

 Aadva™

# IOS Intraoral Scanner

INSTRUCTIONS FOR USE

**GC**

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## 2 Preface

Dear IOS Customer,

We would like to thank you for purchasing our GC Aadv Intraoral Scanner.

Our GC Aadv IOS allows you to capture 3D dental impressions.

Please carefully read and follow the instructions for use described in this manual in order to safely operate the GC Aadv IOS. Improper use of the device will result in personal injury and hazardous situations.

When multiple users are operating the device, make sure that all users read these instructions and are trained prior to operating the GC Aadv IOS. We advise you, prior to scanning a patient, to scan gypsum models without sectioned dies to fully master our GC Aadv IOS.

Store this manual where you can easily access it when you would need help and/or information.

The begin date of the warranty is the day of activation of your IOS device.

GC Europe N.V.



### 3 Manual for AADVA IOS

The AADVA IOS manual is intended for health professionals (including but not limited to dentists). The completeness and accuracy of this manual have been tested to the best of our knowledge. The information within may be subject to change without prior notice. The unit may be operated only by health professionals (see chapter 8 - "User profile").

This document is the property and copyright of GC Europe N.V., therefore this manual may not be used in whole or in part, copied or reproduced in any form without the express written permission of GC Europe N.V. The information in this manual is subject to change without notice.

This manual provides information on the proper use of the system, information for the maintenance, handling of the system components, information on cleaning and disinfection as well as safety. In addition, instructions for the operation of the system and for the creation of scans are included. Please thoroughly read and follow all safety information in this manual before and during use of this device. Keep this manual for future reference.

### 4 Symbols and warnings



#### WARNING MESSAGE

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



#### CAUTION

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



#### PLEASE NOTE

Indicates a potentially hazardous situation, which could result in property damage.

### 5 Product description

The GC AADVA IOS creates 3D images of individual teeth or groups of teeth and generates standard triangulation language (herein after referred to as 'STL') files using software for further machine processing in e.g. dental milling machines.

### 6 USB port for data storage and Ethernet connection

The STL data created can be loaded onto external USB (Universal Serial Bus) storage through the USB 3.0 ports. Any misuse of data, viruses, data corruption etcetera due to the uploading of cases via a USB stick is the sole responsibility of the dental professional.



The USB ports are not allowed to be used with an external power supply. An Ethernet isolator is included within the system and the Ethernet connection can be used without an additional isolator.

## 7 Indications

The AADVA IOS is an optical impression system with which the topographical properties of teeth are recorded. The IOS device can record bite scans and can scan single and/or multiple elements up to maximum half arch (such as single quadrant and anterior region).

The obtained scans allow the validation of the preparation, definition of margin lines, evaluation of bite registration and creation of 3D model. The simulated model can then be used to create indirect restorations such as veneers, inlays, on lays, single crowns and bridges of up to 4 elements.

The GC Aadva IOS is not be used to mold or manufacture computer-aided restorations. Aadva IOS merely provides the digital model and transfers the model data to an external tool (not part of Aadva IOS).

Other possible uses and applications contrary to the intended use, changes to the components and/or the installation of unauthorized parts may considerably jeopardize safety, reliability and function of the IOS. Any of the above will cause the warranty provided by GC Europe N.V. to void with immediate effect and will transfer responsibility for personal injury and property damage exclusively to the health professional operating the IOS.

## 8 User profile

The IOS shall be handled and operated by the health professionals, in compliance with the national applicable legislation. It is assumed that the users are properly trained and have clinical experience with popular handsets in dentistry as well as the prevention of cross-contamination and disinfection procedures.

## 9 Limitation of patients

AADVA IOS should be used with care for:

- Intubated patients;
- Schizophrenia in patients;
- Major depressed or manic depressed patients;
- Patients affected by severe central nervous system pathologies;
- Mentally ill patients;
- Patients with serious or unstable medical illness including cardiovascular diseases.
- Neurological disease and immunodepressed patients with generalized anxiety disorder.

## 10 Unauthorised parts

Copies of high-quality spare parts and additional components have become increasingly common. Counterfeit devices and/or spare parts are frequently indistinguishable from



the originals to the naked eye. However, please note that in the case of counterfeit products, the material may not meet the requirements for health and safety.

In case repair and/or replacement is deemed to be necessary, please read chapter 11 – “Inspection, Repairs and Replacement”.

The PC component of the AADVA IOS constitutes an integral part of the AADVA IOS and may not be used for any purposes other than for the functionality of the AADVA IOS itself. No components (whether hardware and/or software) and/or other applications may be changed, added or removed.

GC Europe N.V. and/or the GC Europe dealers/distributors approved and appointed by GC Europe N.V. are responsible for delivering and installing patches, fixes, service packs and software upgrades related to the installed software through the Aadva Digital Service Platform (herein after referred to as ‘DSP’) in order to guarantee the proper functioning of the AADVA IOS during the warranty period or in accordance with the maintenance contract, if the latter is concluded.

GC Europe N.V. is not deemed to have knowledge of or to take into account the specific use that will be made by the IOS Customer of the purchased goods, and thus GC Europe N.V. cannot be held liable for any misuse by the IOS Customer. The IOS Customer is expected to use the purchased good in accordance with its intended use (See chapter 6 – “Indications”).

## 11 Inspection, Repairs and Replacement

### Daily inspection by the health professional:

Daily visual inspection of AADVA IOS includes:

- Intactness/integrity of cables;
- Intactness/integrity of AADVA IOS;
- Unusual running noises, vibrations, etc...
- Correct functioning of all parts;
- Illuminating power of scanner.

If any of the above items is observed, please contact your local GC Digital Services Team (see chapter 34 – “IOS Customer Service – GC Digital Services Team”)

Maintenance and repair of parts by third parties is forbidden and voids the warranty with immediate effect. Repair and/or replacements needs to be executed exclusively by GC Europe N.V. and/or GC Europe authorized third party dealers.

The expected service life of the device is 10000 hours in operation (5 years).





#### **WARNING MESSAGE**

Upon sending/returning the Aadva IOS to GC Europe, it must be cleaned and disinfected in a correct way. Effective disinfectants consist out of a combination of ethanol and didecyldimethyl-ammonium chloride. (FD 333 and FD 333 wipes from DÜRR Dental AG<sup>1</sup> (Bietigheim-Bissingen, Germany).



#### **WARNING MESSAGE**

Improper and unauthorized repairs represent considerable danger to the user and will void the warranty with immediate effect. Only the GC Digital Services Team of GC Europe N.V. and/or authorized third parties may service the IOS device.

## **12 Odontogram used**

The software uses the international odontogram (FDI).

## **13 Copyrights**

Copyright © GC Europe n.v. All right reserved.

This document is the property and copyright of GC Europe N.V., therefore this manual may not be used in whole or in part, copied or reproduced in any form without the express written permission of GC Europe N.V. The contents may only be copied for private, in-house use.

## **14 Intellectual Property Rights - IP**

All Intellectual property rights to the GC Aadva IOS (including but not limited to patents and trademarks) are the exclusive property of GC.

Microsoft® , Windows 8® and Windows™ are trademarks of Microsoft Corporation.

## **15 Warranty**

GCE is liable for non-conformity (hard- and software), hidden defects and manufacturing defects to the Aadva IOS that manifest themselves within a period of one year from the activation date by the GCE digital services team. The warranty only covers deliveries made and activations by GCE or an appointed service provider by GCE. Please refer to the Aadva IOS general terms and conditions for further information.

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<sup>1</sup> FD 333 and FD 333 wipes are products from Dürr Dental. Dürr Dental is not a trademark of GC.

The user/health professional is solely responsible for the application and the intended use of the product. For any damage to the product that occurs within the warranty period, please refer to the Aadva IOS general terms and conditions.

**Notice : Any attempt to open the device or service it yourself may cause damage to the device which may lead to personal injury. Any attempt to open the device or service it yourself also voids the warranty with immediate effect.**

## 16 Limitation of liability

To the extent permitted by law, GC Europe N.V. rejects any liability for any direct, indirect or consequential damages or loss of any kind in connection with this product, regardless of whether the legal demands made are related to assets or liabilities or are of other nature.

## 17 License manager

The license manager manages the IOS software licence, which will allow the user to access and work on the GC AADVA IOS and the GC AADVA DSP.

Depending on the chosen duration of the license, the license will be active for 1 or 3 years. One month prior to the expiration date, a notice will be given to the user, stating that the license will expire soon. The amount of days left to expiration can be viewed in the settings menu.

The user can extend their license by paying the invoice sent by GC Europe N.V. If the invoice is not paid, certain functions will gradually be disabled until it reaches the phase in which only previous cases can be accessed and viewed.

## 18 Installation

The AADVA IOS must be installed by IOS experts from GC Europe N.V. or authorized third parties. The software is installed before the device leaves the factory. After the installation the IOS expert will train the user to achieve the best results with the GC AADVA IOS.

The AADVA IOS should be connected only to a power supply of the same voltage as the one indicated on the voltage display, and can only be operated on single-phase AC supply.



### WARNING MESSAGE

The IOS device should not be used adjacent to or stacked with other equipment, if this is necessary the IOS device should be observed to perform normally before use on patients.

## 19 GC AADVA IOS components



The AADVA IOS system consists of hardware and embedded software.



#### **WARNING MESSAGE**

All components are delivered **non-sterile**

#### **HARDWARE COMPONENTS:**

Hardware components of the AADVA IOS are: the wheeled cart with integrated computer, safety power supply, touch-screen monitor, scanner application device and cradle for the support of the scanner application device.

#### **CART:**

The cart consists of a metal base frame with PU coated thermoformed plastic housing which is coated with structure lacquer. The cart also includes a vertically movable monitor arm with swivel joint to enable the vertical pivot of the monitor. The monitor arm can be locked in an upright position to put the cart in transport mode. Four wheels with an easily accessible brake system based on a, one-touch technology, allows sufficient mobility and fixation in the dental office respectively.

#### **COMPUTER:**

The high-performance computer has a graphics card on which the parallel graphics processes run in real time. Connectivity is provided by an Ethernet port, two USB 3.0 ports and one SD card port. The operating system and user program must not be modified by the user. Software updates are managed by GC Europe N.V.

#### **POWER SUPPLY:**

A medical PC power supply is built in accordance with EN60601-1 for the electrical supply to ensure the users' and patients' safety requirements.

#### **TOUCH SCREEN MONITOR:**

The monitor is a Touch LCD monitor. The monitor meets the requirements of EN60601-1 as well as major international requirements. It is used for the display and control of the acquired images, scans and videos. The touch screen is used to interact with the system software and allows the entry of patient information, assignments, etc.

#### **SCANNER APPLICATION DEVICE (HAND PIECE):**

The application device for scanning is an optic-electronic device that captures high-resolution video images in real time during a patient scan. It is connected to the cart via a USB 2.0 high-speed cable for data transfer. The application device comprises of optics and sensor electronics, which detect the real-time images which can then be further processed by the computer.



#### **Caution**

The application device is fragile, please use caution when handling.

## CRADLE FOR SCANNER APPLICATION DEVICE

The cradle for the application device for scanning is an open case for the placement of the hand piece in resting position. It contains a heating plate responsible for the maintenance of the temperature of the glass plate at the head of the hand piece in order to avoid fogging when used in the mouth.



### Please note

The hand piece may not be actively scanning when placed into the cradle.

## FIGURES WITH DESCRIPTIONS

### 1. Monitor

- 1.1. Monitor Movement
- 1.2. Stylus pen
- 1.3. GC AADVA Cradle Inlay

### 2. Scanner application device (hand piece)

### 3. Monitor arm

- 3.1. Power button, USB ports (x2),SD Card port (x1)
- 3.2. Monitor arm locking

### 4. Wheels and brake

### 5. Power switch, LAN connector, power plug and label

### 6. Ventilation apertures

### 1 Monitor

#### 1.1 Monitor Movement



Figure 1: Monitor movement

The monitor can be easily moved with 2 handles located on the upper and lower side of the monitor (Fig. 1). The system is self-locking and adjusted for a smooth two-hand

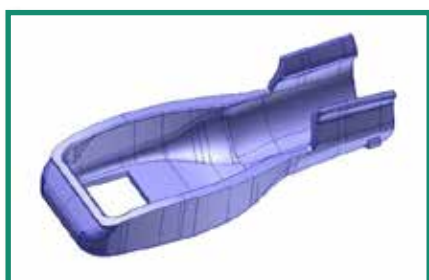


operation within a 160° angle. The upper monitor handle can also be used for transportation of the GC AADVA IOS device in the transport mode with the monitor arm in a locked position. (See chapter 31 – “transport and packaging”).

