1 ICam System

Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operations and precautions related to the Imetric ICam System. Before initial use of the Imetric ICam System, it is essential for operators to be familiar with the intended use, warnings, cautions, notes, and contraindications mentioned in these instructions.

2 Product Description

The ICam System uses photogrammetry to locate the 3D coordinates of endosseous dental implants that were implanted in the mandible or maxilla. The system consists of the following hardware and software components:

ICam System		
ICam	The ICam Camera is used to locate the 3D coordinates of Imetric ICamBodies.	
Cable Bundle	The Cable Bundle contains cables for both power and data transmission. It must be connected both to a power source and to your computer.	
Power Supply	This is the power source for the ICam Camera. Both the Power Connector on the Cable Bundle and the Power Cord must be plugged into the Power Supply.	
Calibration Plate and Calibration Plate Holder	This is used to calibrate the ICam Camera before every measurement. This calibration verifies that the ICam Camera is working properly and accounts for variations in device temperature as well as any component shift due to minor impacts.	
Super Speed Hub (SSH)	The Super Speed Hub is a USB 3.0 hub that is used to connect the ICam Camera to the computer.	
Super Speed Hub Cable	The Super Speed Hub Cable comes in two variants: either a USB-B to USB-A cable or USB-C to USB-A cable. It is used to connect the Super Speed Hub to the computer.	

Software	
IScan 3D Dental	The IScan 3D Dental software is used with the ICam Camera during the measurement process.

Further equipment.

ICam System		
Power Cord	This cable plugs into the Power Supply and into the wall outlet to supply the ICam with power. **Note**: Depending on the region you want to use the ICam system you have to order to correct power cord.	

CAUTION: The power cord is sold separately. You have to choose the correct version of the power cord. A computer is not included in the set. Check section 12 to be sure that the computer fulfills the demands on hardware and software. Use only cables or a speed hub from Imetric.

3 Compatibility

The Imetric ICam Camera uses specially developed scanbodies, called ICamBodies and ICamRefs. These scanbodies are screwed onto Multi-Unit abutments or directly into dental implants. Please review the compatibility list to select ICamBodies, ICamRefs and ICamBody Screws that are compatible with the implant system or Multi-Unit abutment used.

Link https://imetric4d.com/ifu/

4 Intended Use

Product	Intended use
ICam System	Obtain and output the 3D coordinates of endosseous dental implants, either directly from the patient's mouth or from models.

5 Indications for Use

Product	Indications for use
ICam System	Indicated for use with the Imetric accessories to locate the 3D coordinates of endosseous implants after they have been placed in the maxilla or mandible.

6 Multiple-Use Devices

The Imetric ICam System is a multi-use device. The ICam System does not come in contact with the patients. The ICam System cannot be sterilized.

7 Contraindications

- The patient is medically unfit for oral surgery.
- The number, size or position of implants is not sufficient to support the forces exerted by the prosthesis.
- The ICam and/or the accessories is/are damaged.
- Do not use two or more ICamBodies with the same dot pattern in a scan process.

- To use other scanbodies or accessories other than those from Imetric.
- The user is not physically able to handle the ICam with its weight around the patient.

CAUTION: It is not permitted to open the ICam or manipulate the enclosed accessories. This can reduce accuracy. Correct application is no longer possible.

8 Cautions

Inaccurate measurements of the implant coordinates may lead to a poor fit of the prosthesis. To avoid inaccurate measurements, please consider the following:

- Close collaboration between the surgeon, restorative dentist and dental laboratory technician is essential for successful treatment.
- It is strongly recommended to use only accessories that are intended to be used in combination with the ICam.
- When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications.
- Ensure the implant is stable prior to mounting ICamBodies or ICamRefs.
- Do not use the ICam System if it is damaged in any way.
- Do not allow liquids to come in contact with the ICam Camera or Calibration Plate.
- Do not allow any liquids or cleaning agents to come in contact with the ICam Camera lenses or Calibration Plate.
- Do not touch the ICam Camera lenses.
- Do not touch the face of the Calibration Plate with the target pattern. Only the sides and white backing may be handled.
- Do not take measurements with the ICam System until the calibration cycle is complete.
- Do not take measurements with the ICam Camera before the 20-minute warm-up period is complete.

Damage to the ICam System may lead to decreased accuracy of measurements or a complete system outage. To avoid damaging the ICam System, please consider the following:

- Do not drop, toss, or roughly handle the ICam System
- Do not exert excessive force or twisting on the Cable Bundle or ICam Camera ports.
- Do not store the ICam System on soft or uneven surfaces when not in use.
- Do not store the ICam System in a humid environment when not in use.
- Do not expose the ICam System to sharp objects or liquids.
- Do not mechanically or electrically modify any component of the ICam System.

