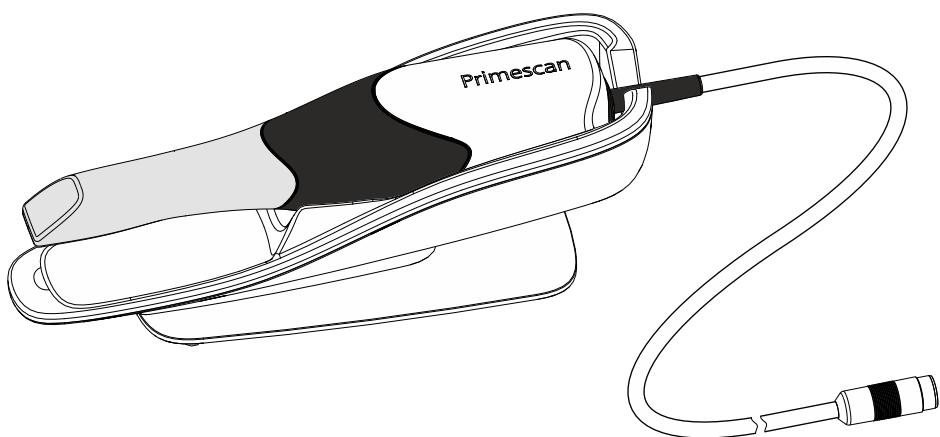
2022-09



# Primescan Connect

Operating Instructions (not valid for USA)

English



# Table of Contents

<b>1</b>	<b>General data .....</b>	<b>5</b>
1.1	Dear Customer,.....	5
1.2	Contact information .....	5
1.3	General information about these operating instructions.....	6
1.3.1	Notes to the repository .....	6
1.4	General conventions and structure of the document .....	7
1.4.1	Structure of the document .....	7
1.4.1.1	Identification of danger levels .....	7
1.4.1.2	Formats and symbols used.....	7
1.4.2	Operating conventions .....	8
1.5	Warranty and liability .....	8
1.6	Intended use .....	9
1.7	Legend .....	10
<b>2</b>	<b>Safety instructions .....</b>	<b>12</b>
2.1	Basic safety information .....	12
2.1.1	Prerequisites .....	12
2.1.2	Connecting the unit .....	12
2.1.3	General safety information .....	12
2.1.4	Transporting the scanner .....	14
2.1.5	Stability of the unit .....	14
2.1.6	Maintenance and repair.....	15
2.1.7	Modifications to the product .....	15
2.1.8	Accessories .....	15
2.2	Electrostatic charge.....	15
2.2.1	ESD warning labels .....	15
2.2.2	ESD protective measures.....	15
2.2.3	About the physics of electrostatic charges .....	16
2.3	Wireless phone interference with equipment .....	17
2.4	Integrating the laptop in the network.....	18
2.5	Disposal .....	18
<b>3</b>	<b>Product description .....</b>	<b>19</b>
3.1	Technical description .....	19
3.2	Technical data.....	20
3.3	Major components.....	21
3.4	Controls and functional elements.....	21
3.4.1	Overview .....	21
3.4.2	Coupling box .....	22
3.5	Certification .....	23

3.6	Electromagnetic compatibility.....	24
3.6.1	Electromagnetic emission .....	24
3.6.2	Interference immunity .....	25
3.6.3	Working clearances.....	28
<b>4</b>	<b>Installation and commissioning .....</b>	<b>29</b>
4.1	Transport and unpacking .....	29
4.2	Disposal of packaging materials .....	29
4.3	Scope of supply.....	29
4.4	Initial startup.....	29
4.4.1	Plug connections .....	30
4.4.2	Switching the units on .....	33
4.4.3	Switching the units off .....	34
<b>5</b>	<b>Operation .....</b>	<b>35</b>
5.1	Optical impressions with the scanner.....	35
5.2	Scanner guide.....	38
5.2.1	Occlusal scan .....	39
5.2.2	Buccal scan .....	39
5.2.3	Lingual scan .....	40
5.2.4	Approximal surface scan .....	40
5.2.5	Single and multiple buccal registration.....	41
5.2.6	Square and full jaw scan .....	42
5.2.7	Scan strategy for edentulous cases .....	44
5.2.8	Concluding the optical impressions .....	44
5.3	Software for the scanner .....	45
5.3.1	Cut out model areas .....	45
<b>6</b>	<b>Maintenance.....</b>	<b>46</b>
6.1	Cleaning, disinfection, and sterilization.....	47
6.1.1	Cleaning agents and disinfectants .....	47
6.1.1.1	Cleaning agents.....	47
6.1.1.2	Wipe disinfectants (virucidal limited).....	47
6.1.1.3	High-level disinfectant.....	47
6.1.2	Non-critical surfaces .....	48
6.1.3	Scanner .....	49
6.1.3.1	General information .....	50
6.1.3.2	Components of the scanner.....	51
6.1.3.3	Removing the sleeve .....	52
6.1.3.4	Attaching the sleeve .....	52
6.1.3.5	Preliminary cleaning of the sleeve .....	52
6.1.3.6	Wipe disinfection of the scanner and window sleeve .....	53
6.1.3.7	High-level disinfection of the window sleeve .....	54

6.1.3.8	Hot air sterilization of the window sleeve.....	59
6.1.3.9	Using disposable sleeves .....	60
6.1.3.10	Sterilizing autoclavable sleeves in the autoclave and using disposable windows.....	61
6.1.4	Cleaning the inside of the sleeve window .....	63
6.2	Calibrating the scanner .....	64
6.3	Color calibration .....	67
6.4	Replacing the O-ring .....	70
<b>7</b>	<b>Disposal .....</b>	<b>72</b>
<b>8</b>	<b>Appendix .....</b>	<b>74</b>
8.1	Making backup copies.....	74
	<b>Index .....</b>	<b>75</b>

## 1 General data

### 1.1 Dear Customer,

Thank you for your purchase of this Primescan Connect® unit from Dentsply Sirona.

Primescan Connect allows you to send digital scans to a laboratory of your choice for manufacture at your laboratory partner.

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

Also pay attention to the safety instructions to prevent personal injury and material damage.

Your  
Dentsply Sirona 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](mailto:contact@dentsplysirona.com)  
[www.dentsplysirona.com](http://www.dentsplysirona.com)

## 1.3 General information about these operating instructions

### Follow 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 comply with the warning and safety information listed.

Always keep the operating instructions handy in case you or another user require(s) information at a later point in time. Print out the operating instructions and note where they are stored on the unit or online.

If you sell the unit, make sure that the operating instructions 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 specified warning and safety information.

### "Download Center" for technical documents

We have set up a "Download Center" or the technical documents at [dentsplysirona.com/ifu](http://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.

### Help

If you continue to have difficulties despite having thoroughly studied the operating instructions, please contact your dealer.

### Original language

Original language of the present document: German

#### 1.3.1 Notes to the repository

It is mandatory to keep this operating manual in an easily accessible place for the purpose of later reference. In the event of a sale or transfer of the device to another user, make sure that the device is supplied along with the operating manual, so 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.

##### NOTE

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	Request for action.
1. First action step	
2. Second action step	
or	
➢ Alternative action	
↳ Result	
➤ Individual action step	
see "Formats and symbols used [→ 7]"	Identifies a reference to another text passage and specifies its page number.
● List	Identifies a list.
"Command / menu item"	Indicates commands, menu items or quotations.

## 1.4.2 Operating conventions

Example	Meaning
Click	A single click down and releasing of the left mouse button.
Double-click	Clicking and releasing of the left mouse button twice in quick succession.
Move the mouse in one direction	Moving the mouse on the surface in the corresponding direction.
" <i>Ctrl+N</i> "	On the keyboard: Press the <b>Ctrl</b> and <b>N</b> keys simultaneously.

## 1.5 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 the implementation of the maintenance work.

As a manufacturer of electro-medical 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 fault messages are ignored, Dentsply Sirona or its authorized dealer does not assume any liability for damage caused.

## 1.6 Intended use

The Primescan Connect acquisition unit creates digital impressions for dental purposes. The unit may be operated only by medically trained and qualified personnel.

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. The system may only be used in conjunction with the Primescan intraoral scanner intended and approved for this purpose.

Intended use also includes compliance with these Operating Instructions 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.

## 1.7 Legend



Year of manufacture



Safety labels

Identifies labels/imprints on the unit (see "Safety labels").



Product disposal symbol (see "Disposal [→ 72]").



Follow the operating instructions.

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



This product is intended for single use only



This product is a medical device.

### Symbols on the packaging

Take note of the following symbols on the packaging:



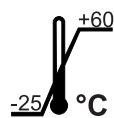
Up



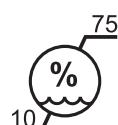
Keep dry



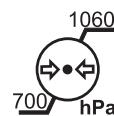
Fragile; handle with care



Temperature during storage and transport



Relative humidity during storage and transport



Air pressure during storage and transport



### Electronic Instructions for use

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

## 2 Safety instructions

### 2.1 Basic safety information

#### 2.1.1 Prerequisites

##### NOTE

###### 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.

##### NOTE

###### Restrictions regarding installation site

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

##### NOTE

###### Do not damage the unit!

The unit can be damaged if opened improperly.

It is expressly prohibited to open the unit with tools!

#### 2.1.2 Connecting the unit

Perform connection by following the directions given in the present operating instructions.

#### 2.1.3 General safety information

##### ⚠ CAUTION

###### Risk group 2: Potentially hazardous optical radiation!

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

> During operation, do not look directly at the lamp for long periods.

##### ⚠ CAUTION

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

The Primescan Connect acquisition unit is Class B equipment (classified according to CISPR 11, EN 60601-1-2: 2015 based on IEC 60601-1-2: 2014).

This unit may be used in professional equipment of health services.

##### NOTE

###### Install only approved software

To prevent interference with the runtime reliability of the program, only software approved by Dentsply Sirona may be installed.

## **WARNING**

### **Danger of touching live parts**

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

- Check that the unit is intact. The unit can only be used for work purposes if it is intact.
- If the housing is damaged, the unit must be put and left out of operation until it has been professionally repaired.

## **CAUTION**

### **Restoration to be checked by trained personnel**

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

## **IMPORTANT**

Immediately notify the manufacturer and the national competent authority of any serious incident that has occurred with the product.

### **Plug connections of external PC 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.

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

## **CAUTION**

Low voltages are applied to the coupling box for connecting external interfaces.

- Do not touch the pins of the connectors.

## **NOTE**

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

## **CAUTION**

### **Trip/fall hazard**

The installation of the supply cable (cable between the coupling box and the scanner) may result in a trip hazard.

- Lay the cable so that there is no risk of tripping.
- Attach the supply line so that it remains fixed at all times.

## **CAUTION**

To maintain electrical safety, the laptop must not be operated within the patient area (1.5m around the patient).

## 2.1.4 Transporting the scanner

### CAUTION

#### Trip/fall hazard

When transporting the scanner, you may trip over the cable and fall.

- > Ensure that the free cable ends are coiled when transporting the scanner.

The scanner can be detached from the coupling box for use in different treatment rooms.