### 1.2 Stylus Pen

The accessory stylus pen is a useful accessory tool for those who prefer not to work with their finger to manipulate the touch screen. The special-designed head of the stylus pen reacts easily with the monitor. For further information, please see the instructions for use document, accompanied with the acquired stylus pen.

### 1.3 GC AADVA Cradle Inlay



*Figure 3: Hand piece/cradle inlay*



*Figure 2 : GC AADVA Cradle Inlay*

In between patients, the hand piece (Fig. 4) can be stored in the cradle (Fig. 3.2). The cradle is self-locking and can be easily moved upwards and downwards at +/- 30°. Before mounting the hand piece into the cradle inlay part (Fig. 2), the cradle inlay needs to be mounted into the cradle which is easily done by the locking brackets at the rear lower side of the inlay. When mounting the hand piece into the inlay, two stabilization brackets will support the holding mechanism and the backside of the inlay.

## **2 Scanner Application Device**



*Figure 4: Scanner Application Device (Hand Piece)*

The scanner application device (Fig. 4) is working with a stereo-camera system and is based on a real-time scanning system. While scanning, a status LED light is shining on the back of the hand piece, indicating the scan is operational. The scanner automatically starts to scan once the start button is pushed on the GUI (Graphical User Interface, also

referred to as the screen or monitor) or by a simple up-and-down hand gesture. The scanner device is an ergonomic, optimized device with accessibility to move in the mouth for scanning the lower -and upper jaw, and recording the bite registration. After preparing the IOS device for scanning, take out the scanner from the GC AADVA Cradle Inlay and follow the instructions on the GUI (Screen) until the start button needs to be selected. After the scan procedure, clean and disinfect the hand piece (See chapter 23 – “cleaning and disinfection procedures”) and place the hand piece back into the cradle. The button, located on top of the scanner application device is redundant and not active in this version of the IOS device.

### 3 Monitor Arm

#### 3.1. Power Button, USB Ports (x2), SD Card Port (x1)

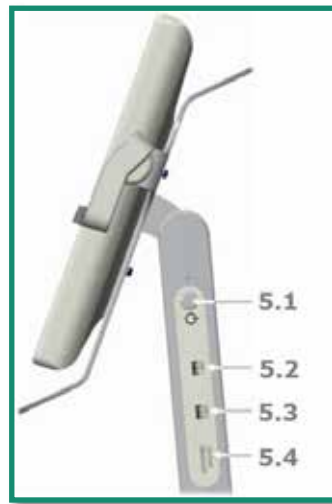


Figure 5: Monitor Arm

The AADVA IOS will be turned on/off by pressing the power button (Fig. 5.1) which is located on the right side of the monitor, seen from the front view. Once the 'I/O' button is pushed, the GUI will be directly shown on the monitor. The GC AADVA IOS also has the possibility to connect with USB memory sticks on two USB 3.0 ports (Fig. 5.2 and 5.3), which are also suitable for USB 2.0 connections. You will also find one SD card slot (Fig. 5.4).

### 3.2. Monitor Arm locking



Figure 7: Lock/unlock mechanism

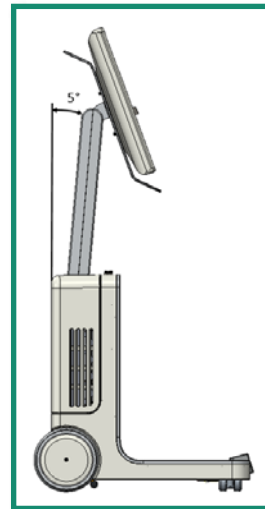


Figure 6: Transport position

Before bringing the monitor arm to the transport position, slide the lock button to the left (Fig. 7.1). The lock button is located on the upper side of the front cover. Once the monitor arm is in the correct transport position (5°), release the lock button. Once you have the correct transport position, the red band will disappear which indicates the monitor is locked correctly. When moving the monitor arm to the working position push the lock button again, move the monitor arm forward and release the locking button until the red level disappears.

## 4 Wheels and Brake

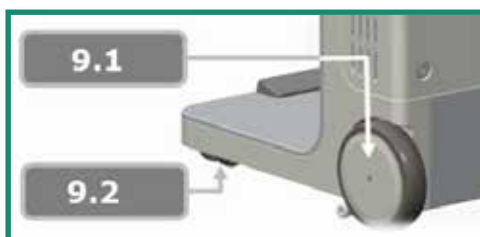


Figure 8: Wheel

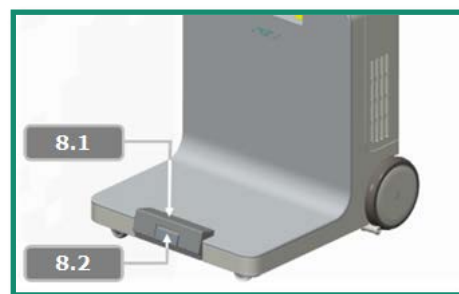


Figure 9: Brake mechanism

The GC AADVA IOS consists of two radial turning front wheels (Fig. 9.2) for easy movement and turning the device with the touch of your foot. The device also has two back wheels (Fig. 9.1) which are fixed. By pushing the brake lock pedal (Fig. 8.1) with your foot, the back wheels of the IOS will be immovable and the device will have a stable, locked position. By pushing the release button (Fig. 8.2) the brake will be released and the GC AADVA IOS can be moved again. The bottom rubber part is enabling the operator to slightly adjust and fine tune the device into correct position.



## 5 Power Switch, LAN connector, Power Plug and Label

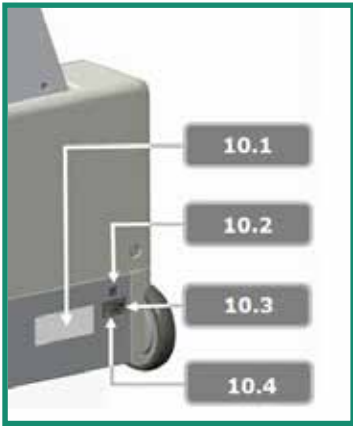


Figure 10: IOS Power switch



Figure 11: Back of IOS Cart

To provide the device with electricity, the accompanied power cable must be connected to the device by connecting the power cable with the power outlet. (Fig. 10.4) The power switch (Fig. 10.3 and 11.1) is located at the backside of the IOS and needs to be flipped to enable the power.

For making a connection to a local area network, the GC AADVA IOS can be connected through a LAN connector, also located on the back of the device (Fig. 10.2). The product label with according technical information can be found on the left side of the power outlet (Fig. 10.1).

## 6 Ventilation apertures:



Figure 12: Ventilation apertures

For cooling the system, fans are installed inside the GC AADVA IOS device and will blow hot air out of the ventilation apertures on the right and left side of the housing cover.



### PLEASE NOTE

Do not cover these areas, do not disturb the cooling process and clean the apertures at least once per month or anytime there is noticeable contamination.

## 20 Warnings, safety regulations and other notes



### WARNING MESSAGES

#### To reduce the risk of electrical hazards:

- Check the application device and the system (cart screen) for physical damage before each use;
- The AADVA IOS is not to be operated under any circumstances if the power cord, plug or housing is visibly damaged;
- Never attempt to remove the plug from the wall socket or plug it in if your hands are wet;
- The system has 2 available USB ports. Do not connect any other devices, including USB hubs and excluding USB memory sticks, to these connectors;
- If the cart is damaged by a fall or if the cables are damaged, disconnect the AADVA IOS from the power supply before it is repaired;
- Look for loose parts, sharp edges, as well as wear and damage that could affect the proper use of the scanner;
- If there is any visible damage or if the device is not working properly please consult our customer service: the GC Digital Services Team (see chapter 34 – 'IOS Customer Service – GC Digital Services Team')
- To ensure safe shutdown and disconnection of the device, first, push the power button at the side, on the flexible arm of the device and secondly, flip the main power switch on the back of the device. Now, the cable can be disconnected from the wall socket and the device. (Please also read chapter 21 – 'Starting, terminating and disconnecting the device')
- Do not handle liquids (E.g. beverages or cleaning agents in the immediate vicinity of the GC Aadva IOS. Do not spill liquids on the system as this can result in personal injury (e.g. skin burns, heart rhythm disturbance...)

#### To reduce the risk of electrical and fire hazards:

- Only use the power cord accompanied with the IOS device. Do not replace this cable yourself, please contact our GC Digital Services Team in case of loss or damage.
- Only use an earthed shockproof wall socket. Do not use extension cords or multiple-socket plugs;
- The electrical components or cables must not be damp or wet;
- The scanner must not be connected to an uninterruptible power supply (IJSV).
- Do not use an adapter for the power supply;
- Do not try to open the cart's housing or perform maintenance on the device yourself;

- Always contact the GC Digital Services Team or authorised GC Europe N.V. service personnel
- Do not make any modifications to parts of the AADVA IOS;
- Do not place the unit in locations where it is difficult to unplug the power cord from the outlet.

**To reduce the risk of fire hazards:**

- Do not use the scanner application device in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide;
- After cleaning and disinfection it is necessary to ensure that the system is completely dry;
- The system is not intended or designed for use in outside areas or humid environments.

**To reduce risks of cross-contamination:**

- Please read and follow the instructions for cleaning and disinfecting in this Manual;
- Disinfect the application device prior to every use, including the first use. See Cleaning and Disinfection session (see chapter 23 - "Cleaning and Disinfection procedures")
- After each patient, clean the touch screen, the monitor frame, the housing of the application device and any other parts that may be contaminated.
- Always store the hand piece in the sterilised GC AADVA Cradle Inlay.
- Use personal protective equipment (PPE).



**PLEASE NOTE**

**To reduce risks from impacts or pressure:**

- The cart must not be exposed to any impacts;
- The locking mechanism of the rollers must be enabled when using the system;
- The cart must always be moved under control, especially on hard floors;
- It may only be lifted up from the base. Lifting of the cart from the side panels, front or back covers or from the monitor is not permitted;
- The trolley is not to be lifted from the handles. The handles are designed to pivot the monitor or to move it in the transport position;
- The system must always be lifted by two people (e.g. in transit over high thresholds, steps or in vehicles);
- The power cord and the connecting cable of the handset must be placed so that they do not create a tripping hazard.
- Position the device in such a way, that all the buttons and switches are easily handled and are easily accessible.
- Do not place the IOS device in a corner.

**Risk reduction of environmental impact:**

- Follow the local regulations when disposing of all electronic equipment parts and related spare parts;
- Ensure that the disinfectants used are disposed of in accordance with the applicable law. Please refer to the material safety data of the used disinfectant for more detailed information.

**PLEASE NOTE**

In order to reduce the risk of damage to the GC AADVA IOS, please read and follow the following instructions.

**To prevent damage to the system:**

- The device may only be used by qualified personnel (see chapter 8 – “user profile”)
- The power switch may only be operated; or the plug of the GC AADVA IOS may only be removed from the power outlet; after you have logged out and have shut down the system;
- Make sure that the ventilation slots are not covered or otherwise blocked, and do not place items in an enclosure around the device;
- The air intake must not be blocked;
- The scanner must not be connected to an uninterruptible power supply (USV).
- Existing connections to the GC AADVA IOS may not be interrupted or otherwise modified;
- The start switch on the monitor arm must not be pressed and held;
- Do not use any ammonia-based cleaners on the touch screen, the screen frame, the application device, the associated cable or the cart's surfaces;
- Do not pour any liquid on the screen, the screen frame, the application device or its cable or on the cart's surfaces;
- Make sure that the power cord is unplugged before moving the system;
- Plugging in the cable and turning on the system are the only performance or maintenance-related activities carried out by the user for the GC AADVA IOS. If the system does not function properly, please contact IOS Customer Service;
- The installation and use must be carried out in a temperature range from +10 °C to +40 °C.
- During storage and operation of the scanner, ensure that the limits for temperature, humidity and height are observed.
- Make sure that the power cord is connected to the IOS device in a way that the IOS device has the freedom to be moved without pulling out the power cord.

**To prevent damage to the application device:**

The scanner application device is a high-precision optoelectronic instrument. Improper handling of the scanner application device, e.g. dropping, shaking or bumping can lead to malfunction or damage. Respect the following basic guidelines:

- Always use the scanner application device with great care;
- If you are not using the application device, place it in the designated Cradle;



- Make sure that the cable is not bent on the back of the scanner application device;
- For more information on handling, please see the section on cleaning and disinfection.
- Do not use sharp objects on the surface of the scanner application device neither clean it with an abrasive material as this can damage the device.

