DENACAM

USER MANUAL

VERSION 2.5

mininavident
FOR INNOVATORS IN IMPLANTOLOGY

CONTACT INFORMATION

Manufacturer's address

mininavident AG
Gerberstrasse 5
4410 Liestal
Switzerland

www.mininavident.com

info@mininavident.com

EC representative

Axxos GmbH
Im Sägenloh 3
78333 Stockach
Germany

Authorized service partners

mininavident's authorized service partners cover all service needs for the entire system life cycle.

To find your local authorized service partner visit our website:

www.mininavident.com/servicepartner

Ordering components

Only use original accessories and spare parts. Order DENACAM components from an authorized mininavident service partner.

↗ For order information, see "Reference numbers" on page 106

FAQ

www.mininavident.com/faq

INTENDED USE OF THE DENACAM SYSTEM

The DENACAM navigation system is a real-time computerized navigational system intended to provide assistance in the intra-operative surgical phases of dental implantation surgery.

The system provides precise navigational guidance of surgical instruments according to the preoperative planning in the dental implantation procedure.

Patient population

Partially edentulous patients who require dental implants as part of their treatment plan.

Intended user

Oral surgeons, cranio maxillofacial surgeons, and general practitioners with knowledge of dental implant surgery and preoperative planning software, who understand written and spoken English, and who have successfully completed training on the DENACAM System.

Anatomical location

Complete upper and lower jaw, depending on the individual mouth opening and the placement and line of sight of the marker.

Intended medical indication

All dental implantations are indications for using this navigation system.

Intended medical contraindication

All contraindications for dental implants apply as well as a contraindication for this navigation system.

Dental implants contraindications

General:
Serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, maxillary and mandibular growth not completed, poor general state of health, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged therapy-resistant functional disorders, xerostomia, weakened immune system, illness requiring periodic use of steroids, titanium allergy, uncontrollable endocrine disorders.

Relative contraindications:
Previously irritated bone, diabetes mellitus, anticoagulation drugs/hemorrhagic diatheses, bruxism, parafunctional habits, unfavorable anatomic bone conditions, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, inadequate oral hygiene.

Local contraindications:
Inadequate bone volume or quality, local root remnants.

Navigation system contraindications

Heavy artefacts in region of marker, preventing unambiguous detection.

Electromagnetic compatibility (EMC)

The DENACAM System is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information.

mininavident only guarantees compliance of the DENACAM System with the EMC directives when it is used with original spare parts, consumables, and accessories. The use of spare parts, consumables, and accessories that have not been approved by mininavident may lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference.

↗ For more information about the EMC manufacturer's declaration, see "EMC manufacturer's declaration for the DENACAM System" on page 114

NOTES ON THE USER MANUAL

General information on the User Manual

Table 1 Revision history

Publication version	Software version	Revision date	Change description
1.0	1.0.0	August 2017	First version
1.1	1.0.0	January 2018	Additional information about the precision of the optical system
1.2	1.1.0	July 2018	Software update. Minor content changes. New address
1.3	1.1.1	February 2020	Software update. Screenshots updated. The "To export log files" task moved to System overview. Minor content changes.
2.0	1.2.0	July 2020	Additional content: Setting up the database, workflows for marker setup, registering different instruments, customize the screens. Changed procedure about take a dental impression. Minor content changes.
2.1	1.2.0	May 2021	Address of EC representative added. EC representative symbol added in table “Symbols used on the components”. Open-source licenses information added in appendix.

Table 1 Revision history

Publication version	Software version	Revision date	Change description
2.2	1.2.0	June 2022	Adjustment of "Intended use of the DENACAM system" section "Patient population".
2.3	1.3.0	September 2022	Software update. Screenshots updated. Changed procedure about take a dental impression. Renamed Drilling screen to Navigation screen. Minor content changes.
2.4	1.4.0	March 2023	Software update. Additional information added in appendix. Updated EMC Manufacturer`s Declaration based on updated norm IEC 60601-1-2:2014/ AMD1:2020. Added FCC Notice. Minor content changes.
2.5	1.4.0	October 2023	Address of EC representative changed. Additional marker (M1501), registration tool (M1801), and adapter (M1204) mentioned. New touchscreen (M1401) integrated. Changed the term “teaching” to “calibration” throughout the manual. System cart replaced with new version. Care and cleaning procedures added and updated. Adjustments to the cleaning agents used. Illustrations updated. Applicable standards updated. Minor content changes and additions.

Edition notice

This User Manual is intended for operators of the DENACAM System.

Every effort has been made to ensure that all the information contained in this User Manual is correct at the time of publishing. However, mininavident may need to update the User Manual information as a result of product surveillance.

Observe the User Manual information

Please familiarize yourself with the unit by reading through this User Manual before putting it into operation. It is essential that you comply with the specified warning and safety information.

↗ For more information about safety, see "Safety information" on page 11

Keep the User Manual safe

Always keep the User Manual handy in case you or another user requires information later. Save the User Manual on the computer or print it out. If you sell the unit, make sure that the User Manual is 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.

Online portal for technical documents

mininavident has set up an online portal for the technical documents at http://www.mininavident.com/manuals.

From there, you can download this User Manual along with other documents.

Help

If you continue to have difficulties despite having thoroughly studied the User Manual, please contact an authorized service partner.

↗ For information about your local authorized service partner, see "Authorized service partners" on page 2

Other valid documents

Documents	Supplement of
Quick Start Guide	DENACAM® System

Equipment options

This document describes the full version of the DENACAM System. It may therefore cover components that are not included in the package you purchased.

Names, symbols, and abbreviations

Component names

Component name	Descriptor
DENACAM® System	System
DENAOPT®	Camera
DENACOMP®	Computer
DENASOFT®	Software
DENASCREEN®	Touchscreen
DENADAPT®	Adapter
DENAREG®	Registration tool
DENACART®	System cart
DENAMARK®	Marker
DENATRAY®	Tray

Symbols used on components

Symbol	Explanation
CE 1250	CE mark with identification number of the notified body
	Consult instructions for use
	Consult User Manual
	Data matrix code for product information including UDI
EC REP	EC representative
	Date of manufacture
	Do not dispose of with domestic waste

Symbol	Explanation
Rx Only	Federal law restricts this system to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the system.
IP54	Limited protection against dust ingress (no harmful deposit). Protected against low pressure water jets from any direction. Limited ingress permitted.
	Keep dry
	Manufacturer
	Non sterile
	Not for re-use
REF	Reference number
SN	Serial number
	Thermo washer disinfectable
	Sterilizable in a steam sterilizer (autoclave) at the specified temperature
	Electrical security. Applied part type B
LOT	Batch code or Lot number

Abbreviations

Abbreviation	Definition
3D	Three-dimensional
AC	Alternating current
ANSI	American National Standards Institute
CBCT	Cone beam computed tomography
DC	Direct current
DIN	Deutsches Institut für Normung
EMC	Electromagnetic compatibility
EN	European standard
ESD	Electrostatic discharge
FAQ	Frequently asked questions
HDMI	High-definition multimedia interface
HF	High frequency
IEC	International Electrotechnical Commission
IFU	Instructions for use
ISO	International Organization for Standardization
LED	Light emitting diode
RF	Radio frequency
UDI	Unique device identification
USB	Universal serial bus

WARRANTY AND LIABILITY

Care and cleaning

The owner is responsible for making sure that all care and cleaning activities are performed.

Repair

As manufacturers of medical electrical equipment, mininavident can assume responsibility for the safety properties of the system only if repairs on the system are performed by authorized service partners, and if components of the system are replaced only by original spare parts in case of failure.

Exclusion of liability

Any customer modification of the system renders the warranty or service agreement null and void.

In the event that the system owner fails to fulfill its obligation to perform care and cleaning activities or ignores error messages, mininavident and its authorized dealers cannot assume liability for any damage thus incurred.

Duration

mininavident grants a product warranty of 24 months from the date of purchase.

ACCEPTANCE PROTOCOL / TRAINING

Product name: DENACAM® System		Serial number (SN):	
The product is:	☐ ☐ ☐	Purchased Rented Loaned until: _____	
Manufacturer (incl. address): mininavident, Gerberstrasse 5, 4410 Liestal, Switzerland			
Distributor (incl. address):			

Name of user:	
Hospital / practice / departement (incl. address):	
Signature of user:	
☐	**The signature confirms that the user has been successfully trained on the DENACAM system,** in accordance with the legal regulations (medical devices marketing regulation, medical devices act) and has understood the content of this manual. Particular attention has been paid to the chapter of safety notes, operation, care, and cleaning.
☐	**The signature confirms the hand over of the the fully functional DENACAM system.**

Name of instructor / authorized service partner		Date of instruction / handover	
Address of instructor / authorized service partner			
Signature of instructor / authorized service partner			

Training intended for users - Training about the DENACAM System is provided by mininavident in English or local language.
The following are the training materials in English or in local language:

- Scope of training
- User Manual
- Basic user training presentation
- Quick Start Guide (if planned and available)
- Workflow steps
- User feedback about the training provided - Training questionnaire

Only qualified trainer are allowed to train users. Qualified means they passed successful an advanced training.

SAFETY INFORMATION

GENERAL

General attention

To avoid serious or fatal injury, read this User Manual thoroughly before you use the system and its components.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this User Manual.
- Do not use the system in a way that is not described in this User Manual.
- Keep this User Manual in a safe place to ensure that it is not damaged and remains available for use.
- This User Manual must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

Safety alert

The safety alert symbol is used to alert you to potential physical injury hazards. Comply with all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

Warning

Warning...
...indicates a hazardous situation which, if not avoided, could result in death or serious injury.

Caution

Caution...
...indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

Notice

Notice...
...indicates a hazardous situation that, if not avoided, may result in damage to the system or components.

Important information that is not safety relevant is indicated with the following icon:

Note
Indicates additional information on correct use or useful tips.

SAFETY MESSAGES

Safety precautions

⚠ To avoid serious or fatal injury, read and comply with the following safety precautions.

RESPONSIBILITY OF THE SURGEON

This is a supporting device, providing additional information to the decision-making process during the surgical procedure. It is by no means intended to replace the surgeon's judgment.

- The final decisions as to the exact location and depth of the surgery are the sole responsibility of the surgeon.
- Under no circumstances does the device relieve the surgeon of his or her ultimate clinical responsibility.

ON-SITE INSTALLATION

- Only an authorized mininavident service partner shall install the system.
- The installation must have been performed according to the requirements of mininavident.

↗ For more information about the installation, see "Installation and setup" on page 33

EXCHANGE OR REMOVAL OF PARTS

Unauthorized exchange or removal of system parts can damage the system or stop it from functioning correctly.

- Do not exchange or remove any part of the system not specified in the user documentation.
- Leave replacement of components to an authorized mininavident service partner.

NON-SPECIFIED ACCESSORIES AND CONSUMABLES

Use of non-specified accessories and/or consumables can lead to incorrect navigation.

- Do not use components, accessories, or consumables that are not intended for use with the system.

↗ For a list of supported materials, see "Overview of the system components" on page 21

UNSUITABLE OPERATING CONDITIONS

Operation outside of the specified ranges may lead to incorrect navigation or malfunction of the system.

- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Keep the User Manual undamaged and available for use. It must be easily accessible for all users.
- The system is not intended for use in conjunction with oxygen rich environments or flammable anesthetics.

UNAUTHORIZED ACCESS

Unauthorized access to the components of the system can result in data loss, system damage, or system unavailability.

- Only authorized persons may access system components.

TOUCHSCREEN

The touchscreen is equipped with touch-sensitive control technology. Operating with pointed objects such as ballpoint pens, pencils, etc. could damage or scratch its surface.

- Always operate the touchscreen by pressing it gently with your fingertip.

ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC).

- The installation must have been performed according to the requirements of The installation must have been performed according to the requirements of mininavident.
- The use of spare parts, consumables, and accessories that have not been approved by mininavident may lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference.
- Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If it is necessary to operate the product close to other devices or in a stack with other

devices, observe the correct functioning of the system.

- HF surgical equipment can influence the operation of the system and may not be operated in combination with the system.
- Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkie etc. can affect the system and should be kept at least a distance of 30 cm away from any part of the system.

↗ For more information about the EMC manufacturer's declaration, see "EMC manufacturer's declaration for the DENACAM System" on page 114

ELECTROSTATIC DISCHARGE

Electrostatic discharge (ESD) from people can damage electronic components when the components are touched. Damaged components usually have to be replaced. Repairs must be performed by qualified personnel.

Measures to protect against ESD include:

- Procedures to avoid electrostatic charging via:
  - Air conditioning
  - Air humidification
  - Conductive floor coverings
  - Non-synthetic clothing
- Procedures to avoid 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 earth

mininavident recommends that all persons working with this system are made aware of the significance of the ESD warning label.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the system, read the warning messages carefully.

OPERATOR QUALIFICATION - INSUFFICIENT KNOWLEDGE AND SKILLS

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual.

- Do not carry out operation and maintenance unless you have read and understood the information provided in the user documentation.
- Leave installation, repair, and preventive maintenance to an authorized mininavident service partner.
- Carefully follow the procedures specified in the instructions for operation and maintenance.

Caution messages

⚠ List of caution messages

Failure to observe them may result in minor or moderate injury.

- Before operating, read the caution messages carefully.

INJURY TO THE PATIENT DUE TO POWER INTERRUPTION

A power failure or momentary drop in voltage may stop the navigation procedure or lead to data loss.

- Always keep case planning data available on a USB storage device during surgery.

↗ For information about how to proceed after a power failure, see "Software Messages/Warnings" on page 100

INJURY TO THE PATIENT DUE TO WRONG INSTALLATION

Incorrect installation and setup of the system may lead to injury to the patient and/or inaccurate navigation procedure.

- Leave installation, repair, and preventive maintenance to an authorized mininavident service partner.
- The person assembling the system is responsible for ensuring conformity according to e.g. Directive 93/42/EEC.
- The system must only be connected to AC mains supply with protective earth.
- Make sure the power supply connector can be easily unplugged in case of an emergency.

↗ For more information about the installation, see "Installation and setup" on page 33

INJURY TO THE PATIENT DUE TO USE OF NON-FUNCTIONAL OR NON-CONFORM COMPONENTS

Use of damaged, contaminated, or not correctly working components may lead to inaccurate navigation procedure.

- Do not use USB storage devices with a separate power supply. USB storage devices with a separate power supply may seriously interfere with the electrical safety of the system.
- Replace damaged components prior surgery.
- Do not use components that are contaminated.
- Do not use components that may not work correctly (e.g. after falling down).
- Do not use components that are not intended for use with the system.
- Do not use components that passed their service interval.

↗ For a list of supported materials, see "Overview of the system components" on page 21

INJURY TO THE PATIENT DUE TO NOT SPECIFIED TEMPERATURE CONDITIONS OF THE COMPONENTS

Distortion of camera housing in case of heating by built-in parts (e.g. LED) or an external source (solar radiation).

- Avoid heat sources close to the system and its components. Exposure to heat may cause the temperature inside of the components to rise.

↗ For information about operating conditions, see "Specifications" on page 106

↗ For information about cooling down the system, see "To cool down the system" on page 102

Notices

List of notices

Failure to observe the notices may result in damage to the system.

- Before operating, read the notices contained in this summary carefully.

DAMAGE TO THE COMPONENTS DUE TO MECHANICAL STRESS

Shock, vibration, or pressure can damage the components of the system.

- Keep sources of vibration away from the components.
- Do not place objects on the components.

INFECTION BY BIOHAZARDOUS WASTE

- Treat the system as biohazardous waste. Decontamination (cleaning, disinfection, and sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the system according to the local regulations. For more information, contact your Service representative.

SAFETY LABELS ON THE COMPONENTS

The system has warning labels to draw your attention to areas of potential hazard.

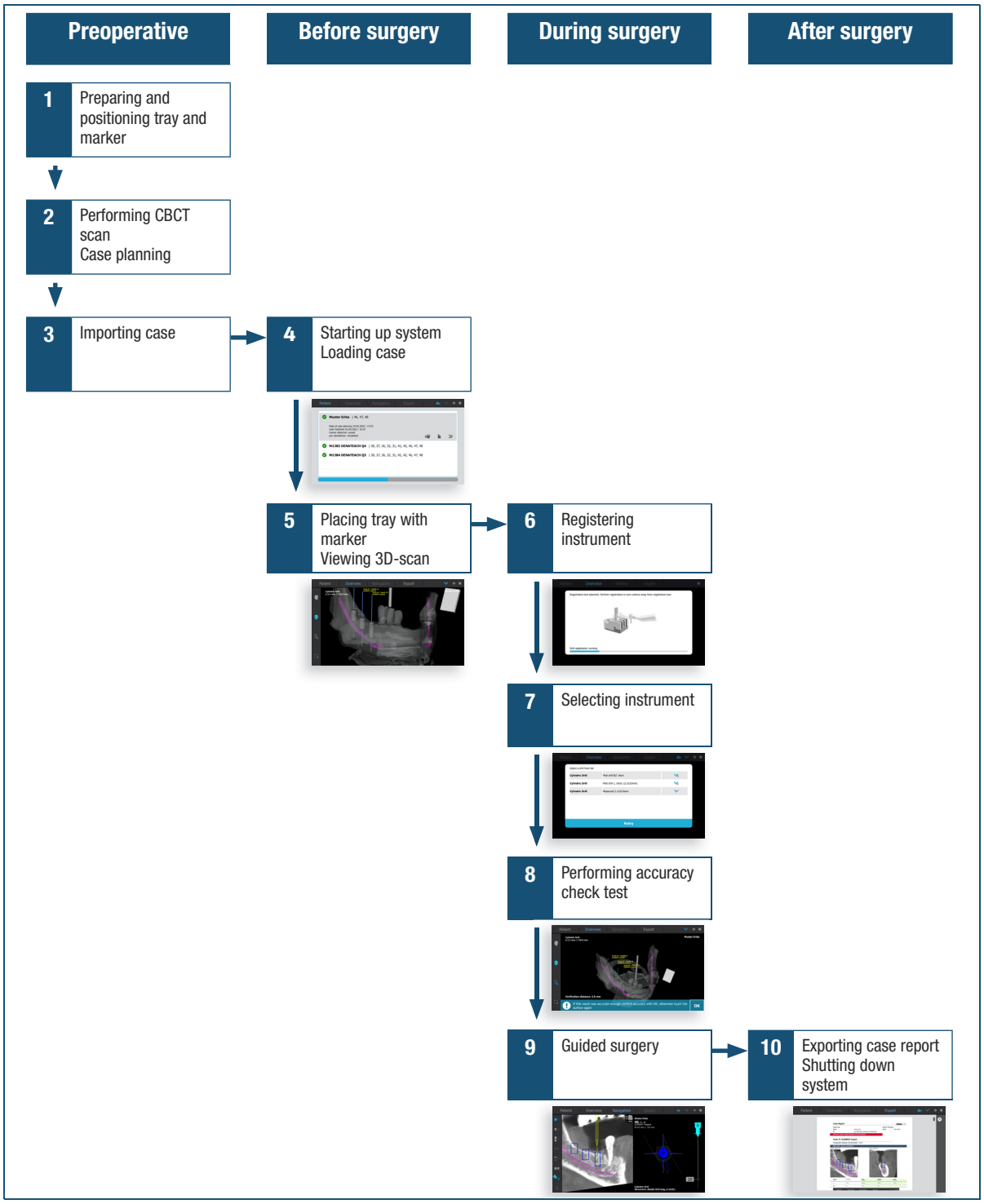
The following list explains the meanings of the labels at the locations where you find the labels.

Table 2 Safety labels on the components

Label	Where to find	Meaning
	Computer	Consult User Manual
	Computer	Do not dispose of with domestic waste
	Marker / Tray	The component has not been sterilized or treated with a process during manufacturing to eliminate potential microorganisms
	Marker / Tray	The component must only be used with one patient and must not be reprocessed
	Adapter - Bien-Air ventilated with cable	Electrical security. Applied part type B.

SYSTEM OVERVIEW

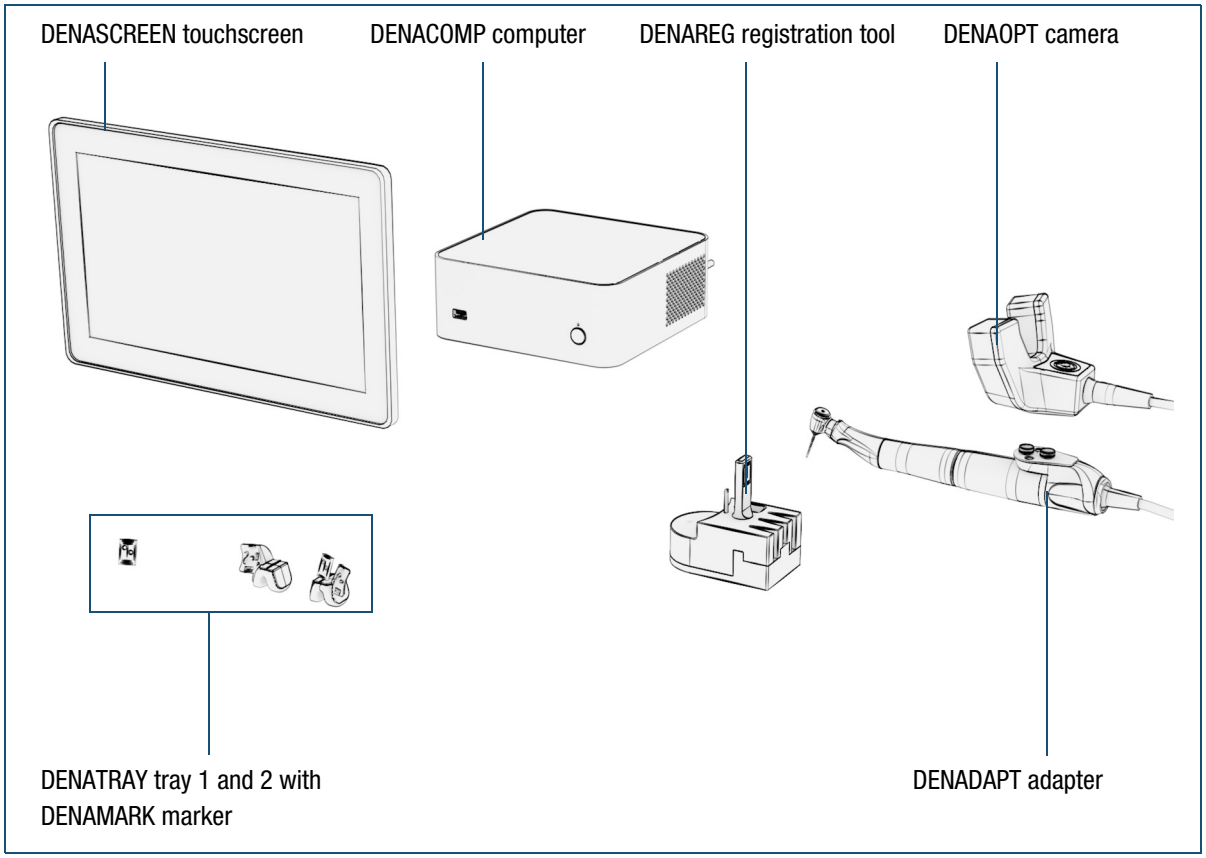
DENACAM WORKFLOW



Picture 1 DENACAM workflow

↗ For more information about operation, see "Operation" on page 47

OVERVIEW OF THE SYSTEM COMPONENTS



Picture 2 System components

- For more information about unpacking the components and setting up the system, see "Installation and setup" on page 33
- For reference numbers, see "Reference numbers" on page 106
- For technical specifications, see "Specifications" on page 106

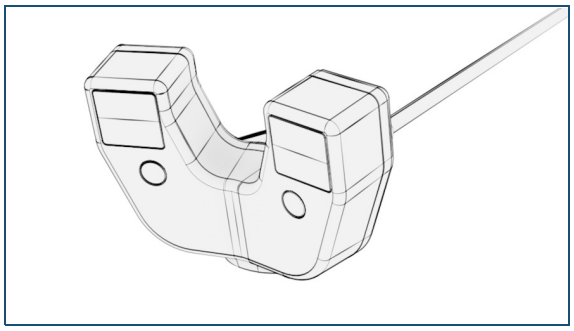
The DENAOPT camera

The camera contains the optical system (stereo camera) which captures the pattern of the marker. In addition, two LED lights are integrated into the housing. These LED lights can be activated via the button in the middle of the housing.

The camera is attached to the handpiece motor using the adapter and connected to the computer via the USB cable.

↗ For information about attaching the camera o the handpiece motor, see "Attaching the camera to the handpiece motor" on page 38

↗ For information about connecting the camera to the computer, see "Connecting the system" on page 37



The housing is made of anodized aluminum alloy.

⚠ For cleaning, the camera must be separated from the adapter / handpiece motor and cleaned individually. Only wipe disinfection is allowed. The camera must not be sterilized.

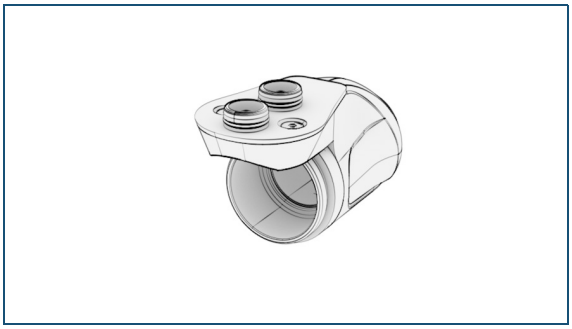
↗ For information about cleaning, see "Individual cleaning instructions" on page 81

The DENADAPT adapter

The adapter connects the camera to the handpiece motor with a magnetic quick-release fastener. It is screwed to the handpiece motor permanently.

↗ For information about mounting the adapter to the handpiece motor, see "Attaching the camera to the handpiece motor" on page 38

By means of a spring mechanism, the plate can be rotated around the handpiece motor, allowing the camera to be fixed in the most suitable position for surgery.



The adapter is mainly made of stainless steel and fiber-reinforced plastic.

⚠ Not all handpiece motors are compatible with the adapter.

↗ For information about compatible handpiece motors, see www.mininavident.com/faq

The adapter is cleaned and sterilized together with the handpiece motor.

↗ For information about cleaning, see "Individual cleaning instructions" on page 81

The DENACOMP computer

The computer is specially designed for the DENACAM System using a LINUX operating system. The DENASOFT software is pre-installed.

The computer is switched on by the power button and switched off by the software.

The USB port on the front is used for connecting a USB storage device for the following purpose:

- Importing case planning data
- Exporting case reports
- Updating the software
- Importing and exporting instrument datasets

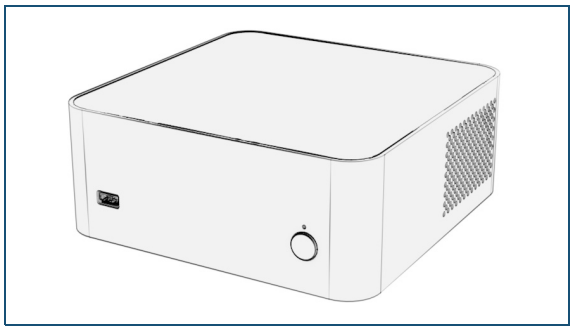
You can connect any USB storage device to the system that does not require the installation of additional driver software. The system can access the highest level only on a USB storage device, i.e. the root directory. You cannot access folders.

↗ For information about setting up the software, see "Service tasks" on page 40

On the back of the computer, you find the following ports:

- AC mains power input
- DC power output for the touchscreen
- USB port for the camera
- USB port for the touchscreen
- DisplayPort for the touchscreen

↗ For information about connecting the computer to other components, see "Connecting the system" on page 37



The surfaces of the computer are made of aluminum.

⚠ For cleaning, the computer must be switched off. Only wipe disinfection is allowed. The computer must not be sterilized.

