





Small Scanner. Great Comfort.

1. Introducing the ione scan Solution

1.1. Introduction	6
1.2 Indications supported	6
1.3 Certification and compliance	6
1.4 Regulatory	7
1.5 Intended Use	7
1.6 Classifications	7

2. What's in the Box

3. System Requirements and Specifications

3.1 System Specifications	9
3.1.1 Scanner	9
3.1.2 Scanning Process	9
3.1.3 Software & Lab Integration	10
3.2 Computer Requirements	10
3.2.1 Required Software and Misc.	10
3.2.2 Required Hardware	10
3.3 Environment Conditions	11
3.4 Power Input	11
3.5 Reusable Tips	11
3.6 Scanner – Base and Handpiece	11

4. How to Connect & Set up the ione scan Solution

4.1 Setting Up and Connecting the ione scan	
4.2 ione scan Components Overview	14
4.3 Settings	14
4.4 cloud storage	

5. Operating the ione scan Solution

5.1 Getting Started	18
5.1.0 Communication with the Lab	19
5.1.1 Case Management Software Overview	19
5.2 Indication workflows	23
5.2.1 Create new order	24
5.3 Important things to know before scanning	26
5.4 Operating the scanner	26
5.4.1 Scanning	26
5.4.2 Mandibular and Maxillary Scanning	27
5.4.3 Bite Alignment	28
5.4.4 Tip	29
5.5 Scanning Tools	30

6. Maintenance

6.1 Cleaning the Handpiece	31
6.2 Cleaning and Sterilization of Tip	31
6.3 Disposal	
6.4 Calibration	

7. Safety Guidelines and Warnings

7.1 Warnings and Symbols	33
7.2 General Guidelines	34
7.3 General Warnings	34
7.3.1 System Modification	34
7.3.2 Approved Software	34
7.3.3 Equipment Failure	35
7.4 Mechanical Hazards	35
7.4.1 Moving Parts	35
7.4.2 Dropped Equipment	
7.4.3 Base	35
7.5 Electrical Safety	36
7.5.1 Electrical Shock	36
7.5.2 Stress on Cables	36
7.6 Eye Safety	36
7.7 Hygiene	36
7.8 During Systems Operation	37
7.9 Symbols on the ione scan and Transport Case	38

8. Support, Warranty and Repair Service

8.1	Support	.39
	Standard Warranty	
8.3	Repair Service	.39
	Out of Warranty Repair Service	
8.5	Troubleshooting	.40



1. Introducing the ione scan Solution

1.1 Introduction

Thank you for purchasing the ione scan solution from imes-icore. The ione scan solution is designed and developed to produce high-quality digital intraoral scans, or models, for dental restoration or analysis.

The ione scan solution is designed with you as a dentist and your patient in mind. The scanner is lightweight, small and easy to use, enabling a fast, accurate scanning and great patient experience. The Case management application is order management as you know it and designed for easy and intuitive use. Enjoy your new intraoral scanner solution!

1.2 Indications supported

ione scan can be used for the following indications:

- Anatomic crowns
- Copings
- Provisional crowns
- Anatomical pontics
- Reduced pontics
- Provisional pontics
- Inlays/Onlays
- Implant abutments

- 3-unit implant bridges
- Up to 5-unitbridges
- Orthodontic aligners
- Nightguards
- Splints
- Retainers
- Bleach trays
- Sleep appliances

1.3 Certification and compliance

The system has been tested and conforms to the following standards:

• IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

• IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances

- Requirements and tests
- IEC 62471, Photobiological safety of lamps and lamp systems

1.4 Regulatory

The ione scan is manufactured and marketed in accordance with US FDA Regulations and EU Medical Device Directive 93-42-EEC.

1.5 Intended Use

The ione scan is an optical impression system. It is used to record the topographical characteristics of teeth, dental impressions, or stone models for use in the computeraided design (CAD) and computer-aided manufacturing (CAM) of dental restorative prosthetic devices.



CAUTION: Rx only - Federal law restricts this device to be sold by or on the order of a Dentist.



WARNING: Unintended use of the system can result in physical injury to the patient and operator, and damage to the system.

1.6 Classifications

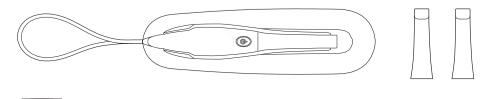
The ione scan system has the following classifications

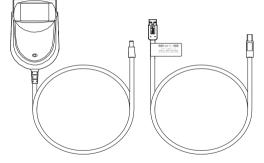
- Protection against electrical shock: Type B Applied Part
- Protection against harmful ingress of water: Ordinary equipment (IPX0)
- Safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

2. What's in a Box

The ione scan system includes the following

Name	Part Number
ione scan System (Inkl. 3 spitzen)	IOS-FP-71-001
USB 3.0 Cabel	IOS-CP-00-043
AC/DC Power Adapter	IOS-CP-00-088





Save the Box: It is highly recommended that you store the box in a safe place and do not throw it away. The box is optimal for any necessary transportation or shipment of the ione scan.