## 21 Starting, Terminating and Disconnecting the device

### 21.1 Starting the device

1. Plug the appropriate power cable into the power supply;
2. Flip the switch on the back of the device to the 'I' position.(Fig. 10.3 and 11.1);
3. Switch on the device:
  - 3.1. In case the flexible arm is in the lock position (vertical position), pull the lock icon (Fig. 7.1) in the indicated direction to unlock the flexible arm and move the arm forward. The device will turn on automatically.
  - 3.2. In case the flexible arm is in the working position, turn on the device by pushing the power button (Fig. 5.1) on the lateral part of the flexible arm.
4. The graphical user interface will start automatically on the monitor.

### 21.2 Terminating the device

1. Push the power button, located at the side of the flexible arm (Fig. 5.1)
2. Flip the main power switch, located on the back of the device to the 'O' position (Fig. 10.3 and 11.1)

The main switch is provided to isolate the device from main voltage.

### 21.3 Disconnecting the device

When all the above steps (21.2) are performed, the power cable can be safely disconnected from the device and wall socket.

## 22 Graphical user interface (GUI)

### 22.1 Screen layout structure

1. Start screen  
The start screen will ask to enter the user name and a 6-digit pin, which will be provided at the installation of the GCAADVA IOS.



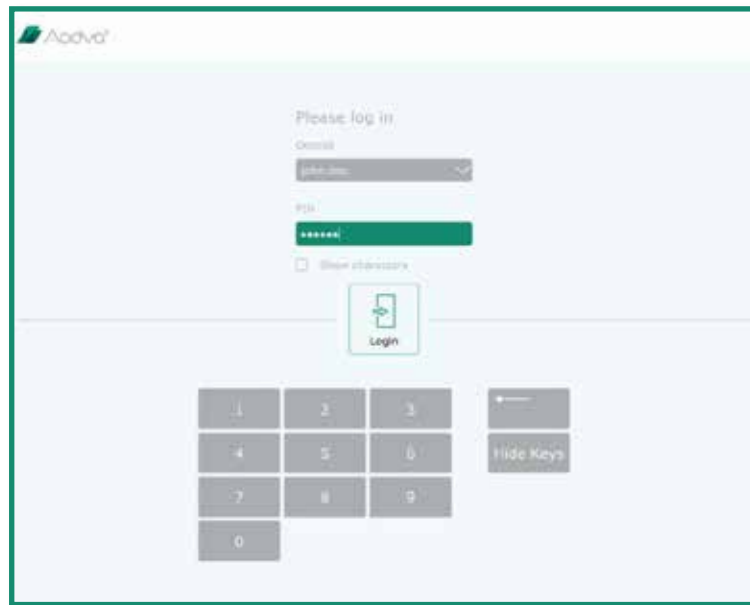


Figure 13: Screenshot Log-in

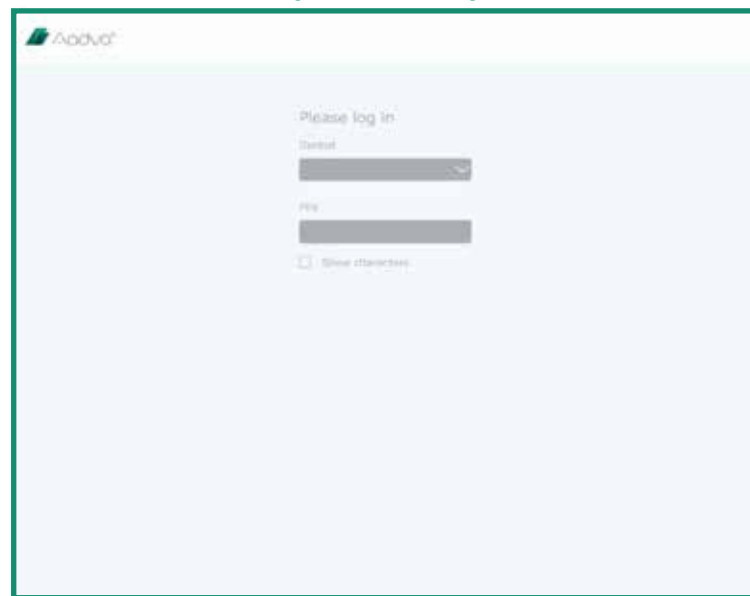


Figure 14: Screenshot Log-in 2

2. Process menu icons at the top of the screen.  
The process menu shows the current section of the digital impression process. Sections are "Patient Database", "Scan", "Model", "Export" "General" and an additional help, FAQ and download area. Each of the sections has its dedicated icon and the current position in the process is highlighted in green. The menu bar remains always visible on the screen.
3. Navigation icons on the right side of the screen during scanning.  
Said features are used to rotate, move, zoom into objects on the screen or reset the view to the default situation. These icons only appear when active in some sessions of the process. When a specific navigation icon is clicked, it is highlighted in green.

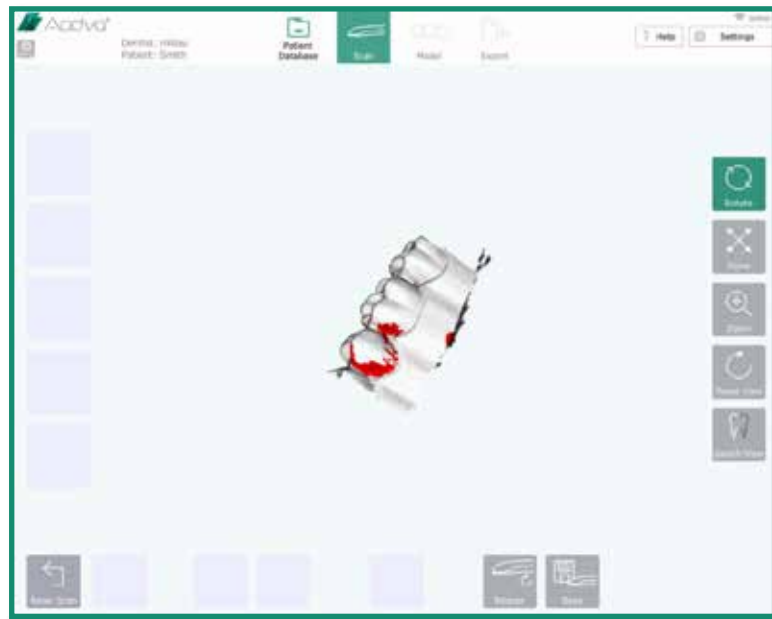


Figure 15: Screenshot navigation buttons

4. Icons on the left side of the screen during scanning.  
 These icons are used to define different scans: "pre-scan upper", "pre-scan lower", "upper", "lower" and "bite". By clicking these icons, the following sub menu icons are enabled: "new", "load" and "delete". When a scan type is present, it is highlighted in green.

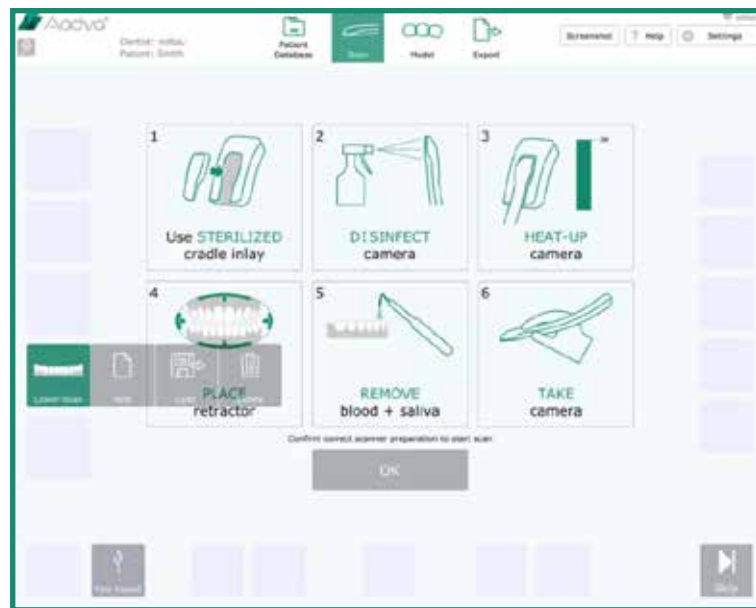


Figure 16: Screenshot icons

5. Action features at the bottom of the screen during scanning.  
 These action icons vary depending on the process sections. Only enabled icons are visible, for example: "start scan", "pause scan", "create model", "save as" and so on.

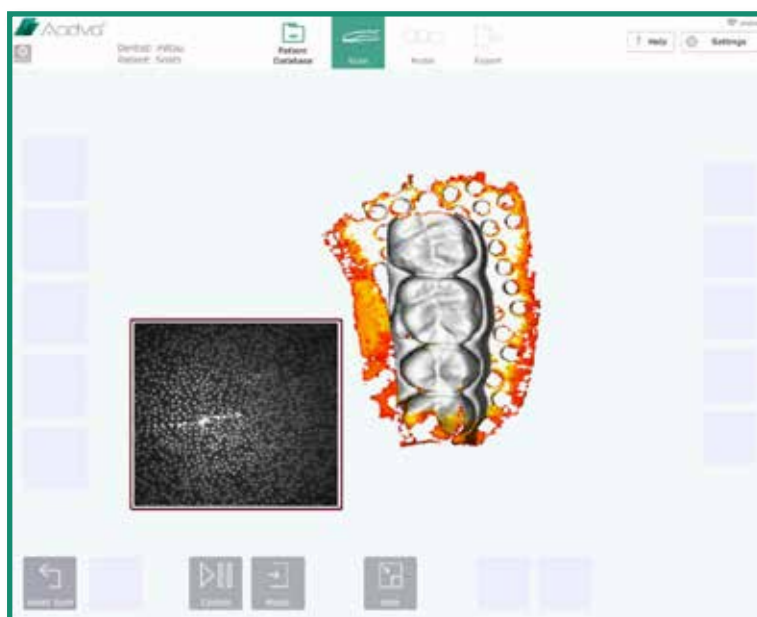


Figure 17: Screenshot action features

- 6. Visualization area in the centre of the screen during scanning.  
This area is used to visualize various objects and general information.
- 7. A “settings” icon can be found in the top right corner, to access the settings and help menu.



Figure 18: Settings icon

## 22.2 Settings

In this section it is possible to define and change the settings of the IOS device.

### General

Gesture control	Enable or disable the gesture control for initiating scanning
Dentist address – Title	Displays title
Dentist Address – First Name	Displays first name
Dentist Address – Last Name	Displays last name
Dentist Address – Street	Displays street
Dentist Address – Zip Code	Displays zip code
Dentist address – Country	Displays country
Cart ID	
Hand piece ID	Displays the unique ID of the hand piece
Dental Notation System	Choose the dental notation type
Keyboard Layout/Language	Choose the keyboard layout



Language	Choose the language
User Management	Displays the active or inactive status of the user management
Wi-Fi Connection	
Status	Displays online or offline status of the Wi-Fi connection
Hidden Network Name	Displays the active or inactive status
Network Name	Displays the network name
Wi-Fi Password	Displays the Wi-Fi password

**Table 1: Settings General**

## Scan

Acoustic Scan Feedback	Activate or inactivate the sound during scanning which indicates the range of focus
Scan Countdown	Activate or inactivate the scan countdown before starting to scan
Miniature Support View	Activate or inactivate the miniature support view during scanning

**Table 2: Settings Scan**

## Model

Bite Reg. Max Dist. (mm)	'Bite registration maximum distance'. With this setting, it is possible to change the visualized distance range between the upper and lower jaw after the bite registration. The scale on the left side of the screen will display the chosen value and will be colorized accordingly.
Default Mesh Colour	Change the colour of the generated mesh
Default Zoom (Model section)	Adjust the default zoom setting in the model section
Maximum Zoom Value	Adjust the maximum zoom value in the model section
Margin Line	
Point Size in % (?)	Adjust the size of the added points in the margin line section
Line Thickness in %	Adjust the line thickness in the margin line section

**Table 3: Settings Model**

## Export

Mesh Export Format	Choose between STL or PLY file type to export
Aadva DSP - Username	Displays the username of the Aadva DSP
Aadva DSP - Password	Displays the password of the Aadva DSP
Export ATF Files	Activate/deactivate the export of ATF files
Export Log Files	Activate/deactivate the export of log files
Network Export Path	Choose the network path to which you want to export your files

**Table 4: Settings Export**

## 22.3 Help menu

Through the help menu you can access the following :



### 22.3.1 Downloads

This section will allow the user to download documents such as, the 'Instructions For Use' as well as software updates.