## 2.1.5 Stability of the unit

### NOTE

#### The Primescan Connect device could slip and fall off the table

Ensure that you place the holder with the scanner and the coupling box on a flat surface. The oval plate on which the scanner holder is mounted is equipped with non-slip feet to help prevent movement.

## 2.1.6 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:

- The maintenance and repair of this unit may be performed only by Dentsply Sirona or by agencies authorized by Dentsply Sirona.
- Components which have failed and influence the safety of the unit must be replaced with original (OEM) spare parts.
- Only original cables may be used, so that EMC requirements are met.

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, name of company and signature.

## 2.1.7 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!

## 2.1.8 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 power cable also supplied or the corresponding original spare part may be used with the unit. The user is responsible for any damage resulting from the use of non-approved accessories.

# 2.2 Electrostatic charge

## 2.2.1 ESD warning labels

ESD warning label

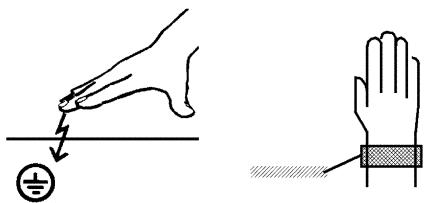


<b>CAUTION</b>	
Risk of injury or damage to components from electrostatic discharge	
For electrical components labeled with an ESD warning label, observe the following instructions.	<ul style="list-style-type: none"><li>➢ Apply the ESD protective measures.</li><li>➢ Do not touch connector pins or sockets without applying ESD protective measures first.</li><li>➢ Do not establish any connections between these connectors without applying ESD protective measures first.</li></ul>

## 2.2.2 ESD protective measures

**ESD** ESD stands for ElectroStatic Discharge.

### ESD protective measures



ESD protective measures include:

- Procedures for preventing electrostatic charge build-up (e.g. air conditioning, air moistening, conductive floor coverings and non-synthetic clothing)
- Discharging the electrostatic charges of your own body on the frame of the UNIT, the protective ground wire or large metallic objects
- Connecting yourself to ground using a wrist band.

### Training

We therefore recommend that all persons working with this system be instructed on the significance of this warning label. Furthermore, they also should receive training in the physics of electrostatic discharges which can occur in the practice and the destruction of electronic components which may result if such components are touched by electrostatically charged USERS.

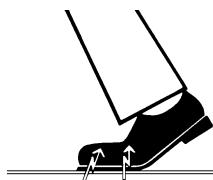
The content of this training is explained in the Chapter "About the physics of electrostatic charges".

## 2.2.3 About the physics of electrostatic charges

### What is an electrostatic charge?

An electrostatic charge is a voltage field on and in an object (e.g. a human body) which is protected against conductance to ground potential by a nonconductive layer (e.g. a shoe sole).

### Formation of an electrostatic charge



Electrostatic charges generally build up whenever two bodies are rubbed against each other, e.g. when walking (shoe soles against the floor) or driving a vehicle (tires against the street pavement).

### Amount of charge

The amount of charge depends on several factors:

Thus the charge is higher in an environment with low air humidity than in one with high air humidity; it is also higher with synthetic materials than with natural materials (clothing, floor coverings).

Electrostatic discharge must be preceded by electrostatic charging.

The following rule of thumb can be applied to assess the transient voltages resulting from an electrostatic discharge.

An electrostatic discharge is:

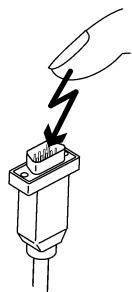
- perceptible at 3000 V or higher
- audible at 5000 V or higher (cracking, crackling)
- visible at 10000 V or higher (arc-over)

The transient currents resulting from these discharges have a magnitude of 10 amperes. They are not hazardous for humans because they last for only several nanoseconds.

### Background

Integrated circuits (logical circuits and microprocessors) are used to implement a wide variety of functions in dental/X-ray/CAD/CAM systems.

The circuits must be miniaturized to a very high degree in order to include as many functions as possible on these chips. This leads to structure thicknesses as low as a few ten thousandths of a millimeter.



It is obvious that integrated circuits which are connected to plugs leading outside of the unit via cables are sensitive to electrostatic discharge.

Even voltages which are imperceptible to the user can cause breakdown of the structures, thus leading to a discharge current which melts the chip in the affected areas. Damage to individual integrated circuits may cause malfunction or failure of the system.

## 2.3 Wireless phone interference with equipment

The use of mobile wireless phones in practice or hospital environments must be prohibited to ensure safe operation of the unit.

## 2.4 Integrating the laptop in the network

### NOTE

#### Observe the following installation instructions

The following installation instructions apply when integrating the laptop into a network:

### Network

The laptop can be connected to a network via WiFi or LAN. When using LAN, ground must be provided via an additional protective conductor.

Cross-section of the protective conductor	in a protected installation	2.5 mm <sup>2</sup>
	laid unprotected	4 mm <sup>2</sup>

## 2.5 Disposal



On the basis of the Directive 2012/19/EU and the country-specific disposal regulations on waste electrical and electronic equipment, we would like to stress that such equipment must be disposed of accordingly within the European Union (EU). These regulations demand environmentally friendly recycling / disposal of waste electrical and electronic equipment. These parts must not be disposed of as domestic refuse. This has been symbolized by the symbol of the crossed out garbage bin.

Please observe the disposal regulations applicable in your country.

## 3 Product description

### 3.1 Technical description

#### CAD system for high-precision intraoral optical impressions

- High-resolution, heated oral scanner (3D scanner) with removable reflective sleeve
- Integrated image processing
- Coupling box, including interfaces
- Scanner holder

#### High-resolution 3D intraoral scanner with control and image processing electronics

- Image acquisition: Image control inside the scanner
- Image data transfer: USB 2.0 standard

No water or air connection required.

## 3.2 Technical data

Type designation	Primescan Connect
Rated line voltage	100-240 V ~ / 50-60Hz
Nominal current	1.0 – 0.6A
Type of protection against electric shock	Class I unit
Type of protection against electric shock (scanner)	Type BF applied part 
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

### Transportation and storage conditions

In the original transport packaging, the acquisition 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 75%
Air pressure	700 hPa to 1060 hPa

### Operating conditions

The acquisition unit may be operated in the following environmental conditions:

Ambient temperature	10 °C to 35 °C (50 °F to 95 °F)
Relative humidity	30% to 85%
Air pressure	No condensation
Operating altitude	700 hPa to 1060 hPa ≤ 3000m

### 3.3 Major components

Medical device Primescan Connect includes the following main components:

- scanner,
- scanner holder,
- coupling box,
- Medical power supply unit  
65 37 158 D3652.
  - FSP030-RFAM  
Input voltage range: 100-240 VAC / 50-60 Hz  
Input current range: 1.0-0.6 A.
  - EM10681C(02) from EDAC Power Electronics Co., Ltd., Taiwan  
Input voltage range: 100-240 VAC / 50-60 Hz  
Input current range: 2.0-1.0 A.

The system ultimately used consists of the Primescan Connect, the Connect software and the laptop.

### 3.4 Controls and functional elements

#### 3.4.1 Overview

##### NOTE

##### Scanner is calibrated

The scanner is calibrated ex works.

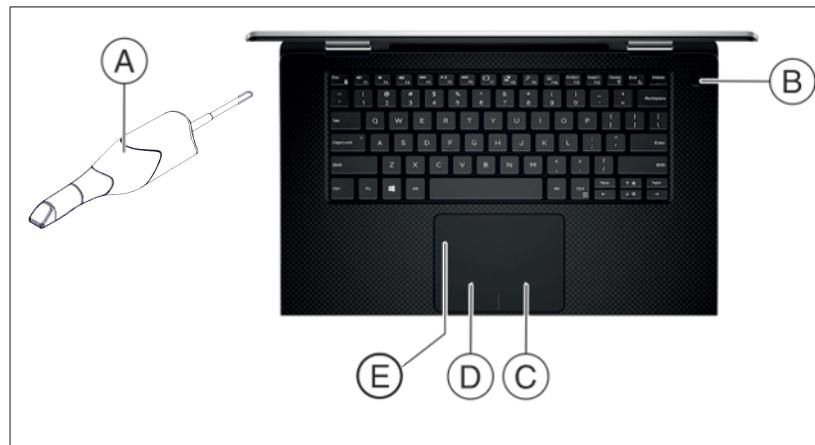
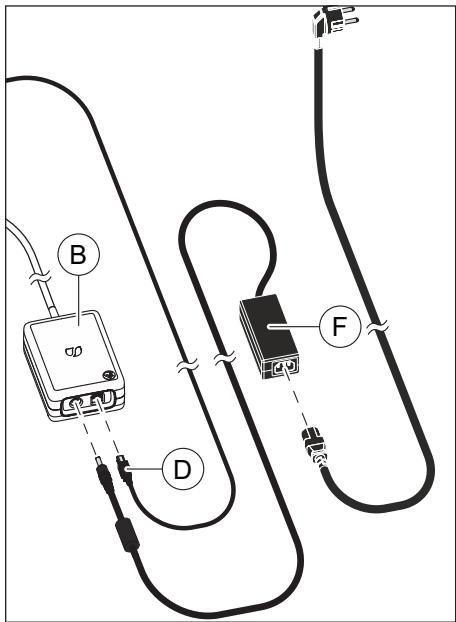


Figure similar to laptop

A	Scanner	D	Left mouse-click area
B	Operating switch	E	Touchpad
C	Right mouse-click area		

### 3.4.2 Coupling box



The connection sockets for the supplied power supply unit (F) and the USB cable (D) to the laptop can be found on the front of the coupling box (B).

**NOTE**

Connection to a USB hub can impair the performance of the coupling box.

**⚠ CAUTION**

Only use the power supply unit supplied by Dentsply Sirona for operating the coupling box!

## 3.5 Certification

### CE mark



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

#### NOTE

##### CE mark for connected products

Further products which 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.

## 3.6 Electromagnetic compatibility

Observance of the following information is necessary to ensure safe operation regarding EMC aspects.

Primescan Connect complies with the requirements for electromagnetic compatibility (EMC) according to EN 60601-1-2: 2015 based on IEC 60601-1-2: 2014.

Primescan Connect is hereinafter referred to as "UNIT".

### 3.6.1 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 <b>UNIT</b> 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	
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker according to IEC 61000-3-3	coincides	

### 3.6.2 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 voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	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 5sec. (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 5sec. (100% dip of $U_T$ )	The quality of the line power supply should be that of a typical commercial or hospital environment. Continued operation of the <b>UNIT</b> is possible following interruptions of the power supply, since the <b>UNIT</b> is powered by an uninterruptible power supply backed up by a storage battery.
Magnetic field of power frequencies (50/60 Hz) according to IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: $U_T$ is the AC 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 <b>UNIT</b> 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 <b>IEC 61000-4-6</b>	3 V <sub>eff</sub> 150 kHz to 80 MHz  6V <sub>eff</sub> in ISM frequency bands between 150kHz and 80 MHz  80% AM at 1kHz	3V <sub>eff</sub>  6V <sub>eff</sub>	d= [1.2] √P
Radiated RF interference <b>IEC 61000-4-3</b>	3V/m 80MHz to 800MHz  3V/m 800MHz to 2.7GHz  80% AM at 1kHz	3V/m  3V/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).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>1</sup> should be less than the compliance level <sup>2</sup> in each frequency range.  Interference is possible in the vicinity of equipment bearing the following graphic symbol.