3. System Requirements and Specifications

3.1 System Specifications

3.1.1 Scanner

Scanner Type	Hand-held (chairside) scanner that creates optical impressions for dental restorations.
Design	Compact, lightweight, ergonomic – designed to be operated with little physical effort.
Dimensions Base	Size: L 306mm, W 98mm, H 72mm
Dimensions Scanner	Weight: 150 grams
	Size: L 256mm, W 43mm, H 43mm
Power Requirement	DC5.0V / 4A (Power supply included)
Scanner Tip	Reusable, sterilize using steam autoclave
Heating Element	Prevents formation of fog on the optics
Acquisition Method	Intraoral camera – active stereo imaging
Color Scanning	24-bit (8-bit per channel)

3.1.2 Scanning Process

Tooth Preparation	No powder or spray required
Scanning Principle	Continuously scanning and accumulating (stitching) depth and color data
Distance Scanner - Tooth	0 – 12mm
Possible contact duration by operator	10 min ≤ t Note: May vary with hardware configuration
Operator Accessible Part	Handpiece
Possible contact duration by patient	10 min ≤ t
Patient accessible part (Type B Applied Part)	Тір
Computer – Scanner Interface	USB 3.0

3.1.3 Software & Lab Integration

Output File Format	STL, PLY, OBJ
Compatibility with CAD/CAM Systems	Open Architecture Output format STL, PLY, OBJ Compatible with most Dental CAD systems
Case Management application Interface	Touchscreen support

3.2 Computer Requirements

3.2.1 Required Software and Misc.

Operating System	Windows 10 (Excluding Windows 10 S, now defunct) Administrative rights required
Disk Space	100 GB of free disk space or greater
Ports	1 x USB 3.0 port (SuperSpeed) 2 x USB port

3.2.2 Required Hardware

•	
СРИ Туре	Intel i7 - 4 Cores or greater (e.g. i7 8700)
CPU Clock	2.8 GHz clock or greater
Memory	16 GB of RAM or greater (DDR4 or better)
GPU	NVIDIA GeForce Graphics Processor000 Series (GTX): 1070 or Greater 1000 Series (GTX): 1070 or greater - At least 6 GB video memory 2000 Series (RTX): 2060 or greater - At least 6 GB video memory



NOTE: AMD GPU's are NOT compatible with the ione scan. Not meeting minimum hardware requirements will affect the performance of the scanner.

3.3 Environment Conditions

Operating Temperature	10°C ~ 40°C
Operating Relative Humidity	10% ~ 80% (non-condensing)
Storage Temperature	- 20°C ~ 60°C
Storage Relative Humidity	10% ~ 80% (non-condensing) Indoor use only
Installation Category	1
Pollution Degree	2
Ingress of Liquids	IPXO
Protective Class	Class IIIb
Overvoltage category	I (Supplied from output DC source, max. 5 V. dc, 600 mA) of notebook or non-me- dical grade PC certified by IEC60950-1
Max. working condition	Continuous cycles with image capture and transmission from/to Notebook or non-medical grade PC.
Other possible accessories (IEC60601-1 3rd, Cl. 16)	Notebook with AC/DC Adapter.
Equipment Maintenance	No user maintenance is required, and no user service is allowed. Please contact technical support if there is a problem.
Cleaning	Do not try to clean the inside of the de- vice. Refer to Chapter 6 for cleaning and sterilization.

3.4 Power Input

The power adapter input is 5V DC, 100-240V AC, 50-60Hz.

3.5 Reusable Tips

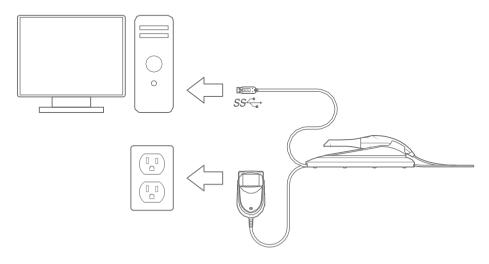
Scanner tip is autoclavable up to 50 times in a steam autoclave. See chapter 6.

3.6 Scanner – Base and Handpiece

The scanner body consists of the Base and Handpiece, which are connected by a flexible, non-detachable cable.

4. How to Connect & Set up the ione scan Solution

4.1 Setting up and Connecting the ione scan



Install the system according to the following steps

You can download the software from <u>https://www.imes-icore.com/support/</u>

Step 1: Place the base on a flat, stable surface and place the ione scan handpiece securely in its base.

Step 2: Connect the AC/DC power adapter cable to the Base; the connector socket is located underneath the Base.

Step 3: Connect the provided USB 3.0 cable to the Base; the connector socket is located underneath the Base.

NOTE: Using a USB cable other than the one provided may result in system malfunction or reduced performance.

Step 4: Connect the other end of the USB cable to the computer.



NOTE: It is strongly recommended to plug the USB cable to a USB port located at the back of the computer; not doing so may result in system malfunction or reduced performance.

Make sure to use a USB port that is compatible with USB 3.0 (SuperSpeed), usually indicated by the following symbol: **SSC** not doing so may result system malfunction or reduced performance.