### 22.3.2 FAQ

This area is dedicated to frequently asked questions. You can find the most frequently asked questions and their answers.

## 22.4 User management

The user management section is accessed by clicking on the 'Admin' button in the upper left corner. This button is located on the left of the 'Log-out' button.

The user administration window will allow the user to change their PIN, remove users and add new dentists.



Figure 19: 'Admin' and 'Log-out' button

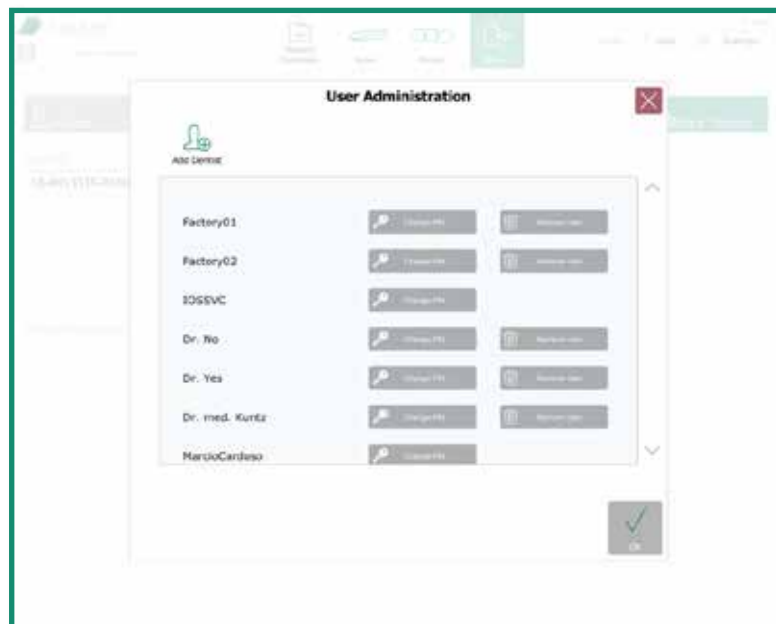


Figure 20: User administration

## 22.5 Patient database



### DISCLAIMER

GC Europe n.v. and its Aadva IOS, including the Aadva Digital Service Platform (DSP) comply with the Data Protection Directive 95/46/EC which regulates the processing of personal data and in particular with the Belgian data protection legislation.

GC Europe recommends that the Aadva IOS IOS Customers use abbreviations or referencing instead of patient names and only collect data when necessary. Furthermore we recommend that personal data is transmitted solely within EU.

The IOS Customer is responsible for informing the patient and receiving the free, specific and informed written consent of the patient for the collection, processing and the storage of the personal data, when necessary according the domestic legislation. The IOS Customer is responsible for the compliance with the applicable data protection law and the delegation of data processing. The IOS Customer is responsible for the compliance with the material and formal requirements thereof. GC Europe processes the data on behalf and according to the instructions of the IOS Customer.

The start-up screen shows the patient database and the "patient database" icon is highlighted in green. This screen comprises of two sections:

### 22.5.1 New Patient

A new patient is defined by entering "First Name", "Family Name", "Birth Date", "Gender", "Social Security Number" and "Dentist Name". Once one of these fields is filled out, the "Start Scan" icon appears and can be pressed to move to the "Scan" section.

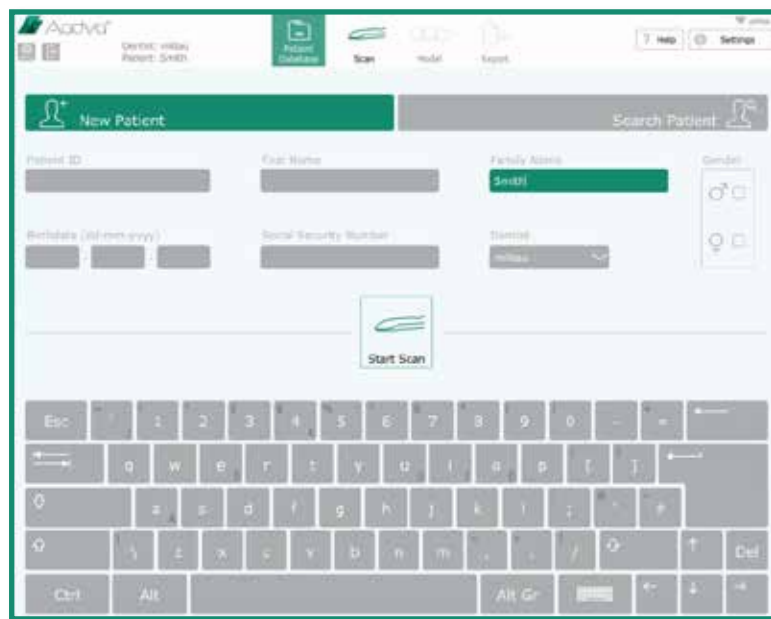


Figure 21: Screenshot New Patient

### 22.5.2 Existing patient

In this section, a search frame on the upper part of the screen allows you to search for a previously registered patient by entering first name, family name or case ID. The list of registered patients is available on the left part of the screen. Once a patient is selected all his previously saved scans and other information will appear on the right side of the

screen. In this section you can edit or delete a scan you have already created or add a new scan.

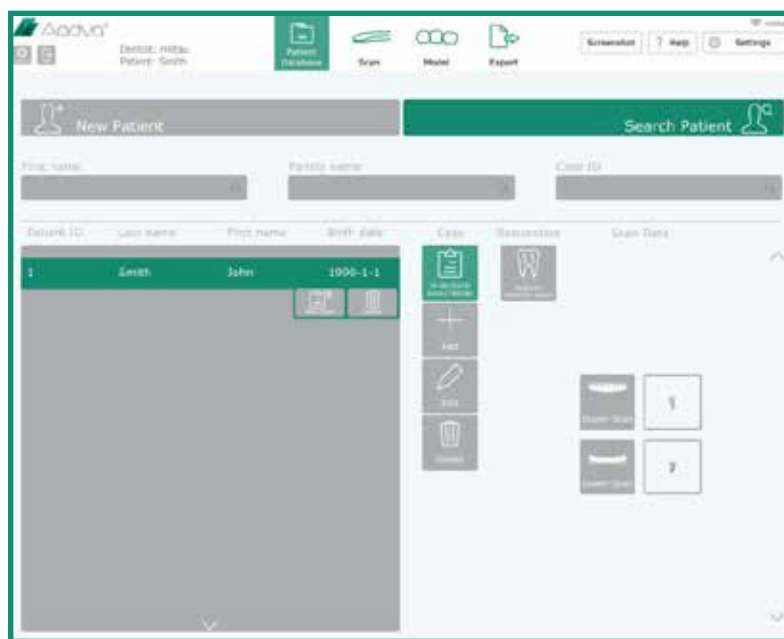


Figure 22: Screenshot Existing Patient

## 22.6 Scan section



### Caution

Before using the AADVA IOS to scan a patient, it is advised that the dental professional performs a visual inspection of the system. The visual inspection should include checks on the application device and cable, for kinks in the cable, discoloration, deterioration or damage of any kind.

Push the "Start Scan" icon in the "Patient Database Screen" to move to the scan screen. When entering the scan screen, the respective top menu icon is highlighted in green. An "Information Screen" will appear mentioning the following important notes:

1. Use a sterilized GC AADVA Cradle Inlay for each new patient;
2. Disinfect the hand piece; (see chapter 23 – "cleaning and disinfecting procedures")
3. Keep the hand piece into the GC AADVA Cradle Inlay until the heating plate has reached the right temperature. This is indicated when the temperature bar becomes green;
4. Use an intraoral retractor to displace soft tissues;

For isolation purposes we recommend the Optiview<sup>2</sup> retractor from Kerr<sup>TM3</sup>;

5. Dry the scan area using air flow and keep relative isolation with cotton rolls, cotton pads and suction appliances;
6. Take the camera from the GC AADVA Cradle Inlay before triggering the scan mode.
7. Start the scan by touching the "OK" icon or by making an up-and-down hand gesture movement while holding the hand piece (if activated in the settings menu).
8. A timer will count down from 5 to 0 seconds, leaving the health professional the time to position him-or herself before the scan begins.

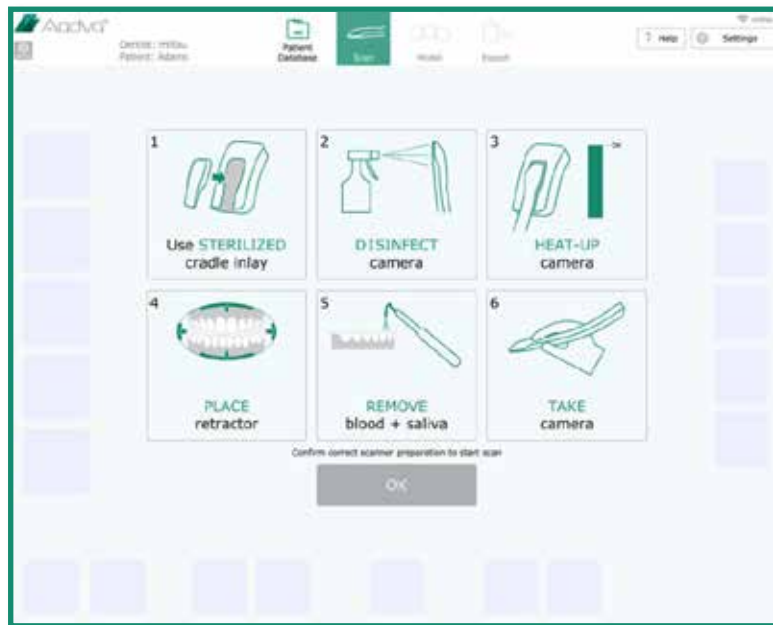


Figure 23: Screenshot Scan Section

## 22.7 How to scan

### 1. Starting position and movement of the hand piece

- 1.1. After touching the "OK" icon or initiating the scan with the horizontal movement mentioned above, the scan will start automatically.
- 1.2. Move the scanner to the start position like the example shown below. The scan can start at any area of the dental arch as soon as the hand piece glass is kept parallel to the occlusal plan.
- 1.3. If the scan flow is interrupted, move the scanner to an already scanned position and make some movements. The scan will continue immediately when an already scanned position is found.

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<sup>2</sup> Optiview is a product from Kerr.

<sup>3</sup> Kerr is not a trademark of GC



Figure 25: Scan parallel to occlusal plane

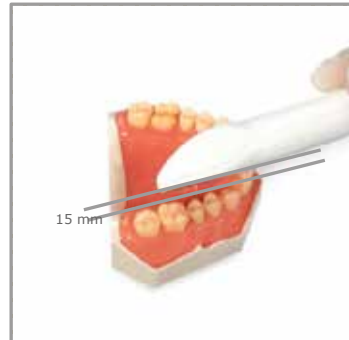


Figure 24: Ideal distance

- 1.4. For scanning a single quadrant, move the scanner over the tooth surfaces, from buccal to palatal while moving the camera towards the anterior or posterior areas of the arch, as shown in the figure below (Fig. 15). When arrived at the premolar, proceed scanning palatal/lingual. Lift the hand piece and start again scanning at the premolar while proceeding vestibular.



Figure 26: Scan flow for half arch (Single quadrant)

## 2. Screen layout

The small "Support Window" shows a real time view of the scan. The blue coloured area is what the camera is actually detecting. Grey areas are the ones in which sufficient information was captured to build the 3d image. Areas with insufficient or poor information appear in red and yellow, respectively. The target is to move the hand piece in such a way that it can detect and capture missing areas. In other words, the target is to bring the blue area into the missing areas (red and yellow) until they are all captured (grey areas). On the main screen you see an overview of the whole scan.

The focus distance for scanning varies from 0 to 15 mm. This means you can touch the tooth during the scan without having it interrupted. Touching defined teeth in defined surfaces (like the occlusal area of molars and pre-molars) create very good reference points ('waypoints') in case you need to retake the scan when it is interrupted for any reason. On the other hand, moving the camera away from the teeth (up to 15 mm) increases the field of view and consequently the scan speed. This also makes it easier to copy undercuts and difficult areas.