Immunity to interference against high-frequency electromagnetic fields in the direct 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 modulation: 18 Hz	27	27
450	FM + 5Hz difference: 1 kHz Sinus	28	28
710 745 780	Pulse modulation: 217 Hz	9	9
810 870 930	Pulse modulation: 18 Hz	28	28
1720 1845 1970	Pulse modulation: 217 Hz	28	28

Immunity to interference against high-frequency electromagnetic fields in the direct 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)
2450	Pulse modulation: 217 Hz	28	28
5240	Pulse modulation: 217 Hz	9	9
5500			
5785			

**Remark 1**

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

**Remark 2**

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

1. The field strengths of fixed transmitters, such as base stations of radiotelephones and mobile agricultural radio broadcast services, amateur radio stations, AM and FM radio broadcast and TV broadcast 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 150kHz to 80 MHz, field strengths should be less than 3 V/m.

### 3.6.3 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/or mobile RF communication devices (transmitters) and the **UNIT**. These values may vary according to the output power of the relevant communication device as specified below.

Rated maximum output power of 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
	$d = [1.2] \sqrt{P}$	$d = [1.2] \sqrt{P}$	$d = [2, 3] \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance  $d$  in meters (m) can be determined using the equation in the corresponding column, where  $P$  is the maximum nominal output of the transmitter in watts (W) specified by 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.

#### Remark 2

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

## 4 Installation and commissioning

### 4.1 Transport and unpacking

All products from Dentsply Sirona devices 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.

#### NOTE

##### Damage during transport

If the product was damaged during transport, please contact your carrying agent.

#### NOTE

##### 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. To do this, the system must be removed from the storage case.

#### NOTE

##### Observe operating conditions

The storage case included in the scope of delivery may only be used for storing the product under the operating conditions specified in the "Technical data [→ 20]" section.

#### ⚠ CAUTION

##### Risk of cross-contamination

After storing and removing the system from the storage case, all components must be reprocessed before use / deployment (see section "Cleaning, disinfection, and sterilization [→ 47]").

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

### 4.2 Disposal of packaging materials

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

### 4.3 Scope of supply

The detailed scope of supply is specified in the document "Checklist".

### 4.4 Initial startup

You can commission the system yourself as the user.

#### 4.4.1 Plug connections

##### NOTE

The Primescan 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 place the sensitive scanner in its holder!

##### NOTE

###### 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.

##### ⚠ CAUTION

###### Placing the scanner holder

The scanner holder must be placed on a flat, horizontal surface inside or outside of the patient environment. Ensure that the cables of the scanner do not pose a safety risk.

##### ⚠ CAUTION

###### Trip/fall hazard

The installation of the supply cable (cable between the coupling box and the scanner) may result in a trip hazard.

- Lay the cable so that there is no risk of tripping.
- Attach the supply line so that it remains fixed at all times.

##### ⚠ WARNING

###### Hazard for patient and user

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

- Only use sockets which are freely accessible at all times. This ensures swift disconnection from the power.

##### ⚠ CAUTION

Only use the power supply unit supplied by Dentsply Sirona for operating the coupling box!

##### ⚠ CAUTION

###### Do not connect laptops without approval

Laptops that have not been approved must not be connected. Only use laptops that are approved according to IEC 62368-1 or IEC 60950-1.

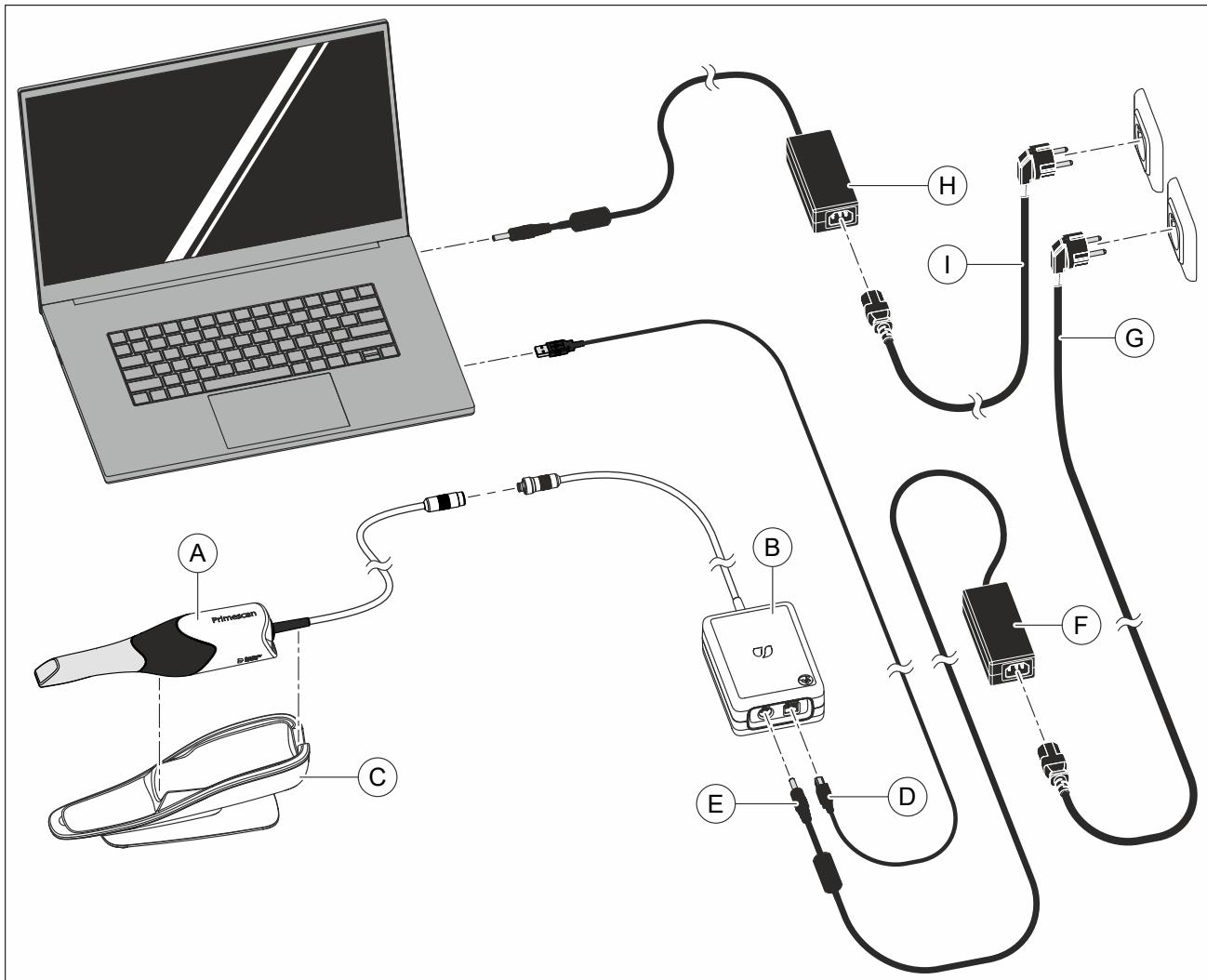
 **CAUTION**

**Connecting additional devices to the external interfaces**

Additional devices connected to external interfaces of the laptop must be tested according to the relevant standards, e.g.: IEC 60601-1, IEC 61010-1 or IEC 62368-1.

**NOTE**

Primescan Connect (USB cable D) and license stick may only be connected to the USB-A ports.



1. Place the window sleeve onto the scanner (A). Exercise a great deal of care. Push the window sleeve carefully onto the cone until it latches in.
2. Carefully insert the connector of the scanner cable into the coupling of the coupling box (B), watching out for the guide nose.
3. Place the scanner in the scanner holder (C).
4. Connect the coupling box to the laptop using a USB cable (D) with a USB female connector.
5. Insert the connector (E) of the supplied power supply unit (F) into the coupling box.
6. Connect the power supply unit to a supply network with protective conductor using the power cable (G).
7. Connect the laptop to a supply network with protective conductor using the power supply unit (H) and the power cable (I).
8. Check the plug connections to the mains connection and the scanner. The scanner always remains connected.

#### 4.4.2 Switching the units on

##### NOTE

###### **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)
- 潮湿 The unit is dry and can be put into operation.



Figure similar

1. Switch on the notebook at the operating switch A.
2. After loading the operating system, start the Connect SW application by double-clicking on the Connect SW button.

##### NOTE

In order to prevent data security breaches, it is recommended that users enable the password-protected login function for the Windows operating system.

#### 4.4.3 Switching the units off

##### NOTE

###### Proper shutdown procedure

The operating system must always be shut down properly to prevent data loss.

To prevent the laptop from becoming slower over time, perform a normal shutdown of the operating system at regular intervals.

1. Exit all programs.
2. Power down the operating system.
  - ↳ The laptop switches off automatically.
3. Unplug the power cord plug from the power supply system. For this purpose, it is necessary to position the unit in such a way that the power connection is accessible at all times.

## 5 Operation

### 5.1 Optical impressions with the scanner

#### CAUTION

##### **Hot tip of the scanner sleeve!**

The tip of the scanner sleeve is continuously heated up! The surface temperature of the sleeve may be as high as 51°C. This may cause an unpleasant heat sensation on contact with a person's skin or mucous membrane. These temperatures will not damage the skin or mucosal membrane. The temperature sensitivity in the mouth is considerably lower than it is on other surfaces of the skin. The scanner does not produce any pressure on the mucosa of the mouth. Temperatures up to 51°C must therefore be classified as being non-critical for the patient.

The scanner is therefore suitable for use in the patient's mouth for an unlimited period of time.

#### **NOTE**

##### **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 weakly 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.

#### 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.

#### WARNING

##### **Risk of injury for those diagnosed with epilepsy**

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

- Patients who have been diagnosed with epilepsy cannot be treated with the scanner.
- Dentists and dental assistants who have been diagnosed with epilepsy cannot work with the scanner.

## 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.

## 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. The heating starts immediately after connecting the scanner to the coupling box and connecting the coupling box to the mains using the power supply unit. After around five minutes the scanner is free of condensation. This is usually the case through to navigation into the exposure phase.

## IMPORTANT

### Changes to the Windows settings

Do not make any changes to the Windows settings that could affect the performance of the system.

## IMPORTANT

### Power supply during the scanning process

Do not disconnect the power supply to the laptop during the scanning process, as this will restrict the performance of the system.

## CAUTION

### Possible damage during transport

Use the supplied storage container to transport the Primescan Connect. Make sure that the components are properly stowed in the storage container.

## CAUTION

### Avoid contamination of the laptop

Be careful not to contaminate the laptop including the keyboard.

## IMPORTANT

### Detection of the scanner by the Connect SW

Exit the Connect SW, **before** you disconnect the scanner from the power supply, e.g. to transport it inside the rooms of your practice.