↗ For information about cleaning, see "Individual cleaning instructions" on page 81

The DENASCREEN touchscreen

The touchscreen displays the user interface and is equipped with a touch sensitive panel. It can be used with gloves.

The software can be fully operated by the touchscreen. No mouse or keyboard is necessary.

A screen protector film or sterile foil may be attached to the touchscreen to protect it against damage or for touching intra-operatively.

The touchscreen turns on as soon as the computer is switched on and turns off when the computer is shut down.

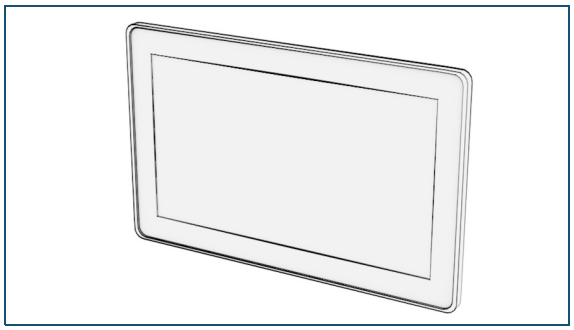
On the back of the touchscreen, you find the following elements:

- DC power input from the computer
- USB port for the computer
- DisplayPort for the computer
- Ports not used for the DENACAM System (Audio, VGA, DVI-D)
- Operating buttons not used for the DENACAM System (Input, menu, plus, minus, power)

↗ For information about connecting the touchscreen to the computer, see "Connecting the system" on page 37

In the basic version, the touchscreen is placed on a stand. Alternatively, it can be mounted on the swivel arm of the DENACART system cart.

↗ For information about mounting the touchscreen to the system cart, see"Installing the system cart (optional)" on page 35



The surfaces of the touchscreen are made of plastic, glass, and silicone rubber.

⚠ For cleaning, the computer and touchscreen must be switched off. Only wipe disinfection is allowed. The touchscreen must not be sterilized.

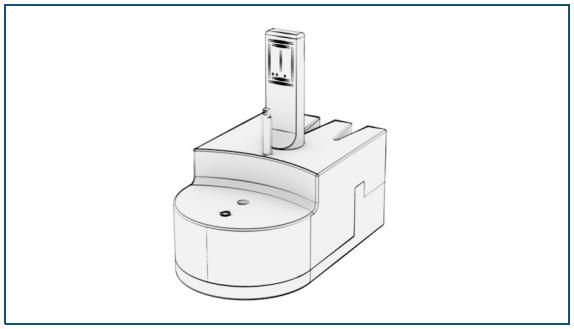
↗ For information about cleaning, see "Individual cleaning instructions" on page 81

The DENAREG registration tool

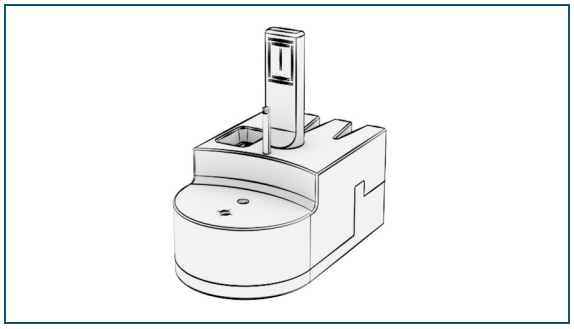
The registration tool is used to calibrate the handpiece and to register the drill and the round bur. It consists of the following:

- An upper plate (registration tool M1800), or
- an upper plate with embedded second marker (registration tool M1801)
- A base plate, attached by a magnet
- A pin for calibrating the handpiece
- Three tapered slots for different drill lengths
- A conical cavity for different round bur diameters
- A deepening with cross marking for locator drills, taps, other shape drills and implant adapters
- A centrally positioned marker

REGISTRATION TOOL M1800



REGISTRATION TOOL M1801 WITH EMBEDDED SECOND MARKER



The registration tool is made of stainless steel and zirconia.

The marker on the registration tool has a pattern that is captured by the camera. The pattern may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the registration tool no more than 50 times.

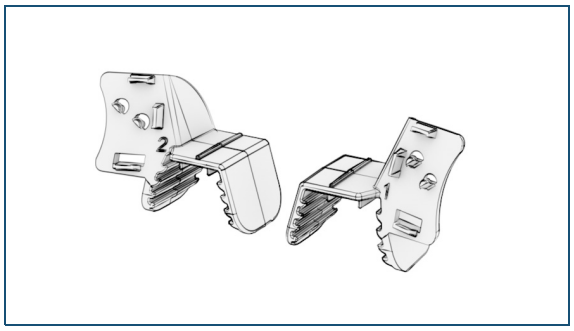
↗ For information about cleaning and inspecting, see "Individual cleaning instructions" on page 81

The DENATRAY tray

The tray holds the DENAMARK marker and is fixed to the lower or upper jaw by means of impression material.

↗ For information about handling the tray and the marker, see "Assembling, positioning, and attaching the tray with the marker" on page 50

It is available in two versions. Tray 1 holds the marker on the right side, tray 2 on the left side.



The tray is made of plastic.

⚠ The tray is a single-use product and must be disposed after each patient.

↗ For information about disposing the tray, see "To dispose the tray after use" on page 94

The DENAMARK marker

Mounted on a tray, the marker serves as a reference point for the navigation system in the lower or upper jaw of the patient.

Two marker are available:

- Reusable marker M1500
- Single-use marker M1501

↗ For information about mounting the marker onto the tray, see "Assembling, positioning, and attaching the tray with the marker" on page 50

It has a pattern that is captured by the camera.

The marker M1500 and M1501 is made of aluminum oxide.

The pattern of the reusable marker M1500 may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the marker no more than 50 times.

↗ For information about cleaning and inspecting, see "Individual cleaning instructions" on page 81

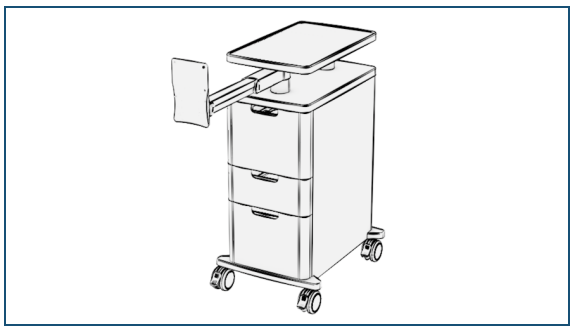
The DENACART system cart

The system cart is an accessory that can be ordered optionally.

It offers the following possibilities for working with the DENACAM System:

- A swivel arm for holding the touchscreen
- Storage space for the computer
- Three drawers for extra storage space
- Equipment for cable management (pre-installed cables, holder for a magnetic multiple socket)

↗ For information about installing the system cart, see"Setting up the workspace" on page 58

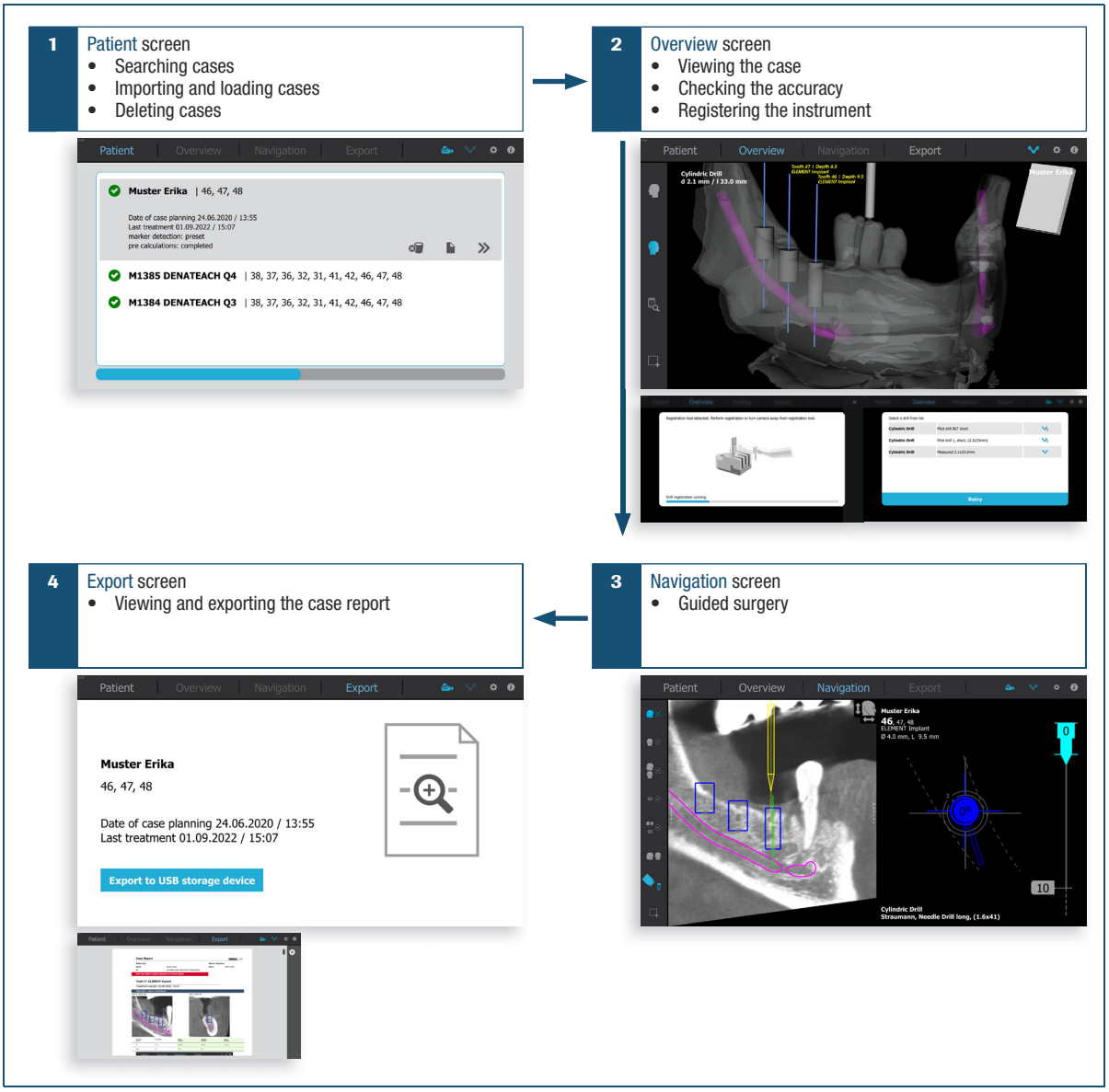


The surfaces of the system cart are made of plastic, steel, and aluminum.

⚠ Only wipe disinfection is allowed. The system cart must not be sterilized.

↗ For information about cleaning, see "Individual cleaning instructions" on page 81

OVERVIEW OF THE SOFTWARE



Picture 3 Overview user interface

The DENACAM software can be fully operated by the touchscreen. No mouse or keyboard is necessary.

For working with the DENACAM System, the user interface guides the user through the four main menu entries **Patient**, **Overview**, **Navigation**, and **Export**.

Each main menu entry has its own screen, and if necessary, additional overlays.

1. **Patient** screen
2. **Overview** screen
   - Drill registration overlay
   - Drill selection overlay
3. **Navigation** screen
4. **Export** screen
   - Case report viewing overlay

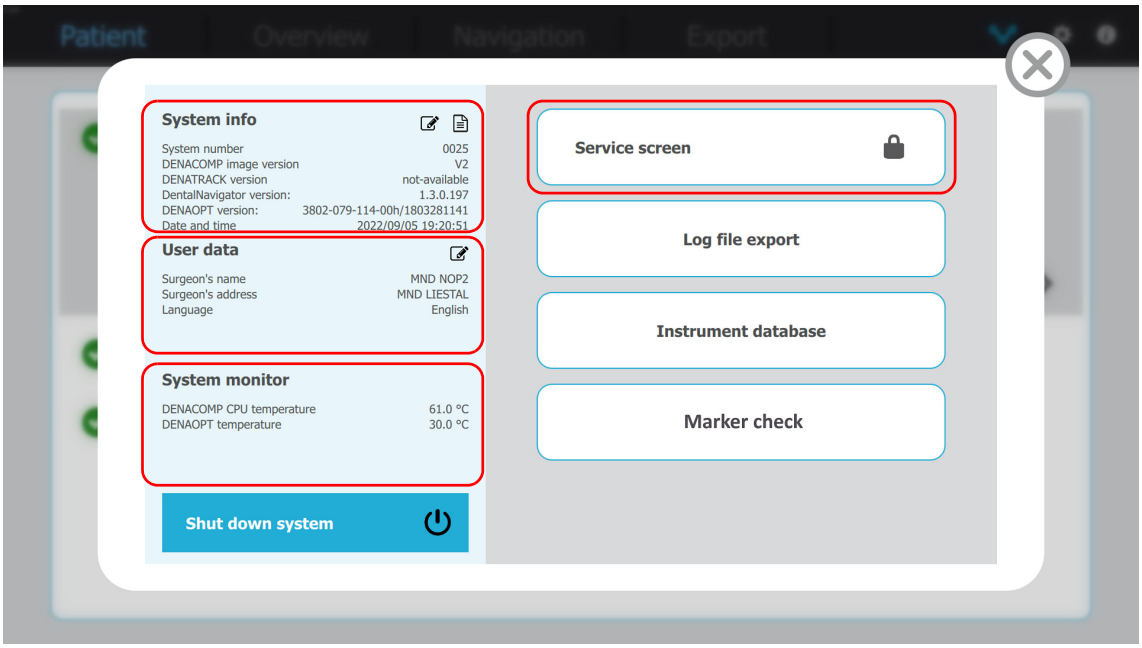
The DENASOFT software continuously calculates the three-dimensional position and angle of the handpiece and instrument in relation to the DENAMARK marker in the mouth.

Together with data from case planning and the information on the exact implant position, the angle and depth of the instrument for preparing the implant bed and placing the implant are displayed in real time on the DENASCREEN touchscreen.

The necessary dimensions of instruments are stored in the integrated instrument database.

↗ For information about setting up the software, see "Service tasks" on page 40

System and user information



Picture 4 System and user information - Configuration overlay

To start up the system, press the power switch on the computer. Wait until the **Patient** screen is displayed.

Patient screen > ⚙ button

On the configuration overlay, you have access to following information and functions:

- **System info**:
  - **System number**
  - **DENACOMP Image version**
  - **DENATRACK version**
  - **DENTALNAVIGATOR version**
  - **DENAOPT version**
  - Choose the 🗎 button to view the legal notice
- **User data**:
  - **Surgeon's name**
  - **Surgeon's address**
  - **Language**
  - **Date and time**
  - Choose the ✎ button to edit the user data

↗ For information about how to set up the user data, see "To set up the user data" on page 32

- **System monitor**:
  - **DENACOMP CPU temperature**
  - **DENAOPT temperature**
- Choose the **Shut down system** button to shut down the system
- Choose the **Log file export** button to export the DENACAM log files to an USB storage device
- Choose the **Service screen** button to access the service screen overlay (password required):
  - **LED timeout**
  - **System calibration**
  - **Monitoring**
  - **Software update**

↗ For information about logging in to the service screen, see "Service tasks" on page 40

- Choose the **Instrument database** button to import/ export datasets of instruments, delete, edit, or add single instruments.

  ↗ For more information about the instrument database, see "Setting up the instrument database" on page 44

- Choose the **MARKER check** button to perform a marker visibility check.

  ↗ For more information about the marker visibility check, see "To perform a marker visibility check" on page 83

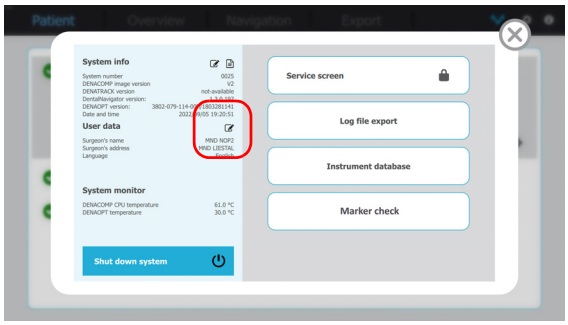
To set up the user data

1 To start up the system, press the power switch on the computer.

Wait until the **Patient** screen is displayed.

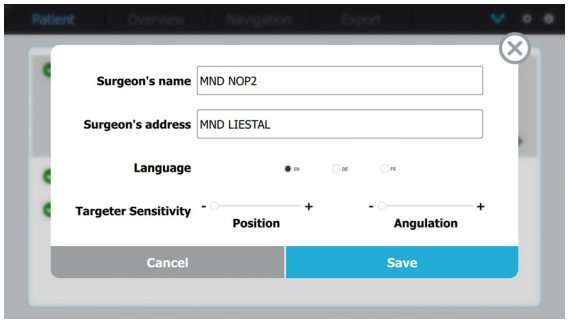
2 On the menu bar, choose the ⚙ button.

The configuration overlay is displayed.



3 To access the user data, choose the ✎ button on the configuration overlay.

The user data overlay is displayed.



4 Edit the user data.

A virtual keyboard is displayed when you place the cursor in an editable field.

5 With the **Targeter Sensitivity** you can choose low/middle/high sensitivity of the targeter for the translation position and the angulation.

6 Choose the **Save** button.

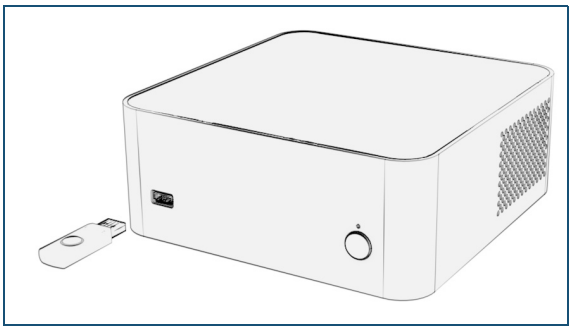
If you don't want to save, choose the **Cancel** button

To export the log files

1 On the menu bar, choose the ⚙ button.

The configuration overlay is displayed.

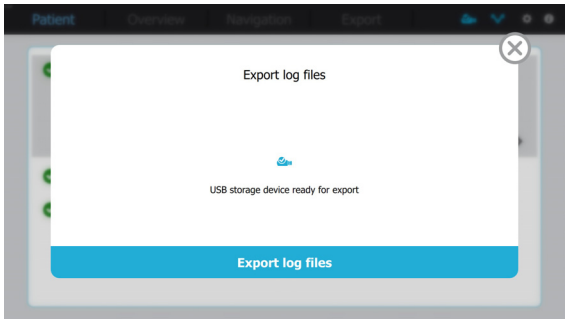
2 On the front of the computer, insert the USB storage device with adequate storage capacity.



3 To export log files, choose the **Log file export** button.

The **Export log files** overlay is displayed.

The USB storage device indicator lights up in blue when a valid USB device is connected ( ).



4 Choose the **Export log files** button and wait until the log files are saved on the USB storage device.

5 Remove the USB storage device.

6 Choose the ⊗ button to exit.

INSTALLATION AND SETUP

UNPACKING AND SETTING UP THE SYSTEM

As manufacturers of medical electrical equipment, mininavident can assume responsibility for the safety properties of the system only if repairs of the system are performed by authorized service partners,

The main tasks for unpacking and setting up the system are:

1. Unpacking all components
2. Installing the system cart (optional)
3. Connecting the system
4. Attaching the camera to the handpiece motor
5. Service tasks
6. Calibrating the handpiece

PREREQUISITES

Correct transport and storage of the components.

↗ For more information about the transport and storage conditions, see "Transport and storage conditions" on page 111

SAFETY

Caution

Injury to the patient due to wrong installation

Incorrect installation and setup of the system may lead to injury to the patient and/or inaccurate navigation procedure.

- Leave installation, repair, and preventive maintenance to an authorized mininavident service partner.
- The person assembling the system is responsible for ensuring conformity to Directive 93/42/EEC.
- The system must only be connected to a mains supply with protective earth.
- Make sure the power supply connector can be easily unplugged in case of an emergency.

↗ For more information about safety, see "Safety information" on page 11

Unpacking all components

Carefully unpack all components and check the containers to make sure that all the parts are in the package and in good condition.

Contents of the packages

↗ For reference numbers, see "Reference numbers" on page 106

DENACART SYSTEM CART (OPTIONAL)

- 1 System cart
- 1 Swivel arm inclusive screw for mounting the touchscreen

DENACOMP COMPUTER

- 1 Computer
- 1 AC power cable

DENASCREEN TOUCHSCREEN

- 1 Touchscreen, including stand
- 1 DC power cable
- 1 USB cable
- 1 DisplayPort cable

DENAOPT CAMERA

- 1 Camera, including magnetic mounting plate

DENADAPT ADAPTER

- 1 Adapter

DENAREG REGISTRATION TOOL

- 1 Registration tool

DENATRAY TRAY 1

- 4 Tray 1

DENATRAY TRAY 2

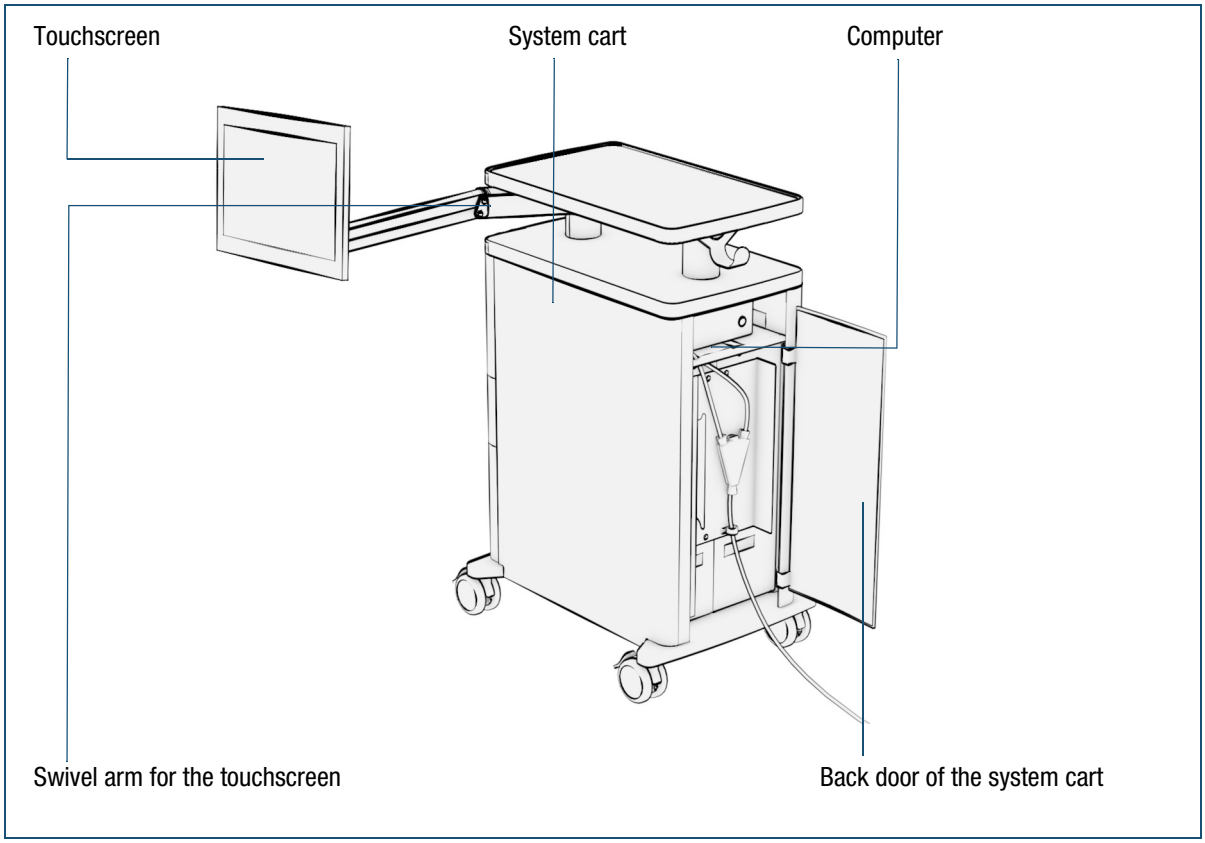
- 4 Tray 2

DENAMARK MARKER

- 2 Markers (reusable M1500)
- 4 Markers (single-use M1501)

DENACAM QUICK START GUIDE

Installing the system cart (optional)



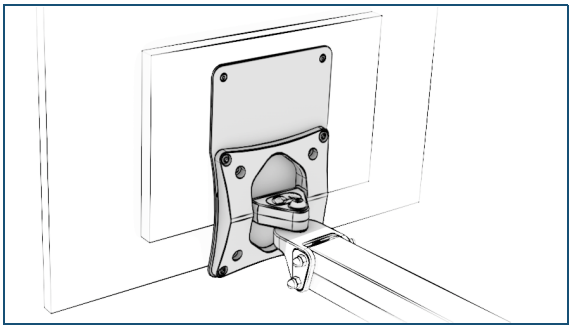
Picture 5 Installing the system cart

To install the system cart

1 Mount the swivel arm on the system cart.

2 Attach the touchscreen to the swivel arm. Use following tools:

- 5.5 mm Socket (Swivel joint with fixing plate/ Mounting plate)
- T20 Torx screwdriver (Mounting plate/ Touchscreen)
- 5 mm Allen key (Swivel joint with fixing plate/ Swivel arm)
- 13 mm Socket (Swivel joint with fixing plate/ Swivel arm)



3 Open the back door of the system cart.

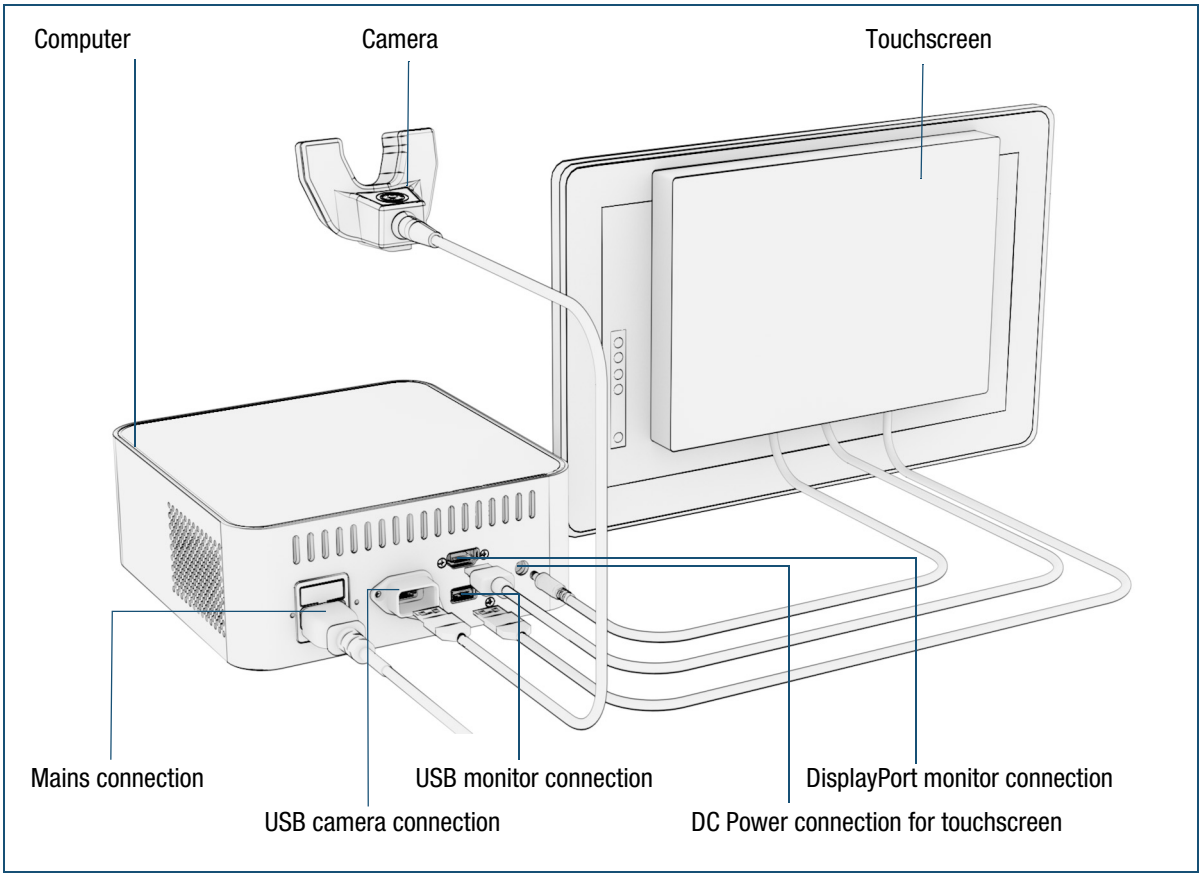
4 Identify the pre-installed cables and connect the system.