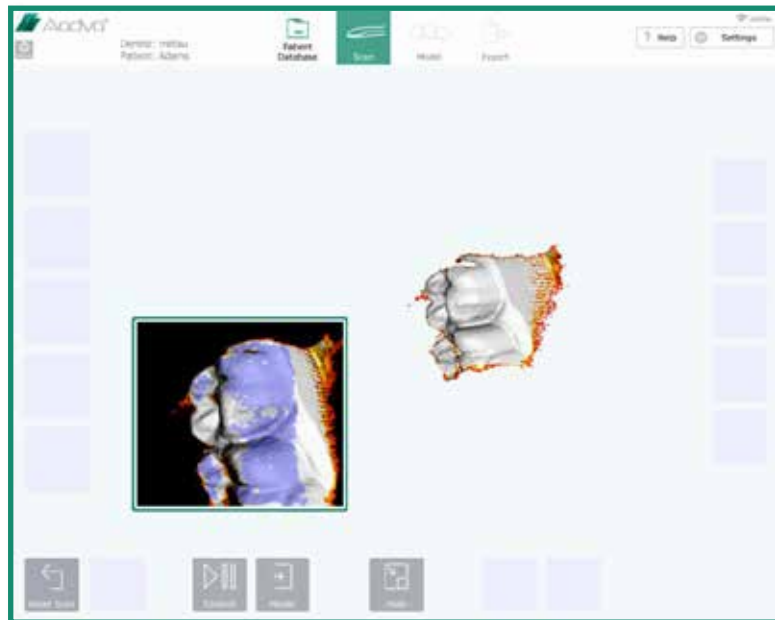







Figure 27: Screenshot screen layout

Touching the "Hide" icon at the lower part of the screen will close the "Support Window".

When the scan is bad and you want to restart the process use the "Reset Scan" icon. A window will then pop up asking if you want to discard the scan.

Use the "Control" button to pause the scan at any moment. This allows you to move the model to evaluate it using the icons at the right side of the screen as shown and described in the figure and table below, respectively.

 Rotate	Rotate: move your finger over the model. It rotates in the all directions according to your command.
 Move	Move: move your finger to move the model in different directions.
 Zoom	Zoom in and out: move your finger up or to the left to zoom in. Move your finger down or to the right to zoom out.
 Reset View	Reset view: this icon brings the model back to the start position and size.
 Switch View	Switch View: touch it to change the contrast. This makes it easier to see the preparation lines.

*Table 5: Screenshot Buttons*

Touch the "Control" icon again to return to the scan mode. Bring the camera to a previously scanned area to retake the scan process. Alternatively, if you are satisfied with the model, use the "Model" icon to create a mesh.

Now you can see the model in a more detailed view and with the non-captured areas filled in red automatically (figure below). These holes (non-scanned areas) are filled by a highly accurate program that uses the information around the missing area to fill it by interpolation. At this phase you can also move the model with the icons on the right side as described above.

The 'fast export' button is visible and will allow the user to quickly export the existing scans to an external memory stick.



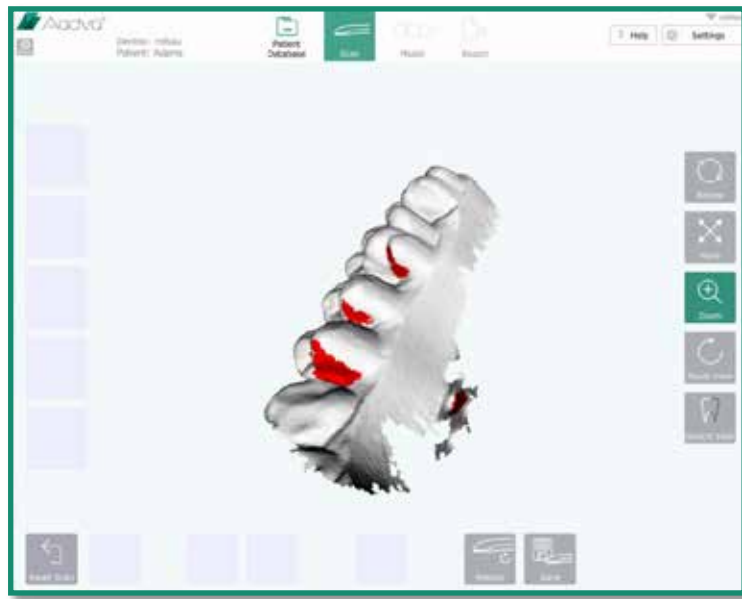


Figure 28: Screen layout 2

If there are still important areas which need to be rescanned, touch the "Rescan" icon and subsequently the "Control" icon to continue the scan.

If you are satisfied with your scan, save by touching the "Save" icon. Four new icons will appear. Chose the scan type you have just processed: "pre-scan lower", "pre-scan upper", "lower" and "upper". Note: "pre-scans" are the ones made before preparations.



Figure 29: Screenshot layout 3

Saving will happen automatically according to the scan type you have chosen. After saving, you are redirected the start screen as shown in the figure below. Note that the scan you have saved will be highlighted in green on the left side indicating that it has been properly processed and saved. You can also make a new scan and overwrite it when you choose the same type by saving the model.

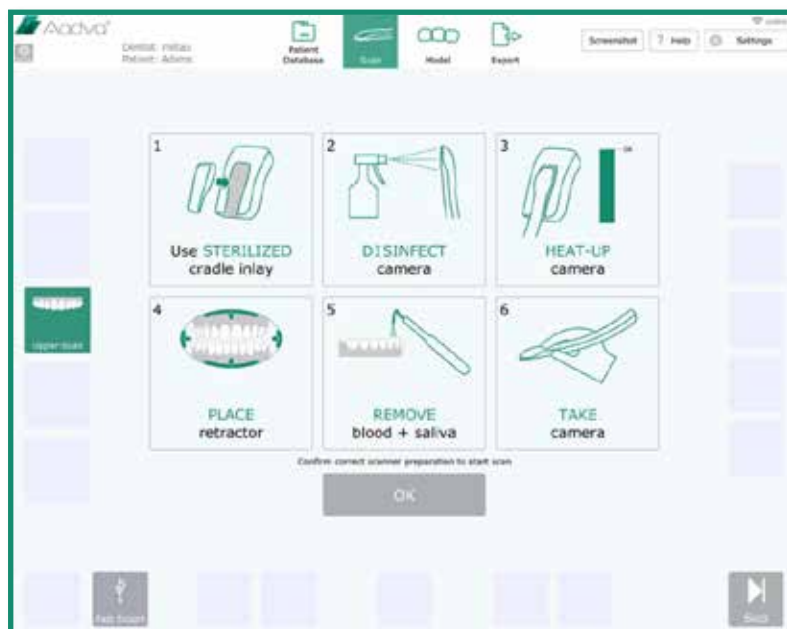


Figure 30: Screenshot Procedure

Proceed with the next scan by clicking the "OK" icon. Otherwise, simply touch the "Skip" icon at the lower right corner in case you do not want to make another scan.

## 22.8 Bite scan

If you have scanned and saved both upper and lower jaws, a new window will open requesting you to proceed with the "Bite Scan" as shown in the figure below. Touch "OK" to proceed with the bite scan. Make it sure you scan the buccal surface of upper and lower teeth while the patient keeps maximum intercuspation. In case you do not want to proceed with the bite scan, use the "Skip" button to proceed.

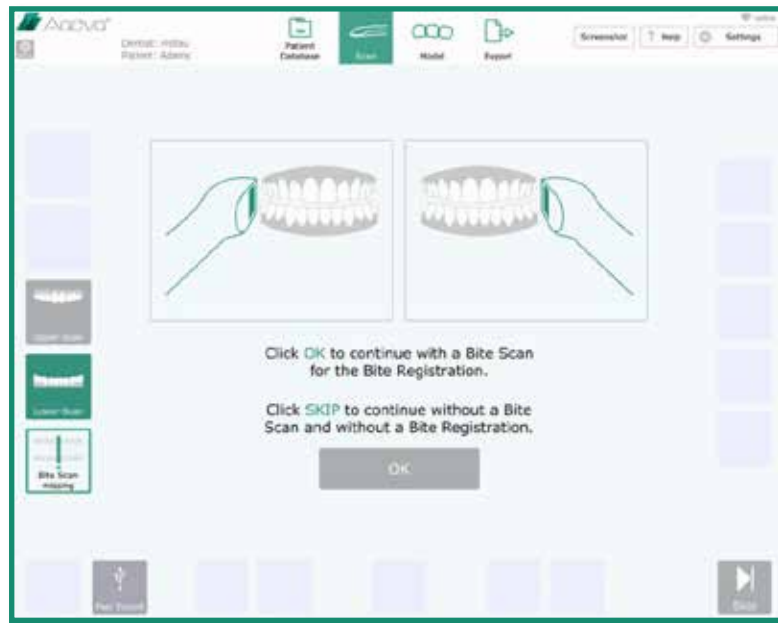


Figure 31: Screenshot Bite Scan

Once the scan types upper, lower and bite are saved, the user is automatically lead to the "Model" section. At this moment, the "Model" icon on the top menu is highlighted in green. Even without having those three scans done, it is always possible to enter the "Model" section by touching the "Model" icon in the top menu.

## 22.9 Margin line definition

This function manages the drawing of the margin line of prepared teeth.

- "Add points": by touching this icon, points can be added around at the margins of the preparation.
- "Undo": by clicking undo, with each click the last action selected point is removed. A history of 40 points shall be stored
- "Delete points": after clicking the delete point icon, points can be removed by clicking them in the model view window
- "Hide": hide position for the support window
- "Save": save function to finish the margin line definition
- "Redo": to start the margin line definition again by deleting all points



Figure 32: Screenshot Margin Line

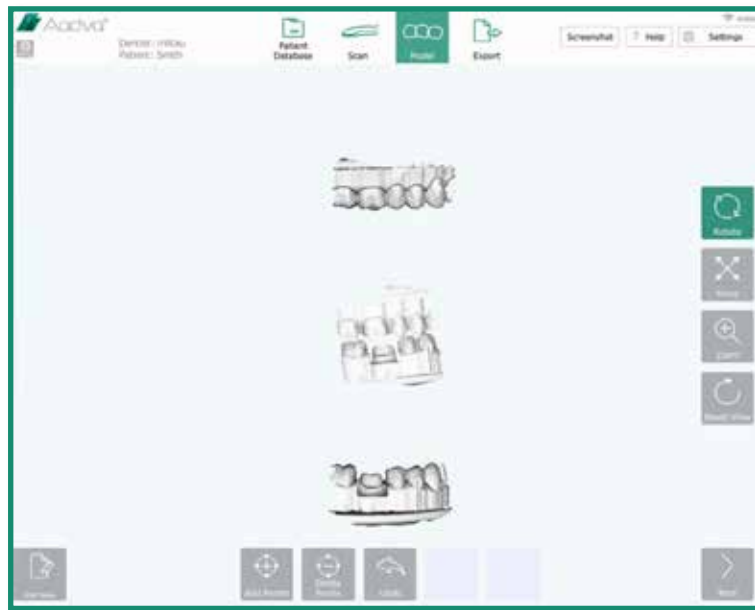
The main central area shows the 3D model with the preparation (chosen scan type) and the dentist can view the model from top position.

When touching the model in the main central area, the support window shows a zoom of this specific area. The specific spot which has been touched is highlighted with a cross. This cross can move by subtle movement of the finger touching the screen until it reaches the exact spot to be marked with a point. By releasing the finger, the point is finally added. By clicking the point again and not releasing the finger, it can be moved again. Multiple points can be marked.

When saving a margin line, a pop-up window asks for moving to the next screen or adding the margin line to an additional preparation.

### 22.10 Bite registration

The bite registration sets and checks the occlusion between upper, lower and bite scan. Therefore, all three scans are loaded.



**Figure 33: Screenshot Bite Registration**

The main model window shows the three 3D-models: upper, bite and lower.

In step one, only the upper and the bite model is visualized in the main model view window. The dentist has to choose "add points" and must set at least three points on the upper scan and the bite scan (Note: The location and the set order must be the same in both scans). The support window zooms the point target location which has been touched with the finger and the dentist can re-locate the points.

**The bottom frame icons are:**

- "add points": by clicking this icon, points can be added by clicking the respective model area
- "delete points": after clicking the delete point icon, points can be removed by clicking them in the model view window
- "Undo": by clicking undo, with each click the last action selected point is removed.
- "match models": merge models
- "add note": by clicking this icon, notes can be added

screen. In this section you can edit or delete a scan you have already created or add a new scan.