- ✓ The teeth are blow-dried.
- 1. Change to the "ACQUISITION" phase.
  - ↳ The scanner is ready for exposure.
  - ↳ As soon as you move the scanner, a live image appears which can be used to look around the patient's mouth.
- 2. Remove the scanner from its holder.
  - ↳ As soon as the scanner is pointed over a tooth or the gums, data acquisition begins. During the continuous data acquisition, a color 3D model is generated automatically on the screen. A white field indicates in which area data will be acquired. If the automatic data flow breaks off, the white field is lost and the audio signal changes. In this case, move the scanner to any area which has already been scanned. The scanning procedure continues.
- 3. Place the scanner in the holder, it then switches off after a few seconds.
- 4. Move the mouse pointer onto the switch at the top right corner of the camera view to stop the scanning procedure.

### Continuing the scanning procedure

1. Click on the switch at the top right corner of the camera view.
  - ↳ The scanning procedure is started.
2. Continue the scanning procedure as described above.

## ⚠ CAUTION

After use, store the scanner including tray and coupling box outside the patient environment to avoid unforeseen damage.

## 5.2 Scanner guide

### CAUTION

#### After each use

Prepare the scanner once again after each patient.

- Follow the instructions in the "Scanner [→ 49]" section on cleaning, disinfection and sterilization in order to avoid cross-contamination between patients.

The scanner acquires images which are used during the ongoing measurement in spatial relation to each other (image registration).

During the acquisition and then during the ongoing registration process, a distinctive sound can be heard.

If the registration cannot be implemented, the acquisition flow is suspended. You are informed of this by means of a sound. This is different to the sound emitted during successful acquisition. You can adjust the volume under configuration and select another type of sound (melody).

### IMPORTANT

#### Registration error

Should a registration error occur, you must return to another acquired point.

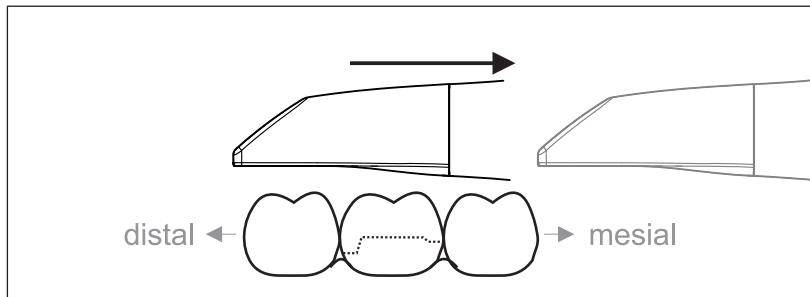
To start with, practice this procedure on the model and then on intraoral areas.

- Move the scanner to a position where a successful acquisition was taken. A point that has already been acquired in the occlusal area is best.
  - ↳ You will be able to hear the sound for registered acquisitions.
- Continue the acquisition.

Divide the acquisition into four consecutive sequences:

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

### 5.2.1 Occlusal scan

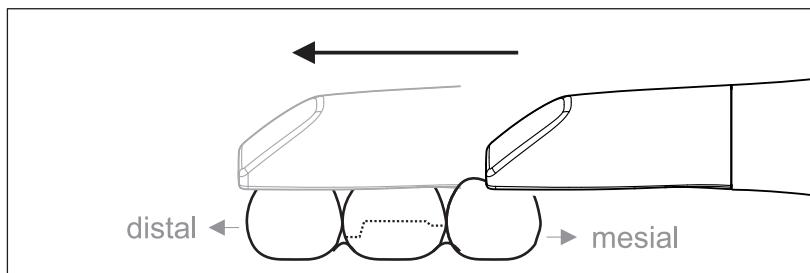


**Important:** Ensure that the distance between the coated sapphire glass of the scanner and the scanned surface is observed.

The distance must be between 0-20 mm (ideally: 2mm). The scanner does not rest on the teeth or the gums.

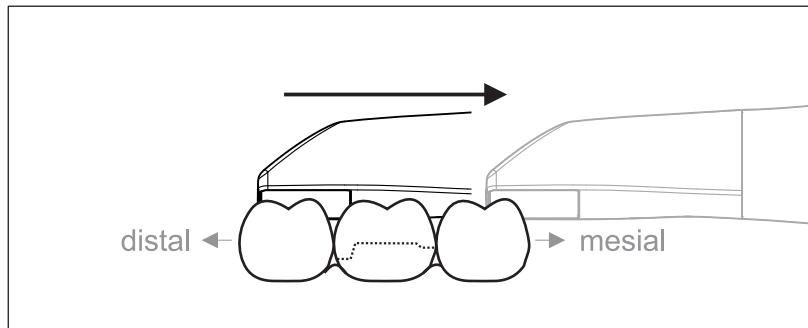
1. Move the scanner to the starting position. For this purpose, the scanner is in the occlusal view of the tooth, which is next to the prepared tooth in the distal direction.
2. Scan in the mesial direction. To do so, move the scanner in the occlusal direction from the distal-positioned tooth over the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

### 5.2.2 Buccal scan



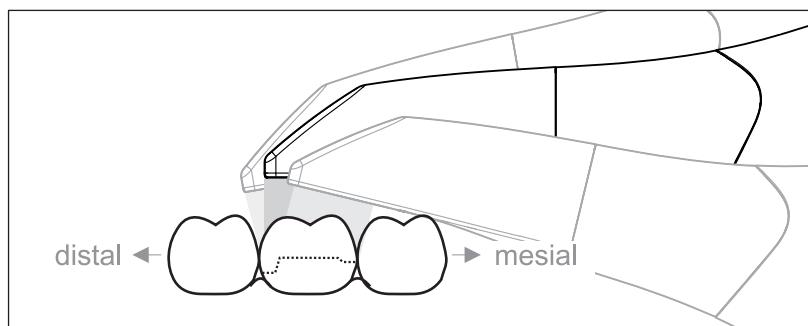
- ✓ The scanner is on the adjacent tooth, in the mesial direction to the preparation.
- 1. Rotate the scanner 20° toward the buccal.
- 2. Guide the scanner over the entire buccal distance in the distal direction over the prepared tooth.

### 5.2.3 Lingual scan



- ✓ The scanner is on the tooth that is positioned next to the preparation in the distal direction.
- 1. Rotate the scanner to maximum 20° toward the lingual direction.
- 2. Guide the scanner over the entire lingual distance in the mesial direction over the prepared tooth.

### 5.2.4 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.

### 5.2.5 Single and multiple buccal registration

The buccal registration establishes the allocation of jaw exposures.

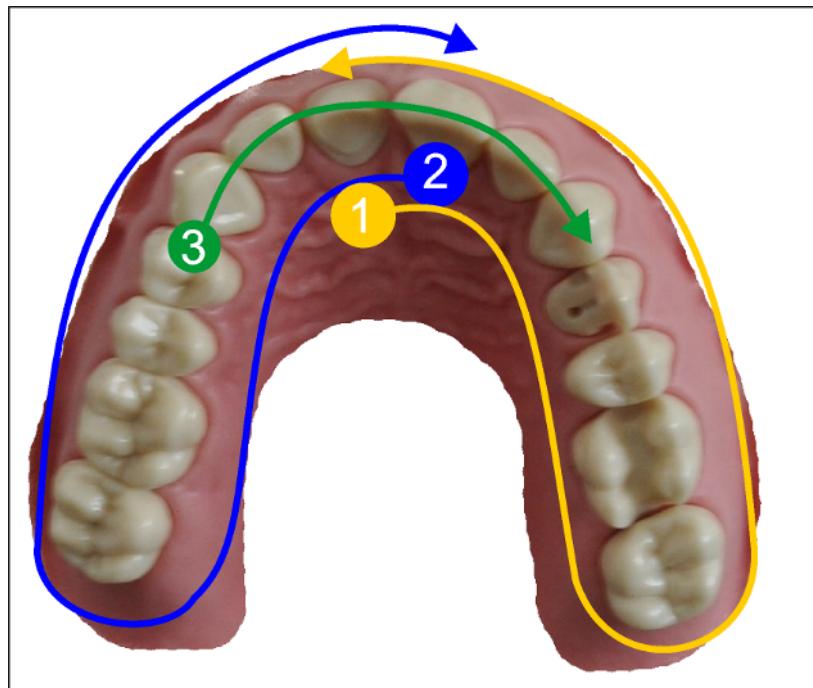
- ✓ The jaw with the preparation is scanned.
- 1. Scan the occlusal, buccal and lingual view of the antagonist (see the section “Occlusal scan [→ 39]”, “Buccal scan [→ 39]” and “Lingual scan [→ 40]”).
- 2. Perform a buccal scan of the bite block prior to completing the registration. This buccal scan should be carried out close-up to 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:** In the case of multiple or long-span restorations over several quadrants, we recommend generating several buccal exposures close to the restoration.

## 5.2.6 Square and full jaw scan

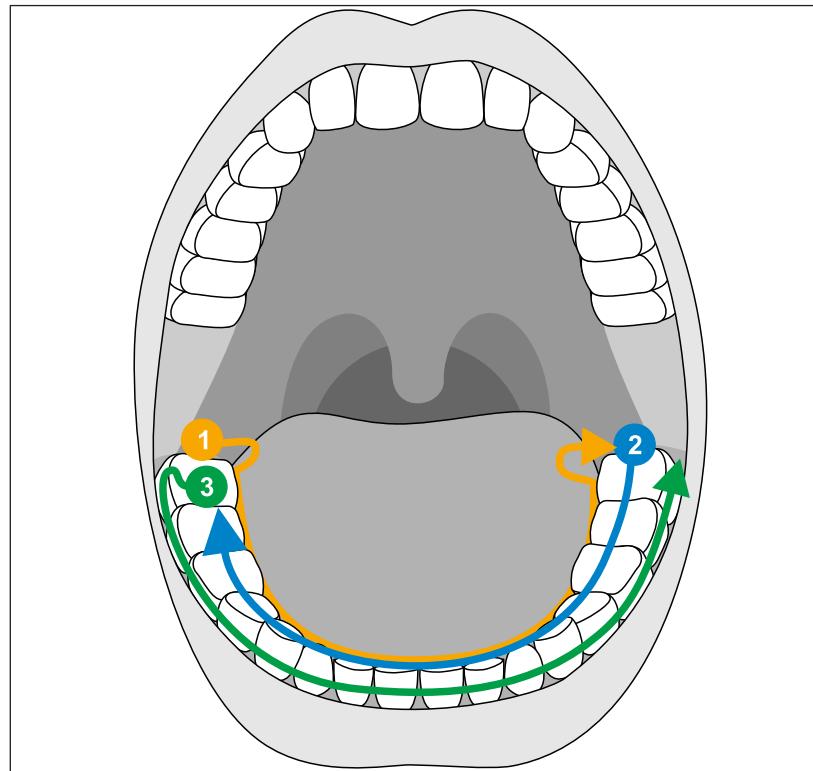
You can use different scanning procedures for scanning a quadrant or a full jaw. Find two procedures as follows to help you gain access should such help be necessary.