↗ For information about connecting the system, see "Connecting the system" on page 37

5 Slide the computer into the intended compartment inside the system cart.

6 Close the back door of the system cart.

Connecting the system



Picture 6 Connecting the system

To connect the system

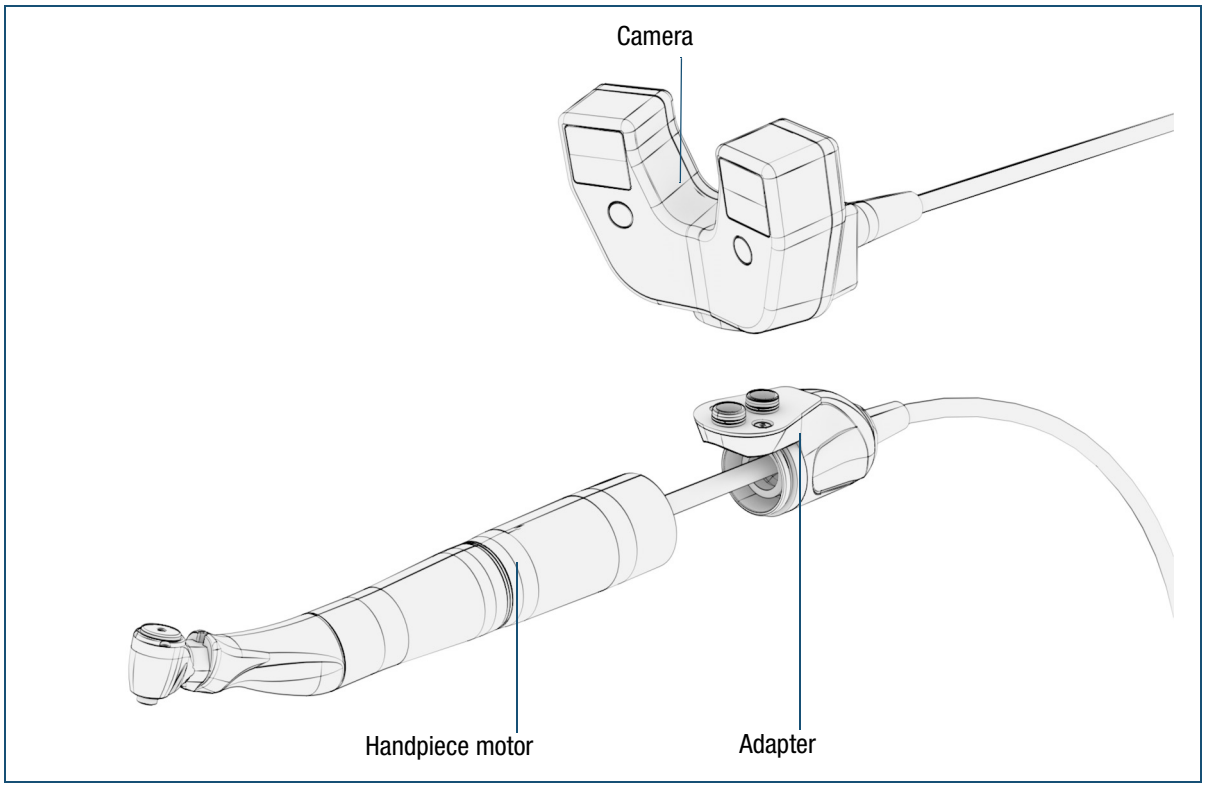
↗ For more information about the system and the components, see "System overview" on page 19

1 Connect the touchscreen to the computer.
   - Connect the DisplayPort cable.
   - Connect the USB cable.
   - Connect the DC power cable.

2 Connect the USB cable of the camera to the USB camera port on the computer.

3 Connect the AC power cable to the mains connection on the computer.

Attaching the camera to the handpiece motor



Picture 7 Attaching the camera to the handpiece motor

The camera is attached to the handpiece motor using the adapter.

↗ For information about compatible handpiece motors, see www.mininavident.com/faq

To fix the adapter to the handpiece motor

1 At the cable outlet of the handpiece motor unscrew the hose coupling and remove it completely from the cable.

2 Guide the cable through the adapter.

3 Align the connection tubes of the motor with the connection openings of the hose.

4 Screw the adapter to the motor.

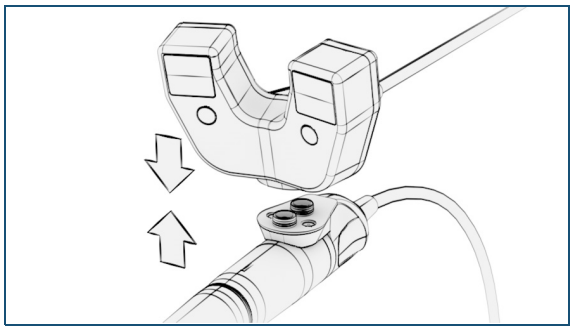
5 Visually inspect the fixed adapter. Check that the adapter is firmly connected and no gap is visible between the adapter and the motor.

6 Before first use, the handpiece must be calibrated together with the adapter.

↗ For information about calibrating the handpiece, see "To calibrate the handpiece" on page 43

To attach the camera to the adapter

1 Move the camera over the adapter.

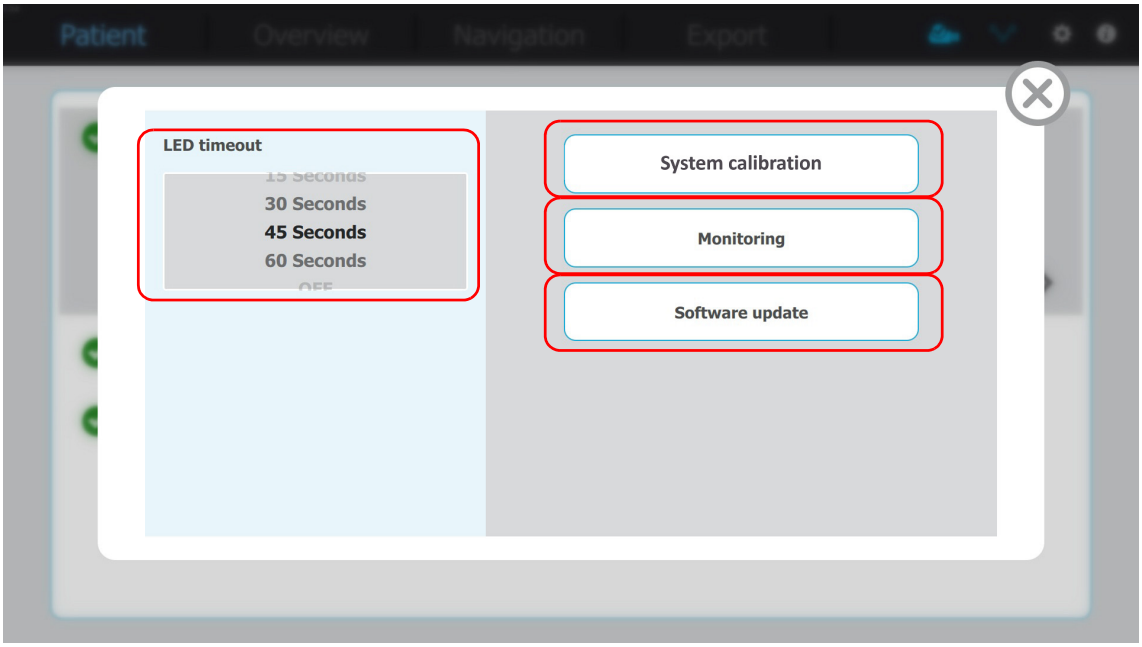


2 Bring the camera and the adapter together.

The camera is automatically fixed and adjusted to the plate by magnets.

3 Visually inspect the fixed camera. Check that the camera is firmly connected to the adapter.

Service tasks



Picture 8 Service tasks - **Service** screen overlay

↗ For information about calibrating the handpiece, see "Calibrating the handpiece" on page 42

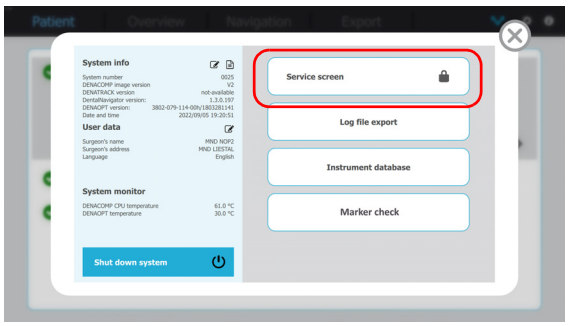
To access the service screen

1 To start up the system, press the power switch on the computer.

Wait until the **Patient** screen is displayed.

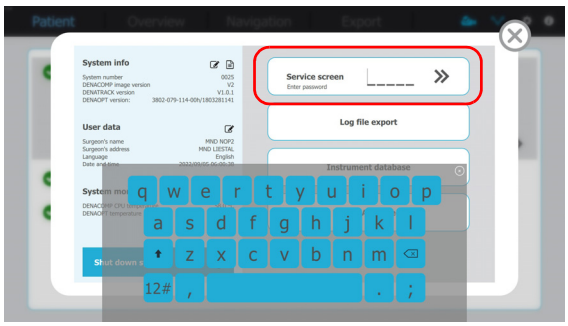
2 On the menu bar, choose the ⚙ button.

The configuration overlay is displayed.

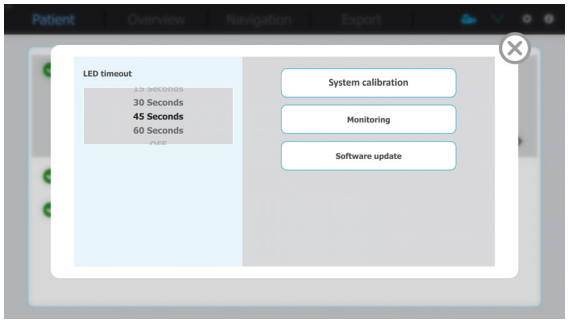


3 Choose the **Service screen** button.

A keyboard is displayed.



4 Enter the service password and choose the » button.



5 Choose the ⊗ button to exit.

To update the software

↗ For information about new software versions, see www.mininavident.com/faq

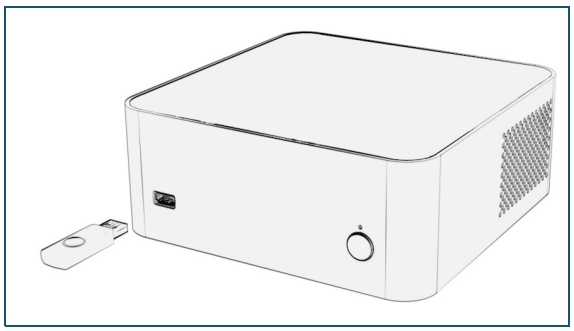
1 **Patient** screen > ⚙ button > **Service screen** button.

2 Place the software update file on the root directory of the USB storage device.

The system can access the highest level only.

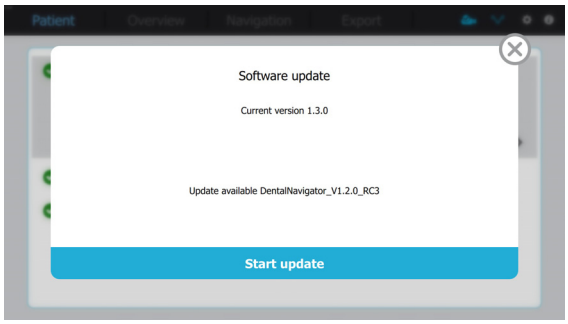
3 On the front of the computer, insert the USB storage device containing the software update file.

The USB storage device indicator lights up in blue when a valid USB device is connected ( ).



4 On the service screen overlay, choose the **Software update** button.

If a valid update file is available, the **Software update** overlay is displayed.



5 Choose the **Start update** button and wait until the update is finished.

6 Remove the USB storage device.

7 Choose the ⊗ button to exit.

To set the LED timeout

If no action is performed, the LED lights on the camera turn off after a certain time. The timeout value can be set in the service screen overlay.

1 **Patient** screen > ⚙ button > **Service screen** button

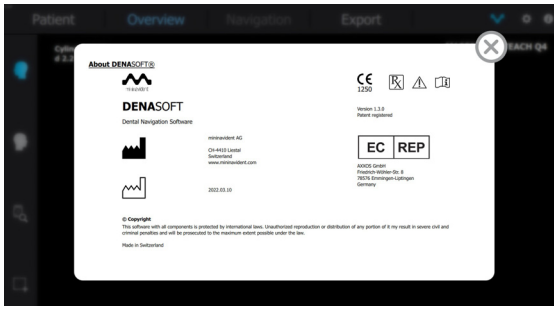
2 On the service screen overlay, select a **LED timeout** value.

3 Choose the ⊗ button to exit.

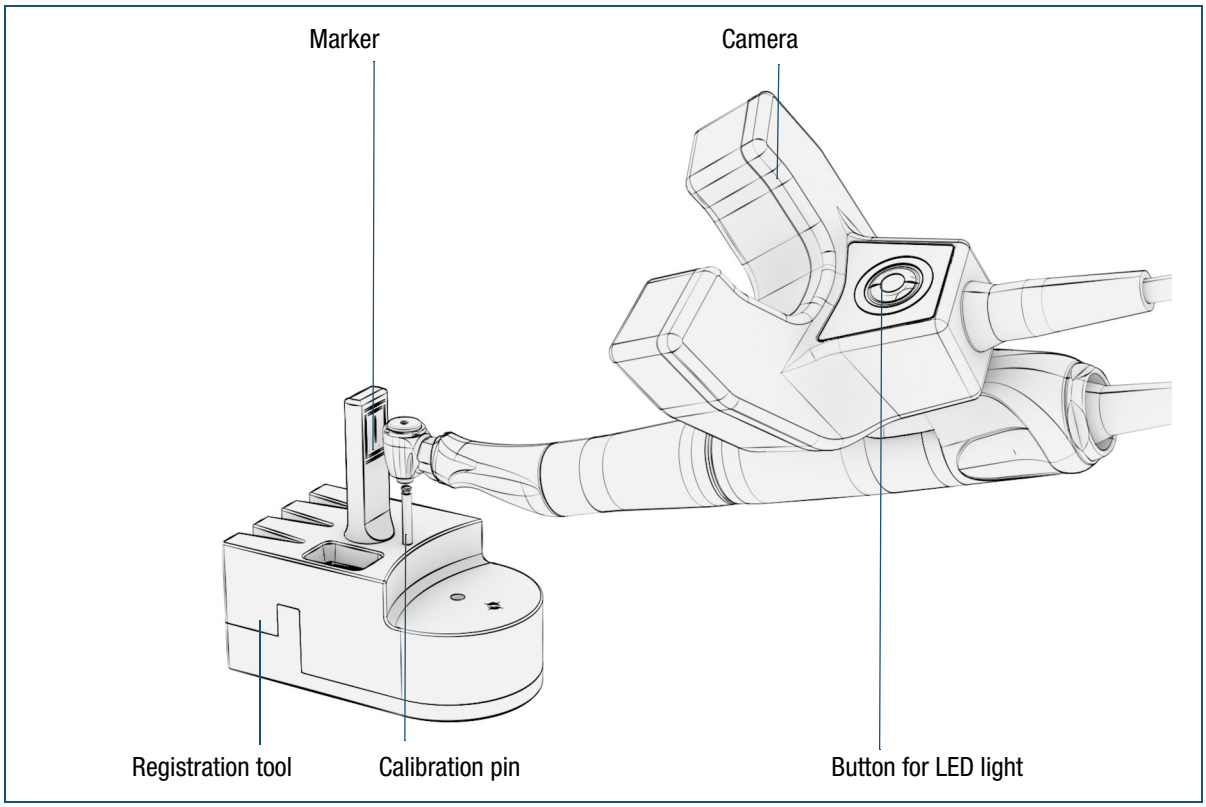
To check the software label

1 **Patient** screen > ⓘ button > **Service screen** button.

The software label is displayed.



Calibrating the handpiece



Picture 9 Calibrating the handpiece

Caution

Injury to the patient due to incorrect camera / handpiece motor handling

Incorrect handling of the camera and handpiece motor may lead to inaccurate / shifted navigation procedure.

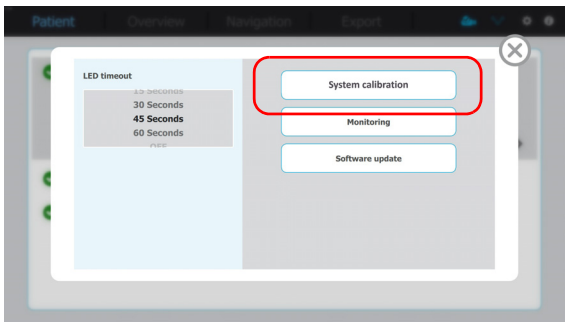
- Assemble the adapter and the handpiece motor correctly
- Attach the camera correctly on the adapter
- Make sure the adapter is always fully locked in position
- Register the handpiece in the software prior drilling
- The handpieces and motors used must have a rotational play around the motor axis of <=1.2 degree (stop to stop)

To calibrate the handpiece

The handpiece must be calibrated once after the adapter has been screwed onto the handpiece motor.

1 **Patient** screen > ⚙ button > **Service screen** button

↗ For information about how to access the service screen overlay, see "To access the service screen" on page 40

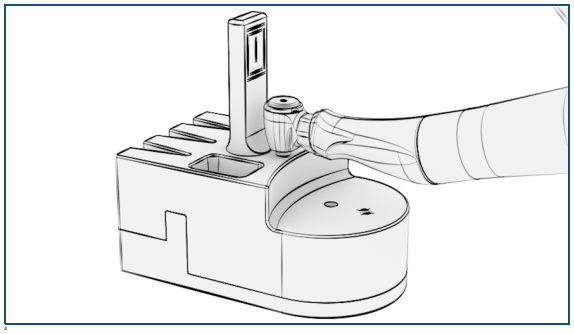


2 On the service screen overlay, choose the **System calibration** button.

The calibration overlay is displayed.

3 Move the drill chuck entirely over the calibration pin of the registration tool as far as it stops.

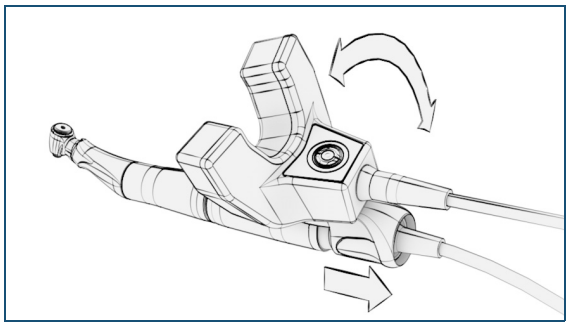
The LEDs light up automatically when the marker of the registration tool is in the field of view of the cameras.



4 Slide the camera backwards over the handpiece motor (by means of the adapter), and rotate the camera counterclockwise to a 90° position relative to the handpiece motor.

Move the camera forwards over the handpiece motor into the secured position.

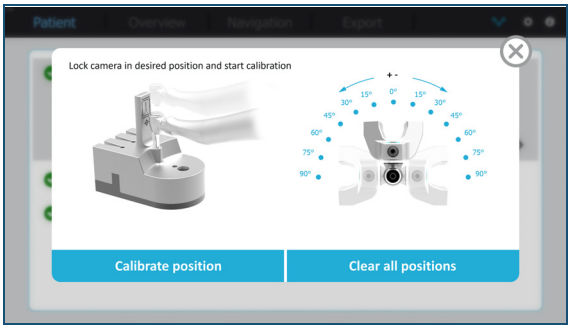
↗ For information about rotating the camera, see "To rotate the camera on the handpiece motor" on page 59



5 On the calibration overlay, choose the **Calibrate position** button.

Make sure the handpiece stays in position and the camera has a clear view on the marker.

A blue dot next to the angle indicates the calibration of this position is finished.



6 Follow the angle markings and turn the camera into the next position.

7 For each angle, choose the **Calibrate position** button.

The calibration of the handpiece is finished when all positions from +90° to -90° are marked with a blue dot.

8 If necessary, choose the **Clear all positions** button to start the calibrating process again.

9 Remove the handpiece from the calibration pin.

10 Choose the ⊗ button to exit.

Setting up the instrument database

The DENACAM system has an integrated database in which instruments for preparing the implant bed or cavity and placing the implant are stored. The instruments and necessary dimensions can either be imported as a complete dataset or created manually.

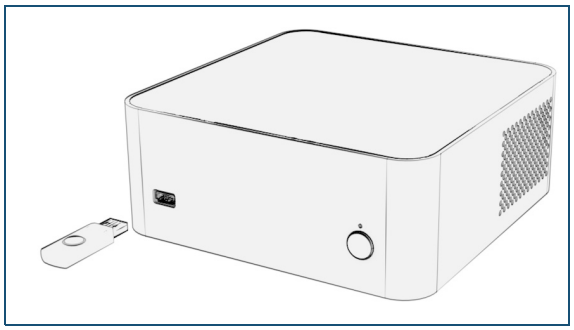
To import instruments from a predefined dataset to the database

1 To start up the system, press the power switch on the computer.

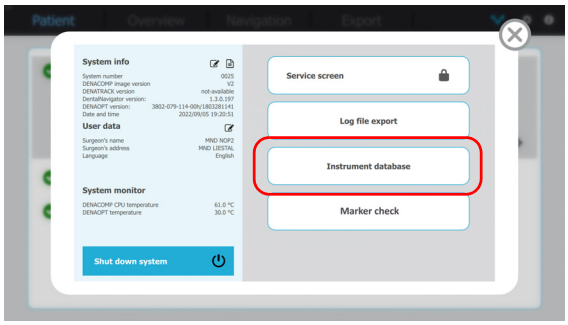
Wait until the **Patient** screen is displayed.

2 Insert the USB storage device containing the dataset of the instruments.

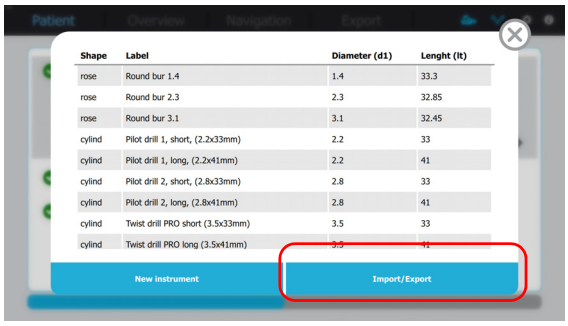
The USB storage device indicator lights up in blue when a valid USB device is connected ( ).



3 Choose **Patient** screen > button > **Instrument database** button.

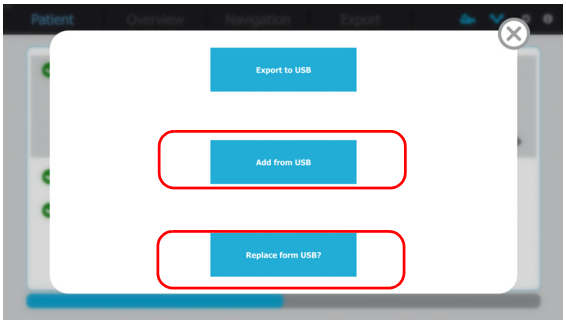


4 On the **Instrument database** overlay, choose the **Import/Export** button.



5 On the **Import/Export** overlay, choose:

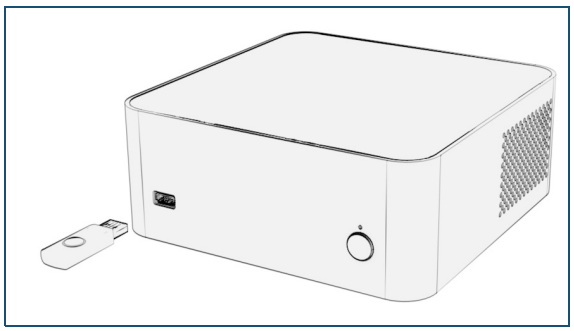
- **Add from USB** button to import a complete dataset or individual instruments into the database. Existing instruments are not replaced or overwritten.
- **Replace from USB** button to import and replace a complete dataset in the database. All instruments are replaced.



To export a dataset of instruments from the database

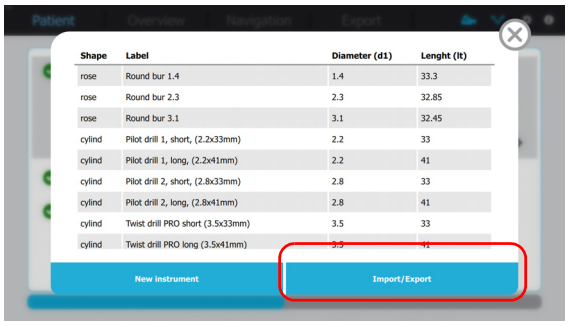
1 To export a dataset, insert a USB storage device with adequate storage capacity.

The USB storage device indicator lights up in blue when a valid USB device is connected ( ).



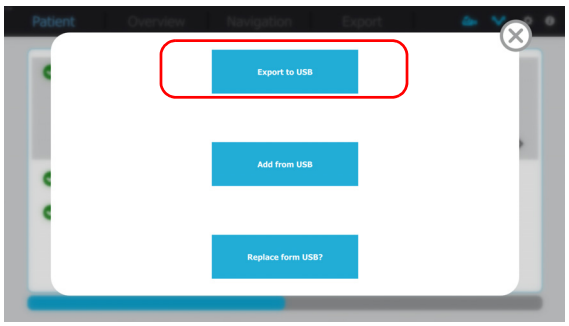
2 Choose **Patient** screen > button > **Instrument database** button.

3 On the **Instrument database** overlay, choose the **Import/Export** button.



4 On the **Import/Export** overlay, choose the **Export to USB** button.

The dataset is saved on the USB storage device.



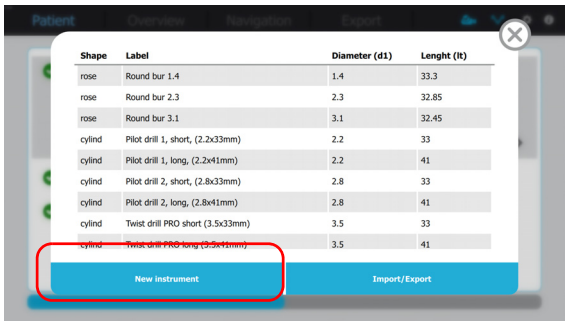
To add a single new instrument to the database

1 To start up the system, press the power switch on the computer.

Wait until the **Patient** screen is displayed.

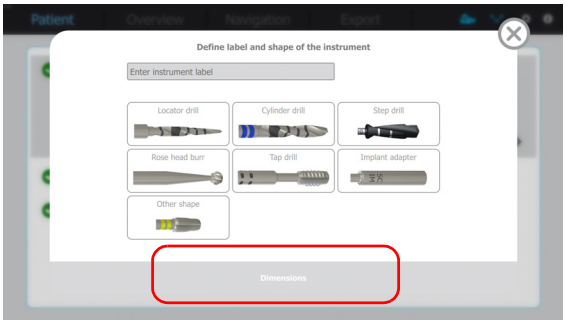
2 Choose **Patient** screen > button > **Instrument database** button.