9 Handling Instructions

9.1 Unboxing and assembling

- Remove each component and set on a clean and steady workspace.
- Plug the provided Super Speed Hub into your computer. The light on the Super Speed Hub should turn on when properly connected.

Figure 1:Plug the USB-A connector end of the provided cable bundle into the Super Speed Hub.

- Plug the USB-B connector end of the provided Cable Bundle into the back of the ICam Camera.
- Plug the provided Power Cord into the provided Power Supply, then plug into the wall.
- Connect the Cable Bundle into the Power Connector

Figure 2: Connection point of the Cable Bundle and Power Connector

- Connect the circular Power Connector end of the Cable Bundle to the back of the ICam Camera and gently tighten the cuff.
- Press the power button on the back of the ICam Camera to power it on. The power button should light up blue and the ICam Camera should project “Heating Up”.
- Allow the ICam Camera to heat up for at least 20 minutes prior to taking measurements. When the ICam Camera is fully heated, it will project a blue light

9.2 Setting a project in the software

- Open the IScan3D Dental software on your computer.
- Under Client Name, type the name of the client. If necessary, use the Ref 1 and Ref 2 text boxes to type additional information relevant to the measurement, such as clinical information or the date of the measurement.
- On the tooth diagram, select the tooth position numbers that correspond to the implant sites.
- In the ICamBody Selection Window, select the Exocad® implant library you plan to use in the restoration design process.
- In the ICamBody Selection Window, select the ICamBody Set to be used in the measurement.

- Click apply and close the ICamBody Selection Window.
- You are now ready to begin calibrating the ICam Camera.

9.3 Calibrating

- Ensure the 20-minute warmup period has completed prior to calibrating the ICam Camera.
- Set the Calibration Plate on a flat surface next to the ICam Camera.
- Position the screen of your computer so you can see it during the measurement process.
- Once the project is set up in the IScan3D Dental software, the software will transition to Calibration Mode and the ICam Camera will project a light.
- Pick up the ICam Camera using the handles. Position it 12” (30 cm) away from the front of the Calibration Plate and center it on the six large targets in the middle of the Calibration Plate.
- While keeping the six large targets in the middle of the live camera view, slowly move the ICam Camera towards the Calibration Plate until the green plane of disks appears above the red square on the left side of the calibration window.

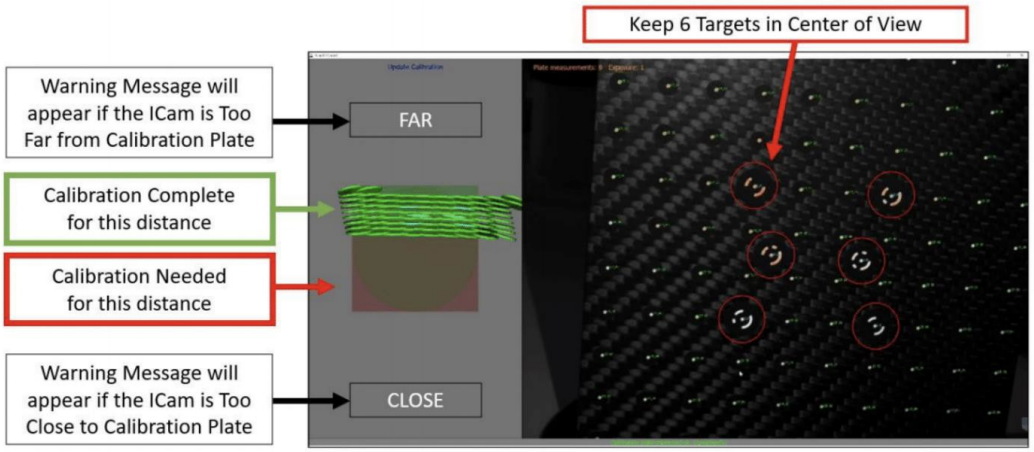

Figure 3: Calibration of the ICam Camera

- Continue slowly moving the ICam Camera towards the Calibration Plate until the green plane of disks has passed to the opposite side of the red square.
- Once the square is completely green, the calibration process is complete.

9.4 Measuring

- Once the calibration is complete, the IScan3D Dental software will automatically transition from Calibration Mode to ICamBody Measurement Mode.
- Start on one side of the patient’s mouth and position the ICam Camera so that the ICamBodies are in the center of the live camera view.
- Move the ICam Camera closer or further away from the ICamBodies so that all the ICamBodies appear within the green circle on the left side of the software.

Figure 4:Acceptable distance between the ICam Camera and the ICamBodies, as seen on the left side of the IScan 3D Dental software

- While maintaining the distance between the ICam Camera and the ICamBodies, slowly orbit the ICam Camera around the patient's mouth so that two faces of the ICamBodies are captured.