### Procedure 1



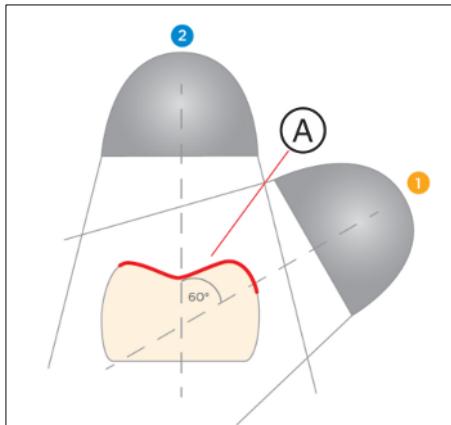
1. Start with the oral surface of the anterior teeth and move the scanner in the oral direction along the quadrant. Move the scanner over the distal tooth to the vestibular side and track the first quadrant to the anterior teeth. Gently tilt the scanner approx. 30° in the coronal-apical direction.
2. 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

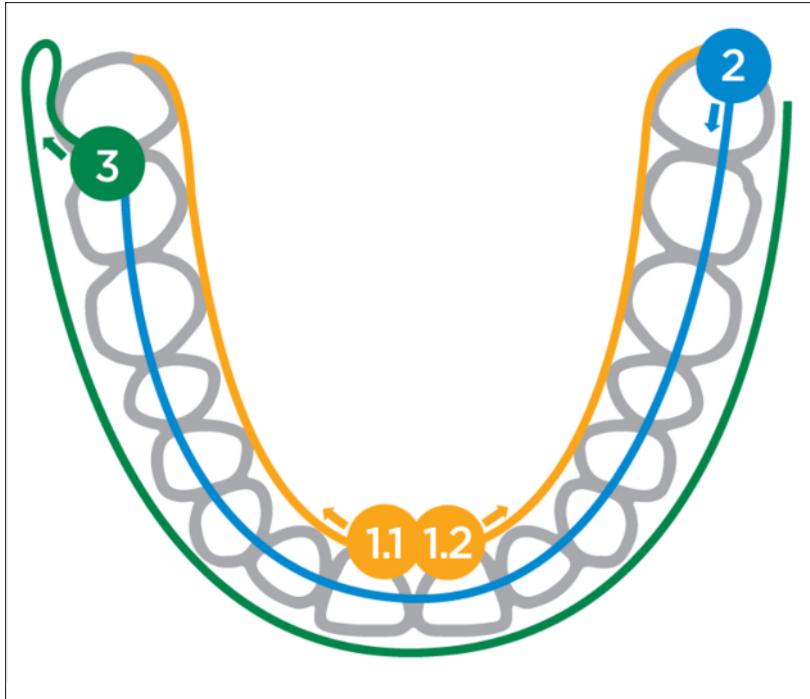


1. Start occlusally on the distal tooth, tilt the scanner approx. 60° in an oral direction and move it orally along the dental arch up to the opposite distal tooth.
2. Guide the scanner occlusally from the distal tooth across the entire dental arch back to the other side.
3. To complete the scan, tilt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

### 5.2.7 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 occlusally in the incisal area and tilt the scanner approx. 60° in the oral direction and move it orally along the dental arch to the distal area. Repeat this on the opposite side. Ensure that 1.1 and 1.2 overlap each other at the starting point.
2. Guide the scanner occlusally 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 the buccal direction and move it buccally along the entire dental arch.

### 5.2.8 Concluding the optical impressions

- ✓ The exposures are complete.
- 1. Click on the "Next" button.
  - ↳ The virtual model is calculated and displayed in color.
  - ↳ Beige brown sections highlight data material that is missing from the calculated model.
- 2. If missing data emerges in the preparation area, carry out further scans.

Change back to the "ACQUISITION" phase. Perform additional scans to complete the model structure.

## 5.3 Software for the scanner

### 5.3.1 Cut out model areas

With the "Cut" function, you can should be able to cut out model areas. These can be areas in which parts of cotton rolls or cheeks were unintentionally acquired.

When performing this activity, be careful not to accidentally cut out any areas that e.g. are located behind the model or are otherwise cut away from the line.

- ✓ You are now in the ACQUISITION phase.
- 1. Click on the Tool icon in the side palette on the right edge of the screen.
- 2. Click the "Cut" button.
  - ↳ The cursor changes to a cross.
- 3. Begin the cut line with a double-click.
- 4. Click to set additional points.
- 5. Finish the cut by double clicking.
  - ↳ The model area is cut out.
- 6. Click the "Apply" button to implement the change.

#### "Undo" and "Reset"

With the "Undo" button in the tools you can undo all changes made on the selected restorations since the tool was started.



With the "Reset" button in the tools you can undo all changes made on all restorations since the tool was started.



## 6 Maintenance

### WARNING

#### Danger of touching live parts

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

- > Check that the unit is intact. The unit can only be used for work purposes if it is intact.
- > If the housing is damaged, the unit must be put and left out of operation until it has been professionally repaired.

### NOTE

#### Regular inspection

Some countries have legal regulations which 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 so-called "retest" (repeat test) must be carried out for the Primescan Connect at least every three years. In addition, this retest also must be performed following every repair or retrofit of components such as the laptop, the laptop power supply unit, the Primescan scanner and the scanner cable. and coupling box

### NOTE

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

### NOTE

#### Replacing components

A component can be replaced in accordance with the "Installation and commissioning [→ 29]" section.

## 6.1 Cleaning, disinfection, and sterilization

### NOTE

#### Approved cleaning agents and disinfectants

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

### 6.1.1 Cleaning agents and disinfectants

#### 6.1.1.1 Cleaning agents

Alpro	• Minuten Wipes
Merz	• Pursept-A
Dürr	• FD 366 sensitive • FD 366 sensitive wipes
Various manufacturers	• 60%-90% isopropyl alcohol
	• Neutral soap

#### 6.1.1.2 Wipe disinfectants (virucidal limited)

Alpro	• Minuten Wipes
Merz	• Pursept-A
Dürr	• FD 366 sensitive • FD 366 sensitive wipes
Various manufacturers	• 60%-90% isopropyl alcohol

#### 6.1.1.3 High-level disinfectant

Johnson & Johnson	• CIDEX OPA
-------------------	-------------

## 6.1.2 Non-critical surfaces

### NOTE

Never use corrosive cleaning agents, wax or solvents.

### ⚠ CAUTION

#### Risk of infection

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

- > Wipe-disinfect the following non-critical contact surfaces after each treatment:
- Scanner holder
  - Scanner body except sleeve
  - Coupling box
  - Medical power supply unit
  - Scanner cable and all connection cables.

1. Use a new cotton gauze moistened with one of the cleaning agents listed in the "Cleaning agents and disinfectants [→ 47]" section to disinfect the contact surfaces of the product described above.
2. Dispose of the absorbent gauze.

Please ensure that **no colored cloths** are used for this as these can result in discoloration of the surfaces, e.g. when used in combination with disinfectants.

#### Protection against medicaments

Due to their high concentrations and the substances they contain, many medicaments can dissolve, etch, bleach or discolor surfaces.

### NOTE

The only way to prevent damage is to **wipe off medicaments immediately** with a damp cloth and a cleaning agent!

### 6.1.3 Scanner

#### CAUTION

##### Risk of injury

An evidently damaged scanner must no longer be used on patients. If the Primescan scanner accidentally falls off, check to make sure that the sapphire glass is not damaged. If the Primescan scanner has been damaged, it must no longer be used on patients.

The Primescan scanner must be recalibrated.

#### NOTE

Do not sterilize the Primescan scanner and the scanner cable!

#### NOTE

The window sleeves cannot be sterilized in the autoclave.

#### NOTE

##### For markets where the RKI\* guidelines are to be observed

The window sleeve is classified as a "semicritical medical device A" according to RKI guidelines and therefore does not have to be autoclaveable.

\*RKI=Robert Koch Institute, Berlin (Germany).

### 6.1.3.1 General information

The Primescan scanner is a very sensitive optical device and must therefore be handled with the utmost care. Protect the coated sapphire glass and the scanner window against scratches and clean them with a lint-free cloth and ethanol (commercially available cleaning alcohol) if any haze is noted during the acquisition. Wipe down the sleeve afterwards again with the absorbent cotton gauze dipped in drinking water.

#### NOTE

##### Hygiene processes

Observe the following hygiene processes.

#### NOTE

##### Observe country-specific requirements

Observe the country-specific requirements. In case of uncertainty regarding the specific regulations, we recommend using disposable sleeves.

The following methods are available for cleaning the sleeves:

- Wipe disinfection of the scanner and window sleeve [→ 53]
- High-level disinfection of the window sleeve [→ 54]
- Hot air sterilization of the window sleeve [→ 59]
- Using disposable sleeves [→ 60]
- Sterilizing autoclavable sleeves in the autoclave and using disposable windows [→ 61]

### 6.1.3.2 Components of the scanner

#### **⚠ CAUTION**

##### **Risk of cross-contamination**

The scanner must not be used inside the patient's mouth without a window sleeve/disposable sleeve/autoclavable sleeve. Without the window sleeve/disposable sleeve/autoclavable sleeve, the scanner cannot be disinfected or sterilized and cross-contamination may occur.

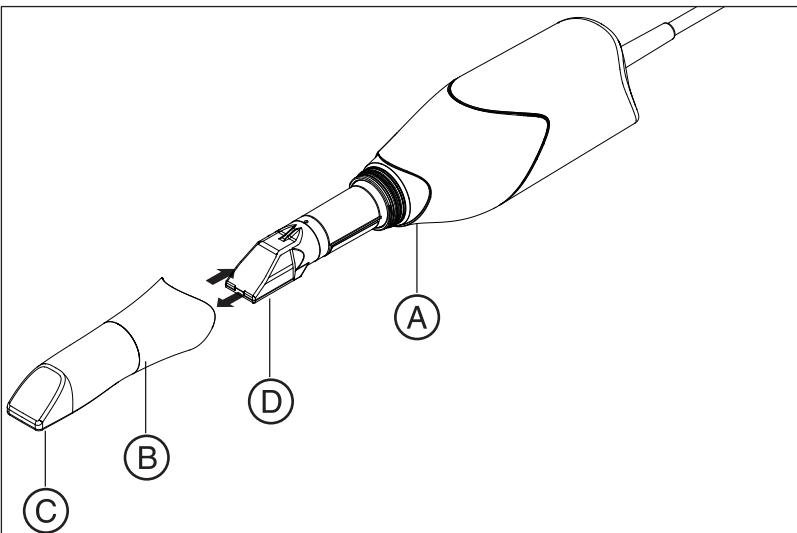
- Always put on the window sleeve, disposable sleeve or autoclavable sleeve with disposable windows.

#### **⚠ CAUTION**

##### **Risk of injury**

The window of the window sleeve is made of glass and is fragile.

- Use the sleeve with care so that the glass does not crack.
- If the glass has been cracked, the sleeve must no longer be used on patients.



A	Area for gripping in order to remove the sleeve from the body.	C	Sleeve window (made of coated sapphire for window sleeve / made of plastic for disposable sleeve and autoclavable sleeve)
B	<ul style="list-style-type: none"> <li>Window sleeve (standard sleeve)</li> <li>Disposable sleeve</li> <li>Autoclavable sleeve with disposable windows</li> </ul>	D	Scanner window

### 6.1.3.3 Removing the sleeve

If it is necessary to remove the sleeve, proceed as follows:

1. Grip the sleeve in the marked area.

#### NOTE

There is a risk of damaging the scanner window or the sleeve window if the sleeve is not pushed straight toward the front.

- > Push the sleeve straight toward the front; **do not tilt it**.