3 On the **Instrument database** overlay, choose the **New instrument** button.



4 On the **New instrument** overlay, enter the label of the instrument and choose one of the predefined instrument categories.

If possible, use the label used by the manufacturer.



5 Choose the **Dimensions** button to enter the dimensions of the new instrument.

↗ For information about the dimensions, see "Instrument dimensions" on page 108

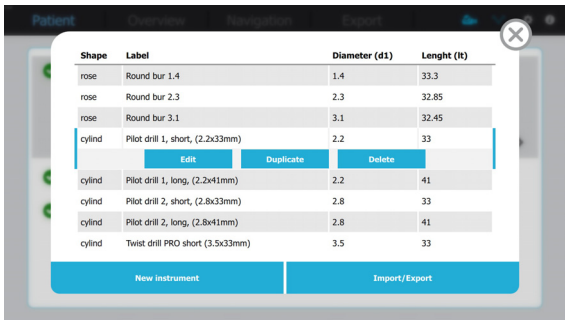
To edit, delete, or duplicate an instrument in the database

1 Choose **Patient** screen > ⚙ button > **Instrument database** button

2 On the **Instrument database** overlay, search and select the instrument and choose the **Edit** button to edit the instrument.

- Choose the **Delete** button to delete the instrument.
- Choose the **Duplicate** button to duplicate the instrument.

↗ For information about the dimensions, see "Instrument dimensions" on page 108



OPERATION

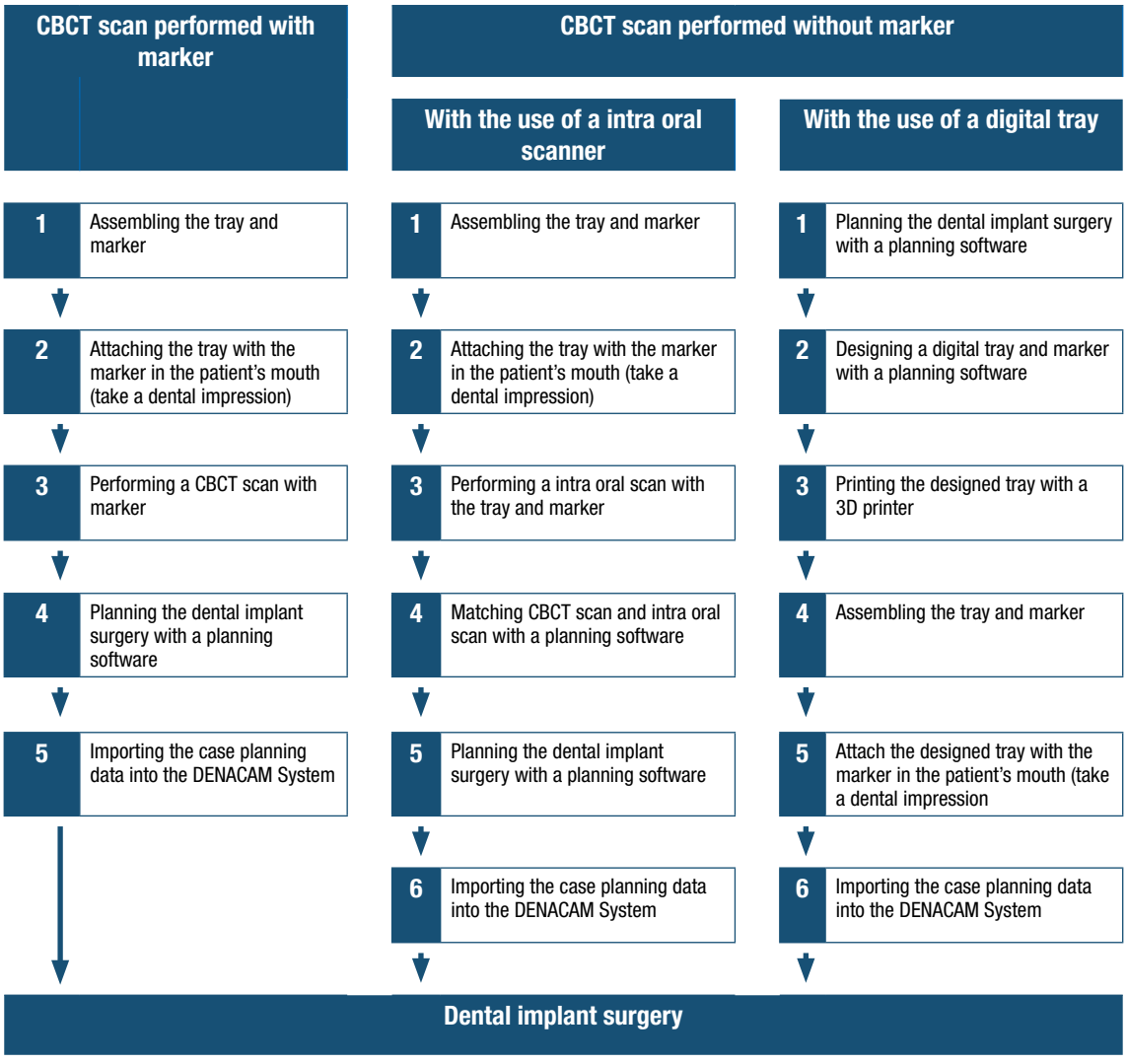
PREOPERATIVE PHASE

The main tasks in the preoperative phase are:

1. Assembling, positioning, and attaching the tray with the marker in the patient's mouth.
2. Planning the dental implant surgery.
3. Importing the case planning data into the system.

WORKFLOWS FOR MARKER CAPTURING

To capture the marker for case planning, three different options are available:



Picture 10 Workflows for marker capturing

PREREQUISITES

- Markers and trays (if necessary) are available and ready to use.
  - ↗ For more information about the system and the components, see "System overview" on page 19
- Impression material is available and ready to use.
- A suitable case planning software is available.
  - ↗ For information about suitable case planning software, see www.mininavident.com/faq
- A suitable CBCT scanner is available.
  - ↗ For information about suitable CBCT scanner, see www.mininavident.com/faq
- Optionally, a suitable intra oral scanner is available.
  - ↗ For information about suitable intra oral scanner, see www.mininavident.com/faq
- Optionally, a suitable 3D printer is available.
  - ↗ For information about suitable 3D printer, see www.mininavident.com/faq
- The patient is prepared for taking CBCT scans.

SAFETY

Warning

Serious injury to the patient due to incorrect handling

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual.

- Do not carry out operation, care and cleaning unless you have read and understood the information provided in the user documentation.
- Follow best practices, especially when you work with biohazardous material.

Caution

Injury to the patient due to incorrect tray, marker, or CBCT scanner handling

Incorrect tray or marker handling may lead to bad CBCT scan and/or inaccurate or shifted navigation procedure.

- Do not use a defect tray or a defect marker.
- Assemble the tray and marker correctly.
- Use only the recommended impression material.
- Use only recommended scanners with suitable settings.
- Make sure that the patient or the tray inside the mouth are not moved during hardening of the impression material or CBCT scanning.

Notice

Delayed treatment due to incorrect data handling

Incorrect data handling may lead to discontinuation of the treatment.

- In the case planning software, export case planning data in a correct file format.
- On a USB storage device, place the case planning data file on the root directory. The system can access the highest level only.
- Connect only a USB storage device to the system that does not require the installation of additional driver software.
- Do not use USB storage devices with a separate power supply. USB storage devices with a separate power supply may seriously interfere with the electrical safety of the system.

Notice

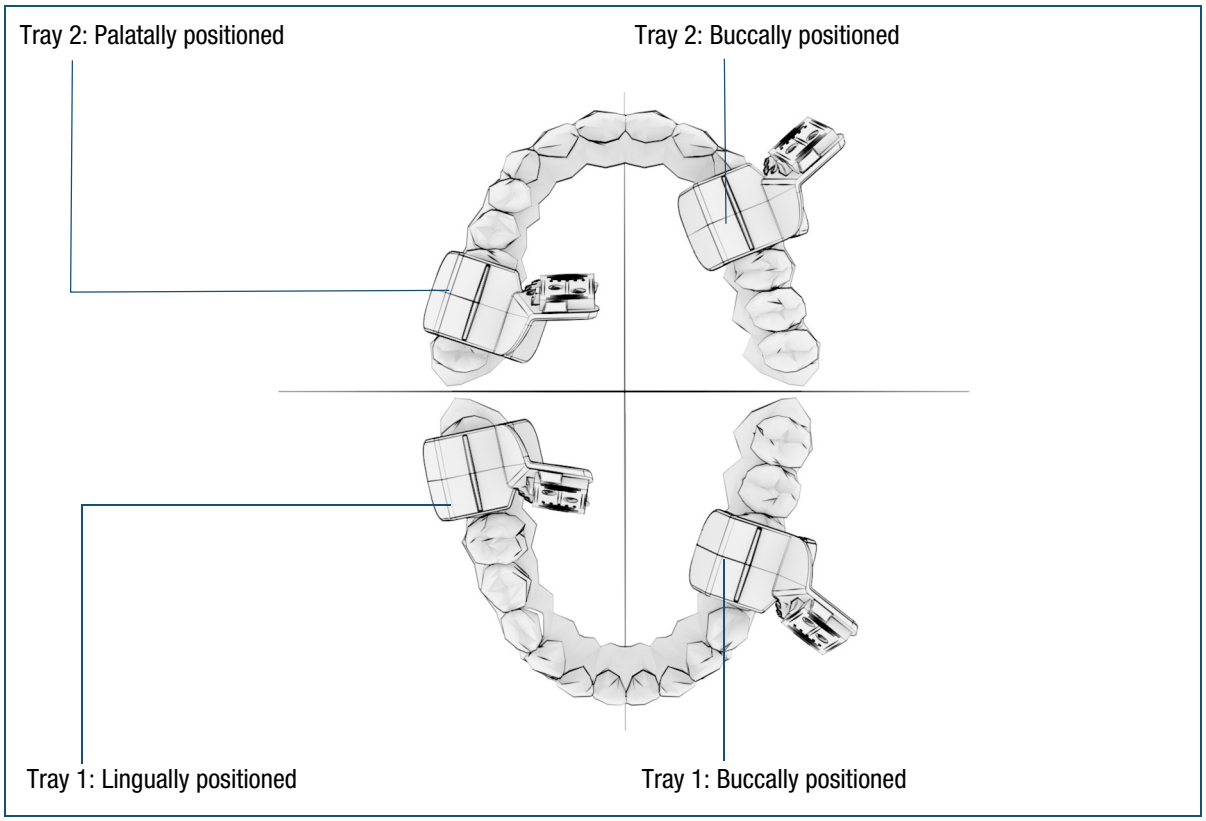
Delayed treatment due to incorrect application of software and hardware

Incorrect application of software and hardware may lead to discontinuation of the treatment.

- If you are using for the different workflows software/ products/ materials from other manufacturer refer to their IFU.

↗ For more information about safety, see "Safety information" on page 11

Assembling, positioning, and attaching the tray with the marker



Picture 11 Positioning of the tray and the marker

Fixated to the jaw where one or more implants have to be placed, the marker serves as a reference point for the navigation system in the patient's mouth.

The marker is mounted on a tray that is attached to the lower or upper jaw by means of impression material.

To assemble and position the tray and marker

1 Select the appropriate tray for the case. Two versions are available:

- Tray 1 holds the marker on the right side.
- Tray 2 holds the marker on the left side.

2 Identify the appropriate position on the jaw to place the tray with the marker.

Taking into account the patient's situation, place the marker either buccally, lingually, or palatally.

Place the tray close to the implant site. More distance leads to more inaccuracy.

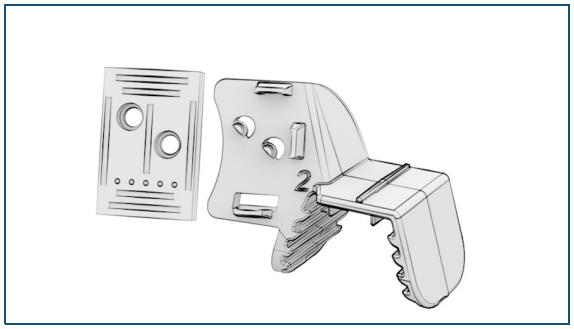
Make sure to leave enough space for working with dental instruments between the tray and the implant site.

Make sure that the marker can always be seen from the camera. Take into account the implant position

in the mouth and the position of the handpiece during surgery.

3 Snap the marker into its position on the tray.

Make sure the visual pattern of the marker is visible.



To attach the tray with the marker in the patient's mouth (take a dental impression)

Taking a precise dental impression is of the utmost importance.

Prepare the impression material according to the IFU from the corresponding material (we recommend DMG O-Bite). Then apply on the teeth, make sure it covers the occlusal region.

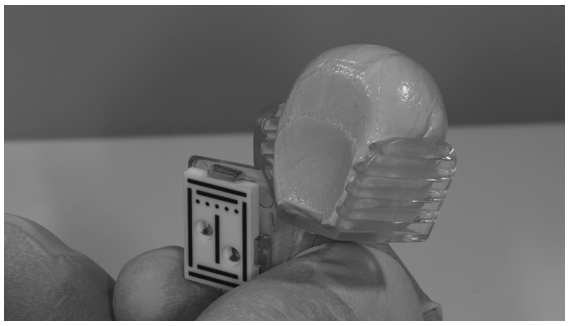
1 Load the tray with impression material according to the instructions for use of the used impression material.

Make sure to use enough impression material. Make sure that the impression material does not get in contact with the mucous membranes.

Use only recommended impression material.

↗ For information about recommended impression material, see www.mininavident.com/faq

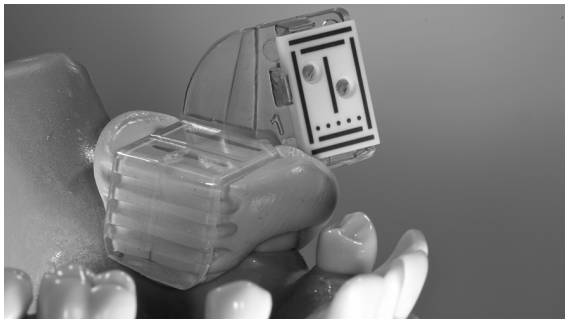
2 Press the impression material from both sides so that it flows more towards buccolingual than mesiodistal.



3 Slowly position the loaded tray in the patient's mouth parallel to the vertical axes of the teeth.

Once the tray is seated, hold it in place without applying pressure.

Avoid to contact the teeth with the tray.



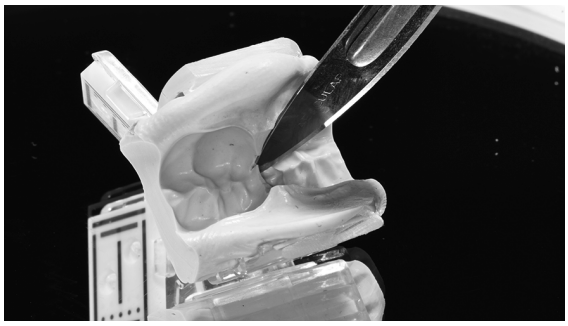
4 Wait until the impression material is hardened.

5 Remove the tray from the patient's mouth.

Remove any residual cured impression material from the patient's mouth.

6 Improve the dental impression:

- For a simple and safe reposition, remove the interdental areas.
- To check the correct fit of the tray, cut the impression material mesially and distally.
- Remove interfering impression material buccally and lingually / palatinally.



7 Reposition the tray in the patient's mouth and check the firm fit of the cured impression material on the teeth.

Make sure there is no gap visible between the impression material and the teeth.

8 Remove the tray from the patient's mouth.

Planning the dental implant surgery

CASE PLANNING OPTION A - CBCT SCAN PERFORMED WITH MARKER

To plan the dental implant surgery

1 Position the prepared tray with the marker in the patient's mouth.

2 Perform a CBCT scan with a suitable scanner.

Make sure the patient is not moving or shifting the tray with the tongue or the cheek.

Make sure that there is at least 5 mm distance between the marker and the edge of the CBCT scan field. Not fully scanned marker will lead to inaccuracy.

↗ For information about the suitable CBCT scanner, see www.mininavident.com/faq

3 Remove the tray from the patient's mouth and store it.

Do not remove the marker from the tray anymore until the implant surgery is completed.

4 Plan the dental implant surgery with a suitable planning software.

↗ For information about the suitable case planning software, see www.mininavident.com/faq

5 Export the case planning data to a USB storage device.

On a USB storage device, place the case planning data file on the root directory.

6 Import the case planning data into the DENACAM System to validate the data.

↗ For more information about importing the case planning data, see "Importing the case planning data" on page 55

CASE PLANNING OPTION B - MARKER CAPTURING WITH USE OF A INTRA ORAL SCANNER

To plan the dental implant surgery

1 Perform a CBCT scan with a suitable scanner.

↗ For information about the suitable CBCT scanner, see www.mininavident.com/faq

2 Position the prepared tray with the marker in the patient's mouth.

3 Perform a intra oral scan with a suitable scanner.

↗ For information about the suitable intra oral scanner, see www.mininavident.com/faq

4 Remove the tray from the patient's mouth and store it.

Do not remove the marker from the tray anymore until the implant surgery is completed.

5 Match the CBCT scan and the intra oral scan with a suitable planning software.

6 Plan the dental implant surgery with a suitable planning software.

Note: If the digital marker model is matched to the intraoral scan containing a tray and a marker, the matching has to be done with an accuracy of 0.6 mm translation and 0.6 mm degree rotation.

↗ For information about the suitable case planning software, see www.mininavident.com/faq

7 Export the case planning data to a USB storage device.

On a USB storage device, place the case planning data file on the root directory.

8 Import the case planning data into the DENACAM System to validate the data.

↗ For more information about importing the case planning data, see "Importing the case planning data" on page 55

CASE PLANNING OPTION C - MARKER CAPTURING WITH USE OF A DIGITAL TRAY

To plan the dental implant surgery

1 Perform a CBCT scan with a suitable scanner.

↗ For information about the suitable CBCT scanner, see www.mininavident.com/faq

2 Plan the dental implant surgery with a suitable planning software.

↗ For informations about design guideline and application guideline for digital trays, see ww.mininavident.com/faq

3 Design a digital tray with a suitable planning software.

↗ For information about the suitable case planning software, see www.mininavident.com/faq

4 Print the designed tray with a 3D-printer and assemble the tray and marker.

Note: The printed tray must have an accuracy of <=0.1 mm on its surface which are in contact with teeth or DENAMARK

↗ For information about how to assemble, see "To assemble and position the tray and marker" on page 50

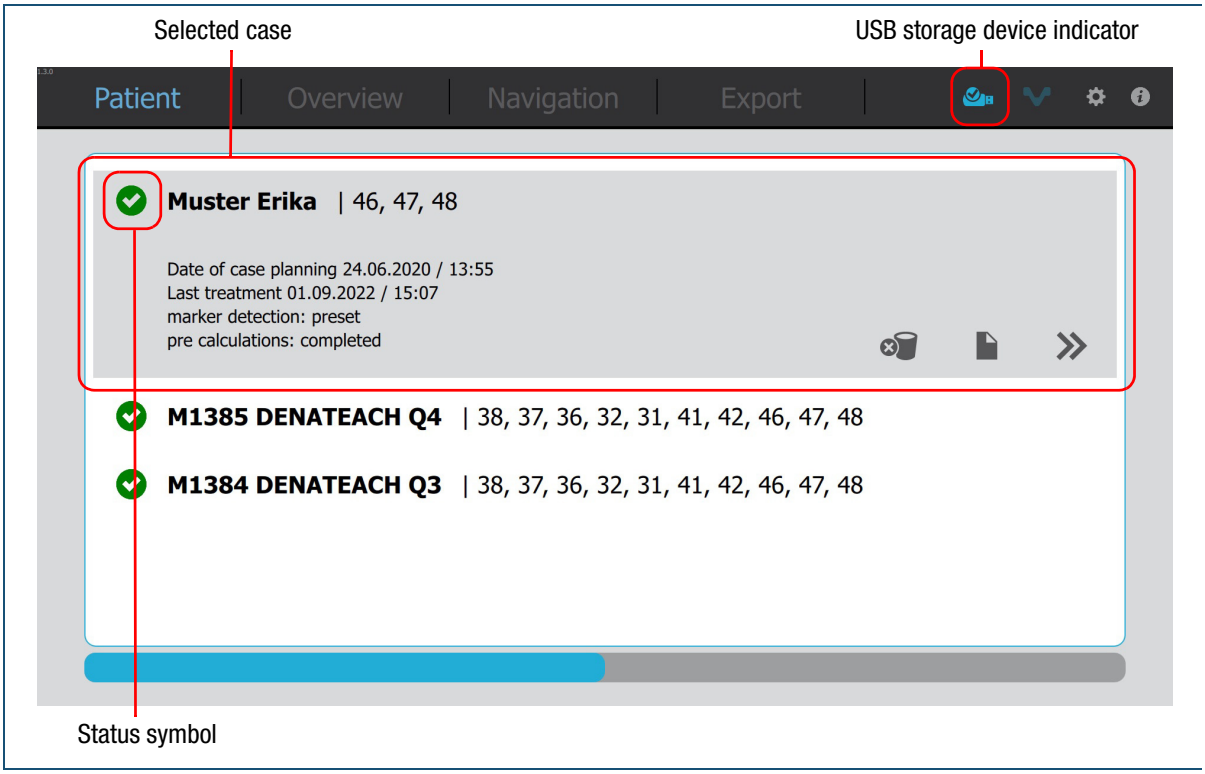
5 Export the case planning data to a USB storage device.

On a USB storage device, place the case planning data file on the root directory.

6 Import the case planning data into the DENACAM System to validate the data.

↗ For more information about importing the case planning data, see "Importing the case planning data" on page 55

Importing the case planning data



Picture 12 Importing the case planning data - Patient screen

To import the case planning data

1 To start up the system, press the power switch on the computer.

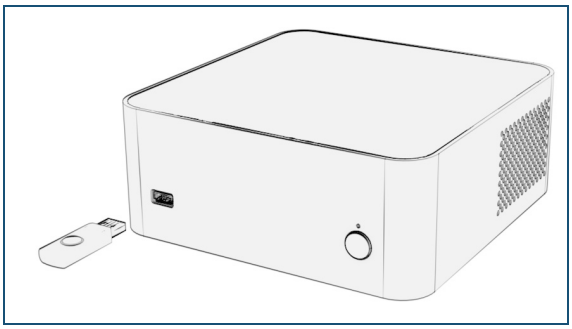
Wait until the **Patient** screen is displayed.

2 Insert the USB storage device containing the case planning data for the planned surgery.

The USB storage device indicator lights up in blue when a valid USB device is connected ( ).

The import starts automatically. Wait until the import is finished.

The import is finished when the patient name is listed on the **Patient** screen and the status symbol of the imported case planning data is green ( ).



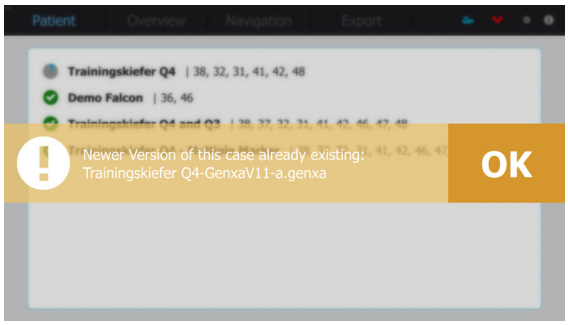
3 If the marker cannot be evaluated by the software, the status symbol of the imported case planning data becomes red ( ). In this case, the marker was not detected correctly during the CBCT scan.

Perform a new CBCT scan or change to case planning option B or C.

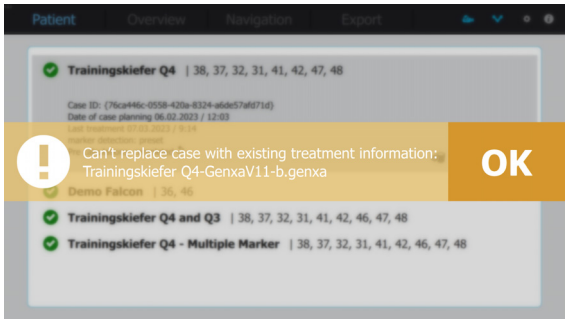
↗ For information about performing a CBCT scan, see "Planning the dental implant surgery" on page 53

4 If a case still exists on the computer, there are 3 options if you try to load it again:

- If an older version of the planning exists that does not have any treatment data, the new version replaces the old one.
- If a newer version of the planning exists, the case won't import and give a message.



- If an older version with treatment data exists, the case won't be imported and give a message.



BEFORE SURGERY

The main tasks before the surgery are:

1. Setting up the workspace.
2. Loading the case into the DENACAM System.
3. Placing the tray with the marker in the patient's mouth.

PREREQUISITES

- The DENACAM System is available and ready to use.

  ↗ For more information about setting up the system, see "Installation and setup" on page 33

- A case planning was carried out in advance and the valid data is available on the system.

  ↗ For more information about planning a dental implant surgery, see "Planning the dental implant surgery" on page 53

- The tray with the marker for the case is available and ready to use.

  ↗ For more information about the tray and marker, see "Assembling, positioning, and attaching the tray with the marker" on page 50

SAFETY

Warning

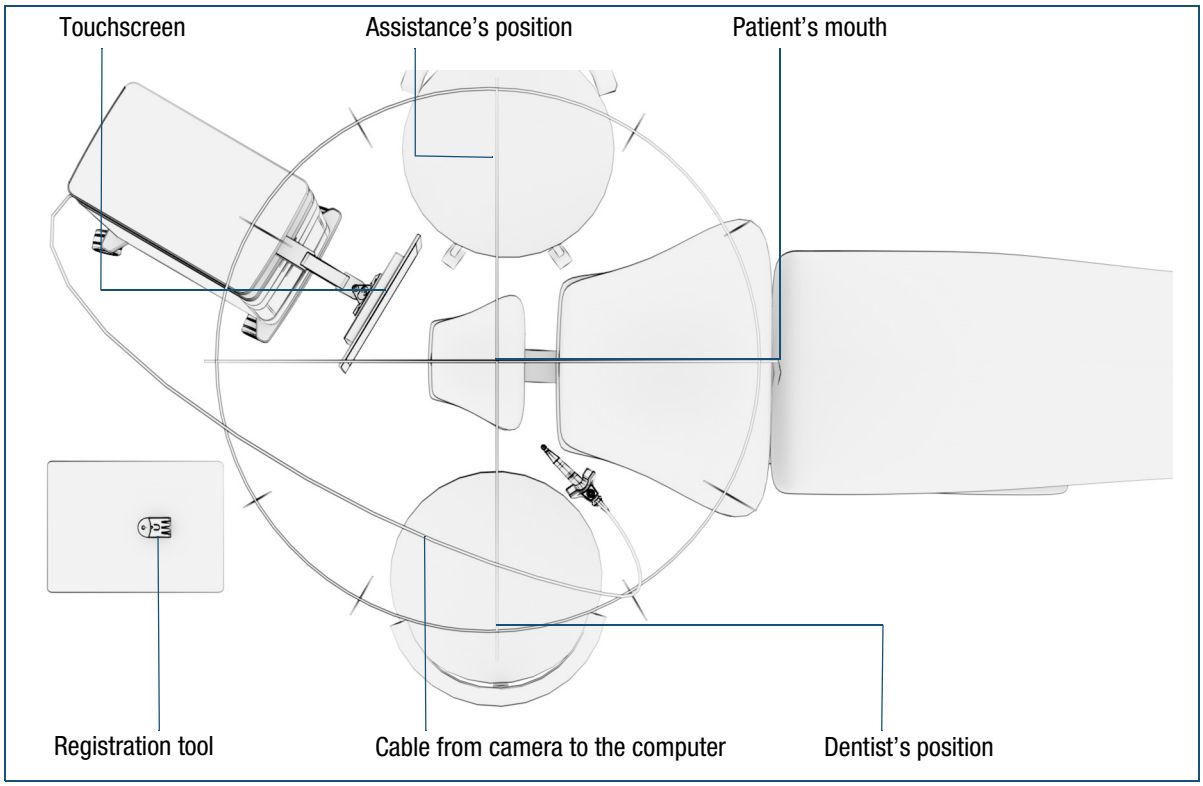
Serious injury to the patient due to incorrect handling

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual.