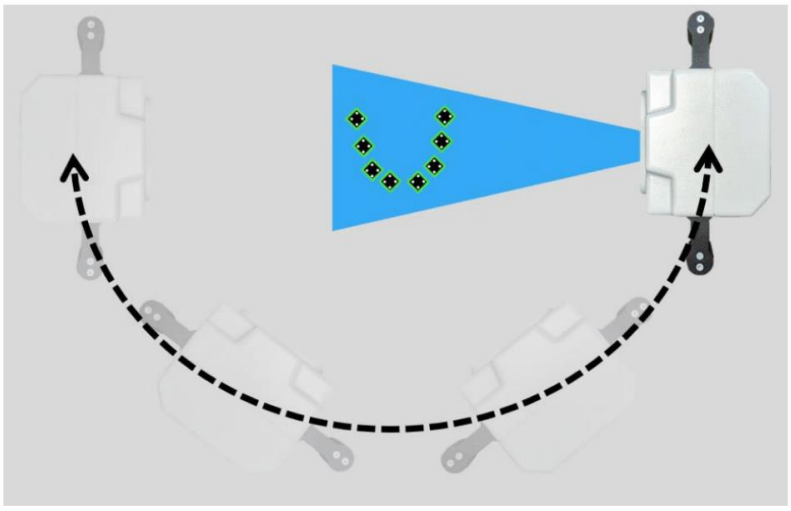

Figure 5: Example of the ICam Camera orbiting motion as viewed from above

- Once all ICamBodies are green, continue slowly orbiting the ICam Camera from side to side to reach at least 50 views for optimum accuracy.
- When you are done measuring, click anywhere on the screen to stop the ICamBody Measurement Mode.
- Select the green check mark button at the bottom of the screen to accept the adapter labeling for the ICamBodies.
- If the green check mark is greyed out, please see section 10 of the troubleshooting section.
- In the next window, click the save button. If you do not select the save button, your measurement data will not be saved.
- The ICam Camera measurement process is now complete. The ICam Camera can now be turned off and stored.

9.5 Data Export

⚠ The results of the ICam True Photogrammetry system are the position and orientation of the ICamBody in a local coordinate system defined by the software. Imetric offers two data export options:

- The export of the data as coordinates and/or a transformation matrix in various file formats including “TransformedPoints.txt”, “.implantPosition”, and “ImplantDirectionPosition.xml”.
- The export of an STL that can be placed at the position of the implant interface. This is referred to as the “Change Geometry” workflow.

⚠ It is expressly recommended **not** to transfer STL data (Change Geometry) for position information. The highest accuracy of the ICam photogrammetry system is achieved by using the Imetric text file or the XML-based files.

The use of STL data can lead to accuracy degradation and mismatches.

10 Troubleshooting

If problems occur while operating the ICam System, please use this troubleshooting guide to identify the cause and correct the error.

10.1 ICamBodies appear red in the IScan3D Dental Software

Cause	Action
Incorrect Exposure Settings	Increase or decrease the Target Exposure (located in the lower left section of the screen in the IScan 3D Dental Software) by increments of 1 until the ICamBodies change color to yellow or green in the IScan3D Dental software.
ICamBody Orientation Incorrect	Reorient the ICamBodies so that two sides are visible from the opening of the patient’s mouth.
ICamBodies Too Close Together	Stop the measurement and remove the successfully measured ICamBody from the patient’s mouth that is blocking the red ICamBody. Click the Live Measurement button to take more measurements of the red ICamBody.
Not Enough ICamBodies in View	If an object is blocking some of the ICamBodies, move the obstruction so that all ICamBodies are visible.
ICamBody is Worn or Damaged	If the ICamBody appears worn or damaged, remove it and either replace it with another ICamBody from the set or move an ICamBody mid-measurement.

10.2 ICamBodies Appear Purple in the IScan3D Dental Software

Cause	Action
Incorrect ICamBody Set Selected	In the project page in the IScan3D Dental software, click on the tooth positions to open the ICamBody Selection window. Check to make sure the correct ICamBody Set is selected.
More ICamBodies in Patient than in Project	Stop the measurement, open the Project tab, and add the additional tooth position(s).

Cause	Action
Measuring Incorrect Arch	Stop the measurement, open the Project tab, remove the tooth position selections, and select tooth positions on the correct jaw.
Moving the ICam Camera too Quickly	Stop the measurement, click the Delete Measurement button, and retry the measurement. Make sure to move the ICam Camera in a slow and steady orbit.

10.3 No Camera Found

Cause	Action
No Cameras Found	Power cycle the ICam Camera.
	Check all physical connection points between your ICam Camera and computer.
	Check the USB Tree on your computer to see whether four cameras show up.
	Allow the IScan3D Dental software through your firewall.