2. Remove the sleeve from the scanner body.

### 6.1.3.4 Attaching the sleeve

#### NOTE

##### Risk of damage to the windows

There is a risk of damaging the scanner window or the sleeve window if the sleeve is not pushed in a straight way.

- > The sleeve must not come into contact with the scanner window.  
> Push the sleeve straight toward the scanner body; **do not tilt it**.

- > Carefully refit the sleeve up to the stop.

### 6.1.3.5 Preliminary cleaning of the sleeve

Clean the scanner immediately after use as follows:

1. Carefully wipe the sleeve while it is on the scanner body so that no dirt whatsoever can remain stuck and can harden on the surface of the sleeve. For this purpose, use the following:
  - a dampened wiping cloth (see "Cleaning agents [→ 47]"),
  - an absorbent cotton gauze or a lint-free cloth, dipped in cleaning agent (see "Cleaning agents [→ 47]").
2. Wipe down the sleeve afterwards again with the absorbent cotton gauze dipped in drinking water.
3. Next dry the sleeve using a lint-free cloth.

#### 6.1.3.6 Wipe disinfection of the scanner and window sleeve

##### NOTE

Do not spray the Primescan scanner or immerse it in cleaning agents or disinfectants!

1. Carry out a preliminary cleaning process (see "Preliminary cleaning of the sleeve [→ 52]").
2. Use a dampened wiping cloth (see "Wipe disinfectants (virucidal limited) [→ 47]") or an absorbent cotton gauze, dipped in an agent named in section "Wipe disinfectants (virucidal limited) [→ 47]". Observe the reaction time according to manufacturer specifications. First wipe the scanner enclosure and then the sleeve. The scanner enclosure and sleeve are disinfected through this step.
3. Wipe down the sleeve afterwards again with the absorbent cotton gauze dipped in drinking water.
4. Next dry the sleeve using a lint-free cloth.

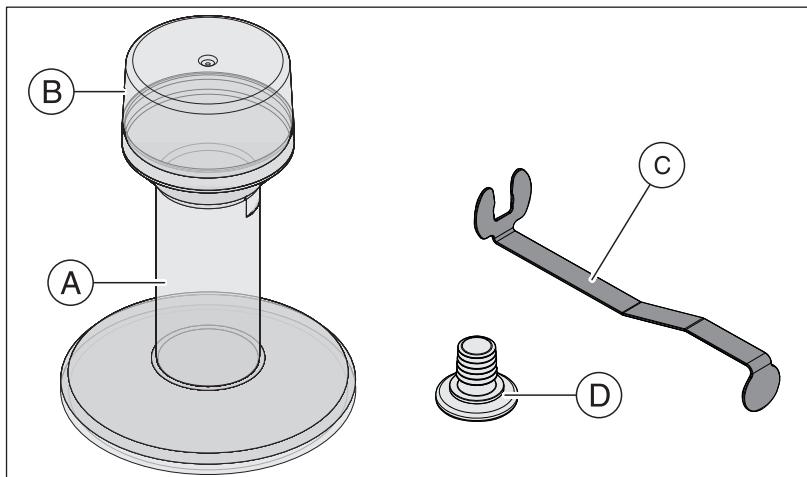
### 6.1.3.7 High-level disinfection of the window sleeve

#### NOTE

The hot air sterilization and high-level disinfection must not be combined.

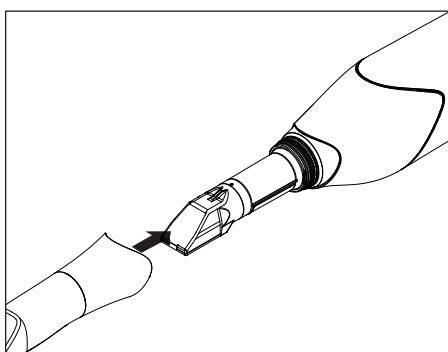
The complete process for high-level disinfection (HLD) is as follows – assuming the CIDEX® OPA disinfectant is available in your country via your dealer:

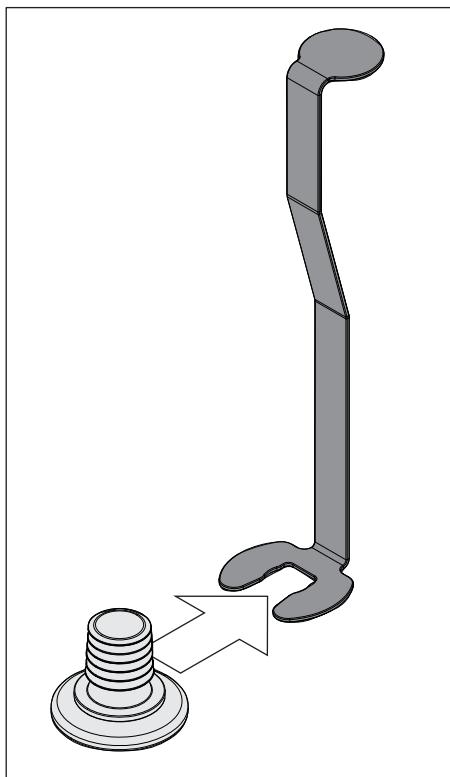
A HLD set to support the HLD processes can be ordered from Dentsply Sirona with REF 66 83 184.



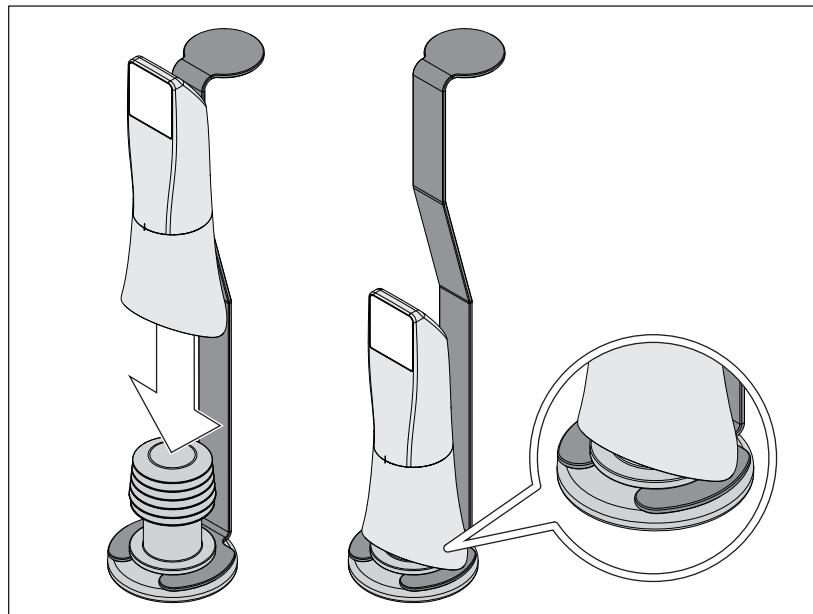
A	HLD tank	C	Metal bracket
B	Cover	D	Plugs

1. Carry out a preliminary cleaning process (see "Preliminary cleaning of the sleeve [→ 52]").
2. Always use personal protective equipment when implementing the high-level disinfection if not before.
3. Remove the sleeve from the scanner body (see "Removing the sleeve [→ 52]") section.
4. Place the white protective sleeve on the scanner head and place the scanner body in the scanner holder.
5. Use the following disinfectant for the high-level disinfection: CIDEX® OPA.





6. Push the plug completely into the metal bracket.

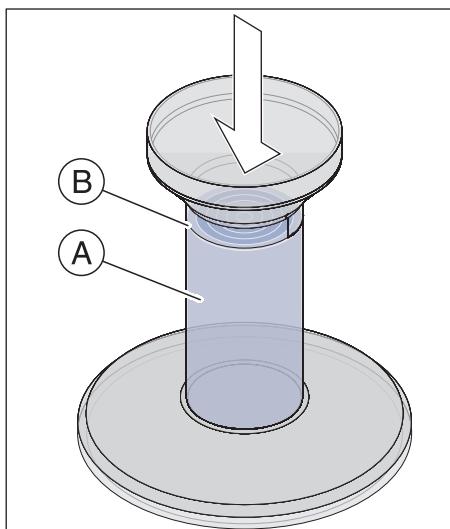


7. Press the sleeve onto the plug while holding the metal bracket firmly in place in order to ensure that no particle contamination or fluids penetrate the inside of the sleeve.

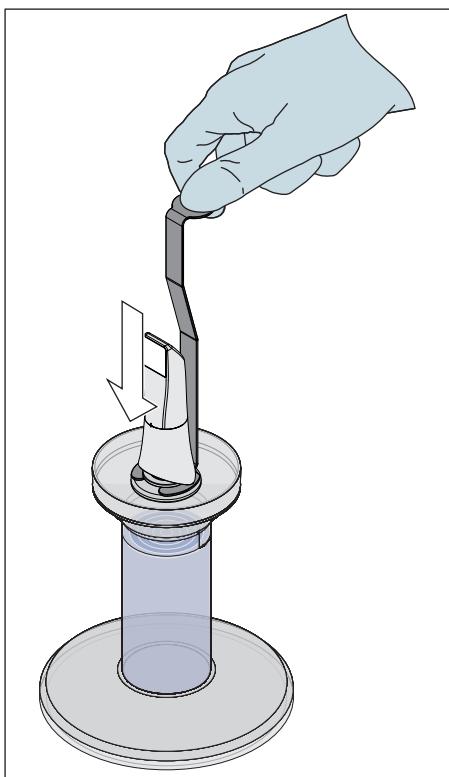
☞ The plug provides a waterproof seal for the sleeve when attached correctly.

**⚠ CAUTION**

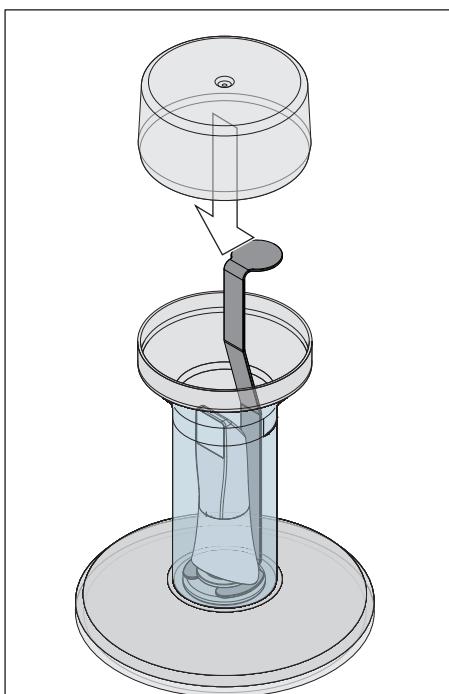
Observe the safety instructions from the disinfectant manufacturer.



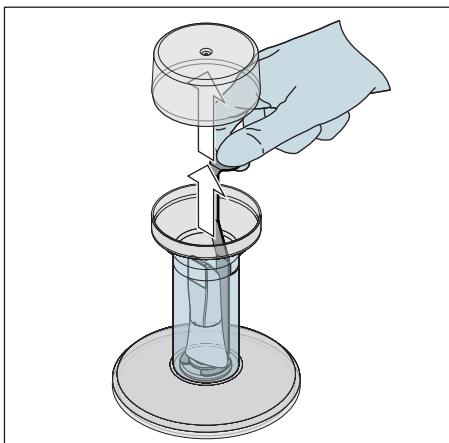
8. Carefully fill the HLD container up to the marking (B). You can use a funnel to pour in the fluid (A). Do not spill any disinfectant. Observe the safety instructions from the disinfectant manufacturer when cleaning if you do spill any disinfectant.