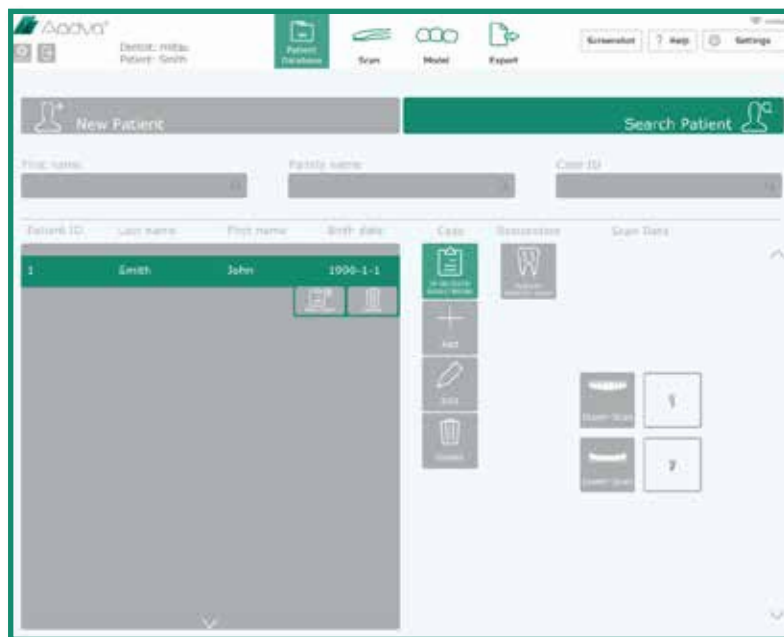


Figure 22: Screenshot Existing Patient

## 22.6 Scan section



### Caution

Before using the AADVA IOS to scan a patient, it is advised that the dental professional performs a visual inspection of the system. The visual inspection should include checks on the application device and cable, for kinks in the cable, discoloration, deterioration or damage of any kind.

Push the "Start Scan" icon in the "Patient Database Screen" to move to the scan screen. When entering the scan screen, the respective top menu icon is highlighted in green. An "Information Screen" will appear mentioning the following important notes:

1. Use a sterilized GC AADVA Cradle Inlay for each new patient;
2. Disinfect the hand piece; (see chapter 23 – "cleaning and disinfecting procedures")
3. Keep the hand piece into the GC AADVA Cradle Inlay until the heating plate has reached the right temperature. This is indicated when the temperature bar becomes green;
4. Use an intraoral retractor to displace soft tissues;

colored with rainbow colours, showing the contact points and the distance between teeth in a range of X mm (X to be configured in the settings menu). A histogram is shown on the left side of the main model window.

By clicking on a model, it is visualized a second time and can be rotated, moved or zoomed via the navigation menu on the right side. By using the "add note" icon, notes can be added.

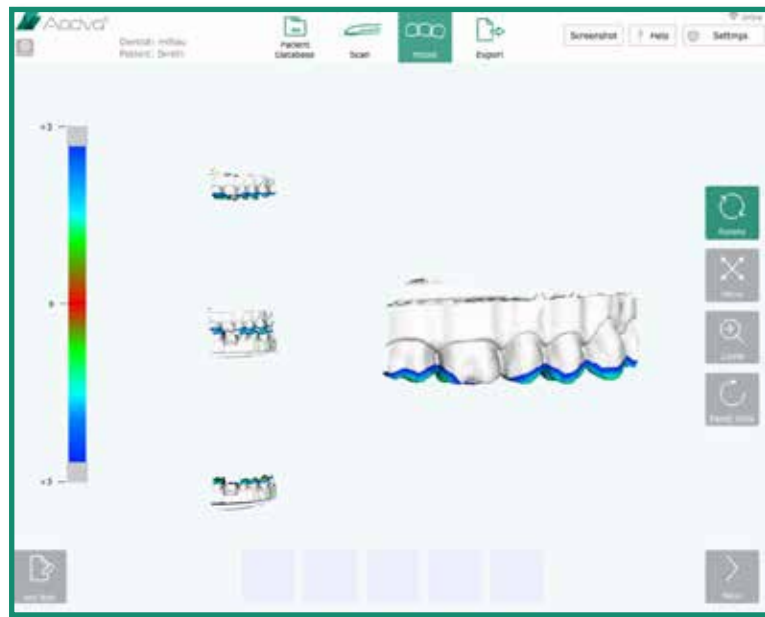


Figure 36: Screenshot Bite Registration 4

By clicking the "Next" icon, the export section is entered and the "Export" icon in the top menu is highlighted in green.

## 22.11 Restoration tab

### 22.11.1 Patient tab

Fill out the remaining fields with the missing patient information in case you have not done it before starting the scan. All empty fields are surrounded by a red contour and must be filled out before you can proceed. After full and successful completion of the patient data, a random case ID is automatically ascribed and visualized on the upper-right area in the screen. The Case ID is unique for each case. When all fields are filled out, the "Next" icon will be activated at the lower right corner so that you can proceed to the "Restoration" tab.

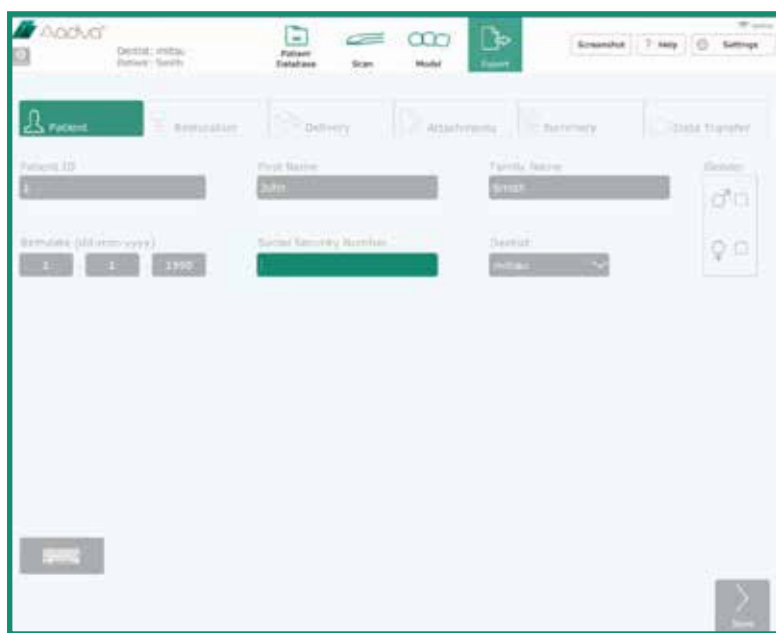


Figure 37: Screenshot Completing Data

Choose a restoration touching the respective tooth and then the "Add" Button. Select the "Restoration Type", "Material Type" and "Shade". When touching each item, a drop down menu will appear so that you can make your choices. Use the icon "Add" to include additional prosthetic work. Click on 'Clone restoration' to duplicate the specifications on an additional restoration.

Note: only Classical Vita Shades<sup>4</sup> are available. If you use another shade guide, please add it as a "Note" at the "Attachments" tab.

The Restoration will be saved when you push the "Next" Button.

---

<sup>4</sup> 'Vita shades' is not a product from GC.



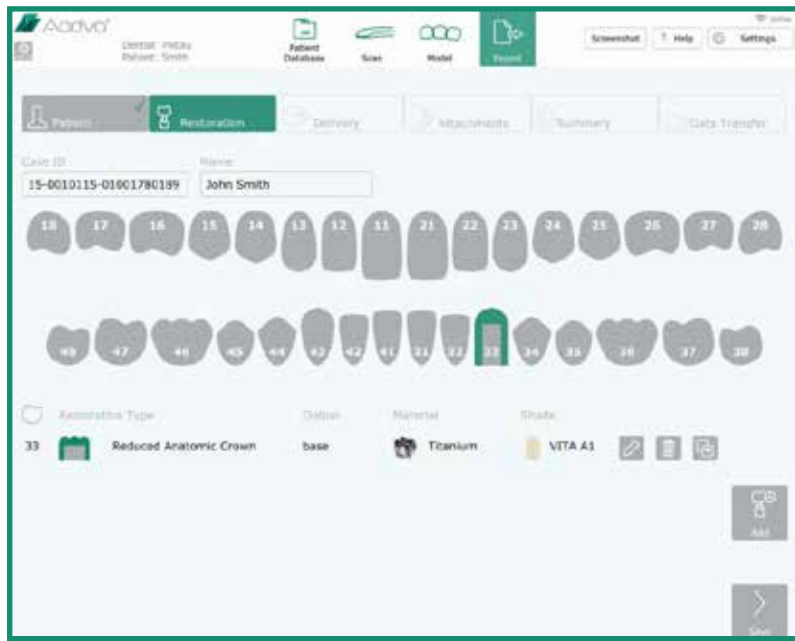


Figure 38: Screenshot Restoration Tab

## 22.12 Delivery tab

Choose a delivery date by using the "select date" icon. Then choose an already stored address in the field highlighted in green or create a new one touch the icon "New Address" to enter the new delivery address. You can also save this address by using the "Add to Favourites" icon.

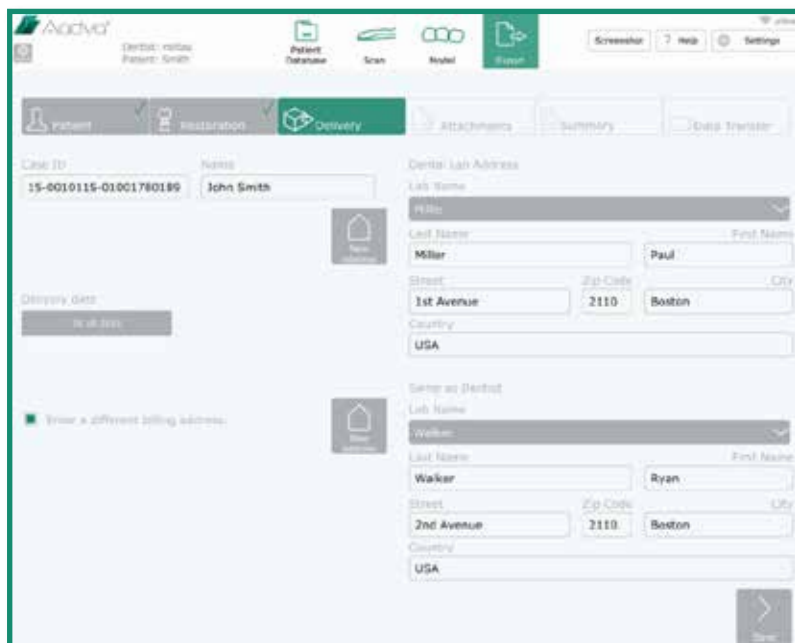


Figure 39: Screenshot Delivery Tab

In case of a different billing address, select the check box (red arrow in the figure below) and enter the billing address. Use the "Next" button for saving and proceeding to the next step.

### 22.13 Attachments tab

Add external files (from a USB stick or flash card) by using "Add" icon on the left side. An Explorer window will appear so that you can choose the files you want to transfer (digital pictures of patients, for example). All added files will be listed on the left side and will be saved in the folder of the clinical case together with the order form and STL files.

Add notes by using the "Add" icon on the right side. Enter a title in the first blank space and the information in the field below it. Minimize the keyboard by pushing the keyboard icon on the right of the "Alt Gr" key. Touch the "Add" icon again to add other notes.

Use the "Next" icon to save the attachments and notes and to proceed to the next step.

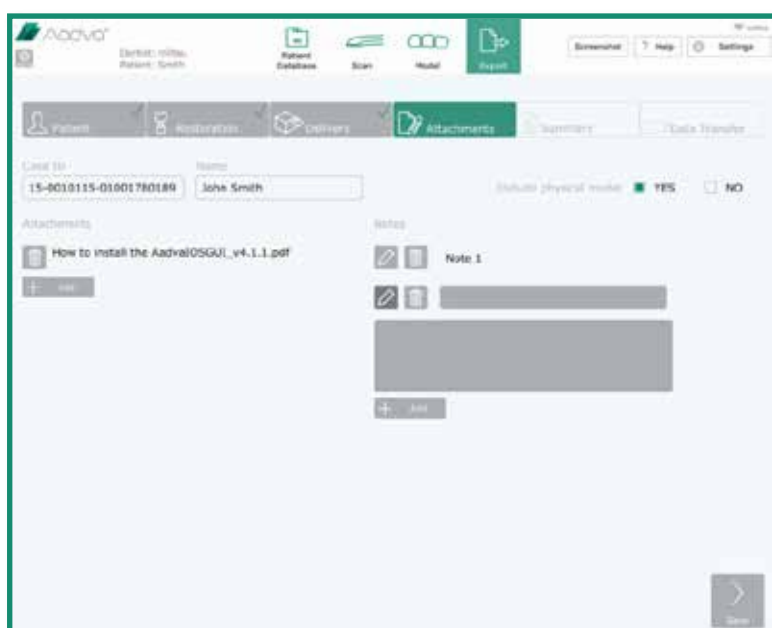


Figure 40: Screenshot Attachments Tab

### 22.14 Summary tab

This tab shows a short summary about your entered data including list of annexes, notes, scans and restorations ordered.