If using a laptop computer, make sure the power supply is connected to an outlet and not running on battery power.

Step 5: Connect the AC/DC power adapter to a power outlet.



WARNING: Unsuitable Installation sites

· Locations with excessive humidity ordust

· Locations subject to high temperature

Locations subject to shaking or vibration

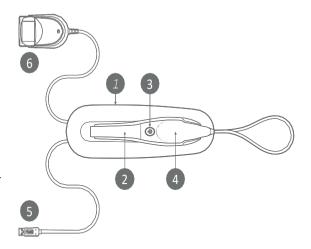
• Locations exposed to considerable electrical or magnetic noise, or other forms of electromagnetic energy

4.2 ione scan Components Review

Please review the ione scan features shown in this section. This will help you locate the features when they are described in sections 5-7.

- 1. The base and scanner
- 2. Tip
- 3. Scan Button
- 4. Handpiece
- 5. USB 3.0 Cable
- 6. AC/DC Power Adapter

4.3 Settings



General:

- Language, Currently only English.
- 3D Output format can be STL, PLY, OBJ.
- Picture formats can be PNG, JPG.
- Preferred start page can be chosen to be Recent Patients or Recent Cases.
- The workflow Fast Scan can be enabled if Patient or Case is not needed.
- View Software version (Copy function to the right)
- View Scanning module version (Copy function to the right)
- Manual software Update check. Automatic check is done at every launch.
- Link to User manual and to imes-icore support homepage.

General		
System Language	English	~
Preffered Output Format	.571.	~
Picture Save Format	.FNG	~
Preferred Start Page	Recent Patients	~
Enable Fast Scan Workflow		-
Software Version	1.4.456.3321234	G
Serial Number	123456789	G
Scanner Model	Haron	~
Check for Software Updates		CHECKNOW
User Manual		6
3DISC Support		~

System

Under system the option to export or import the patient database.

Sounds

Select to use the sound during scanning or not. Pre select volume and select between different sound effects.

Users

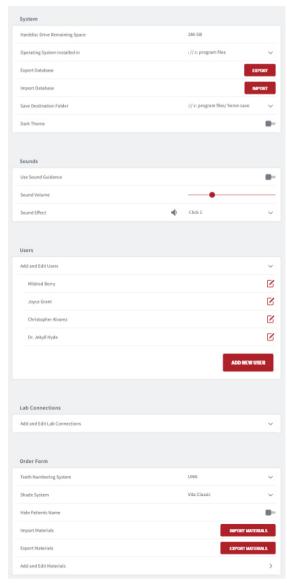
Add, edit and delete users with Email name and picture Also Passwords can be added on the user.

Lab Connections

Setup and select connections with Labs. Also setup the preferred Lab as default.

Order Form

Select Tooth numbering system. Shade system can be selected. Patient names can be hidden in case needed. New materials can be imported and exported. Also special materials can be created and edited.



4.4 Cloud Storage

One cloud is the file transfer cloud supplied with your one system. It can be found on onecloud.imes-icore.com

Labs and users create an account and share the files free via the cloud. Logging in will give an overview of the cases created by the user or cases sent to the user with current status.

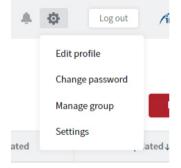
The interface supports the following languages: English, Danish, German, Spanish, French, Chinese, Korean

Connections with Labs and dentists is managed by clicking the connections button

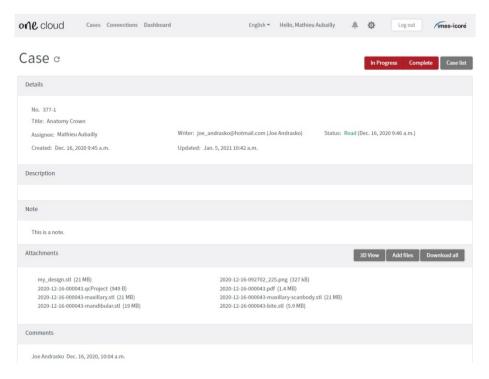
þ.		•	Search				New Case
	No.	Title	Assignee	From	Status	Created	Updated 4
0	117-21	Anatomy Crown	abc (Joshua Kim)	Joshua Kim	Read	April 21, 2021	April 21, 2021
0	117-20	Anatomy Crown	abc (Joshua Kim)	Joshua Kim	Open	April 19, 2021	April 19, 2021
0	117-19	Screw Retained Crown	abc (Joshua Kim)	Joshua Kim	Open	April 12, 2021	April 12, 2021
	117-18	Anatomy Crown	abc (Joshua Kim)	Joshua Kim	Open	Jan. 19, 2021	April 1, 2021
0	117-17	Bridge	abc (Joshua Kim)	Joshua Kim	Dpen	Dec. 14, 2020	Dec. 14, 2020
0	117-16	Anatomy Crown	abc (Joshua Kim)	Joshua Kim	Open	Sept. 23, 2020	Sept. 23, 2020
	117-8	Anatomy Crown (1)	abc (Joshua Kim)	Joshua Kim	Closed	July 20, 2020	Sept. 4, 2020
0	117-5	Bridge	abc (Joshua Kim)	Joshua Kim	Open	March 18, 2020	March 18, 2020
0	117-4	Provisional crown	abc (Joshua Kim)	Joshua Kim	Open	March 18, 2020	March 18, 2020
	117-3	Coping	abc (Joshua Kim)	Joshua Kim	Dpen	March 18, 2020	March 18, 2020

Options for the Cloud

- 1. Edit Profile enables to edit name, mail and soon.
- 2. Possibility to Changepassword.
- 3. Groups can be created.
- 4. Settings can change the look of the Case view.