- Do not carry out operation, care and cleaning unless you have read and understood the information provided in the user documentation.
- Carefully follow the procedures specified in the instructions for operation, care and cleaning.
- Follow best practices, especially when you work with biohazardous material.

↗ For more information about safety, see "Safety information" on page 11

Setting up the workspace



Picture 13 Setting up the workspace

To set up the workspace

1 Position the touchscreen so that the patient's mouth as well as the touchscreen are simultaneously in view during surgery.

Make sure you can reach the touchscreen with your fingers.

2 Route the cable from the camera to the computer outside of the operating area over the patient.

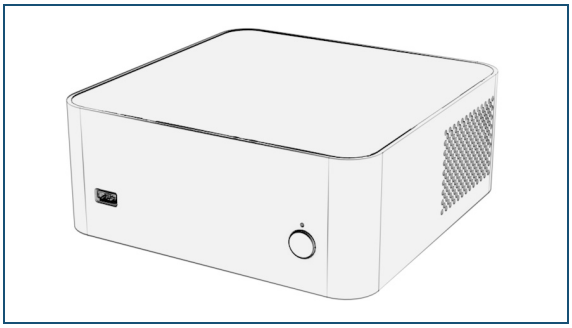
3 Place the registration tool on a stable and level surface.

Make sure that the registration tool is easy to reach with the handpiece.

To start up the system

1 On the computer, press the power switch.

Wait until the **Patient** screen is displayed.

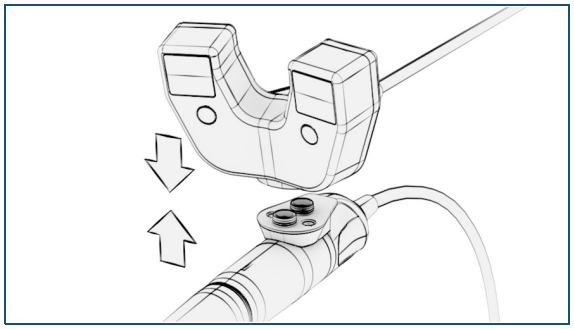


To attach the camera to the adapter

1 Place the camera over the adapter.

2 Bring the camera and the adapter together.

The camera is automatically fixed and adjusted to the plate by magnets.



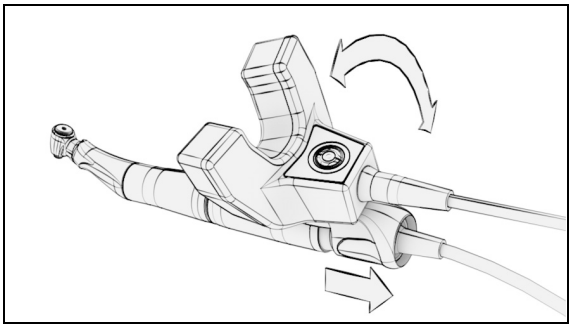
3 Visually inspect the attached camera. The camera must be firmly connected to the adapter.

To separate the camera from the adapter, pull the two components apart.

To rotate the camera on the handpiece motor

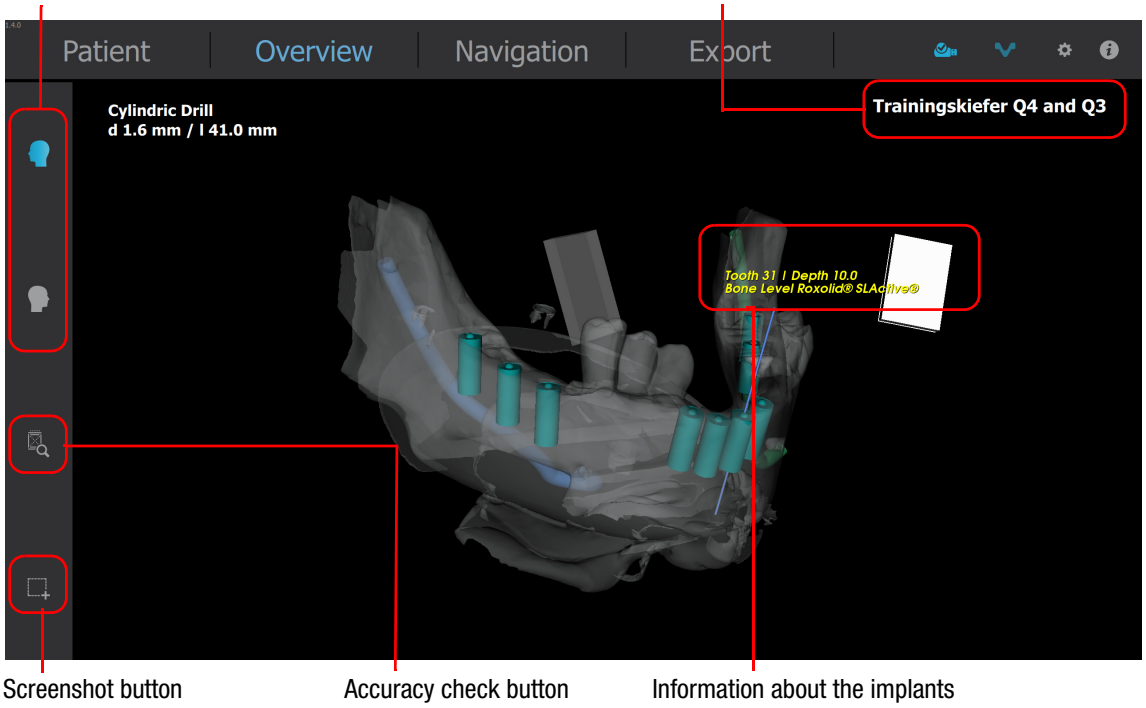
You can rotate the camera in a position which you prefer for surgery.

1 Slide and hold the camera backwards over the handpiece motor (by means of the adapter), and rotate the camera into the required angle relative to the handpiece motor.



2 Release the camera over the handpiece motor into the secured position.

Loading the case and place the tray with the marker



Picture 14 Overview screen

Caution

Injury to the patient due to incorrect tray or marker handling

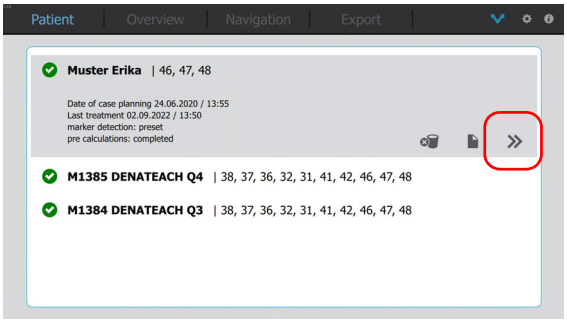
Incorrect handling of the tray or marker may lead to inaccurate or shifted navigation procedure.

- Make sure that the tray is attached correctly in the patient's mouth.
- Make sure that the marker is not soiled.
- Check if the retention of the tray is sufficient.
- Make sure that the patient does not shift the tray with the tongue or the cheek.
- Perform an accuracy check.

To load the case

1 On the **Patient** screen, select the case.

If the case is not displayed, scroll through the list.



2 Choose the » button.

Wait until loading is finished.

The case loading is finished when the **Overview** screen with the 3D model is displayed.

On **Overview** screen, you have the following possibilities:

- View the 3D model either from posterior or anterior direction by choosing either the button or the button.
- Rotate the 3D model with your finger on the touchscreen.
- Move the 3D model with two fingers on the touchscreen (two finger swipe).
- Take a screenshot by choosing the button.

  The screenshot is added to the case report. It is labeled with the current date and time.

↗ For more information about the case report, see "Viewing and exporting a case report" on page 73

To place the tray with the marker in the patient's mouth

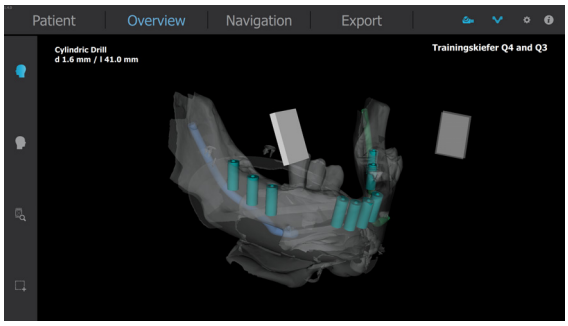
1 On the **Overview** screen, check if the correct case is loaded.

2 Place the tray with the marker in the patient's mouth according to the displayed position.

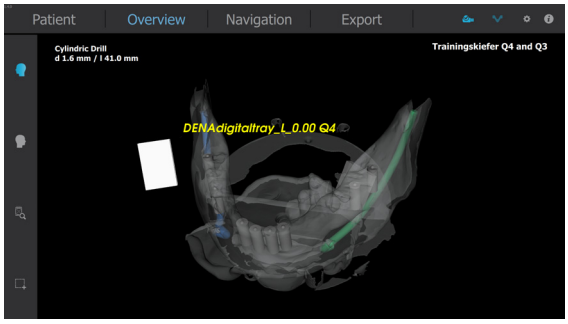
↗ For information about handling the tray and marker, see "Assembling, positioning, and attaching the tray with the marker" on page 50

Handling of cases with multiple markers

When loading a case with multiple markers, one marker is the active one (opaque white) and all others are displayed slightly transparent.

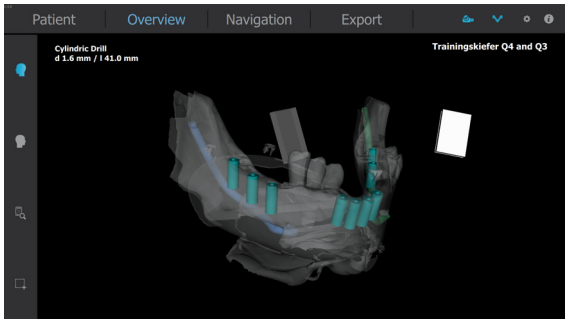


With a short press on a marker, its name, as given during planning, is displayed.

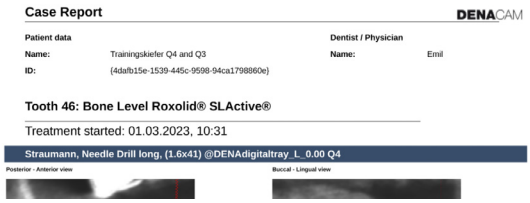


When doing a long press on an inactive marker, this marker is selected as the active marker (transparency changes to opaque, the previous active marker turns transparent).

- After a marker change, an accuracy check is mandatory, to ensure that the correct marker is active.



In the report it is noted which marker was active.


Case Report

DENACAM

Patient data

Name: Trainingskiefer Q4 and Q3

ID: {4dafb15e-1539-445c-9598-94ca1798860e}

Dentist / Physician

Name: Emil

Tooth 46: Bone Level Roxolid® SLActive®

Treatment started: 01.03.2023, 10:31

Straumann, Needle Drill long, (1.6x41) @DENAdigitaltray_L_0.00 Q4

Posterior - Anterior view

Buccal - Lingual view

DURING SURGERY - GUIDED SURGERY

Note

The DENACAM System can be used in two different modes:

- Map mode: The system is only used to display the position and the angle of the instrument within the CBCT scans. In this case, the CBCT data is imported directly into the DENACAM System without using planning software.
- Guiding mode: The DENACAM system guides the instrument using the planning data with the correct angle to the correct position and depth.The software guides you through the process.

The main tasks during the surgery are:

1. Registering the instrument.
2. Performing the guided surgery.

PREREQUISITES

- The DENACAM System is available and ready to use.

  ↗ For more information about setting up the system, see "Installation and setup" on page 33
- The case planning data is imported and loaded.

  ↗ For information about importing and loading the case planning data, see"Importing the case planning data" on page 55
- The tray with the marker is correctly placed in the patient's mouth.

  ↗ For more information about positioning the tray correctly, see "Loading the case and place the tray with the marker" on page 60
- All necessary equipment for a dental implant surgery is available and ready to use.
- The instruments, according to the Surgical Procedure Protocol of the implant system, are available and ready to use.
- The patient and the implant site or cavity is prepared for a treatment.

SAFETY

Warning

Serious injury to the patient due to incorrect handling

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual.

- Do not carry out operation, care and cleaning unless you have read and understood the information provided in the user documentation.
- Carefully follow the procedures specified in the instructions for operation, care and cleaning.
- Follow best practices, especially when you work with biohazardous material.

Caution

Injury to the patient due to incorrect case planning data

Incorrect case planning data may lead to injury of the patient.

- Before surgery, always verify that the loaded case planning data is correct.

Caution

Injury to the patient due to mechanical instability

Loose or damaged components may lead to injury of the patient.

- Before surgery, always check the mechanical integrity of the plate on the camera and the counterpart on the adapter as well as the backlash-free connection of the camera components to each other and to the motor.


Caution

Injury to the patient due to wrong handling or damage of marker and tray, wrong registration of instrument or damage of registration tool

Injury to the patient due to wrong handling or damage of marker and tray, wrong registration of instrument or damage of registration tool.

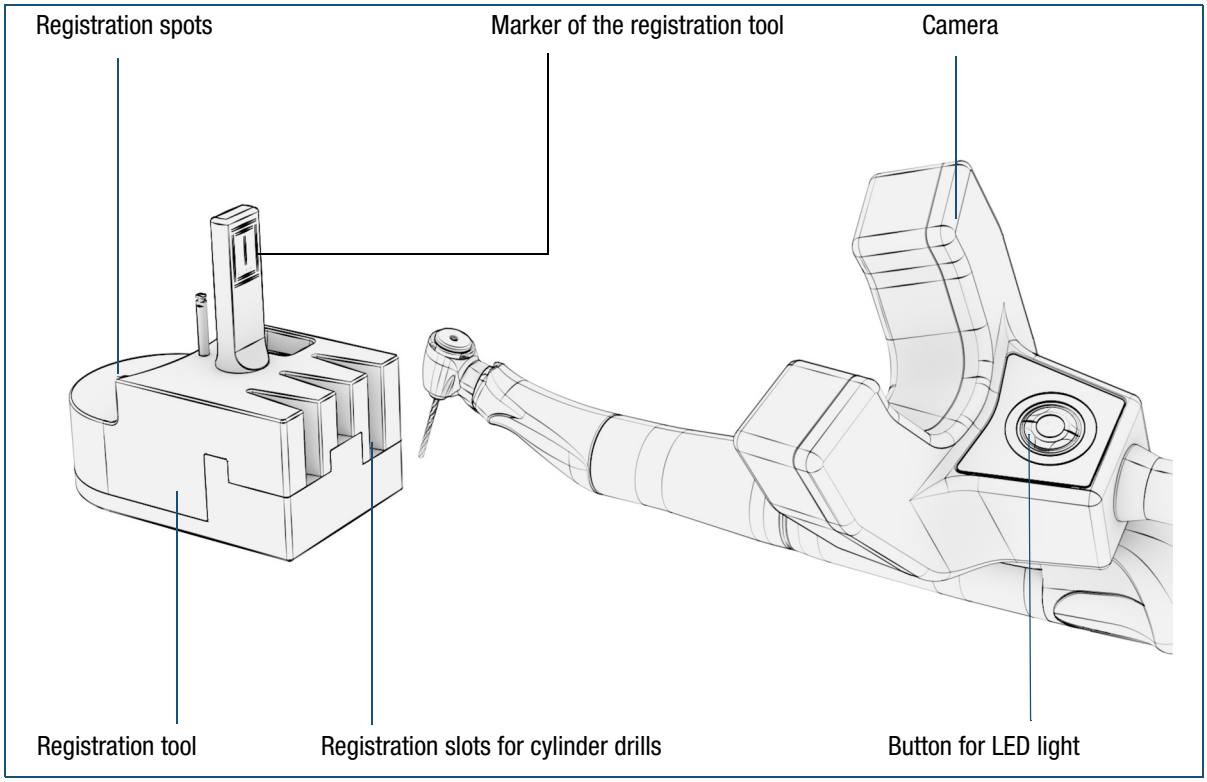
- Before starting the surgery, it is mandatory to register an instrument and proceed the accuracy check. If the registration procedure is not smooth or the accuracy check shows a unacceptable deviation (>1 mm) you are not allowed to treat the patient.

↗ For more information about safety, see "Safety information" on page 11

Note

- The software guides you through the process.
- The sequence of the instruments may differ depending on the implant system.
- The procedures in this User Manual do not replace the Surgical Procedure Protocols of the dental implant system.

Registering the instrument



Picture 15 Registering the instrument

Caution

Injury to the patient due to incorrect drill or registration tool handling

Incorrect handling of instruments or the registration tool may lead to inaccurate or shifted navigation procedure.

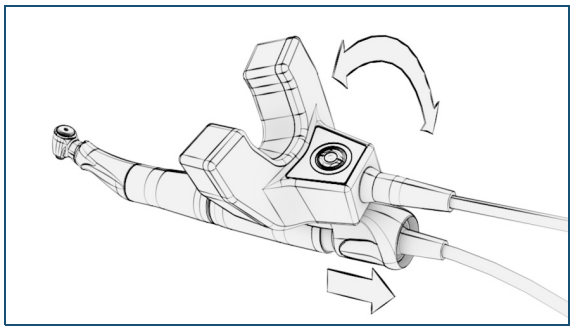
- Always verify the chosen instrument prior drilling.
- Follow the Surgical Procedure Protocols of the dental implant system.
- Register each instrument you want to use in the software prior surgery.
- Re-register the drill once you have rotated the camera.

To register the instrument

1 Rotate the camera in a position you prefer for surgery.

Make sure that the camera has a direct and frontal view on the marker. Deviations up to 45 ° are acceptable.

↗ For information about turning and locking the camera, see "To rotate the camera on the handpiece motor" on page 59



2 Select the instrument

3 Insert the instrument into the drill chuck.

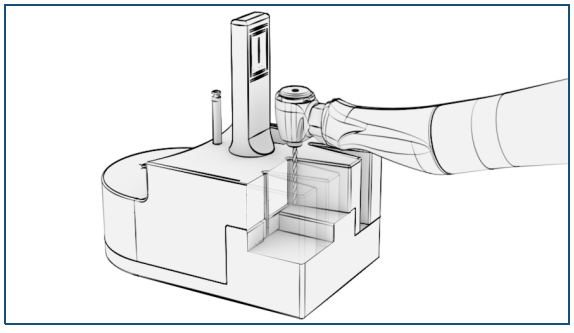
4 Guide the instrument to the registration tool.

The LEDs of the camera light up automatically when the registration tool is in the field of view of the camera.

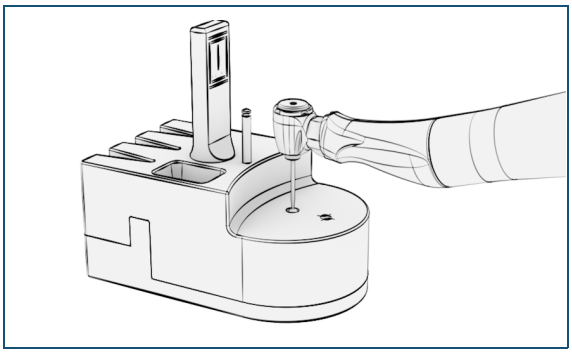
5 Depending on the instrument do one of the following:

- For a cylindrical drill, insert the drill at an angle into one of the slot so that the drill bit faces forward.

  Turn the instrument if the registration does not start automatically.



- For a round bur, place the sphere of the round bur in the deep cavity of the registration tool.

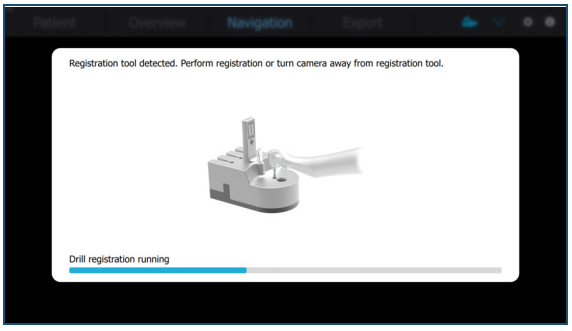


- For an implant adapter, place the implant attached to the adapter with the tip on the cross marking.
- For all other instruments, place the instrument with the tip on the cross marking.

6 The registration starts automatically as soon as the instrument is in a valid position.

On the touchscreen, the instrument registration overlay is displayed.

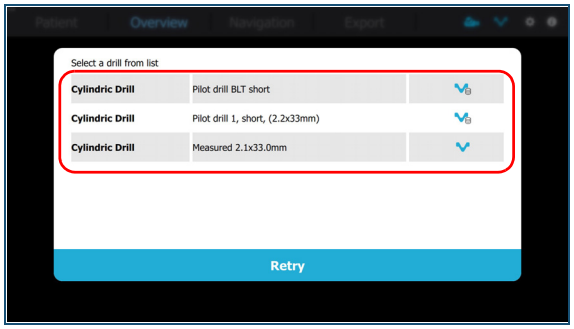
Make sure that the instrument stays in the valid position while the registration is running.



7 Wait until the registration is finished and the instrument selection overlay is displayed.

8 On the instrument selection overlay, select the correct instrument.

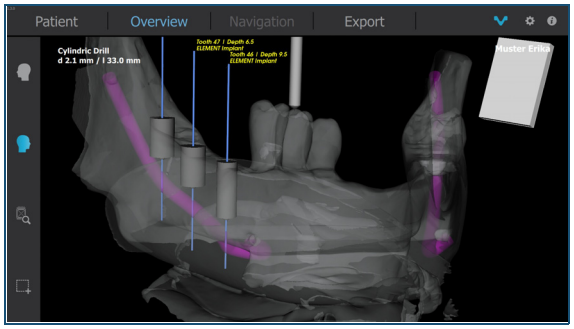
If you want to use another instrument, or to re-register the instrument, guide the instrument again to the registration tool and choose the **Retry** button.



9 The navigation starts automatically as soon as the instrument is selected.

On the touchscreen, the **Overview** screen is displayed.

The system is now ready for surgery.



To check the accuracy

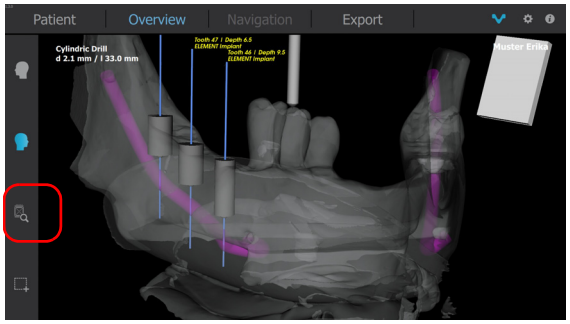
Note
The accuracy check is most effective the further away from the marker it is performed. However, the control site should be at least close to the implant site furthest away from the marker.

You must check the correct position of the tray with the marker in the patient's mouth using the accuracy check function.

1 Register a round bur or drill.

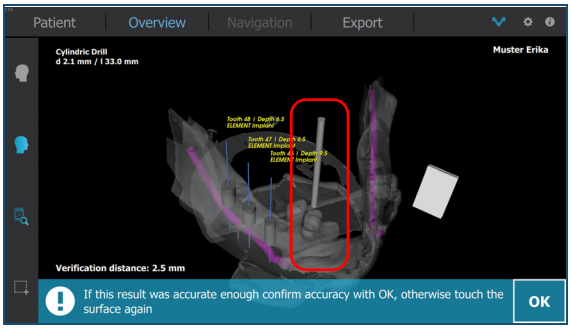
↗ For information about registering a round bur or drill, see "To register the instrument" on page 66

2 On the **Overview** screen, choose the button.



3 Follow the instruction on the screen.

The round bur or drill is displayed.



4 Compare the position of the instrument in the patient's mouth and on the touchscreen. Observe the verification distance.

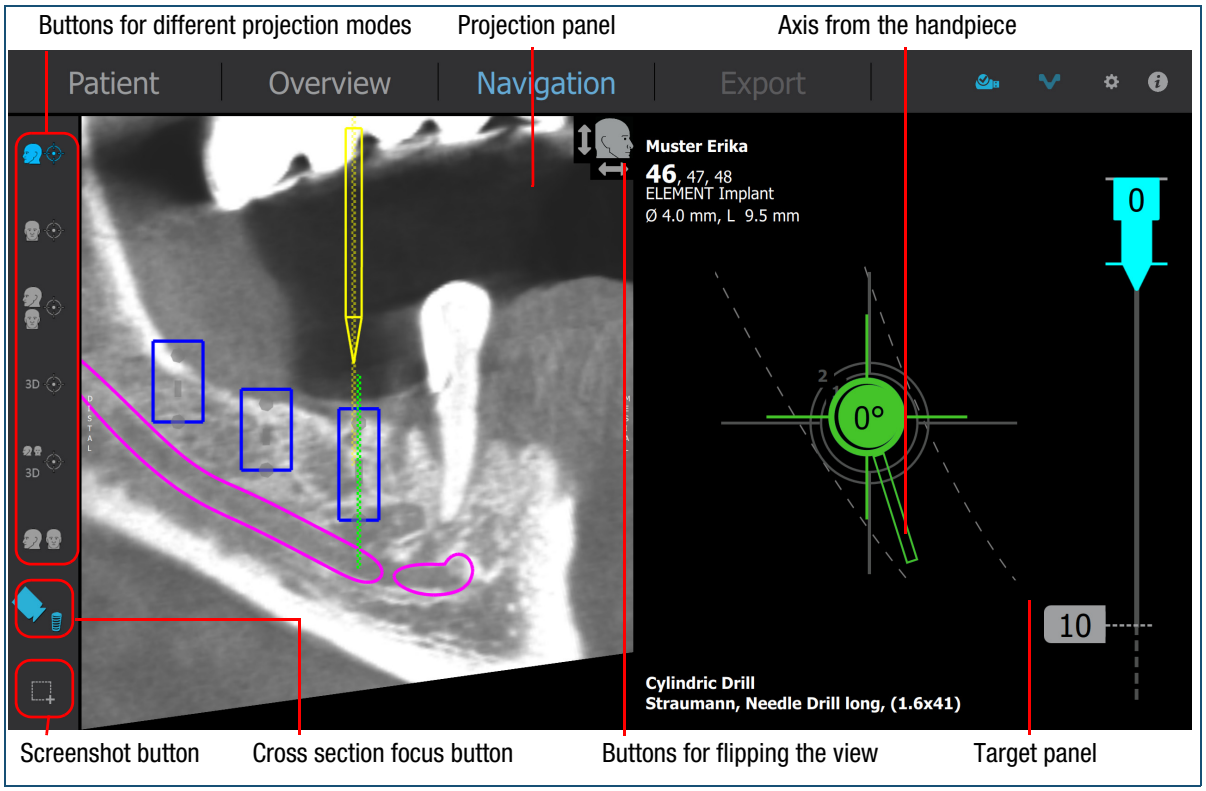
If the positions are identical, you can choose the **OK** button and proceed with centering or drilling.

If the positions are not identical, reposition the tray with the marker and perform the test again.