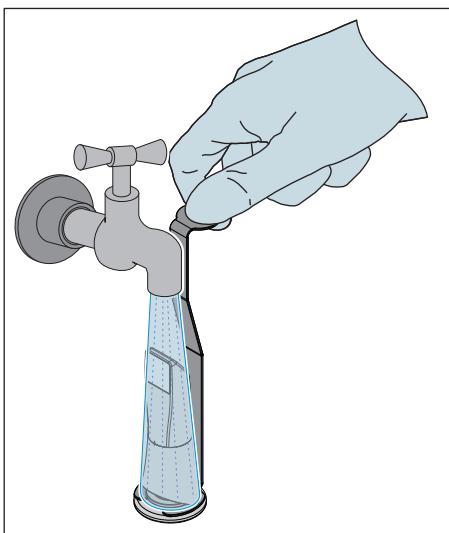
9. Insert the metal bracket with the sleeve.



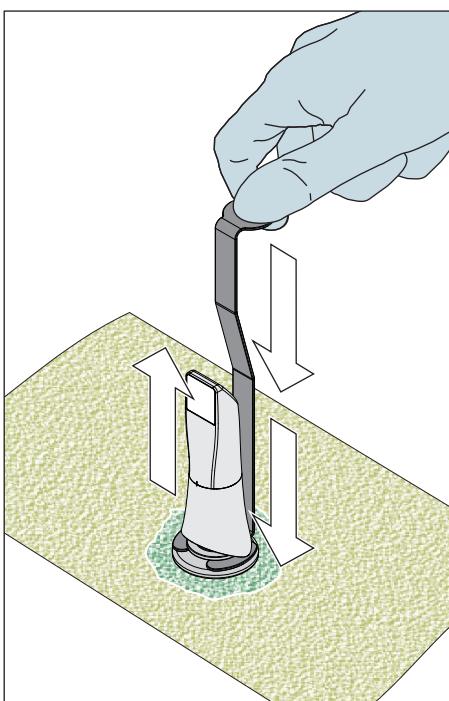
10. Place the cover on the container and leave the sleeve in the disinfectant for at least 12 minutes (CIDEX<sup>®</sup>OPA). The sleeve will not be damaged if it remains in the disinfectant for longer than the required time, but removing it shortly after the required time is recommended.



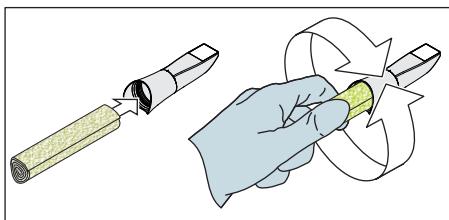
11. Remove the cover and take the bracket with the sleeve out of the container.



12. Carefully rinse the sleeve with tap water for at least 30 seconds while holding it with the bracket.



13. Remove the bracket from the sleeve carefully and slowly by pushing the bracket downwards. Ensure that the sleeve is pointing upwards so that no fluids are able to penetrate into the interior of the sleeve.
14. Remove the plug from the bracket.
15. Dry the plug.
16. Dispose of the fluid and store the bracket in the empty container if the HLD set is not used for more than one week.



17. Dry the entire outer surface of the sleeve as well as the inner section around the plug using a soft lint-free cloth. Ensure that no fluid is able to penetrate the inside of the sleeve.
18. Store the sleeve in such a way that it is protected from contamination until the next use.
19. Remove the white protective sleeve from the scanner head before use.
20. Carefully re-attach the sleeve and allow it to lock in place (see "Attaching the sleeve [→ 52]"). Hold the scanner in other places, not just on the sleeve in order to prevent it from falling.

#### 6.1.3.8 Hot air sterilization of the window sleeve

##### NOTE

Hot air sterilization and high-level disinfection must not be combined.

The process for hot air sterilization is as follows:

1. Carry out a preliminary cleaning process (see "Preliminary cleaning of the sleeve [→ 52]").
2. Remove the sleeve from the scanner body (see "Removing the sleeve [→ 52]" section).
3. Place the white protective sleeve on the scanner head and place the scanner body in the scanner holder.
4. The sleeve can be sterilized using hot air (180°C, 30min). Please ask your dealer for deals on hot air sterilizers. Place the sleeves in the hot air sterilizer and follow the manufacturer's instructions.
5. Store the sleeve in such a way that it is protected from contamination until the next use.
6. Carefully re-attach the sleeve and allow it to lock in place (see section "Attaching the sleeve [→ 52]"). Hold the scanner in other places, not just on the sleeve in order to prevent it from falling.

### 6.1.3.9 Using disposable sleeves

The Primescan scanner can be operated with disposable plastic sleeves in order to ensure maximum infection control. The sleeves are available using order number 66 86 880.

#### NOTE

The disposable sleeves cannot be used in the following circumstances:

- when using color analysis.

1. Following each patient, remove the disposable sleeve from the scanner body and dispose of it according to the standard procedure.
2. Clean the scanner head with a dry cloth.
3. Remove one disposable sleeve from its packaging. Slide the sleeve up to the stop on the scanner body, so that it is securely positioned on the Primescan scanner. To prevent the Primescan scanner from falling, hold the Primescan scanner in other places, not just on the sleeve.
4. Position the Primescan scanner in the holder, so that it can warm up briefly prior to the intraoral exposure. Make sure that the holder has been wipe-disinfected (see "Non-critical surfaces [→ 48]").

#### 6.1.3.10 Sterilizing autoclavable sleeves in the autoclave and using disposable windows

The Primescan scanner can be operated with autoclavable metal sleeves with replaceable disposable windows. These parts can be ordered using the following order numbers:

- Autoclavable metal sleeve: 67 24 640
- Replaceable disposable window (50 units): 66 64 267

##### NOTE

The standard window sleeves cannot be treated in the autoclave.  
➤ Use only the autoclavable metal sleeves in the autoclave.

##### NOTE

The autoclavable metal sleeves with replaceable disposable windows cannot be used in the following circumstance:  
- When using color analysis.

##### NOTE

When using autoclavable metal sleeves with replaceable disposable windows, the scanner must be calibrated after every batch (50 sleeves) (see "Calibrating the scanner [→ 64]").

##### NOTE

The autoclavable metal sleeve may only be used with the disposable window inserted.

- Make sure that a disposable window is inserted each time you use it.

1. Carry out a preliminary cleaning process after each patient (see "Preliminary cleaning of the sleeve [→ 52]").
2. Remove the sleeve from the scanner body (see "Removing the sleeve [→ 52]").
3. Pull on the disposable window to remove it from the sleeve and dispose of it in accordance with standard procedures.
4. Clean the scanner head with a dry cloth.
5. Disinfect the scanner holder (see "Non-critical surfaces [→ 48]").
6. Place the white protective sleeve on the scanner head and place the scanner in the scanner holder.
7. Place the autoclavable sleeve without the disposable window in a bag that is suitable for sterilization in an autoclave.
8. Place the bag with the sleeve in the autoclave and perform the sterilization in accordance with the specifications of the autoclave manufacturer.
9. Remove the bag with the sleeve from the autoclave and store the sterilized sleeve in such a way that it is protected from contamination until the next use.
10. To use the autoclavable sleeve for the next patient, take a disposable window out of its packaging and push it into the window holder of the sleeve.
11. Remove the white protective sleeve from the scanner head.

12. Slide the sterilized sleeve that has been fitted with the disposable window onto the scanner body as far as it will go, so that it is securely positioned on the Primescan scanner. To prevent the Primescan scanner from falling, hold the Primescan scanner in other places, not just on the sleeve.
13. Position the Primescan scanner in the holder, so that it can warm up briefly prior to the intraoral exposure. Make sure that the holder has been wipe-disinfected.

The following autoclaving processes have been tested and approved for treatment of the autoclavable sleeves:

#### **Gravity**

- 121°C, 30 min holding time, wrapped
- 132°C, 15 min holding time, wrapped
- 134°C, 10 min holding time, wrapped
- 135°C, 10 min holding time, wrapped
- 134°C, 3 min holding time, unwrapped
- 135°C, 3 min holding time, unwrapped

#### **Fractioned pre-vacuum**

- 132°C, 3x fractioned pre-vacuum, 4 min holding time, wrapped
- 134°C, 3x fractioned pre-vacuum, 3 min holding time, wrapped
- 135°C, 3x fractioned pre-vacuum, 3 min holding time, wrapped

#### 6.1.4 Cleaning the inside of the sleeve window

**NOTE!** This process applies only to the window sleeve (standard sleeve). If you notice during the scanning process that the inside of the window sleeve (standard sleeve) is dirty, then follow the process described below:

1. Remove the sleeve from the scanner body (see "Removing the sleeve [→ 52]").
2. Place the white protective sleeve on the scanner head and place the scanner body in the scanner holder.
3. Gently tap the sleeve on a soft surface / on your hand.
4. Blow out the sleeve with compressed air.
5. **NOTE!** Do not moisten the inside of the sleeve window with liquid (this can lead to marks). Clean the inside of the steel part with ethanol or isopropanol.  
Ensure that the removed impurities do not drop inside onto the sleeve window.  
Wipe the inside of the steel sleeve with a clean, dust-free and grease-free cloth and ensure that no droplets remain.
6. Remove the scanner body from the holder and remove the white protective sleeve.
7. Before placing the sleeve on it, clean the scanner head with a clean, dust-free and grease-free cloth to remove any dirt/adhesions.
8. Carefully re-attach the sleeve and lock it in place (see "Attaching the sleeve [→ 52]"). To prevent the scanner from falling, hold it in other places, not just on the sleeve.  
Check whether the process has had the desired effect until now.
9. **NOTE!** Do not allow any finger sweat or external pollutants to access the sleeve. If contamination is still visible, then clean the inside of the sleeve window with a cleaning swab that is suitable for the cleanroom. This type of cleaning swab has been added to the scope of delivery. If you have not received any cleaning swabs, you can order them using REF 65 04 364. Ensure that finger sweat or external pollutants are not able to access the sleeve.
10. Carefully re-attach the sleeve and lock it in place (see "Attaching the sleeve [→ 52]"). To prevent the scanner from falling, hold it in other places, not just on the sleeve.

## 6.2 Calibrating the scanner

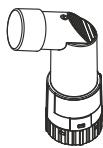
### NOTE

**Always calibrate scanner with window sleeve (standard sleeve) or autoclavable sleeve**

The scanner must always be calibrated with the window sleeve (standard sleeve) or autoclavable sleeve.

> Do not use the disposable sleeve for calibration.

The measurement procedure used by the system requires the use of a calibrated scanner. The scanner is calibrated ex works. Calibrate the scanner after every re-installation and after each time that it is transported.



The 3D calibration set supplied is available for the calibration process.

In order to achieve optimum results, the Primescan scanner must be allowed to warm up for **2 minutes before calibration**.