Opening a case from the list will show all the information needed. Possibilities for changing status, looking at scans in 3D Viewer, downloading files and adding files are found here.



5. Operating the ione scan Solutions

5.1 Getting Started

Sign in and Creating a new account

A new account needs to be created before it can be linked to a user in the software. On onecloud.imes-icore.com click "Create New Account". Fill in the required fields (marked with a red *) and click "Create".

A mail will be sent to confirm the mail address. Click the confirmation link and you are ready to log in to the cloud.

🔹 OneClinic.com Login 🛛 🗙	
one cloud	one cloud New Account
Sign In	Email •
Login	Password +
Forgot Password Create New Account	Repeat Password +
Or sign in with one click Image: State Stat	First Name •
	Last Name •
	Role *
	Institution

Country •

5.1.0 Communication with the Lab

The Case Management application, one clinic, contains two built-in methods for communicating with the lab. You can either:

1. Access the scans directly by clicking the "export files" tab, select desired files and drag and drop in your desired platform.

- 2. Use one cloud
 - 1a. Share files directly by locating the file in the "open in Explorer" tab and copying the file into Dropbox, wetransfer.com, email etc.

	To	MyDertallab@yahco,gr
Send	Ce	
Here A M		.
0 M		

2b. After you have created your account you can now connect with a lab by going to connections menu and adding connection.

one cloud	Cases	Connections	Dashboard	English •	Hello, Mathieu Aubailly	ø	Log out	/imes-icore
Connectio	ons							
		Search	1					Add Connection

 Add your one cloud connection to settings, your connected labs will now appear as options.

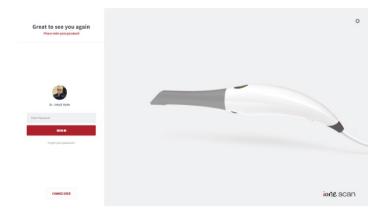


Send the cases via one cloud in the finalize page.



Login screen

User login page is the first page when the software is started. Select the user and type in password if the user is set up with that.

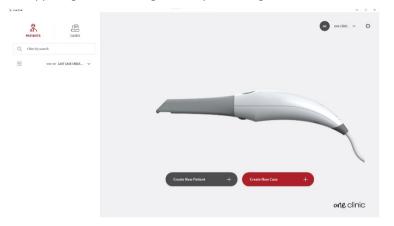


5.1.1 Case Management Software Overview

Start Screen Patients

When logged in you will have Patients or Cases as default view (selected in settings). Select an already created patient, in the left side of the screen, to view and/or create new cases for the patient.

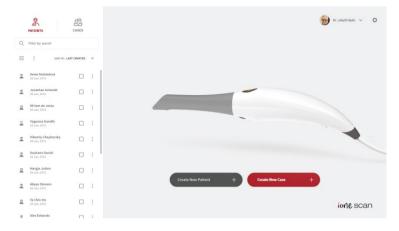
Create new Patient or case by using the buttons in the main part of the screen. Settings are found in the upper right corner by clicking the gearwheel. Clicking on the user in the upper right corner will give the option to log out.



Start Screen Cases

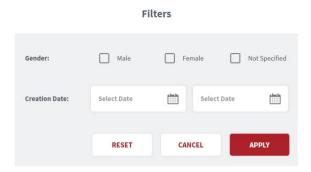
When logged in you will have Patients or Cases as default view (selected in settings). Select an already created case, in the left side of the screen, to view the scans and continue to all the cases for the same patient.

Create new Patient or case by using the buttons in the main part of the screen. Settings are found in the upper right corner by clicking the gearwheel. Clicking on the user in the upper right corner will give the option to log out.



Filters

Patients and cases can be sorted with filters or with a search for a specific word/name. Filters are chosen via this button:



Creating a new Patient

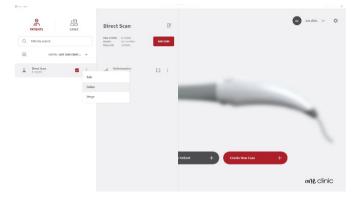
Creating a new patient will open the screen to the right. Fill in the data. Patient ID is automatically created but it is possible to change to a different ID if needed. First and Last name are mandatory.

	Create New Patient
Patient ID: *	ID000002 (auto generated)
First Name: *	1
Last Name: *	
Date of Birth:	MM DD YYYY
Gender:	Male Female Not Specified
Notes:	
	CANCEL

When filled in click create and you will be ready to create cases.