Figure 41: Screenshot Summary Tab

By touching the icon "View PDF Order Form" on the right side of the screen a view of the PDF Order Form is generated with all information which had been input. This PDF will be exported together with the scan data in the next step (Data Transfer).

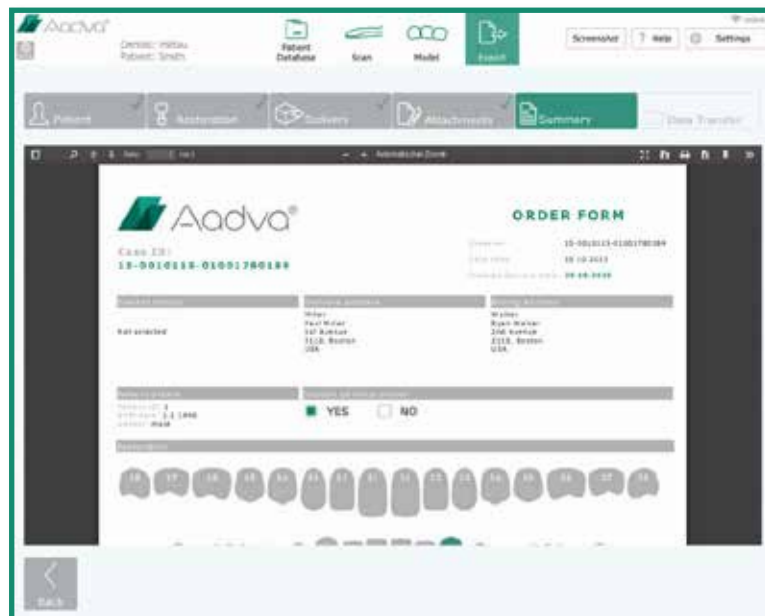


Figure 42: Screenshot PDF form

After confirming the accuracy and the completeness of the information in the PDF Order Form, check the box on the lower part of the screen and touch the "Confirm" icon.



## 22.15 Data transfer Tab

Choose the data transfer method: USB only, Aadva DSP only, or both USB and Aadva DSP or export to network. When exporting data to an external drive, place a USB memory stick or an SD Card in the respective ports at the side of AADVA IOS flexible arm before selecting the icon "USB only" or "USB and Aadva DSP". All cases will also be saved at the AADVA IOS hard disk by default.

After doing so, wait till the message "Export to USB successful" appears on the screen.

After uploading files, a "Close case" icon will appear. By touching it, the case is closed even if uploads are running in the background and the patient input screen is visualized for a new patient case.

When choosing the export to Aadva DSP, the estimated time to export will be calculated, this can vary as the time is estimated, assuming the upload speed is 1000KB/s.



Figure 43: Screenshot Data Transfer Tab

Please refer to the DSP Quick guide for further information on how to export to 'Aadva DSP'.

## 23 IOS Cleaning and disinfection procedures

### NOTICE:

- Use only disinfection agents which have been approved by GC Europe N.V.
- Before disinfection read the manufacturer's manual and safety data sheets carefully.
- Wear Personal Protection Equipment (PPE)
- Do not use any coloured cloths for cleaning, since they may cause staining of the surfaces, e.g. in combination with disinfectants.
- Never use corrosive cleaning agents or solvents.
- Avoid over wet cloth. It can penetrate into the ventilation slots.

Effective disinfectants consist out of a combination of ethanol and didecyldimethylammonium chloride. (FD 333<sup>5</sup> and FD 333<sup>6</sup> wipes from DÜRR Dental AG<sup>7</sup> (Bietigheim-Bissingen, Germany)).

Follow the method below for the disinfection of the application device, screen and other surfaces of the device:

- 1 Rub the surfaces thoroughly for about 30 seconds with disinfection wipes or a dry, soft, non-abrasive cloth and undiluted cleaning solution according to the manufacturer's instructions. Then dispose the cloth in a rubbish container with the classification 'Biohazard' following local applicable regulations.
- 2 Dry the surfaces with a clean, non-abrasive, lint-free cloth and allow it to completely react for 5 min.
- 3 Examine the application device for visible contamination. If the application device is not completely clean, repeat the cleaning steps 1 to 3.

## 24 GC AADVA Cradle Inlays

### 24.1 Insertion and removal

To remove the GC AADVA Cradle Inlay, please remove the hand piece scanner first by tilting the arm upwards. This movement will allow the hand piece to easily click out of the GC AADVA Cradle Inlay. (Fig. 16)



Figure 44: Removal of the hand piece

Once the hand piece scanner is removed, you can grasp the two protruding ends of the GC AADVA Cradle

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<sup>5</sup> FD 333 and FD 333 wipes are products from Dürr Dental

<sup>6</sup> FD 333 and FD 333 wipes are products from Dürr Dental

<sup>7</sup> Dürr Dental is not a trademark of GC.

Inlay and gently compress them. Tilt the GC AADVA Cradle Inlay horizontally and downwards. This movement will detach the GC AADVA Cradle Inlay from its cradle. (Fig. 17)

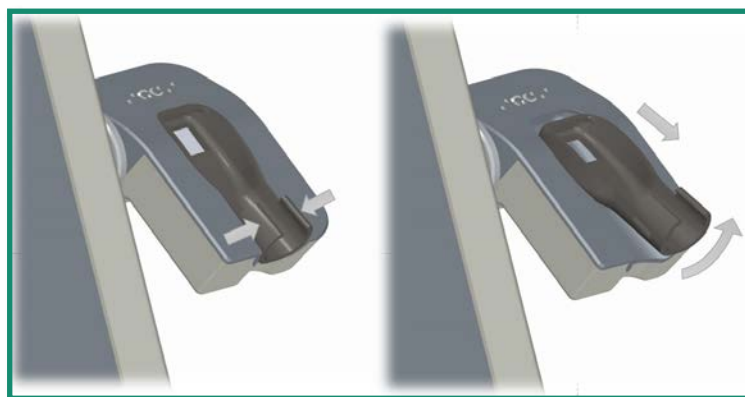


Figure 45: Removal of cradle inlay

## 24.2 Cleaning and sterilization procedures

Follow the method below for sterilisation of the inlay of the storage station:

1. Rub the surfaces thoroughly for about 30 seconds with disinfection wipes. Effective disinfectant wipes consist out of a combination between ethanol and didecylmethyl-ammonium chloride. (FD 333 wipes, DÜRR Dental AG<sup>8</sup>, Bietigheim-Bissingen, Germany) or a dry, soft, non-abrasive cloth and undiluted cleaning solution (FD 333, DÜRR Dental AG<sup>9</sup>, Bietigheim-Bissingen, Germany) according to the manufacturer's instructions. Then dispose the cloth in a rubbish container with the classification 'Biohazard' (dispose of these materials according to local regulations)
2. Dry the surfaces with a clean, non-abrasive, lint-free cloth and allow it to completely react for 5 min.
3. Examine the application device for visible contamination. If the application device is not completely clean, repeat the cleaning steps 1 to 3.
4. Wrap the inlay part in a sterilization foil with sterilization detector and autoclave it at 121 °C and 1.16 bar damp heat for 18 min plateau time.
5. Store the sterile inlay parts in a clean, dry place.

1 GC AADVA Cradle Inlay can be used and sterilized twenty times. However, it should be immediately replaced if any of the following conditions are observed:

- Roughening of surface
- Delamination of surface
- Discolouring of the GC AADVA Cradle Inlay
- Any other changes on the surface
- Dimensional change
- Staining

<sup>8</sup> FD 333 and FD 333 wipes are products from Dürr Dental, Dürr Dental is not a trademark of GC

<sup>9</sup> FD 333 and FD 333 wipes are products from Dürr Dental, Dürr Dental is not a trademark of GC

- Cracks on the GC AADVA Cradle Inlay
- Structural damage

A new GC AADVA Cradle Inlay or sterilized GC AADVA Cradle Inlay is installed by clicking it into the IOS device again in the preformed shape.



### **WARNING MESSAGE**

#### **To reduce risks of cross-contamination:**

- Disinfect the application device before each use.
- Do not clean the application device using ultrasound.

#### **To reduce the risk of electrical and fire hazards:**

- The strain relief area (the area where the cable is connected to the application device) must not be held under water or made moist. If this area is held under water or made moist otherwise, it must be wiped dry immediately. The strain relief must first be completely dry before the application device is reconnected.

#### **To reduce the risk of electrical hazards:**

- Check the application device and the system (cart, monitor and cable) for physical damage before each use.

#### **To reduce the risk of electrical and fire hazards:**

- Only use an earthed electrical outlet
- Do not use extension cords or multiple-socket plugs.



### **CAUTION**








#### **Reducing the environmental impact:**

Ensure that the disinfectants used are disposed of in accordance with the applicable guidelines.

## 25 Safety / Guidelines / Technology

Materials of the device which come into human contact (scanner application device) are certified in regards to the biocompatibility in accordance with ISO 10993-1 and applicable subparts.

The definition of safety and regulatory markings are listed below:

	Read the accompanying documents. Proceed according to the Manual.
	Only suitable for indoor use.
	AC voltage (alternating current).
	<b>This equipment is subject to the European WEEE Directive 2002/96/EC.</b> This symbol alerts the user not to dispose of electrical and electronic equipment in accordance with Directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment) as waste or as unsorted municipal waste, but separately at an appropriate collection.
	Weight
	This symbol indicates the manufacturer of the medical device in accordance with EU Directive 93/42/EEC.
	This symbol indicates "Conformité Européenne"; which directly translates as: 'European Conformity'. This sign is a manufacturer's declaration that the product complies with the essential requirements of applicable European legislation regarding health, safety and environmental protection.








	Serial number
	Article number
	Date of manufacture
	Type BF applied part (Scanner Application Device)
	Mechanical hazard Pinch Point – keep hands and fingers clear

Table 6: Symbols

## 26 Care with the Unit

- Keep the device dust-free and covered when not in use for a long time;
- The AADVA IOS can be kept running if necessary, but the device can be turned off as an energy-saving measure; ensure that you have saved your data before turning off the device.
- Unplug the device and remove any objects adjacent the device prior to routine cleaning and maintenance of the unit;
- Do not attempt to open the hand piece as this may damage the device;
- While cleaning the device make sure that the capacitors or other electrical parts of the AADVA IOS do not come into contact with any moisture;
- Do not place any objects on top of or above the scanner, as this may interfere with the scanning functionality;
- Make sure that no liquids could accidentally spill on the device.



### WARNING MESSAGE

Do not sit on the cart or monitor or do not put any weight on the cart and monitor as this will result in damage to the device and to personal injury.

## 27 Information for electromagnetic compatibility (EMC)

This product has been developed and tested in accordance with the EMC standard IEC 60601-1-2. The documentation contains information and warnings that must be followed by the user to ensure safe operation and to keep the product in a safe condition.



### WARNING MESSAGE

The use of accessories, cable and components other than those provided may result increased emissions or decreased immunity of the medical equipment.



### WARNING MESSAGE

This IOS device must be installed and put into service according to the EMC information provided.

### Guide and manufacturer's declaration - electromagnetic radiation

AADVA IOS is suitable for use in the electromagnetic environment specified below. The IOS Customer or the user of the AADVA I IOS must ensure that the equipment is used in such an environment. Referring to DIN EN 60601-1-2: 2007-12; VDE 0750-1-2: 2007-12 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance features - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2: 2007, modified); German version EN 60601-1-2: 2007

Guidance and manufacturer's declaration – electromagnetic emissions		
The [AADVA IOS] is intended for use in the electromagnetic environment specified below. The customer or the user of the [AADVA IOS] should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The [AADVA IOS] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The [AADVA IOS] 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 purposes.