↗ For information about repositioning the tray with the marker, see "To place the tray with the marker in the patient's mouth" on page 61

5 Choose the button again to stop the accuracy check.

Performing the guided surgery



Picture 16 Guided surgery - Navigation screen

Caution

Injury to the patient due to incorrect instrument or registration tool handling

Incorrect handling of instruments or the registration tool may lead to inaccurate or shifted navigation procedure.

- Always verify the chosen instrument prior surgery
- Follow the Surgical Procedure Protocols of the dental implant system
- Register each instrument you want to use in the software prior to surgery
- Re-register the instrument once you have rotated the camera.

On the touchscreen, the **Overview** screen changes to the **Navigation** screen as soon as you move the handpiece to the patient's mouth.

On the **Navigation** screen, you have the following possibilities:

- View the 3D model either from different directions by choosing a button.
- Align the view of the jaw with your fingers on the touchscreen. Means: Rotate the target view of the jaw as you see it real on the patient.
- Flip the projection mode by choosing a button.
- Take a screenshot by choosing the button.
- To change the cross section focus between implant and instrument, choose the button.

  The screenshot is added to the case report. It is labeled with the current date and time.

  ↗ For more information about the case report, see "Viewing and exporting a case report" on page 73

To perform the guided surgery

1 On the **Overview** screen, check if the correct case is loaded.

2 Register the instrument.

↗ For information about registering the drill, see "Registering the instrument" on page 65

3 Check if the correct instrument is selected.

4 Move the instrument to the entry position.

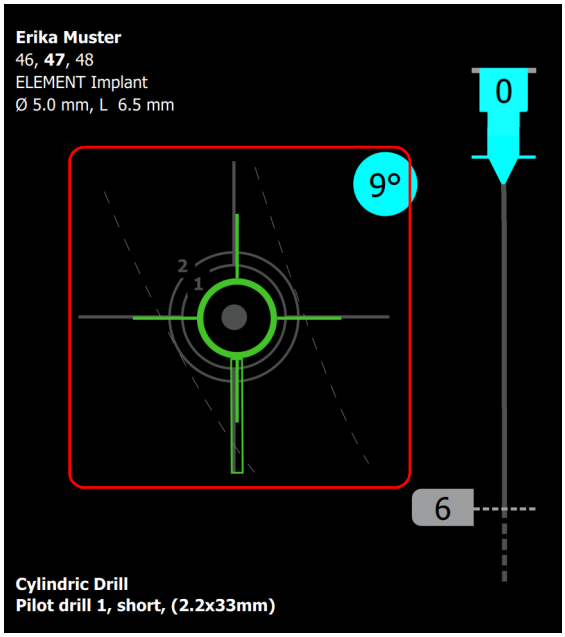
On the touchscreen, the **Navigation** screen is displayed.

5 On the target panel, guide the instrument over the target.

The lateral accuracy is within circle 2 at < 2 mm, within circle 1 at < 1 mm.

The cross-hair turns from white to green as soon as the instrument is in best position (lateral accuracy < 0.5 mm).

Make sure the camera has a clear view on the marker.



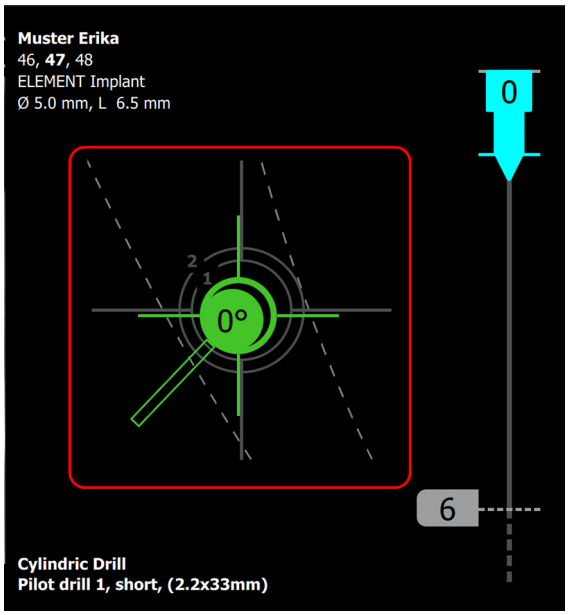
6 Depending on the instrument, do one of the following:

- For centering the entry point of the implant site, place the round bur on the bone.

  While centering, make sure the round bur remains in this position (cross-hair remain green).

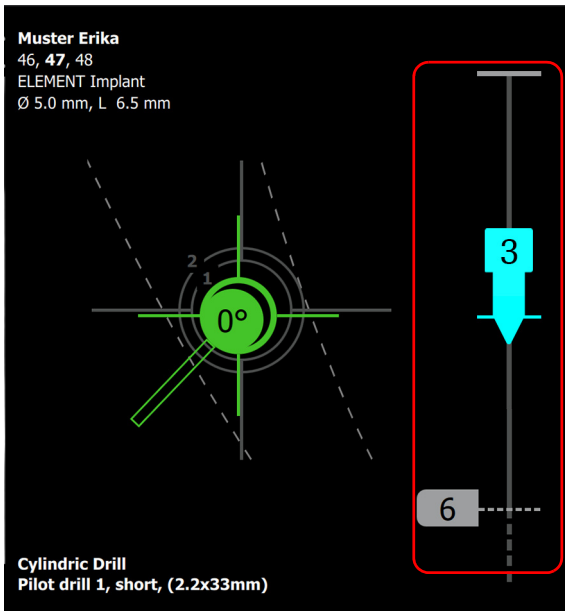
- For all other instruments, place the instrument on the planned position and change the angle of the instrument until you reach 0° on the angle display in the circle.

  The circle turns from blue to green as soon as the instrument is in best position and at best angle (angle accuracy < 0.5°).



7 Proceed with the instrument to the final depth by following the depth indicator.

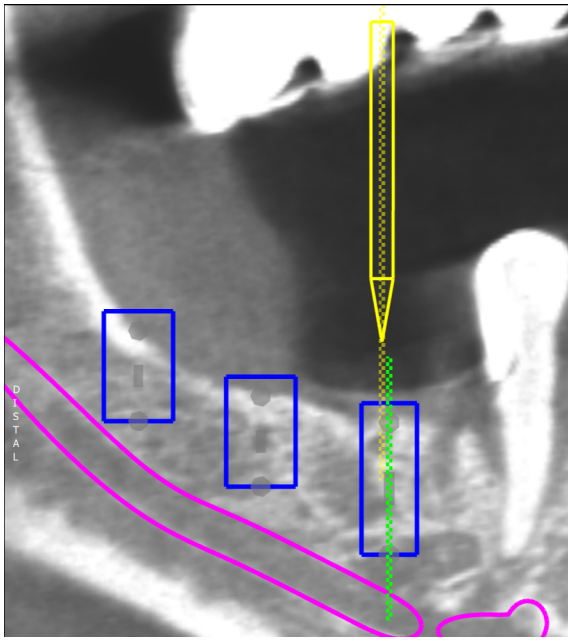
While working, make sure the instrument remains in the best position and angle (cross-hair and angle display remain green).



8 Observe the situation on the projection panel.

The planning and the current instrument position is displayed.

Pay particular attention to the situation around the nerve channel.



9 Register the subsequent instruments if necessary.

AFTER SURGERY

The main tasks after the surgery are:

1. Viewing and exporting the case report.
2. Removing the case if desired.
3. Completing the guided surgery.

PREREQUISITES

The dental implant surgery is completed.

SAFETY

Warning

Serious injury to the patient due to incorrect handling

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in this User Manual.

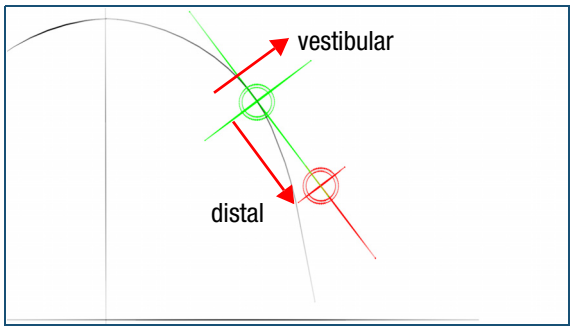
- Do not carry out operation, care and cleaning unless you have read and understood the information provided in the user documentation.
- Carefully follow the procedures specified in the instructions for operation, care and cleaning.
- Follow best practices, especially when you work with biohazardous material.

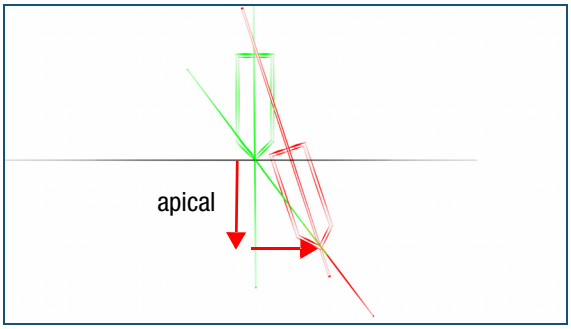
↗ For more information about safety, see "Safety information" on page 11

Viewing and exporting a case report

Picture 17 Viewing and exporting the case report - Case report

On the case report, the accuracy values show the deviation of the performed to the planned surgery in buccal-lingual and anterior-posterior direction.





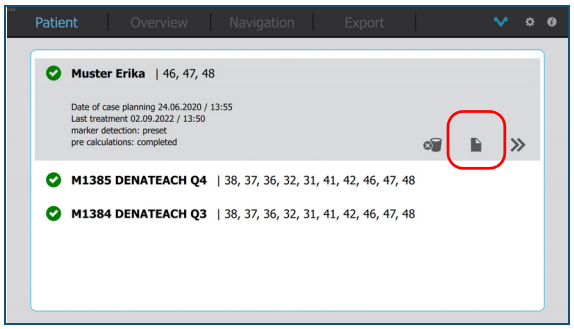
Note

- At predefined drills there is an offset between implant depth and drill depth resulted from the recommended offset of the implant manufacturer. This offset is part of the accuracy value in implant direction in the case report. Minus value means the hole is shorter, plus value means it is deeper than planned.

To view and export the case report

1 On the **Patient** screen, select the case and patient.

If the case is not displayed, scroll through the list.



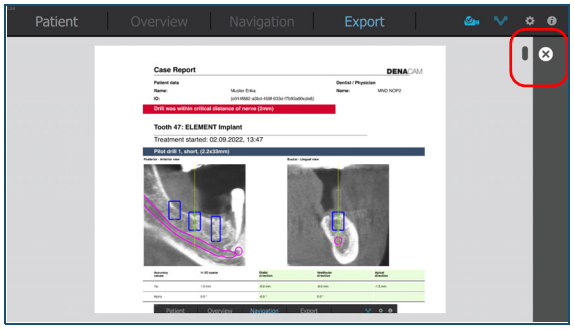
2 Choose the button.

The **Export** screen is displayed.

3 To view the case report on the touchscreen, choose the button.

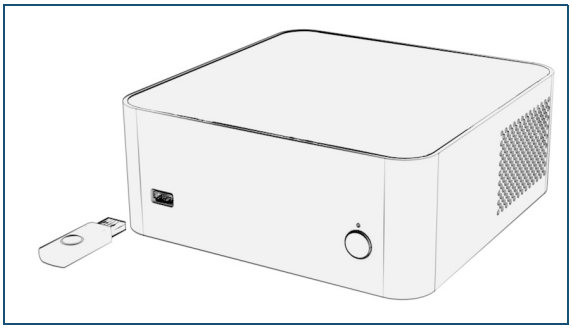
The case report is displayed.

4 Choose the button to close the case report.



5 To export the case report, insert a USB storage device with adequate storage capacity.

The USB storage device indicator lights up in blue when a valid USB device is connected ( ).



6 Choose the **Export to USB storage device** button.

The case report is saved on the USB storage device.

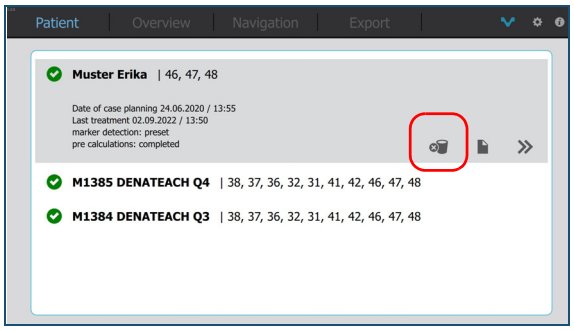
7 Remove the USB storage device.

Deleting a case if desired

To delete the case

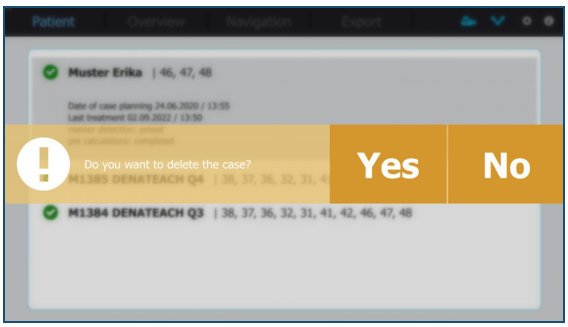
1 On the **Patient** screen, select the case and patient.

If the case is not displayed, scroll through the list.



2 Choose the button.

A confirmation message is displayed.



3 To confirm the deletion, choose the **Yes** button.

If you do not want to delete the case, choose the **No** button.

Completing the guided surgery

Notice

Infection by biohazardous waste

- Treat the system as biohazardous waste. Decontamination (cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the system.
- Dispose of the system according to the local regulations. For more information, contact your Service representative.

To complete the guided surgery

1 Remove the tray and marker from the patient's mouth.

2 Prepare the components for cleaning.

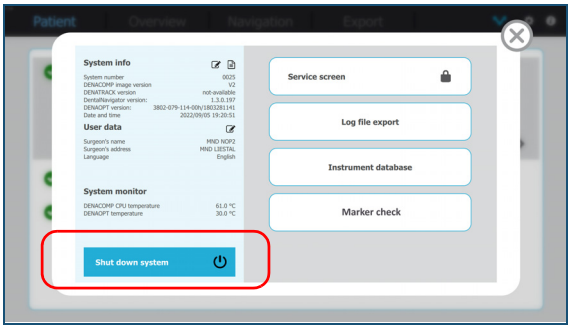
↗ For information about the cleaning, see "Care and cleaning" on page 77

To shut down the system

1 Remove the round bur or drill from the handpiece.

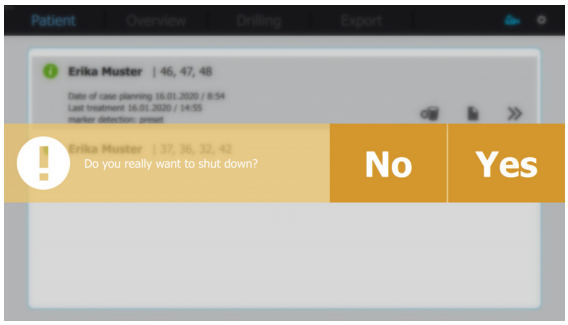
2 On the menu bar, choose the button.

The configuration overlay is displayed.



3 Choose the **Shut down system** button.

A confirmation message is displayed.

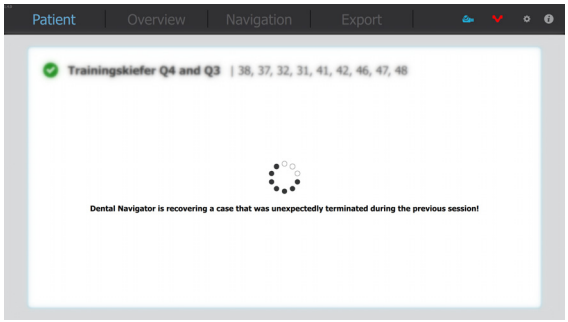


4 Choose the **Yes** button.

Wait until the computer is shut down

If you do not want to shut down, choose the **No** button.

When the system is shut down while a case is still open (or when there is a crash), recovery of the data, that hasn't been saved yet, is being started and the report of that case updated with the missing information. This can take a bit, so there is a loading screen.



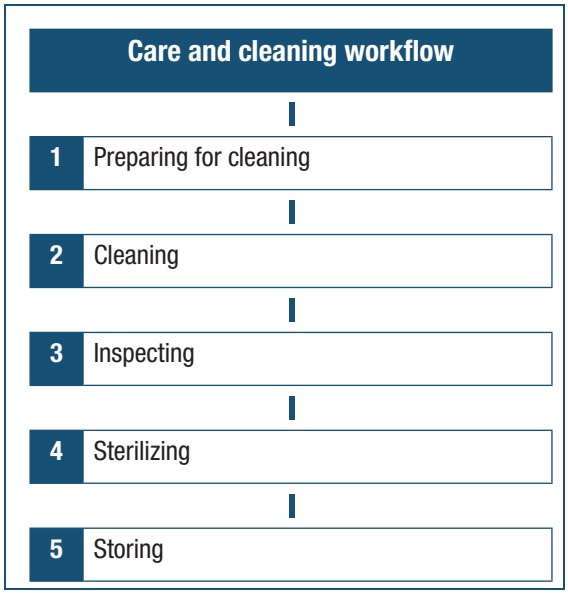
CARE AND CLEANING

BASIC PRINCIPLES

The basic principles, which are described in this section, have to be followed for all reprocessing steps.

Inappropriate care and cleaning of the components can result in failure or damage. Technical personnel must be trained in the handling of medical devices.

Care and cleaning involves the following basic steps:



About the reuse of components

Single use components

Components that are intended for single use (for example the tray) are labeled with the following symbol: ②.

Single use components that came into contact with blood or other bodily fluids of a patient are not allowed to be reused or used for another patient.

The manufacturer excludes any liability when single use components are reused.

Reusable components

Components that are not labeled for single use use may be reused. These reusable components have to be reprocessed before each use. Frequent reprocessing has minor effects on the components. The end of the product life is normally determined by wear and damage during use. Therefore, components can be reused with appropriate care, provided that they are undamaged and not contaminated.

The reprocessing of the components described in this document was tested and validated by mininavident.

Components with limited life cycles

mininavident defines a maximum number of reuses for certain reusable components (for example the markers). Inspect these components carefully before and after each use.

About appropriate cleaning solutions and cleaning equipment

Notice

Damage to the components due to wrong cleaning, inspection, and sterilization

Inappropriate cleaning solutions, cleaning processes, or sterilization may lead to damage of the component.

- Do not use alkaline or acidic cleaning solutions.
- Do not use excessive concentrations of cleaning solutions.
- Do not use aggressive cleaning equipment like metal brushes, steel wool, etc.
- Do not clean or rinse with a high pressure water jet.
- Do not sterilize components that are not suitable for sterilization.

DETERGENTS AND DISINFECTANT

mininavident has used the following detergents and disinfectants for the validation process of the manual / automatic disinfection and has followed the instructions of the manufacturer:

- For manual cleaning: Sekusept® MultiEnzyme P (ECOLAB®), Cidezyme™ Enzymatic Detergent
- For manual disinfection of the DENAMARK marker M1500: Sekusept® PLUS (ECOLAB®)
- For manual disinfection of the tray with DENAMARK marker M1500: MD 520 impression disinfectant (DÜRR DENTAL)
- For manual disinfection of the tray with DENAMARK marker M1501: Cidex® OPA
- For automated cleaning Neodisher® Medizym

Always follow these points when selecting cleaning solutions and cleaning equipment:

- They must be suitable for their intended use, for example for cleaning or for ultrasonic cleaning.
- The cleaning solution used must have a proven effectiveness. It must be approved by VAH / DGHM or FDA, or marked with a CE mark.
- The cleaning solutions must be suitable and compatible for use with the components.
- The manufacturer's instructions, such as those regarding concentration, exposure time, or temperature, must be followed.

mininavident recommends the use of freshly produced solutions.

ADDITIONAL INFORMATION:

The cleaning and sterilization information is provided in accordance with ISO 17664, AAMI TIR 12 and ISO 17665-1.

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing non-sterile mininavident medical devices. It remains the responsibility of the user to ensure that the processing is actually performed using appropriate equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the user from the recommendations provided should be properly evaluated for effectiveness and potential consequences.

Drying equipment

For drying, mininavident recommends lint-free single-use paper wipes or medical compressed air (according to the European Pharmacopoeia).

Water quality

Use only cold (20 °C ±2 °C / 68 °F ±3.6 °F) tap water of at least drinking water quality or deionized water for cleaning, sterilization, and rinsing steps.

Personal protective equipment

Wear personal protective equipment:

- Gloves
- Water repellent protective clothing
- Face protection mask or protective glasses

↗ See also the instructions of the manufacturer for the detergent and the disinfectant.

About preparing for cleaning

It is recommended to clean and disinfect the components as soon as possible, but within 2 hours after each use.

It is recommended to transport contaminated components in a closed box or container.

Preliminary cleaning should be done with lint-free disposable paper wipes.

To ensure that components undergoing cleaning can be properly assembled / re-assembled, pay attention to the individual assembly / re-assembly instructions.

INDIVIDUAL CLEANING INSTRUCTIONS

It is your responsibility to ensure that the components are completely sterile when used. In addition, always follow these points:

- Wear personal protective equipment
- Use only device and component specific procedures for cleaning and sterilization. The procedures must be sufficiently validated.
- Make sure that the equipment used (washer-disinfector, ultrasonic bath, sterilizer) is serviced and inspected on a regular basis.
- Respect for each cleaning cycle the validated parameters that are recommended by the equipment manufacturer.
- Consider the statutory regulations applicable in your country as well as the hygiene requirements of the practice or clinic. This applies in particular to the various instructions for effectively deactivating prions.

Table 3 Individual cleaning instructions - Overview

Component	Preparing for cleaning	Cleaning	Sterilizing
Computer, touchscreen, system cart	Shut down computer	Wipe disinfection of the surfaces	Not allowed
Camera	Separate camera from adapter	Wipe disinfection of the surfaces	Not allowed
Adapter	Separate camera from adapter	Automated or manual cleaning and disinfection	Steam sterilization
BienAir Adapter	For BienAir Adapter see IFU BienAir. https://dental.bienair.com/en_ch/support/download-center/		
Registration tool	Disassemble tool	Automated cleaning and disinfection	Steam sterilization
Marker	Detach marker from tray	Manual cleaning and disinfection	Steam sterilization
Tray with marker and dental impression	No preparation required	Manual cleaning and disinfection	Not allowed
Tray	Detach marker from tray before disposing	Dispose after each patient	Not allowed

Cleaning the computer, touchscreen, and system cart

Notice

Damage to the touchscreen, computer, or system cart due to sterilization

Sterilizing may damage the components.

- Do not sterilize the touchscreen, computer, or system cart

It is recommended to clean the components as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

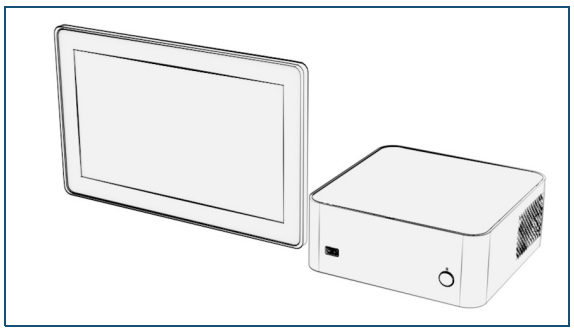
REQUIRED EQUIPMENT

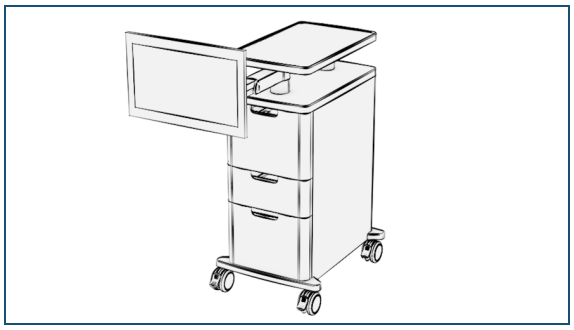
- Surface disinfectant, for example:
  - MinutenSpray-Classic (ALPRO MEDICAL GMBH)
  - PlastiSept-eco (ALPRO MEDICAL GMBH)
  - FD 333 quick disinfectant (DÜRR DENTAL)
  - Isopropanol 70%
- Lint-free, disposable paper wipes

To clean the computer, touchscreen, and system cart

1 Shut down the computer.

2 Spray the surfaces of the computer, touchscreen, and system cart with a surface disinfectant.





3 Clean the surfaces using lint-free, disposable paper wipes.

4 Visually inspect the computer, touchscreen, and system cart for:

- Damaged surfaces
- Contamination

5 If the components are still contaminated, repeat the steps. In case of damage, replace the components.

Cleaning the camera

Notice

Damage to the camera due to sterilization
Sterilizing may damage the component.
- Do not sterilize the camera

It is recommended to clean the camera as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

REQUIRED EQUIPMENT

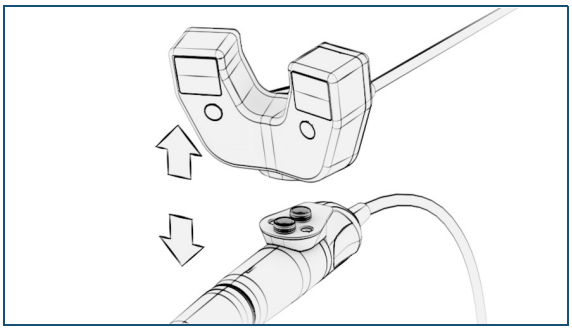
- Surface disinfectant, for example:
  - MinutenSpray-Classic (ALPRO MEDICAL GMBH)
  - PlastiSept-eco (ALPRO MEDICAL GMBH)
  - FD 333 quick disinfectant (DÜRR DENTAL)
  - Isopropanol 70%
- Lint-free, disposable paper wipes

To prepare and pre-clean the camera

1 Remove large debris using lint-free, disposable paper wipes.

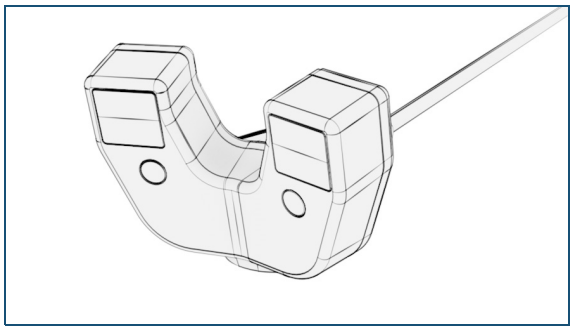
2 Separate the camera from the adapter by pulling the two components apart. They are held together by magnets.

The camera does not need to be disconnected from the computer.



To clean the camera

1 Spray the surfaces of the camera with a surface disinfectant.



2 Clean the surfaces and the connecting cable using lint-free disposable paper wipes.

3 Visually inspect the camera for:

- Damaged surfaces
- Fissures
- Chipping
- Other abrasion
- Contamination

4 If the camera is still contaminated, then repeat the steps. In case of damage, replace the camera.

5 Store the camera.

Cleaning, disinfecting, and sterilizing the adapter

Note

- The adapter can be exposed to temperatures up to a maximum of 135 °C (275 °F).
- The adapter is cleaned, disinfected, and sterilized together with the handpiece motor.
- For BienAir Adapter see IFU BienAir https://dental.bienair.com/en_ch/support/download-center/

It is recommended to clean and disinfect the adapter as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

REQUIRED EQUIPMENT:

- Multistage enzymatic cleaner detergent. E.g. Sekusept® MultiEnzyme P (ECOLAB®)
- VAH-listed disinfectant on peroxide basis. E.g. Sekusept® PLUS (ECOLAB®)
- Detergent tank
- Ultrasonic bath
- Cold tap water of at least drinking water quality or deionized water
- Soft brush
- Sterile 20 mL syringe
- Lint-free, disposable paper wipes

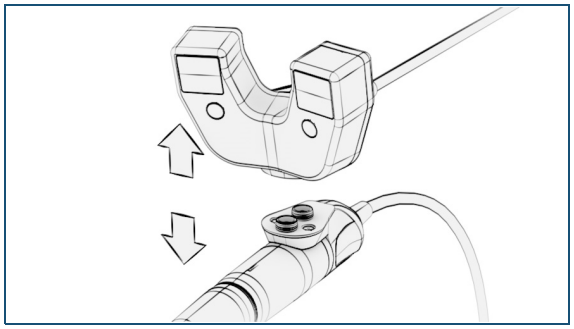
To prepare and pre-clean the adapter

1 Remove large debris using lint-free, disposable paper wipes.

2 Separate the camera from the adapter by pulling the two components apart. They are held together by magnets.

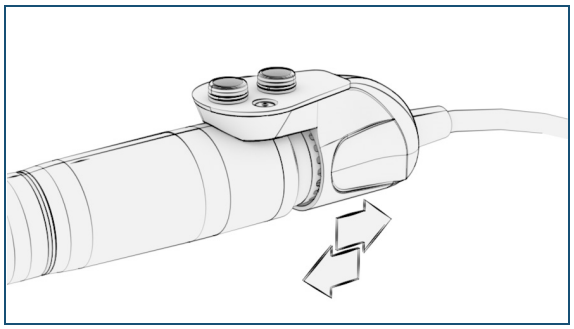
The camera does not need to be disconnected from the computer.