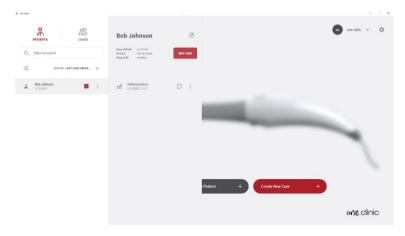
Delete a Patient

It is possible to delete a Patient by clicking the 3 dots to the right of the name and selecting Delete. Note that only patients with no cases can be deleted so any cases under the patient must be deleted first. It is done by clicking the 3 dots next to the case. Multiple cases can be deleted simultaneously.



Create a new Case when Patient is selected.

When a patient is selected a preview will appear with name and cases already on the patient. Here you also have the option to create a new case for the same patient, by pressing add case.



5.2 Indication Workflows

one clinic supports the following restorations and appliances:

Anatomic crowns	3-unit implant bridges
Copings	Up to 5-unit bridges
Provisional crowns	Orthodontic aligners
Anatomical pontics	Nightguards
Reduced pontics	Splints
Provisional pontics	Retainers
Inlays/Onlays	Bleach trays
Implant abutments	Sleep appliances

5.2.1 Create new order

To create a new patient order for the above-mentioned indications, follow the steps below.

Create new Case

When creating a new case the Order Form will be displayed. Check the correct patient and Lab is selected and the desired delivery date from the Lab.



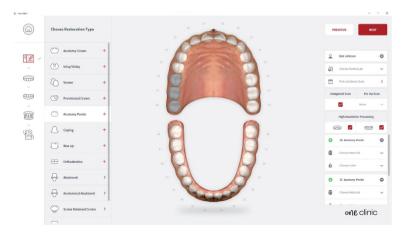
Selecting the Restoration

Select the teeth and choose the restoration type. Teeth are selected by clicking on them and multiple teeth can be selected simultaniously. Antagonist are selected automatically but can be de-selected if needed. **Pre-op scan can be selected if desired.**

	Choose Restoration Type			n n n	n		PR	EWOUS	80	T.
	Anatomy Crown	+		P -			2	Jonathan Sc	hmidt	Q
	Anatomy Pentic	+	(100			<u>â</u> j	San Francisc	to Dental Lab	~
	(U) inlay / Onlay	+	C	7/1		28		21 Septemb	er 2019	>
الله ، الله الله الله المانين ا المانين المانين	C Veneer	+		1 184		11	Artag	pnist Scan	Pre-Op Scan	~
	Provisional Crown	+	C	1			0	28: Anatom	ry Crown	0
	Coping	+	Ø		0		0	Choose Mate	erial	~
	Standard Pontic	+					6	Choose Colo	*	~
	Reduced Coping	+		-						
	Wax up	+			R					
	Abutment	+	6	C						
	Screw retained Crown	>			and a					
	CCC Bridge	+		4. 41.	31.			101/1	e scar	1

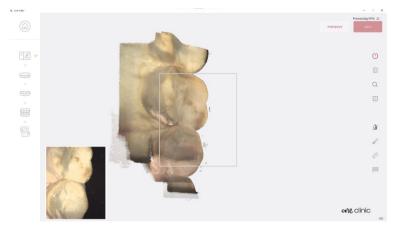
Die After Restoration is selected

The colour and material is chosen. Note a bridge is shown by the outer lines and dots next to the coloured teeth. **Push Next when the Order Form is finished.**



Scanning Page

The live View window in the lower left is showing what the ione scan is actually seeing. It can be changed In size. Small, Medium and Large. The 3D building of the scan is shown in the middle of the screen. You can capture 2D images by pressing "C".



5.3. Important things to know before scanning

If doing a crown, prepare the tooth with a gingiva retraction cord. This is optional however highly recommended. Prior to scanning, remove the retraction cord and dry the surface of any blood or saliva using an air/water syringe or a 2x2 gauze.

5.4 Operating the scanner

5.4.1 Scanning

1. Start Scan

To begin scanning, press the button on the top of the scanner or you may click 'scan' on the right tool bar window.

Recommended distance from tip to tooth is from 0-12 mm.

2. Green Image

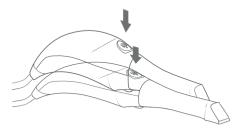
When the green box is present, it indicates the scan is successfully stitching together. To maintain the green indicator, remain steady and precise with your movements.

3. Red Image

In the event of a red box, the scan has lost it's track and is no longer stitching the scan together. This is caused by unsteady and sudden movements of the handpiece as well as a lack of cheek/tongueretraction.

4. Restart

If your scan has lost track, simply place the scan tip on the occlusal surface of an already scan- ned tooth. The occlusal surface has the most detail and will allow the software to recognize its position quickly. Facial surfaces are difficult to recognize as their surfaces are flatter.







5.4.2 Mandibular and Maxillary Scanning

1. Begin your scan by starting on the arch of chosen restoration. If scanning both arches, you may select either arch to begin.

2a. For a full arch, follow a scan path of occlusal, lingual then buccal. Beginning on the posterior terminal molar, working across the entire occlusal plane of the arch, you will end at the opposing terminal molar. When scanning the anterior region, ensure to slightly roll the scan tip at least 1mm over the incisal edges to capture some facial surface.