Harmonic emissions IEC 61000-3-2	Class B
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 7: electromagnetic emissions



**WARNING MESSAGE**

Portable and mobile RF communication can affect the IOS device

Guidance and manufacturer's declaration – electromagnetic immunity			
The [AADVA IOS] is intended for use in the electromagnetic environment specified below. The customer or the user of the [AADVA IOS] should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the [AADVA IOS], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz  $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz




			<p>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 metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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.		
<p><sup>a</sup> 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 [AADVA IOS] is used exceeds the applicable RF compliance level above, the [AADVA IOS] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [AADVA IOS].</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 8: electromagnetic immunity

<b>Recommended separation distances between portable and mobile RF communications equipment and the [AADVA IOS]</b>			
<p>The [AADVA IOS] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [AADVA IOS] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [AADVA IOS] as recommended below, according to the maximum output power of the communications equipment.</p>			
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 2,5 GHz  $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3

100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

*Table 9: Recommended separation distances between portable and mobile RF communications equipment and the AADVA IOS*

**Please note:** The separation distance for the higher frequency is applied with 80 MHz and 800 MHz. These instructions may not apply in all situations. The distribution of electromagnetic waves will be affected by the absorption and reflection from structures, objects and people

Field strengths of fixed transmitters, such as base stations for mobile or cordless telephones and mobile radio services (CMR), amateur radio AM and FM radio stations cannot be theoretically predicted with accuracy. An electromagnetic survey should be considered to determine the electromagnetic environment from fixed RF transmitters. If the measured field strength in the location in which the AADVA IOS system is used exceeds the applicable RF compliance level mentioned above, the AADVA IOS system should be monitored for its proper functionality. If a different performance level is determined, possible reducing measures such as re-positioning or relocating the AADVA IOS are necessary.

Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## 28 Electrostatic discharge (ESD)

Protection against electrostatic discharges is of paramount importance when connecting or disconnecting cables from the GC AADVA IOS. Static electricity can build up in your body and damage sensitive switching elements with the discharge. Even small, not noticeable discharges can cause permanent damage to electronic components. To prevent damage to the GC AADVA IOS:

- Make a visual inspection of the work area to ensure that no non-conducting work surfaces and no materials or tools that generate static electricity are present;
- Keep electrostatic discharge sensitive devices at a distance of at least 1 meter away from objects that generate static electricity;
- Non-insulated people must maintain at least a 1 meter distance from this ESD protected area;
- Avoid a build-up of electrostatic charges (e.g. from air conditioning, humidification devices, conductive floor coverings, non-synthetic clothing);
- Discharge your body through contact with the ground or a large metal object.
- Only touch the pins marked with the ESD symbol with your fingers or a tool, if the proper precautions have been followed.



All users of the GC AADVA IOS should be familiar with the proper ESD procedures before working with the scanner. This training should include at least an introduction to the physics of the electrostatic discharges that occur under normal circumstances, voltage levels and the possible damage to electronic components by contact with an electrostatically charged operator. In addition, methods should be taught to avoid electrostatic charging and on how to earth the body.

If an electrostatic discharge or other electrical anomaly interferes with the operation of the hand piece, the operator should (if possible) just start the scan again or leave the scanning screen and call it up again.

If a transient electrical event interferes with the operation of the monitor, the operator must restart the monitor via the monitor's power switch.

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>			
<b>The [AADVA IOS] is intended for use in the electromagnetic environment specified below. The customer or the user of the [AADVA IOS] should assure that it is used in such an environment.</b>			
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>	
RF emissions CISPR 11	Group 1	The [AADVA IOS] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The [AADVA IOS] 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 purposes.	
Harmonic emissions IEC 61000-3-2	Class B		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The [AADVA IOS] is intended for use in the electromagnetic environment specified below. The customer or the user of the [AADVA IOS] should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – Guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) 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 input lines IEC 61000-4-11	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 1/2 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 s	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.  If the user of the [AADVA IOS] requires continued operation during power mains interruptions, it is recommended that the [AADVA IOS] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



NOTE  $U_T$  is the a.c. mains voltage prior to application of the test level.

Table 10: Electromagnetic emissions and immunity

## 29 Identification plate and labelling

The information on the identification plate describes the AADVA IOS and contains the serial number along with the necessary regulatory and safety symbols.



Figure 46: Identification plate

## 30 Device specifications and classifications

This device is an imaging system.

General specifications and classifications	
Video capture rate/flash rate	18 frames per second
Size of the touch screen	(19") diagonal 5/4
Dimension of the base of the Cart (footprint)	50 cm x 49 cm
System height (floor to monitor frame) max.	110 cm
Monitor - tilt adjustment	-30° bis + 45°
Input power	100-240 VAC 50/60 Hz, 5A @230AC, 10A @115vAC
Protection against electric shock	Class I
Protection against harmful water penetration or suspended materials	Cart IP21 Application device IP54 (in vivo part) Application device IP53 (non-in vivo part)
Operating mode	Durable
<b>Weight</b>	
Total shipping weight incl. packaging	40,5kg
Cart with monitor	32 kg
Application device	175g including cable



<b>Dimensions of the application device</b>	
Length	210 mm
Width of the application device's tip	22.2 mm
Height of the application device's tip	19 mm
Max. diameter	25.2 mm
Cable length of the application device	1.4 m (visible)
Calibration	No calibration required on site
<b>Temperature</b>	
Operational	10 - 35°C
Storage/transport	-20°C to +60°C
<b>Humidity (ambient)</b>	
Operational	30-60% relative humidity, non-condensing
Storage/transport	10-90% relative humidity, non-condensing
<b>Air pressure (ambient)</b>	
Operational	700-1060 mbar
Storage/transport	700-1060 mbar

*Table 11: Device specifications*

### AADVA IOS cable

No.	Type	Length	Description
1	Non-shielded power cable system	2m	AC to AADVA IOS
1	Shielded USB cable, exposed application device to Cart	2m	USB 2.0 for video recording
1	Shielded VGA cable, monitor	1.5m	Analog video signal to the monitor
1	Shielded USB cable, monitor	1.5m	USB 2.0 for Touch Monitor
3	Shielded USB cable, external media storage	1.5m	USB 2.0 USB memory
1	Non-shielded AC power cable, monitor	1.5m	12VDC/10A

*Table 12: Cable specifications*



### WARNING MESSAGE

#### To reduce the risk of electrical hazards:

Only use the original power cord provided with the IOS device which is specified for this product and certified for the country you are in.

**NOTICE** In order to avoid damages of AADVA IOS adopt the following precautions:

- Protect GC AADVA IOS device against direct insolation to avoid overheating while operation.
- Ensure that GC AADVA IOS device is positioned on solid and even surface.
- DO not touch the touch screen with sharp or pointed objects.
- The GC AADVA IOS components can be damaged by corrosion thus must only be stored indoors

## 31 Transport and packaging

Prior to setting up and assembling the AADVA IOS, please make sure that all parts and components are included in your delivery (refer to the accompanied delivery note). Also check for any visible signs of damage which the device may have incurred during transport.

### The AADVA IOS package includes the following parts:

- AADVA IOS Intra Oral Scanner
- AC power cable
- 10 GC AADVA Cradle Inlays
- AADVA IOS Operating Manual (this manual)
- AADVA IOS quick guide
- AADVA DSP quick guide
- Declaration of conformity
- Customer support sheet

### Shipping:

AADVA IOS is shipped with a standard Euro pallet. In case the device has to be returned, please use the original packing material for re-packaging, as only this ensures safe transport and maintenance of warranty. In case of disposal of the packaging, please ensure that all packing materials are properly disposed of according to current recycling directives.

### Lifting and carrying:

The most practical method of moving and placing the AADVA IOS will be by handling it manually. Uplift AADVA IOS across hindrances by using the front handle grip.



#### WARNING MESSAGE

Be aware of your personal limits or seek assistance when transporting, lifting, packaging and carrying, taking into account the weight of the IOS cart as indicated in the specifications.

For short distance transportation, lock the flexible arm by sliding the lock button outwards and bringing the flexible arm in the vertical position. In case the device is turned on, this procedure will turn it off automatically. Make it sure that all files are saved before the device is turned off to avoid loss of data. Incline the device so that it stands on its back wheels and proceed with the transportation by holding the handle above the monitor screen (Fig. 47).



Figure 47: Transporting the IOS device

## 32 Environment

**Notice:** Do not dispose electric equipment or components together with household waste material.

Your product is marked with this symbol for an environmentally responsible recycling/disposal. Do not discard it with normal waste. The black line under the crossed-out waste bin symbol signifies that this product has been put into circulation after 13.08.2005 (see Directive 2012/19/EU and EN 50419:2006).



Please be aware that this product is subject to the European Directive 2012/19/EU (WEEE) and the laws applicable in your country for environmentally responsible recycling/disposal. Help to protect environment. Dispose of all components in accordance with applicable regulations.

### **Only for EU countries:**

In observance of European Directive 2002/96/EC on waste electric and electronic equipment and its implementation in accordance with national law, electric equipment that have reached the end of their life must be collected separately and returned to an environmentally compatible recycling facility.

To initiate return of AADVA IOS contact your local IOS expert (see chapter 20 - "IOS Customer Service").

### **Other countries:**

Contact your local IOS expert for country-specific information (see chapter 20 - "IOS Customer Service").

### 33 Troubleshooting

<b>No power</b>	<ul style="list-style-type: none"> <li>▪ Is the power cable connected?</li> <li>▪ Is the main power switch I/O button on the back of the device switched to 'I'?</li> <li>▪ Did you press the power button, situated next to the USB ports on the support arm of the touch screen?</li> <li>▪ Is the device in transport position or in scan position? If in a transport position, put it in scan position. Does the device switch on now automatically?</li> <li>▪ Is the fuse, situated next to the ON/OFF button on the back of the device in place?</li> <li>▪ If the green GC logo on the device (CART and cradle) is lighted, is the screen switched off?</li> <li>▪ Are the fans of the PC working, is the device making any noise?</li> </ul>
<b>No image appearing on screen</b>	<ul style="list-style-type: none"> <li>▪ Is the device heated up properly, does the thermos indication mention 'COLD' or 'OK'?</li> <li>▪ Is the hand piece positioned in the cradle?</li> <li>▪ Do you see a small blue LED light when looking into the camera?</li> <li>▪ Is the light in the camera white or black?</li> <li>▪ When holding your finger against the heating element in the cradle, does it feel warm?</li> <li>▪ Is the cover glass of the camera not covered and is it properly cleaned?</li> <li>▪ Is there a scanable object within the scan range of 15 mm?</li> </ul>
<b>Not possible to enter data into the 'Patient ID' field</b>	<ul style="list-style-type: none"> <li>▪ Did you enter numbers or letters into the patient ID field?</li> </ul>
<b>Not possible to transfer data through the Aadvia DSP</b>	<ul style="list-style-type: none"> <li>▪ Is the device connected to internet?</li> <li>▪ Is your GC Connect account still active?</li> <li>▪ Did you transfer the specific data already before?</li> <li>▪ Did you already transfer the specific data to USB?</li> <li>▪ Did you go through the complete validation process and did you click 'confirm' before transferring data?</li> </ul>
<b>It's not possible to move the CART</b>	<ul style="list-style-type: none"> <li>▪ Is the brake pedal, on the front of the device, in upward position?</li> </ul>
<b>No patients listed in 'Search patient' field</b>	<ul style="list-style-type: none"> <li>▪ Did you log in using your own user name and password?</li> </ul>

Case	Error message/indication	Reason	Solution
Wrong PIN	"The dentist and password you have entered are not valid."	The PIN was entered incorrectly.	Enter correct PIN.
No Temperature visualization	The temperature of the scanner is not visualized.	No hand piece reference files found in the Config folder. Scanner driver not installed correctly. Scanner USB cable is broken.	Copy correct hand piece files in the Config folder. Install the correct scanner driver software. Check the USB cable for any physical damage and call the service

			hotline.
No USB drive found	Export to USB failed, because no USB drive was found. Plug in a USB drive. Retry export?	No USB thumb drive connected or thumb drive not appropriately formatted.	Connect a FAT32 or NTFS formatted USB thumb drive.
Network path not specified	Export to network failed, because no export path was defined. Please set the network export path in the settings.	No network export path was specified in the export settings.	Enter a network export path.
No space left on the USB drive	Export to USB failed. Not enough free memory available.	Not enough memory left on the USB thumb drive, to store the case.	Connect a USB thumb drive with enough memory.

### 34 IOS Customer Service – GC Digital Services Team

If you have any questions concerning AADVA IOS and/or this operating manual, our local GC Digital Services Team will be pleased to help you. Please refer to the **DSP** where all local information for support can be found or refer to the separate sheet '**GC Digital Services Team**' accompanied with the IOS device.

First line of support :

- Creation of support ticket using the **DSP**
- Contacting local branch representatives (using the contact details found on the DSP or on the separate sheet 'GC Digital Services Team')

Second line of support :

Tel. : +32 16 74 26 \$0

E-mail : [digitalservices@gceurope.com](mailto:digitalservices@gceurope.com)