The adapter remains on the handpiece motor for cleaning and sterilization.



3 Rinse the adapter for at least 1 minute under running cold tap water and remove dirt with a soft brush.

4 Shift the movable part of the adapter under running cold tap water back and forth several times.



5 Rinse the adapter with deionized water again and check visually the result.

6 Clean the adapter either manually or automatically.

To clean and disinfect the adapter automatically

↗ For information about automatic cleaning, see "Automatic cleaning with a washer-disinfector for adapter" on page 95

To clean and disinfect the adapter manually

CLEANING MANUALLY

1 Place the adapter in the cleaning bath.

- Prepare the cleaner and choose the exposure time in accordance with the manufacturer's instructions.
- Use only freshly prepared solutions.
- Immerse components ensuring all surfaces are completely wet.

2 Clean the adapter in the cleaning bath.

- Brush all hard-to-reach areas (e.g. hinges, threads, sliding rings, crevices, holes and notches) and accessible areas to remove all visible dirt with a soft brush 10 times. The brush must reach the entire length of the cavities.
- Shift the movable part back and forth 10 times so that all areas are cleaned properly.
- Fill a 20 mL syringe with detergent solution and flush the cavities and all hard-to-reach and accessible areas of the component. Repeat this step 5 times.

3 Remove the adapter from the cleaning bath and rinse under running cold tap water for 1 minute.

- Shift the movable part back and forth 10 times so that all areas are rinsed properly.
- Fill a 20 mL syringe with tap water and flush the cavities and all hard-to-reach and accessible areas of the component.

4 Check the component for cleanliness and repeat the steps if dirt is still visible.

5 Leave the adapter to dry on a single use, lint-free wipe or towel.

DISINFECTION MANUALLY

6 Place the adapter in the ultrasonic bath and start ultrasonic.
   - Prepare the cleaner and choose the exposure time in accordance with the manufacturer's instructions.
   - Use only freshly prepared solutions.
   - Follow all manufacturer‘s instructions for the use of the ultrasonic bath.

7 Stop ultrasonic after 5 minutes exposure.

8 Flush and rinse the adapter in the ultrasonic bath.
   - Shift the movable part back and forth 10 times so that all areas are rinsed properly.
   - Fill a 20 mL syringe with disinfection solution and flush the cavities and all hard-to-reach and accessible areas of the adapter. Repeat this step 5 times.

9 Start ultrasonic.

10 After 10 minutes exposure, stop ultrasonic and remove the adapter from the ultrasonic bath.

11 Rinse the adapter under running cold tap water for at least 1 minute.

12 Repeat the rinsing step with deionized water.

13 Wipe the adapter with a single use, lint-free wipe or towel or dry by an air gun with medical compressed air.

14 Visually inspect the adapter for:
   - Damaged surfaces
   - Fissures
   - Chipping
   - Other abrasion
   - Contamination
   - Functionality

15 If the adapter is still contaminated, then repeat the steps. In case of damage, replace the adapter.

To sterilize and store the adapter

The adapter is sterilized and packed together with the handpiece motor.

1 Pack the adapter into an autoclavable packaging in accordance with EN ISO 1160, EN 868-3 to 10, or DIN 58953.

2 Sterilize the packed adapter.

↗ For information about sterilizing, see "Steam sterilization" on page 97

3 Store the adapter together with the handpiece motor.

↗ For information about storing, see "Storing" on page 97

Cleaning, disinfecting, and sterilizing the registration tool

Note

- The registration tool is delivered non-sterile and must be appropriately cleaned and sterilized before the first use after delivery.
- The registration tool can be exposed to temperatures up to a maximum of 135 °C (275 °F).
- The marker inside of the registration tool may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the registration tool maximally 50 times.
- Validated thermal disinfection program of 90 °C for 1 minute reaches A_0 = 600, 90 °C for 5 minutes reaches A_0 = 3000

It is recommended to clean and disinfect the registration tool as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

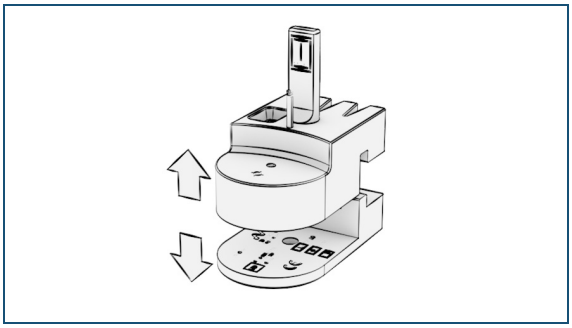
REQUIRED EQUIPMENT:

- Cleaning agent: neutral pH enzymatic detergent. Neodisher® Medizym, Dr. Weigert
- Washer-disinfector compliant with BS/EN/ ISO 15883 part 1 and 2, ISO 15883-5 (e.g. DGHM/ VAH). Belimed WD290IQ
- Steam sterilizer compliant with EN 16060 or EN 285. CISA 6464 LS
- Water bath or sink
- 20 mL syringe
- Autoclavable packaging in accordance with ISO 11607-1 and ANSI/AAMI ST79
- Autoclavable packaging with 510(k) clearance

AUTOMATED CLEANING (EN ISO 15883-1)

To prepare and pre-clean the registration tool

1 Disassemble the base plate from the upper part of the registration tool by pulling the two parts apart from each other. They are held together by a magnet.



2 Place the components in water bath at room temperature for 10 minutes.

3 Remove visible dirt by brushing with a soft bristled brushing under running tap water.

4 Rinse cavities five times (5x) using a 20 mL syringe filled with tap water.

To clean and disinfect the registration tool automatically

1 Place the disassembled registration tool in the washer-disinfector so that water could flow out of cannulas and blind holes.
   - Place the largest part of the registration tool on edge in the washer-disinfector to allow for maximum drainage of all cannulas and blind holes.
   - Place the smaller part of the registration tool flat with the smooth side facing upwards.

2 Ensure that devices do not touch each other.

3 Run the automatic cleaning program based on the parameters in table 4.

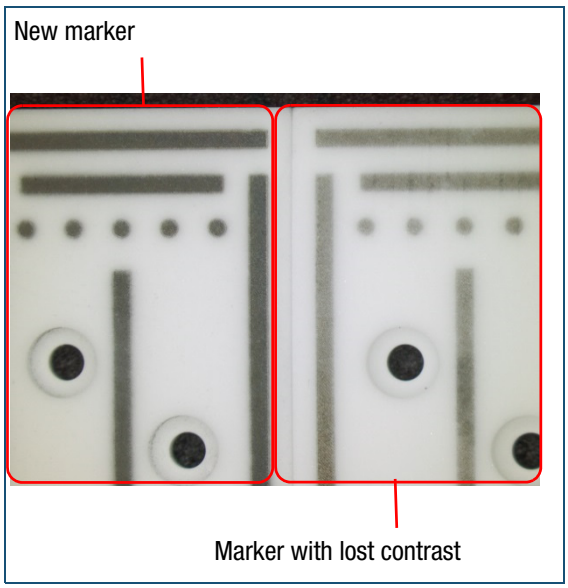
4 Visually inspect the parts of the registration tool using a magnifying glass for:
   - Damaged surfaces
   - Fissures
   - Chipping

- Other abrasion
- Contamination
- Functionality

5 Inspect the marker of the registration tool for loss of marker contrast.

Perform a marker visibility check.

↗ For more information about the marker visibility check, see "To perform a marker visibility check" on page 91



6 Re-assemble the registration tool to check correct matching.

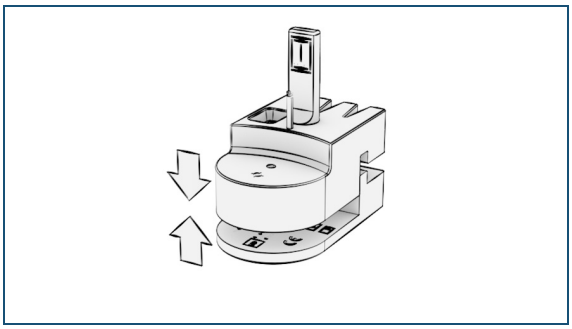


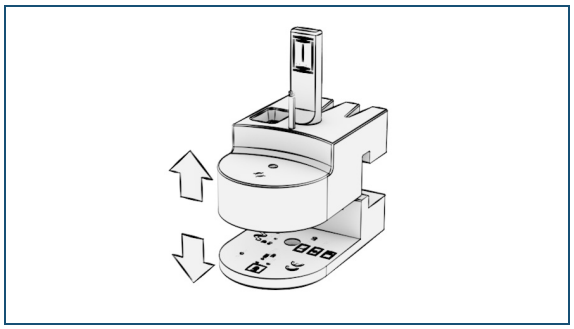
Table 4 Automated cleaning parameter using a washer-disinfector

Phase	Water temperature	Time	Cleaning agent
Pre-rinsing	Cold tap water	2 minutes	N/A
Wash	Hot tap water, set point 55 °C (131 °F)	5 minutes	Neutral pH enzymatic detergent, e.g. Neodisher® Medizym 0.2% (2 ml/L)
Rinse	Cold deionized water	3 minutes	N/A
Rinse	Cold deionized water	2 minutes	N/A
Thermal disinfection	90 °C (194 °F)	5 minutes	N/A

To sterilize and store the registration tool

Steam Sterilization method is validated according to EN ISO 17665

1 Disassemble the base plate from the upper part of the registration tool by pulling the two parts apart from each other. They are held together by a magnet.



2 Ensure the parts of the registration tool are air-dried before packaging them for steam sterilization.

3 Place the registration tool into autoclavable packaging compliant with ISO 11607-1 and ANSI/AAMI ST79.

4 Sterilize the disassembled registration tool based on the parameters in table 5.

5 Store the registration tool.

↗ For information about storing, see "Storing" on page 97

Table 5 Conditions for Steam Sterilization - Moist Heat (Autoclave), Fractionated vacuum

Variable	Europe	USA
Preconditioning Pulses	4	4
Temperature	134 °C (273 °F)	132 °C (270 °F)
Full cycle exposure time	3-18 minutes	4 minutes
Drying time	30 minutes	30 minutes

Cleaning, disinfecting, and sterilizing the reusable marker M1500

Note
This chapter is only applicable for the reusable marker M1500.

Notice

Damage to the marker due to wrong cleaning
Inappropriate cleaning process damages the component.
- Do not clean the marker in a washer-disinfector.
- Do not clean the marker in a ultrasonic bath.

Note
- The marker can be exposed to temperatures of up to 135 °C (275 °F).
- The marker may lose the contrast after several reprocessings. Therefore, mininavident recommends to reprocess the marker no more than 50 times

It is recommended to clean and disinfect the marker as soon as possible, but within 2 hours after each use.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

REQUIRED EQUIPMENT:

- Multistage enzymatic cleaner detergent. E.g. Sekusept® MultiEnzyme P (ECOLAB®)
- VAH-listed disinfectant on peroxide basis. E.g. Sekusept® PLUS (ECOLAB®)
- Detergent tank
- Cold tap water of at least drinking water quality or deionized water
- Soft brush
- Sterile 20 mL syringe
- Magnifying glass
- Lint-free, disposable paper wipes

3 Remove the marker from the cleaning bath and rinse under running cold tap water for 1 minute.

To prepare and pre-clean the marker

1 Remove large debris using lint-free, disposable paper wipes.

2 Detach the marker from the tray.

3 Rinse the marker under running cold tap and remove dirt with a soft brush.

4 Rinse the marker again and check visually the result.

5 Clean the marker manually.

To clean and disinfect the marker manually

CLEANING MANUALLY

1 Place the marker in the cleaning bath.
- Prepare the cleaner and choose the exposure time in accordance with the manufacturer's instructions.
- Use only freshly prepared solutions.
- Immerse parts ensuring all surfaces are completely wet.

2 Clean the marker in the cleaning bath.
- Brush all hard-to-reach areas (e.g. hinges, threads, sliding rings, crevices, holes and notches) and accessible areas to remove all visible dirt with a soft brush 10 times. The brush must reach the entire length of the cavities.
- Fill a 20 mL syringe with detergent solution and flush the cavities and all hard-to-reach and accessible areas of the component. Repeat this step 5 times.
- Fill a 20 mL syringe with tap water and flush the cavities and all hard-to-reach and accessible areas of the component.

4 Check the marker for cleanliness and repeat the steps if dirt is still visible.

5 Leave the marker to dry on a single use, lint-free wipe or towel.

DISINFECTION MANUALLY

6 Place the marker in the disinfection bath.

- Prepare the disinfectant and choose the exposure time in accordance with the manufacturer's instructions.
- Use only freshly prepared solutions.

7 Flush the marker in the disinfection bath after 5 minutes exposure.

- Fill a 20 mL syringe with disinfection solution and flush the cavities and all hard-to-reach and accessible areas of the marker. Repeat this step 5 times.

8 After additional 10 minutes exposure, remove the marker from the disinfection bath.

9 Rinse the marker under running cold tap water for at least 1 minute.

10 Repeat the rinsing step with deionized water.

11 Wipe the marker with a single use, lint-free wipe or towel or dry by an air gun with medical compressed air.

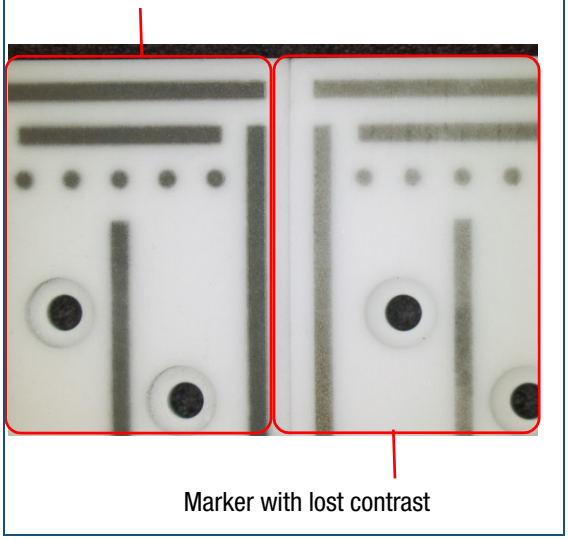
12 Visually inspect the marker using a magnifying glass for:

- Damaged surfaces
- Fissures
- Chipping
- Other abrasion
- Contamination
- Functionality

13 Inspect the marker for loss of marker contrast.

Perform a marker visibility check.

↗ For more information about the marker visibility check, see "To perform a marker visibility check" on page 91



14 If the marker is still contaminated, repeat the steps. In case of damage or loss of contrast, replace the marker.

To sterilize and store the marker

1 Pack the marker into an autoclavable packaging in accordance with EN ISO 1160, EN 868-3 to 10, or DIN 58953.

2 Sterilize the packed marker.

↗ For information about sterilizing, see "Steam sterilization" on page 97

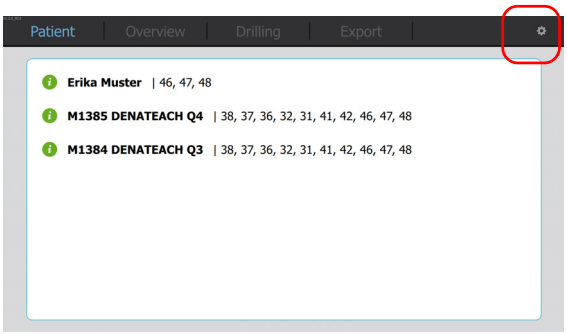
3 Store the marker.

↗ For information about storing, see "Storing" on page 97

To perform a marker visibility check

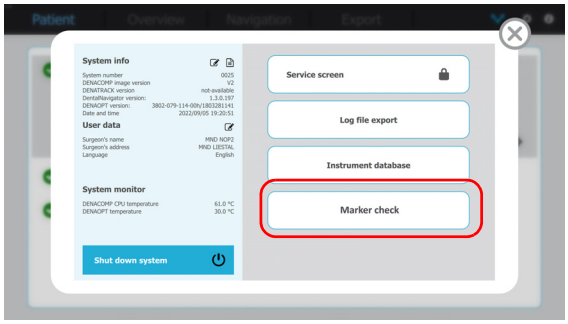
1 To start up the system, press the power switch on the computer.

Wait until the **Patient** screen is displayed.



2 On the menu bar, choose the ⚙ button.

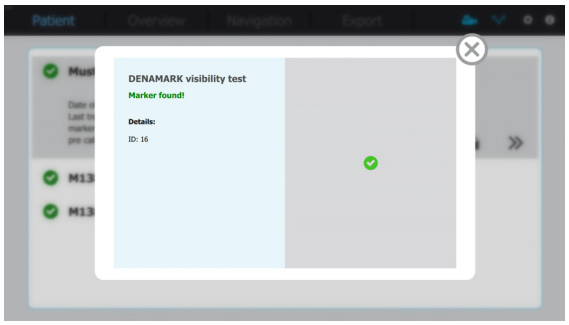
The configuration overlay is displayed.



3 Move the marker in front of the DENAOPT camera and choose the **MARKER check** button.

4 Notice the result of the test on the DENAMARK visibility test.

If the marker pattern is recognized and found by the camera, the marker can continue to be used. If not, use a new marker.



Cleaning and disinfecting the single-use marker M1501

Note
This chapter is only applicable for the single-use marker M1501.

Notice

Damage to the marker due to wrong cleaning
Inappropriate cleaning process damages the component.
- Do not clean the marker in a washer-disinfector.
- Do not clean the marker in a ultrasonic bath.

Note
- The marker can be exposed to temperatures of up to 135 °C (275 °F).

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

REQUIRED EQUIPMENT:

- Cleaning agent: pH neutral enzymatic detergent. Cidezyme Enzymatic Detergent
- Deionized water
- Cidex® OPA
- Disposable syringe, 20 ml
- Basin, stainless steel

To clean and disinfect the marker manually

CLEANING MANUALLY

1 A Cidezyme™ solution is prepared by adding 8 mL of Cidezyme™ to 1 L of deionized water at room temperature (20 °C ± 2 / 68 °F ± 3.6). The volume needed of the solution is 150 ml per marker.

2 Soak the marker into the Cidezyme™ solution for 10 minutes. During soaking mechanically clean the marker with a soft bristled brush for 15 seconds.

3 Remove the marker from the detergent solution.

4 Rinse the marker under running deionized water at room temperature for 10 seconds 3 times.

5 Air dry the marker for 30 minutes.

DISINFECTION MANUALLY

6 Immerse the marker in a disinfection bath of Cidex® OPA for 12 minutes at room temperature (20 °C ± 2/ 68 °F ± 3.6). Bath volume per marker is 1 L.

Ensure that the marker is covered by the disinfection solution and that air is not trapped within features of the device. Ensure that the devices do not touch each other.

7 Rinse out all cavities of the marker 3 times with the disinfection solution at the beginning and at the end of the action time using disposable syringe (minimum syringe volume 20 ml).

8 Remove the marker from the bath.

9 Immerse the marker completely in purified water (5 L of water per device) for 1 minute at room temperature.

10 Rinse the marker thoroughly with water 5 times using a disposable syringe (minimum syringe volume 20 ml).

11 Remove the marker from the bath of water and discard the rinse water. Always use fresh volumes of water for each rinse.

12 Repeat steps 9 to 11, for a total of 3 rinses, in order to remove Cidex® OPA solution residues. Residues may cause serious side effects.

Cleaning and disinfecting, or disposing the tray used with marker M1500 and M1501

Notice

Damage to the tray, dental impression, and marker due to wrong cleaning
Inappropriate cleaning process damages the component.
- Do not clean the tray with marker and dental impression in a washer-disinfector.
- Do not clean the tray with marker and dental impression in a ultrasonic bath.

Note
- The tray is a single-use component and must be disposed after patient.

It is recommended to clean the tray after impression taking and after the CBCT scan.

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

REQUIRED MATERIALS:

- Cleaning agent: neutral pH enzymatic detergent, Cidezyme ™ Enzymatic Detergent
- Deionized water
- Cidex® OPA
- Disposable syringe, 20 ml
- Basin, stainless steel

To clean and disinfect the tray with marker and dental impression manually

CLEANING MANUALLY

1 A Cidezyme™ solution is prepared by adding 8 mL of Cidezyme™ to 1 L of deionized water at room temperature (20 °C ± 2 / 68 °F ± 3.6). The volume needed of the solution is 150 ml per tray.

2 Soak the tray into the Cidezyme™ solution for 10 minutes. During soaking mechanically clean the tray with a soft bristled brush for 15 seconds.

3 Remove the tray from the detergent solution.

4 Rinse the tray under running deionized water at room temperature for 10 seconds three times.

5 Air dry the tray for 30 minutes.

DISINFECTION MANUALLY

6 Immerse the tray in a disinfection bath of Cidex® OPA for 12 minutes at room temperature (20 °C ± 2 / 68 °F ± 3.6). Bath volume per tray is 1 L.
   - Ensure that the tray is covered by the disinfection solution and that air is not trapped within features of the device. Ensured that the devices do not touch each other.

7 Rinse out all cavities of the tray three times (3x) with the disinfection solution at the beginning and at the end of the action time using disposable syringe (minimum syringe volume 20 ml).

8 Remove the tray from the bath.

9 Immerse the tray completely in purified water (5 L of water per tray) for 1 minute at room temperature.

10 Rinse the tray thoroughly with water five times (5x) using a disposable syringe (minimum syringe volume 20 ml)

11 Remove the tray from the bath of water and discard the rinse water. Always use fresh volumes of water for each rinse.

12 Repeat steps 9 to 11, for a total of three (3) rinses, in order to remove CIDEX® OPA solution residues. Residues may cause serious side effects.

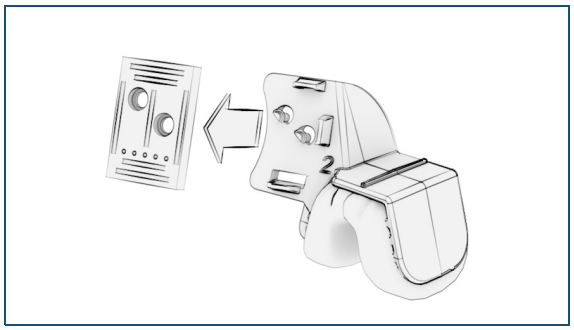
13 Visually inspect the tray for:
   - Damaged surfaces
   - Fissures
   - Chipping
   - Other abrasion
   - Contamination
   - Functionality

To store the tray

↗ For information about storing, see "Storing" on page 97

To dispose the tray after use

1 Detach the marker from the tray.



2 Dispose the tray according to the local regulations.

BASIC INSTRUCTIONS

The basic instructions mainly apply to the system, provided there are no other component-specific instructions in this User Manual.

Manual and automatic cleaning

Two methods, a manual and an automatic method, are described for the cleaning and disinfection of the DENACAM components. If possible an automatic procedure (washer-disinfector) must be used. A manual procedure even with an ultrasonic bath is significantly less effective.

Manual cleaning

Use the manual cleaning procedure for:

- Adapter (mounted on the handpiece motor)
- Marker (do not use a ultrasonic bath)
- Tray (do not use a ultrasonic bath)

For manual cleaning and disinfection, follow the steps that are outlined in the individual cleaning procedures.

Make sure always to follow the general instructions for cleaning solutions and cleaning equipment.

↗ For more information, see "About appropriate cleaning solutions and cleaning equipment" on page 79

Automatic cleaning with a washer-disinfector for adapter

Use the automatic cleaning procedure for

- Adapter (mounted on the handpiece motor)

Make sure always to follow the basic principles for care and cleaning.

↗ For more information, see "Basic principles" on page 78

When using the washer-disinfector, make sure that the cleaning process includes the following phases in accordance with EN ISO 15883:

Table 6 Automated cleaning and disinfection using a washer-disinfector

Phase	Temperature	Duration	Action
Pre-rinsing	Cold	5 minutes	Rinse with cold water
Cleaning[1]	55 °C ±2 °C (131 °F ±3.6 °F)	10 minutes	Adding cleaning solution
Neutralization	Cold	2 minutes	Neutralize with cold water
Rinsing	Cold	1 minute	Rinse with deionized water
Thermal disinfection (A_0 value > 3'000)	≥ 90 °C (194 °F)	5 minutes	With demineralized and purified water; do not add additional detergent
Rinsing	Component specific	Component specific	Rinse with demineralized and purified water
Dry	Component specific	Component specific	Drying process

[1] The information provided is based on the use of „Sekumatic® MultiClean" by ECOLAB®. Times and temperatures may vary if a different cleaning solution is used.

To clean and disinfect components using a washer-disinfector

REQUIRED EQUIPMENT:

- Mildly alkaline cleaner detergent for automatic cleaning. E.g. Sekumatic® MultiClean (ECOLAB®)

  Make sure that the chosen disinfectant is compatible with the detergent in use, in cases where no thermal disinfection is used.
- Washer-disinfector in accordance with DIN EN ISO 15883-1 and 2 with thermal program (temperature 90–93 °C / 194–199.4°F)
- Autoclavable packaging in accordance with EN ISO 1160, EN 868-3 to 10, or DIN 58953

Always follow the preparation and pre-cleaning steps that are outlined in the individual cleaning procedures before cleaning and disinfecting the components automatically.

1 Place the components in the washer-disinfector.
   - Always load the components according to the manufacturer's instructions.
   - If necessary, disassemble components as indicated in the individual cleaning procedures.
   - Do not overload the washer-disinfector.
   - Place large components in a way that they do not cover other components and consequently impact the cleaning process.
   - Make sure that components with cavities are completely rinsed also from the inside. For such components it is suitable to use inserts like flushing appliances.
   - Do not load components with cavities horizontally. Position components with hidden cavities facing downwards to support the rinsing process.
   - Carefully place components to avoid damages.
   - Follow all manufacturer‘s instructions for the use of the washer-disinfector.

2 Start the program.

3 Remove the components from the washer-disinfector after the program ends.

4 Check if the components are completely dry, if necessary wipe the components with a single use, lint-free wipe or towel or dry using an air gun with medical compressed air.

Sterilization and storing

Steam sterilization

Sterilization must be done for the following components:

- Adapter (mounted on the handpiece motor)
- Reusable marker

For both initial and subsequent sterilization, the following parameters were validated by mininavident in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/ AAMI ST79.

Table 7 Steam sterilization

Procedure	Fractionated and dynamic pre-vacuum process	Flow and gravitation processes
Exposure time	≥ 3 minutes	≥ 10 minutes
Temperature	132 °C/135 °C (269,6 °F/275 °F)	132 °C/135 °C (269,6 °F/275 °F)
Drying time	> 20–30 minutes	> 20–30 minutes

Outside the USA

The exposure time can be extended to 18 minutes to meet the recommendations of the WHO and the Robert Koch Institute (RKI). DENACAM components are designed for these sterilization cycles.