2b. The live view window to the left is the main point of reference. While scanning, what is shown in the live window will appear on the 3D image. Ensure the anatomy of the tooth is centered in the view window with little to no cheek or tissue present.

3. When finished scanning the occlusal, starting at the terminal molar, slightly rotate the scanner to 45 degrees scanning the entire lingual surface of the entire arch ending at the opposing terminal molar.

4. To scan the buccal surface, again beginning on the posterior terminal molar, you will rotate at 45 degrees scanning the buccal segment stopping at the midline. You will repeat the process on the opposing terminal molar to connect the midlines. Ensure you do not scan all the way around the entire arch on the buccal facial surfaces. Finalize in scanning the buccal side of the molars with the scanner in a 90 degree angle being sure to capture at least 5mm of gingiva.

5. When scan is complete, turn the scanner off by the power button on the handle of the scanner. If scanning both arches, select the other arch now in the software.

6. Repeat the same scan path and strategy for both arches.









5.4.3 Bite Alignment

In the event of a quadrant scan, you will be asked to scan only the side of the quadrant. When doing full arch scans, you will be prompted to scan bilateral.

When selecting 'bite', allow a few seconds for the arch scans to load.

1. Scanning the occlusion

1a. To capture the bite, you will begin scanning on the central molars capturing both mandibular and maxillary teeth in the first pass. Then scan only the Maxillary molars and gingiva till the arch

1b. Once the arch is locked, the arch will get the initial scan overlayed and a green checkmark will ap- per like described below indicating you are finished scanning that arch. Once the arch is complete, repeat the process for the opposing arch.

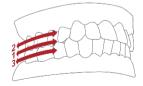
1c. When the bite alignment is complete, you may rotate the 3D image to confirm correct patient occlusion.

2. Finalizing

When scanning is done we get the overview of the case incl 3D preview of the scans. Additional notes can be added and pictures or similar can be attached to the case. If connected to a Lab via one cloud the whole case can now be sent to the lab. Additionally the scans and order form can be exported to a different location on the PC.

3D Viewer

Each of the scans can be opened in the full screen 3D viewer for closer investigation.



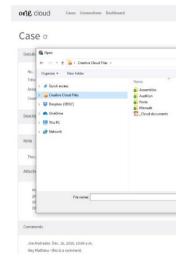








3. In the event you may feel that the alignment needs modification, you or your lab can upload the file into a design software for fine tuning. Access the files directly in Explorer likethis.



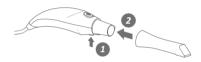
5.4.4 Tip

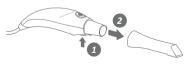
1. Attach the tip with the mirror side facing downward. Firmly press the tip onto the scanner until you hear it lock into place.

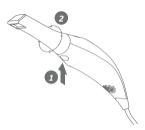
2. Detach the tip by pressing the button located on the bottom of the handpiece (1) while pulling away from the scanner (2).

3. Rotate the tip 180 degrees for maxillary scanning by pressing the button (1) located on the bottom of the handpiece.

*It is not required to rotate the tip for maxillary scanning.







5.5 Scanning Tools

(A Scan Enables the start of scanning as well as pausing the scan.
Ŵ	B Reset Reset will delete the current scan.
Q	C Adjust Zoom level You may change the zoom level, (helpful for touch screens)
	D Center Scan on Screen Moves the scan in the center of the screen
Ø	E Color on/off Toggles between color and non-color scan
	F Brush tool Used to mark areas on the scan for modification/deletion
	G Measurement tool Places points to measure distance
88	H Finalize tool Forces final processing of the scan

6

6. Maintenance

6.1 Cleaning the Handpiece

The entire body, cord and base of the scanner must be wiped down using a Federal Environmental Protection Agency (EPA) approved disinfectant that is labeled and specified for tuberculocidal/ mycobactericidal activity. Do not use disinfectant on the nozzle.



NOTE: All components of the scanner (excluding the tips) must be wiped down and not sprayed. Avoid getting any moisture, alcohol or disinfectant inside the open scanner chamber.

Recommended and approved surface disinfectants:

- Birex Wipes: TB Claim=10 minutes- 'Phenolic (Dual) Water-Based'
- Prospray Wipes: TB Claim=10 minutes- 'Phenolic (Dual) Water-Based'
- · Cavicide Wipes: TB Claim=3 minutes- 'Phenolics (Dual) Alcohol-Based'
- DisCide ULTRA Wipes: TB Claim-1 minute- 'Phenolics (Dual) Alcohol-Based'
- Maxiwipe Germicidal Cloth: TB Claim=5 minutes- 'Phenolics (Dual) Alcohol-Based'
- Ster 1 Plus: TB Claim=5 minutes- 'Quaternary ammonium and Alcohol-Based'

6.2 Cleaning and Sterilization of Tip



NOTE: The included tips must be autoclaved prior to use as they do not come pre-sterilized.



NOTE: Ensure that the surface of the mirror does not show residues, smudges, scratches, or any damage, as this would affect the performance of the device.