Recalibrate the scanner in the following cases:

- following transport (shaking stress) or during first commissioning,
- after storage in unheated or un-air-conditioned rooms (temperature differences exceeding 30°C / 85°F),
- with temperature differences of over 15°C / 60°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 errors can be corrected in doing so.
- As the system may be exposed to vibration loads without knowledge of this, it should be calibrated once a month.

### Starting calibration

1. In the software, navigate to the system menu and click on the "*Configuration*" button.
2. Click on the "*Devices*" button.
3. Click on the "*Primescan*" button.
4. Click on the "*Calibrate*" button.  
↳ The scanner view is displayed in one window.

## Calibrating the scanner

### NOTE

#### Use calibration set only with clean, dry Primescan scanner

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

- Make sure that the Primescan scanner is clean, disinfected and dry.



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 Primescan scanner in the calibration set using one hand. Ensure that the external calibration set screw is fully screwed in a clockwise motion until it gently locks into place.
4. Click on the "OK" button.
  - ↳ The measuring process starts.
  - ↳ The software prompts you to proceed to the next latching.
5. Turn the screw counter-clockwise until you reach the next latching point.
6. Click on the "OK" button. Hold the Primescan scanner still.
  - ↳ The software confirms the calibration process.
  - ↳ The software prompts you to proceed to the next latching.
7. Complete steps 5 and 6 a total of 17 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. Mount the bottom side of the calibration set to the tip of the scanner.
2. Click on the "OK" button.
  - ↳ The calibration process is continued.
  - ↳ Once the calibration is complete, a message is displayed indicating this.
3. Confirm the message by clicking the "OK" button.
  - ↳ The Primescan scanner is calibrated.

### Error message during calibration

The software indicates if an error occurs during calibration. If the calibration process resulted in errors, restart the process.

### End calibration

- ✓ The software indicates that the calibration was completed successfully.
- > Click the "OK" button.
  - ↳ The Primescan scanner is calibrated.

## 6.3 Color calibration

### General information

#### NOTE

**Always perform color calibration with window sleeve (standard sleeve)**

The scanner must always be color-calibrated with the window sleeve (standard sleeve).

- Do not use the disposable sleeve or the autoclavable sleeve for color calibration.

#### NOTE

### Faulty color analysis

The color analysis can be negatively impacted due to strong light incidence and it can lead to varying results.

- Set the scanner up so that it is not located directly in the beam path of an extreme light source (e.g., the treatment light) and not exposed to direct sunlight.

A color-calibrated scanner must be used for the color analysis.

#### NOTE

### Observe color calibration

A color calibration may only be performed at least 20 minutes after the system start/cleaning.

The color calibration must be performed regularly.

The scanner must be color calibrated every 2 weeks in order to carry out a reliable color analysis. You will achieve the best results if the scanner is color calibrated immediately before scanning a new case.

Carry out a color calibration also after changing a sleeve.

Heavily scratched sleeve window may not be used for a color analysis.

### Storing a color-calibration set



The color-calibration set must be stored in its packaging in a dry place which is protected from light. It must be used with a disinfected scanner as the color-calibration set must itself not be disinfected. If dust accumulates on the inside of the color-calibration set, it must be carefully removed using compressed air.

### Switch on the color analysis

1. In the software, navigate to the system menu and click on the "Configuration" button.
2. Click on the "Devices" button.
3. Click on the "Primescan" button.
4. Select the "Shade Detection" option.
  - You can choose between various color systems ("Shade Guide Selection").
  - You can decide whether you would like to be notified in 14 days when the color calibration is needed again.

5. Confirm the changes below with "Ok".
6. Click the "Color Calibration" button and carry out the color calibration.

### Color-calibrating the scanner



#### NOTE

##### Only use color calibration set with clean, dry Primescan scanner

In order to achieve optimum results, the Primescan scanner must be clean, disinfected and dry before color calibration.

➤ Make sure that the Primescan scanner is clean, disinfected and dry.

1. Remove the color-calibration set from the packaging.
2. Use the Primescan scanner to scan the QR code on the underside of your color-calibration set. In order to do this, you must hold the Primescan scanner still in front of the QR code so that it is completely visible in the picture. If the QR code appears to be shiny, hold the scanner at more of an oblique angle in order to avoid any glaring light and to make it easier to scan the codes. If the QR code is recognized, the next "*Please mount color calibration set*" step appears.  
This step of the QR code scan is skipped during the subsequent color calibration and the serial number of the color-calibration set is thus displayed. If this does not match the serial number printed on your color-calibration set, click on the "*Rescan QR Code*" button and scan the new QR code.
3. Mount the color-calibration set on the tip of the scanner until it locks into place.
4. Click on the "Ok"button.
  - ↳ The measuring process starts. Do not move the Primescan scanner or the color-calibration set during this time.
  - ↳ The software provides information on the progress of the calibration and informs you once the procedure is complete.

### Ending the color calibration

- ✓ The software indicates that the color calibration was completed successfully.
1. Click on the "Ok"button.
    - ↳ The Primescan scanner is now color-calibrated.
  2. Remove the color-calibration set from the scanner and place it back in the packaging.

### Error message during color calibration

The software indicates if an error occurs during color calibration. If the color calibration contained an error, ensure the following:

- The color-calibration set is free of dust
  - The color-calibration set was mounted correctly
  - The Primescan scanner exit window is clean.
- Then restart the color calibration.

Do not continue using a damaged color-calibration set; instead, contact your distributor to purchase a new one.

## Replacing the color calibration set

### NOTE

#### Regularly replacing the color calibration set

In order to achieve optimum results, the color calibration set must be replaced regularly.

➤ Observe the following:

Please note that the color calibration set

- can only be used in conjunction with Connect SW  $\geq$  5.
- can only be kept for use for a maximum of 2 years. You can find the expiry date at the bottom of the color calibration set container. Previous storage may mean that the period for use has been reduced to less than 2 years.
- can only be used for one year after the container has been opened. Write the date that the container was opened on the container after "Opened on \_\_\_\_\_" using a waterproof pen and do not use after one year.

The color calibration set may no longer be used once either of the two periods has expired.

The software notifies you that the color calibration set needs to be replaced with a new set before the color calibration expires.

Once the color calibration set has expired the software notifies you that a color analysis can only be carried out based on old calibration data.

Please contact your dealer for replacements for the color calibration set.

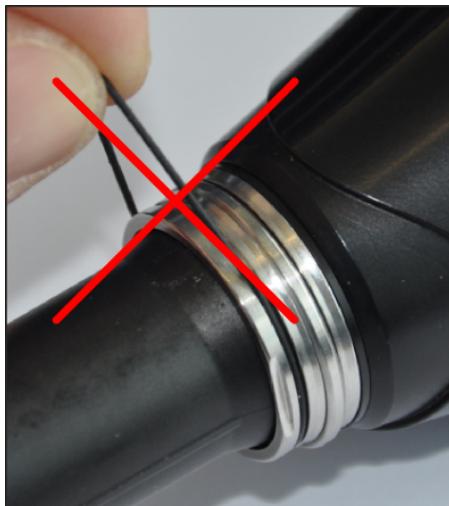
## 6.4 Replacing the O-ring

### Removing the worn O-ring

- ✓ The sleeve has been removed from the scanner body.
- 1. Hold the holding ring between your thumb and index finger.
  - ↳ In doing so, the O-ring is clamped in.
- 2. Use your thumb and index finger to guide towards the holding nut as shown above.
  - ↳ During this process, the O-ring is partially pushed out of the groove and an arc forms.
- 3. Use your other hand to touch the O-ring on this arc and remove it.



### Fitting the new O-ring



#### NOTE

##### Do not damage the O-ring

The O-ring can be damaged if overstretched.

- Never overstretch the O-ring.
- Never shape the O-ring during fitting as shown.



1. Slide the O-ring at one point into the O-ring groove.



2. Starting from this point, carefully use your thumb and index finger to push the O-ring into the groove (in a similar way to pushing it out but without any force).



3. Guide your thumb and index finger in such a way along the groove until the O-ring is fully positioned in the groove.

#### NOTE

##### The O-ring can be damaged

Ensure that the O-ring fits in the groove without twisting in order to prevent damage to the O-ring when fitting the sleeve.

#### IMPORTANT

##### Replacement O-rings

Replacement O-rings are available with the scanner or can be ordered under REF 66 80 974.

## 7 Disposal



On the basis of the Directive 2012/19/EU and the country-specific disposal regulations for old electrical and electronic equipment, we would like to stress that such equipment must be disposed of accordingly within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic equipment. These parts must not be disposed of as household waste. This is indicated by the "crossed out trash can" symbol.

### 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 waste electrical and electronic equipment.

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

#### In Germany

In order to arrange return of the electrical equipment, please send a disposal request to enretec GmbH. The following options are available for this purpose:

- Tel.: +49 800 805 432 1
- Email: [services@enretec.de](mailto:services@enretec.de)

You can arrange for transport to enretec GmbH yourself or request enretec GmbH to organize transport.

Please prepare the unit for transport according to the "Important conditions for returning electrical equipment": available online at ([www.enretec.de](http://www.enretec.de)).

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

By using this return option, we jointly ensure that any possible substances hazardous for the environment and health are disposed of in compliance with the law and that the devices are sent for best possible recycling.

### WARNING

#### Risk of cross contamination!

- > Prior to disassembly/disposal of the unit, all parts must be properly processed (cleaned/disinfected/sterilized).

If your unit is not permanently installed, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

#### Other countries

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

**IMPORTANT**

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

## 8 Appendix

### 8.1 Making backup copies

To increase the system's data security and protect themselves against data losses, users should make backup copies of the data regularly.

# Index

## A

Air pressure

    Operation, 20

    Storage, 20

    Transport, 20

Ambient temperature

    Operation, 20

Application, 9

## B

Building installation, 12

## C

CE mark, 23

Cleaning agents and disinfectants, 47

Compliance, 23

Conditions

    Operation, 20

    Storage, 20

    Transport, 20

Connect SW application, 33

Connect SW button, 33

## D

Dentsply Sirona Product service, 5

Disposal of old electrical and electronic devices, 72

Disposal of waste electrical and electronic equipment, 18

## E

enretec GmbH, 72

## H

HUB, 18

## I

Intended use, 9

## M

Maintenance, 15

Manufacturer's address, 5

## N

Network, 18

Nominal current, 20

## O

Operating mode, 20

## P

Packaging, 29

Plug connections, 32

Product safety, 15

Protection against medicaments, 48

Protection class, 20

Protective conductor, 18

## R

Rated line voltage, 20

Relative humidity

    Operation, 20

    Storage, 20

    Transport, 20

Repair, 15

## S

Safety instructions, 7

Scanner window, 51

Scope of supply, 29

Switch, 18

## T

Temperature

    Storage, 20

    Transport, 20

Touchpad, 21

Type designation, 20

## U

Unpacking, 29

## W

Water, 20



---

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

© SIRONA Dental Systems GmbH  
D3801.201.01.03.02 2022-09

Sprache: englisch  
Ä.-Nr.: 132 941

Printed in Germany

---

**SIRONA Dental Systems GmbH**



Fabrikstraße 31  
64625 Bensheim  
Germany  
[www.dentsplysirona.com](http://www.dentsplysirona.com)

Order No **67 97 216 D3801**