REQUIRED EQUIPMENT:

- Steam sterilizer (autoclave) according to DIN EN 13060, Class B, and/or DIN EN 285.

To sterilize components using a sterilizer

1 Place the packed components in the sterilizer chamber.
   - Follow all manufacturer‘s instructions for the use of the sterilizer.
2 Start the program.
3 Remove the components from the sterilizer after the program ends.
4 Check that the seal of the package is closed and the package is dry.

Storing

After sterilization, the components must be stored in a dry, dust- and humidity-free environment without direct solar irradiation.

Temperature variations have to be avoided to prevent corrosive damage.

The maximum storage time depends on various factors such as packaging, method of storing, environment, and handling. The user should define a maximum storage time for sterile components. The components have to be used within this defined time or sterilized again.

SERVICING

Regular servicing is necessary for safe operation and should be carried out once a year.

mininavident recommends that only an authorized service partner should undertake servicing and checking.

↗ For information about maintenance and repair protocol, see "Maintenance and repair protocol" on page 121

↗ For information about your local authorized service partner, see "Authorized service partners" on page 2

TROUBLESHOOTING

SOFTWARE MESSAGES/WARNINGS

All messages of the system are listed. Follow the indicated troubleshooting information to resolve the issue.

The messages must be confirmed on the touchscreen either by choosing the **OK**, or **No**, or **Yes** button.

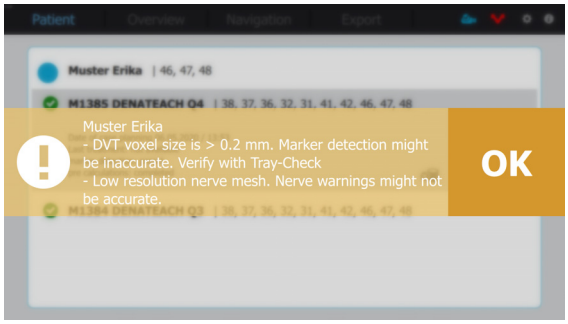


Table 8 Software messages

Severity	Message	Troubleshooting information
Warning	Temperature DENAOPT	• DENAOPT internal sensor > 55 °C (131 °F) • Measure: Cool down the system. ↗ For information about cooling down the system, see "To cool down the system" on page 102
Warning	Temperature DENACOMP	• DENACOMP CPU sensor > 85 °C (185 °F) • System performance not optimal • Possible damage to DENACOMP • Measure: Cool down the system. ↗ For information about cooling down the system, see "To cool down the system" on page 102
Warning	Data import warning	• Error while reading the USB storage device. Use another USB storage device or repair the device with a repair program on your computer. • Patient data could not be loaded. • Some data are not valid or are missing. • Message can provide text for error cause.
Warning	Shut down warning	User is warned, that the system will shut down.
Warning	Update warning	• Software could not be updated. • Some data are not valid or are missing. • Message can provide text for error cause.
Warning	Leak-time warning	• User is warned that the system has too long leak-time

Table 8 Software messages

Severity	Message	Troubleshooting information
Warning	The drill is within critical distance of the mandibular nerve. Stop! Distance XX mm	• Is shown when the distance between drill and nerve is below 2.0 mm (XX is current measured distance)
Warning	Failed to export report to USB drive	• Is shown when the export of the report file failed to work
Warning	Export failed	• Is shown when export of instrument database was failed
Warning	Import failed	• Is shown when importing instrument database was failed
Warning	Include failed	• Is shown when adding instruments to database from USB-drive failed
Warning	Database modification unsuccessful	• Is shown when adding/editing an instrument failed
Warning	Please contact support. Unexpected modification of case:	• The System checks regularly if any files have been unintentionally modified or removed. When a manipulation is detected, the system locks with a red warning message.
Warning	An unexpected change of pre-calculated values has been detected. Pre-calculations are being redone.	• If the pre-calculation files have been detected as manipulated, a repeat of the calculations gets triggered, closing the case if one is open, to ensure that no potentially incorrect values are being used for distance calculation.
Warning	Newer Version of this case already existing:	• If a newer version of the planning exists, the case won't import and give a message
Warning	Can’t replace case with existing treatment information:	• If an older version with treatment data exists, the case won't be imported and give a message
Warning	Marker positions don’t match minimum difference criteria:	• With the updated genxa-file format, multiple marker positions can be planned and added to the case. Marker centers have to have a distance of >8mm or the rotation of the markers have to have a difference of >30°. If these criteria aren't fulfilled, the case can't be imported.

HARDWARE ERRORS

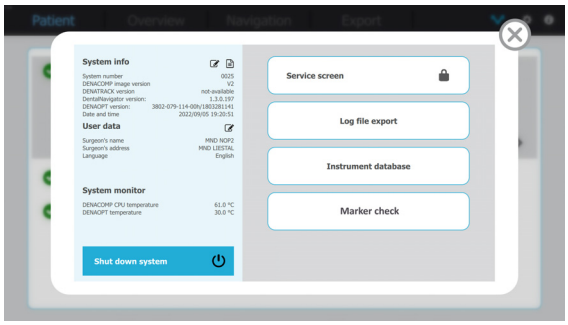
If the system is not responding adequately consider the following points.

Temperature too high

To cool down the system

1 On the menu bar, choose the ⚙ button.

The configuration overlay with the **System monitor** is displayed.



2 Check the DENACOMP CPU temperature and DENAOPT temperature.

3 Wait until the temperature drops to below 85 °C (185 °F) for the DENACOMP CPU temperature, or 55 °C (131 °F) for the DENAOPT temperature.

For a faster cool down, improve the cooling in the room.

4 Choose the ⊗ button to exit.

Power interruption

A Power interruption can be triggered by the system fuse, unintentional disconnection of the power cable, or a power breakdown.

After a power interruption, the system needs to be recovered.

To change a defect fuse

1 Disconnect the power cable.

2 Open the fuse compartment above the mains connector.

There are two fuses.

3 Replace the defect fuse (T1.6 A H 250 V).

4 Close the fuse compartment.

5 Connect the power cable.

To recover the system

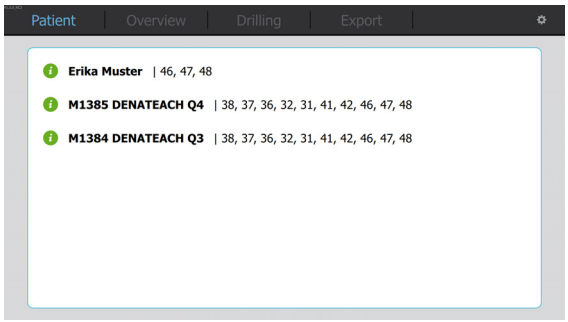
1 If the system is still powered on, shut down the system.

↗ For information about shutting down the system, see "To shut down the system" on page 75

2 Restart the system.

↗ For information about starting up the system, see "To start up the system" on page 58

3 On the **Patient** screen, search for the case.



4 If the case is not displayed, import the case planning data again.

↗ For information about importing case planning data, see "To import the case planning data" on page 55

5 Reload the case planning data.

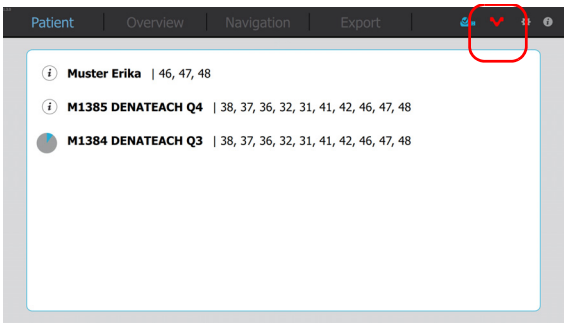
↗ For information about loading case planning data, see "To load the case" on page 61

6 Restart the guided surgery.

↗ For information about guided surgery, see "During surgery - Guided surgery" on page 63

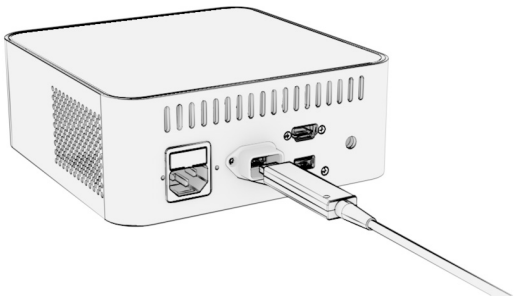
Connection error between the camera and the computer

1 On the screen, a red symbol is displayed.



2 Wait 30 seconds for an automatic reconnection of the camera and computer.

3 Unplug the USB connector to separate the camera from the computer.



4 Reconnect the camera to the computer.

APPENDIX

REFERENCE NUMBERS

Spare part	Product name REF number
Camera	DENAOPT® M1100
Adapter W+H	DENADAPT® M1200
Adapter Bien-Air ventilated with cable	DENADAPT® M1204
Computer	DENACOMP® M1300
Touchscreen 13.3"	DENASCREEN® M1400
Touchscreen 15.6"	DENASCREEN® M1401
Cable Set DENASCREEN (USB/DisplayPort/Power)	M1400-2000

Consumable	Product name REF number
Marker	DENAMARK® M1500
Marker single-use	DENAMARK® M1501
Tray 1	DENATRAY® 01 M1600
Tray 2	DENATRAY® 02 M1700
Registration tool	DENAREG® M1800
Registration tool with embedded second marker	DENAREG® M1801

Accessory	Product name REF number
System cart	DENACART® M2001

SPECIFICATIONS

Technical data

Topic	Specification
Model designation	DENACAM® System
Power connection	100–240 V~
Nominal current	50–60 Hz
Type of system earthing	Protective earth
Protection class	Class I
System fuse	2x T1.6A H 250 V
Device class in accordance with Directive 93/42/EEC	Class IIa
Mode of operation	Continuous operation with intermittent loading, corresponding to the dental mode of working
Operating conditions	Ambient temperature: 18 °C–30 °C (64 °F–86 °F) Relative humidity: 30–50 %, no condensation Atmospheric pressure: 78–106 kPa Altitude: max 2000 m above sea level
• 1 USB port at the front for connecting a USB storage device • 1 USB port at the rear for connecting the camera	USB 2.0 standard
1 USB port at the rear for connecting the touchscreen	USB 3.0 standard
1 DisplayPort port at the rear for connecting the touchscreen	

Precision of the optical system

The precision of the optical system is high enough to detect a drill located in 60 mm distance to the marker with an accuracy of 0.75 mm (xyz).

The system accuracy increases when the implant position is closer to the marker and when the camera looks more even on the marker pattern.

The accuracy (rms value) of the system including user influence was determined in an in vitro study using realistic clinic implant and related marker positions.

Table 9 Precision of the optical system

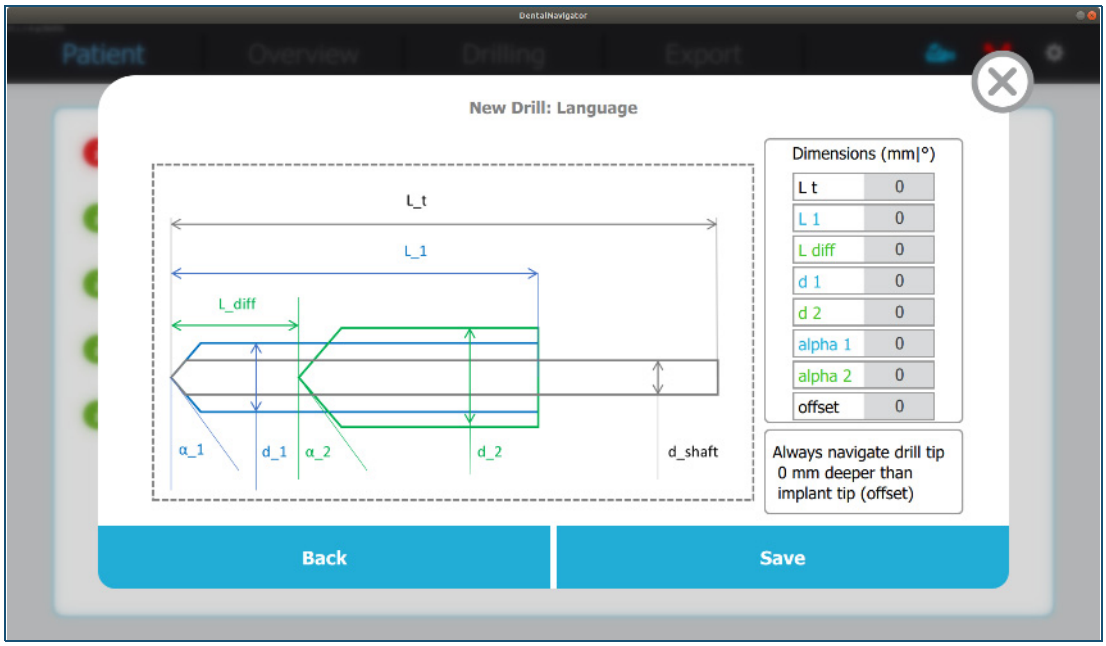
Implant lateral	Implant depth	Angular
0.74 mm	*	2.29 °

* Value is not shown because implants must be screwed in by hand and the vertical position is in the clinical situation usually determined by the relation of the implant shoulder to the crestal bone.

Implant lateral is the accuracy in a plane passing through the planned implant base and orthogonal to the planned implant axis. Implant depth is the accuracy in direction of the planned implant axis. Angular is the angle between the planned and drilled implant axis.

INSTRUMENT DIMENSIONS

Dimensions for cylinder and step drill

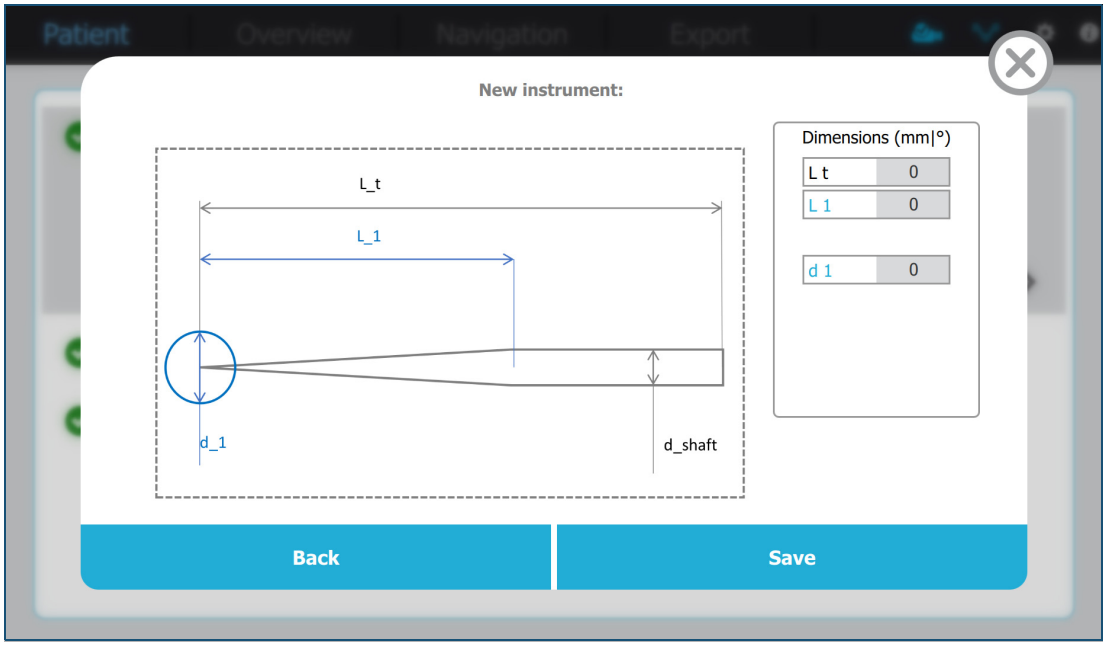


Picture 18 Dimension sheet for cylinder and step drill

Table 10 Dimensions for cylinder and step drill

Dimension	Cylinder drill/Tap	Step drill and other shape
L_t	Total drill length	Total drill length
L_1	Cutting length	Cutting length (total of both steps)
L_diff	-	Cutting length of the first step (small diameter)
d_1	Cutting diameter	Cutting diameter of the first step (small diameter)
d_2	-	Cutting diameter of the second step (large diameter)
alpha_1	Cutting angle	Cutting angle of the drill tip
alpha_2	-	Cutting angle of the second step (large diameter)
offset	Difference between the drilling depth and the implant tip	Difference between the drilling depth and the implant tip

Dimensions for locator, round bur and tab

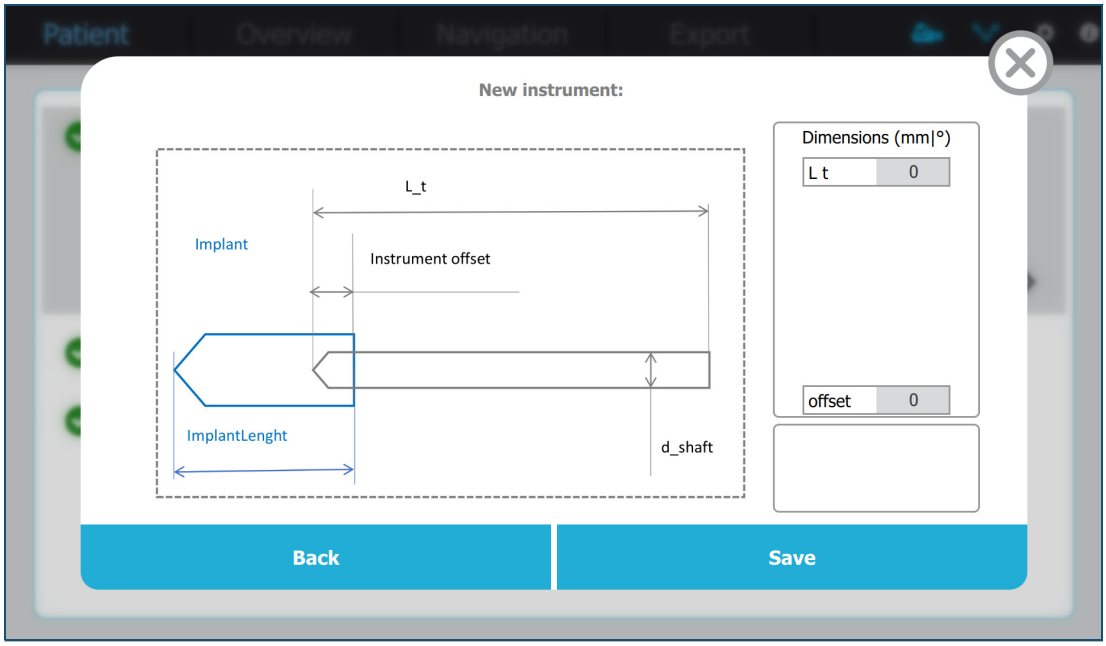


Picture 19 Dimension sheet for locator round bur and tab

Table 11 Dimensions for locator, round bur and tab

Dimension	Locator	Round bur
L_t	Total locator length	Total round bur length from the cutting head center
L_1	Tapered length	Cutting length (total of both steps)
d_1	-	Cutting head diameter

Dimensions for implant adapter



Picture 20 Dimension sheet for implant adapter

Table 12 Dimensions for implant adapter

Dimension	Implant adapter
L_t	Total adapter length
offset	Difference between the adapter and the implant base

TRANSPORT AND STORAGE CONDITIONS

The components can be moved and stored without damage in the associated transport packaging under the following conditions.

Table 13 Transport and storage conditions

Topic	Specification
Temperature range	-10 °C to 55 °C (14 °F to 131 °F)
Relative humidity	10–90%
Vibration	According to DIN EN 60068-2-6 Shape: Sinusoidal Frequency: 7–200 Hz Acceleration: 15 m/s^2 Frequency change: 1 octave/min Each 30 min in x, y, z direction
Shock	According to DIN EN 60608-2-27 Shape: Half-sinusoidal Acceleration: 200 m/s^2 Duration: 11 ±2 ms Repeat: 100 x each in x, y, z, direction
Temperature cycling	According to DIN EN 60068-2-14 T: -10 °C to 55 °C (-4 °F to 131 °F) Repeat: 10 cycles Duration: 3 h
Damp heat	According to DIN EN 60068-2-30 25 °C ±3 °C (77 °F ±5.4 °F), 97.5% ±2.5% 40 °C ±3 °C (104 °F ±5.4 °F), 93.0% ±3.0% 7 cycles over 7 days

STANDARDS AND APPROVALS

The DENACAM System bears the CE symbol in accordance with the provisions of Council Directive 93/42/EEC of June 14, 1993 concerning medical devices. It complies with the following standards, among others:

Standard	Definition
EN ISO 13485	Medical devices - Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
IEC 62366-1 2016	Medical devices - Application of usability engineering to medical devices (IEC 62366:2016)
DIN EN 62304	Medical device software - Software life-cycle processes (IEC 62304:2006 Corr.2008+A1:2015)
ISO 7151	Surgical instruments; non-cutting, articulated instruments; general requirements and test methods
DIN EN ISO 13402	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995); German version EN ISO 13402:2000
ASTM F 1089	Standard Test Method for Corrosion of Surgical Instruments
ASTM F 1744	Standard Guide for Care and Handling of Stainless Steel Surgical Instruments
IEC 62353	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment (IEC 62353:2014)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012)
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020)
AAMI TIR12:2020	Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for the Devices Manufacturer
ANSI/AAMI ST98:2022	Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices
AAMI TIR34:2014/(R)2021	Water for the reprocessing of medical devices
FDA:2015	Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi- critical medical devices
BS/EN/ISO 15883-1:2009	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (international standard)
ISO 14457:2017	Dentistry — Handpieces and motors

Standard	Definition
ISO 15883-5:2021	Washer-disinfectors – Performance requirements and test method criteria for demonstrating cleaning efficacy
	Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices :2017.
ANSI/AAMI ST15883-1:2009/(R)2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (international standard
FDA: 2002	Medical Washers and Medical Washer-Disinfectors - Class II Special Controls

EMC MANUFACTURER'S DECLARATION FOR THE DENACAM SYSTEM

Electromagnetic compatibility (EMC)

The DENACAM System is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information.

⚠ mininavident only guarantees compliance of the DENACAM System with the EMC directives when it is used with original spare parts, consumables, and accessories. The use of spare parts, consumables, and accessories that have not been approved by mininavident may lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference.

⚠ Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

⚠ HF surgical equipment can influence the operation of the system and may not be operated in combination with the system.

⚠ Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkie etc. can affect the system and should be kept at least 30 cm away from any part of the system.

The DENACAM System is suitable for use in a specific electromagnetic environment. The customer and the user of the system should make sure that it is used in an electromagnetic environment as described below.

Electromagnetic Emission

Table 14 Electromagnetic emission (EN 60601-1-2)

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not tested, it assumed that the system does not produce any voltage fluctuation or flicker.	
Warning: This DENACAM System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the DENACAM System should be observed to verify normal operation in the configuration in which it will be used.		

Electromagnetic Immunity I

This DENACAM System is intended for use in the electromagnetic environment specified below. The customer or the user of the DENACAM System should assure that it is used in such an environment.

The DENACAM System was tested for immunity to electromagnetic disturbances and passed using the following criteria:

- No visible change in the operation of the DENACAM System.
- The DENACAM System changes settings, but returns automatically to previous settings.
- The DENACAM System changes settings, but can return to previous settings by intervention of the user.

Table 15 Electromagnetic immunity I (EN 60601-1-2)

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) 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 floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ± 1 kV for input/output lines	±2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 ycles) <5% U_T for 5 s	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic for a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	30 kHz, 8 A/m	30 kHz, 8 A/m	Communication might not be possible when other equipment includes radio equipment.
IEC 61000-4-39	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m	
Note: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Immunity II

The DENACAM System is intended for use in the electromagnetic environment specified below. The customer or the end user of th DENACAM System should assure that it is used in such an environment.

Table 16 Electromagnetic Immunity II

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	6 V	Portable and mobile RF communications equipment should be used no closer to any part of the DENACAM system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz - 6.0 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 6.0 GHz 80% AM at 1 kHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DENACAM System is used exceeds the applicable RF compliance level above, the DENACAM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DENACAM System.

[b] Over the frequency range 1150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 17 Table of frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches):

Band (MHz)	Service
380 - 390	TETRA 400
430 - 470	GMRS 460, FRS 460
704 - 787	LTE 13, 17
800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5100 - 5800	WLAN 802.11 a/n

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DENACAM System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Recommended separation distances between portable and mobile HF communications equipment and the product

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system – according on output power and frequency of the communications equipment – as recommended in the following table.

Table 18 Recommended separation distances (EN 60601-1-2)

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2500 MHz $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/ portable communications equipment could cause interference if it is inadvertently brought into patient areas.

FCC Notice

The DENACAM System complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device mus accept any interference received, including interference that may cause undesired operation.

The DENACAM System 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 determined by turning th equipment off and on, the user is encouraged to try to correct the interference by one or more 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.

MAINTENANCE AND REPAIR PROTOCOL

This protocol is used to document maintenance, safety inspection and repair tasks.

To check the system

1 Check the electrical connection to the computer for visible damage.

Check all other connections and cables from the computer to the camera and to the touchscreen for visible damage.

Replace if a damage or wear is visible.

2 Check the camera, computer, and system cart for visible damage and wear.

Instruct the user to replace them if a damage or wear is visible.

3 Check the adapter for visible damage and wear.

In addition, check the adapter according to the following points:

- The adapter must be firmly attached to the motor and meet the following requirements:
  - The adapter must engage in each possible position.
  - It must be free of a noticeable clearance
  - The adapter is firmly connected and no gap is visible between the adapter and the motor.
- Attach the adapter to the registration tool by the force of the magnets.
  - The magnetic force must be strong enough to lift the registration tool.
- Attach the camera to the adapter.
  - The adapter and the camera must engage tangibly.
  - The adapter and the camera must not be twisted against each other.
  - The camera is firmly connected and no gap is visible between the adapter and the camera.

Check the registration tool and marker under good light for visible damage and wear.

- Instruct the user to replace them if a damage or wear is visible.

4 New calibration of the system and compare the new calibrating data with the old and export the LOG data.

Table 19 Maintenance and repair protocol

Date:	**Signature:**	**Step 1:** Check cabling	**Step 2:** Check camera, computer, system cart	**Step 3:** Check adapter, registration tool, marker	**Step 4:** New calibration	**Repair:**	**Software version:**	**Upgrade to software version:**	**Remarks and observations:**
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐			

OPEN-SOURCE LICENSES OVERVIEW

The following table lists the open-source tools employed in DENACAM system, the web site of the creator of the tool and the open-source license type for each tool.

Table 20 List of open-source packages

Tool	Website	License
ubuntu 16.04 server	https://ubuntu.com/	Contains packages of the main, restricted and universe group.
ITK Toolkit	https://itk.org	Apache License 2.0
VTK Toolkit	https://vtk.org/	BSD License
OpenSSL 1.0.2g	http://www.openssl.org	OpenSSL and SSLeay

Details of license, disclaimers and copyright information's are provided in the specific sections below.

Acknowledgements

- This product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit (http://www.openssl.org/)
- This product includes cryptographic software written by Eric Young (eay@cryptsoft.com)

ITK Toolkit

- Licensed under the Apache License, Version 2.0 (the "License"); you may not use this file except in compliance with the License.
- You may obtain a copy of the License at http://www.apache.org/licenses/LICENSE-2.0
- Unless required by applicable law or agreed to in writing, software distributed under the License is distributed on an "AS IS" BASIS, WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, either express or implied.
- See the License for the specific language governing permissions and limitations under the License.

VTK Toolkit

- VTK is an open-source toolkit licensed under the BSD license.
- Copyright (c) 1993-2008 Ken Martin, Will Schroeder, Bill Lorensen. All rights reserved.
- Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:
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