Step-by-Step Procedure

Step 1: Clean the tip with soapy water, ensuring that the mirror is clean and free of smudges, stains, or any residue. Avoid using abrasive cloth materials as this will scratch the mirror.

Step 2: After drying the tip exterior, carefully dry the interior and mirror with lint free wipes ensuring you do not scratch the sur- face. The mirror should be free of any noticeable debris or water spots.

Step 3: Insert and seal the tip into a sterilization pouch. Make sure the seal is airtight. Each tip should be packaged individually.

Step 4: Sterilize the wrapped tip in a steam autoclave at following parameters:

- 132°C (270°F) at 4 minutes, or
- 134°C (273°F) at 4 minutes

Step 5: Ensure the dry cycle is complete prior to removing the tip from the autoclave. If the pouch is damp with moisture, pro- per sterilization cannot be guaranteed.









WARNING: Always autoclave the tip wrapped in a sealed sterilization pouch; failure to do so will result in permanent stains on the mirror.



WARNING: Do not autoclave the handpiece of the device.



NOTE: Tips should not be placed in an ultrasonic cleaner or any cold sterile solutions. The sterilant solutions will leave a sticky residue or film on the mirror when drying.



WARNING: Do not remove the pouch before the sterilizer completes its full dry cycle. If the pouch is wet or has any signs of moisture, this can potentially leave water spots on the mirror which can affect image quality during scanning.



WARNING: Use extreme caution when cleaning the mirror as it is very delicate and is prone to scratching.

6.3 Disposal

The ione scan is an electrical device with electronical components inside and should be disposed of in accordance with local environmental laws and regulations.

6.4 Calibration

The ione scan is calibrated in the factory and therefore does not require calibration when installed.



WARNING: General prohibition indication. The functionality of the system can be destroyed in the case of incorrect use. If unauthorized changes have been made to the delivered system and accessories, the warranty by imes-icore becomes void. imes-icore will not accept any responsibility or liability for the improper functioning of the product in such a case.

If the ione scan begins to have problems scanning and recognizing teeth models, the system should be examined, which may result in the system being returned for repair/ calibration. See Section 8.4 for further info.

7. Safety Guidelines and Warnings

7.1 Warnings and Symbol



NOTE: Notes represent information that is important to know but which do not affect the functionality of the system.



WARNING: The functionality of the system will be limited in the case of incorrect use.

7.2 General Guidelines

- Do not spill liquids on the body of the device
- Never operate the device in a wet environment.
- Keep the device away from radiators and heat sources.
- Use the device only with the accessories supplied.
- Do not alter the device or open enclosures.



WARNING: General prohibition indication. The functionality of the system can be destroyed in the case of incorrect use. If unauthorized changes have been made to delivered system and accessories, the warranty by 3D Imaging and Simulation Corp. Americas becomes void. 3D Imaging and Simulation Corp. Americas will not accept any responsibility or liability for the improper functioning of the product in such a case.

If any of the following conditions occur, unplug the device from the electrical outlet and contact authorized service personnel:

- The power cord or power adapter is damaged.
- The device has been exposed to water.
- The device has been damaged.
- The device does not operate correctly when the operating instructions are followed.

7.3 General Warnings

7.3.1 System Modification

WARNING: Modifying the system may result in physical injury to the patient and operator, and damage to the system.

7.3.2 Approved Software

The ione scan device is designed to operate with the one clinc software. See section 4 for details.



WARNING: The ione scan should only be used with approved, compatible software.

7.3.3 Equipment Failure



WARNING: In case of system malfunction or failure, you should: Prevent any contact between the system and the patient. Unplug the system from the power outlet and the computer. Store the system away so it cannot be used by someone else. Contact service personal.

7.4 Mechanical Hazards

7.4.1 Moving Parts



NOTE: All moving parts are inside handheld scanner so do not open the unit.

7.4.2 Dropped Equipment



WARNING: If the scanner tip is dropped, ensure that the mirror is not damaged and that it is not detached; if the tip is damaged it should be disposed of immediately. If the scanner handpiece is dropped or bum- ped, ensure that no part of the system is damaged as it could affect performance.

7.4.3 Base



NOTE: When not in use, always rest the handpiece on the Base Do not place the Base on a slanted surface. Place the cables (power cable and USB cable) where people cannot accidentally get caught in them and potentially damage the system.

7.5 Electrical Safety

7.5.1 Electrical Shock



WARNING: There is a risk of electrical shock when opening or attempt-ting to open any part of the system; only qualified service personal should open parts of the system.

7.5.2 Stress on Cables



WARNING: Care should be taken not to apply unnecessary stress on the cables of the system, whether it is the power cable, the USB cable or the cable between the handpiece and the Base.



WARNING: Only use the power adapter supplied as a part of the system.

7.6 Eye Safety



WARNING: During operation, the system emits a bright, flashing light from its tip. Although the system complies with standard IEC 62471 (Pho- tobiological safety of lamps and lamp systems), prolonged exposure to flashing light may result in discomfort, seizure or eye irritation.

7.7 Hygiene



WARNING: In order to maintain safety for the patient, wear surgical gloves when handling any parts of the system. Always ensure that the tip is mounted on the handpiece before inserting it into the mouth of the patient. Before using the system with a new patient, ensure that the system is disinfected, and the tip is sterilized.

7.8 During Systems Operation



WARNING: The ione scan system contains delicate optical and mechanical elements and therefore should be handled carefully. Do not drop, bump, or shake the handpiece or the tip. Always place the handpiece on the Base when not in use. Do not put stress on the cable connecting the handpiece to the Base. Do not submerge the handpiece or the Base in any liquid. Do not place the handpiece with a firm grip when handling it.



NOTE: During operation of the system, the handpiece and the tip may get slightly warm; this is normal.



WARNING: In order to prevent over-heating of the system, the ventilation opening at the bottom of the handpiece should never be obstructed.

7.9 Symbols on the ione scan and Transport Case

Symbol	Description
	Manufacturer's trade name and address (ISO 15223-1w)
	Date of manufacture (ISO 15223-1)
Ċ	Equipment Power On/Off (push/push)
SS←	USB plug
<u>_!</u>	Warning, Consult Accompanying Documents
()	General mandatory action manual
\oslash	General prohibition indication
8	User Manual Reference
X	Directive on Waste Electrical and Electronic Equipment
EF REP	Authorized Representative in the European Community
Eibid Group:2 GL/DGM. Provide hour optical indication prototed from this product indication prototed hours, this inclusion of the optical inclusion of the optical inclu	Warning label for LED
(())	Non-ionizing electromagnetic radiation
	Direct Current
*	Type(B) Level of protection against electric shock
i	Consult operating instruction for use.
CE	European Conformity mark
Rx	Prescription symbol
NON	Non-sterile (Scanner-Tips)
imes-icore.com/support	User manuals are available electronically at the link provided

8. Support, Warranty and Repair Service

8.1 Support

If you have questions about the software, please consult the manual and Help menu in the software. If you are experiencing issues with your software, please check the list of common issues provided in section 8.6 prior to contacting a dealer. It could be simply a question of a minor issue that can be fixed quickly. However, if you're still experiencing problems after following the recommendations in this section, then please contact the dealer where you bought the equipment.

8.2 Standard Warranty

imes-icore warrants its non-consumable hardware products to be free from defects in materials and workmanship. The warranty covers the cost of parts and labor to repair the product.

Please keep the shipping container for future use. Products returned to the factory for repair should be properly packaged. To obtain warranty service, follow the procedure described in the Repair Service section. Failure to do so will cause delays and additional expense to the customer.

The warranty is valid when the product is used for its intended purpose and does not cover products which have been modified without written permission from 3D Imaging and Simulation Corp. Americas, or which have been damaged by abuse, accident or connection to incompatible equipment.

This warranty is in lieu of all other warranties, expressed or implied.

8.3 Repair Sevice

The ione scan cannot be serviced locally. In the event of a hardware malfunction, contact your dealer to arrange for a swap unit (same model or newer) so your unit can be replaced, and work can continue. Some testing might be needed in order to verify the Hardware/Software error ormalfunction.

The company reserves the right to cease providing repair, maintenance, parts and technical support for its non-consumable hardware products five years after a product is discontinued. Technical support for old versions of software products will cease 12 months after they are upgraded or discontinued.

8.4 Out of Warranty Repair Service

Out of warranty repair service is available in selected geographical locations. Contact the supplier for current terms and rates.

8.5 Troubleshooting

Issue	Recommendation
There's a memory full error message that pops up when the software is open.	Clear some space on the C Drive
The status in the Live view window is "Disconnected".	Check that you have external power to the ione scan and that the USB cable is connected to a USB 3 Port.
Scanning is very slow.	Check that the Laptop is connected to an external power source.
The corners are cut in the live view window.	Check that the Tip is correctly mounted and when rotating it is locking in place with a click.
There is a red aquare in the scan window	Go back to a tooth that is scanned and start from there again
No images appear when scanned but everything else (e.g. live window image, sounds, FPS) works fine.	The scanner might need to be recalibrated. Please contact your local dealer for support.
There are spots on the Live view window.	Check and clean the mirror of the tip.
Where can I get the one clinic software and manuals?	Please find them in the Support section of imes-icore website.

We hope this Quick Guide war helpful to you. For additional material and user information go to imes-icore.com/support.

> ione scan Usermanual ione scan How-to Videos ione scan Traning Videos

imes-icore.com/support





USA & Canada



3D Imaging and Simulations Corp. Americas 365 Herndon Pkwy #18 Herndon, VA 20170 United States Tel.: +1 703 430 6080 Tel.: +1 800 670 0363 (Toll free)

Europa, Middle Fast & Afrika



imes-icore Europe

Gydevang 39-41 3450 Alleroed Denmark Tel.: +45 88 276 650

Asia Pacific & Australia

imes-icore Asia

#912, 165, Magokjungang-ro Gangseo-gu, Seul Rep of Korea Tel.: +82 2 6101 3110

Contact imes-icore

info@imes-icore.com

contact Support

support@imes-icore.com