10.4 Bundle Adjustment Error

Cause	Action
Bundle Adjustment Error	Click on the OK of the error message and stop and restart the measurement. Ensure you are using smooth and steady motions when orbiting the ICam Camera.

10.5 Adaptor Labeling Error

Cause	Action
The ICam Camera measured implant positions in different locations than what was selected in project setup or the IScan3D Dental software cannot automatically determine the implant position labels	Click the green Adaptor Labeling button on the bottom ribbon of the IScan 3D Dental software.
	Select the ICamBody that correlates to the black tooth position in the tooth arch diagram on the bottom left side of the screen.
	Verify the ICamBody is labeled with the correct tooth position number.
	Repeat for each ICamBody.

11 Technical Specifications

Cause	Action
ICam Camera	Power Consumption: 162-172.8 W
	Depth of Field: 70 – 250 mm
	Dimensions: 158 x 133 x 146 mm
	Handles: 114.3 mm Height with 30 mm Diameter
	Weight: 782.44 g
Calibration Plate	Dimensions: 100 x 100 x 13 mm
	Weight:

Cause	Action
	164 g (With Holder) 48 g (Without Holder)
Cable Bundle	Cable Bundle: 3.6 m Power Cable
Cable Length	Cable Length: 3.6 m Power Cable
Power Supply	Input: 100-240 V ⎓ 1.62-0.72 A 47-63 Hz
	Output: 12 V ⎓ 5.25 A
	Model: MPU64-105
	Weight: 595 g
Super Speed Hub	Dimensions: 97 x 68 x 23 mm
	Weight: 82.21 g

12 Computer System Specifications

A computer (not supplied by Imetric) with the following system specifications is necessary to operate the ICam System:

Part	Description
System Requirement	Processor: Intel i7 12 generation or newer
	Do not use AMD processors
	Minimum one USB 3.0 Type A or C port
System Recommendations	USB controller: Intel 3.0 or 3.1
	Graphics NVIDIA GTX or RTX
Operating System	Windows 10 or Windows 11

13 Storage, Handling and Transportation

The ICam System must not be dropped, tossed, or roughly handled. The device(s) may be stored at room temperature.

14 Disposal

The ICam Camera must not be disposed of by the user. Please contact your dealer regarding disposal. The dealer will dispose of the ICam Camera free of charge.

Used electrical and electronic products should not be mixed with general waste. For proper treatment, recovery, and recycling, please take this product(s) to a designated collection point. Please contact your local authority for further details of your nearest designated collection point.

Penalties may be applicable for incorrect disposal of waste in accordance with your national legislation. If you wish to discard electrical and electronic equipment, please contact your dealer or supplier for further information.

15 Cleaning, Disinfection and Maintenance

15.1 Calibration Plate

Do not use any liquids or cleaning agents on the Calibration Plate. Keep the Calibration Plate outside of the sterile field. If necessary, use a microfiber cloth to gently wipe the Calibration Plate.

15.2 ICam Camera

Disinfect the outer casing and handles with disinfectant wipes. Do not touch the ICam Camera lenses. Do not use any sprays on the ICam Camera.

15.3 Cable Bundle, Power Supply, and Cords

Do not make tight loops when storing the Cable Bundle. Ensure that the diameter of the looped cable is a minimum of 12-16" (30-40 cm). If the Cable Bundle, Power Supply, Power Cord, or Super Speed Hub Cable are broken or lost, contact Imetric support to order a replacement.

15.4 IScan3D Dental Software

Ensure all updates for the IScan3D Dental software are completed.

16 Side effects

No side effects are known at the moment.

17 Interactions

The ICam system 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. It is unlikely that neighboring electronic devices will be disturbed.

18 Serious incident

Every serious incident that has occurred in connection with a Imetric product must be reported to the manufacturer (complaints@imetric4d.com) and the competent authority in the respective country.

19 Manufacturer

Imetric 4D Imaging Sarl, Le Bourg 9, 2950 Courgenay, Switzerland | Phone: +41 32 599 1199 | mail: Support@imetric4d.com | www.imetric4d.com

20 Authorized representative in the European Union

Imetric 4D GmbH, Im Schwarzenbach 4, 79576 Weil am Rhein, Germany | mail: quality-eu@i-metric4d.com

21 EU Importer

Imetric 4D GmbH, Im Schwarzenbach 4, 79576 Weil am Rhein, Germany

22 Signs and symbols

	Catalogue number		Serial number		Caution
	Manufacturer		Consult instructions for use		Keep away from sunlight
	Unique Device Identifier		Non-sterile		Medical device
	Date of manufacture		Authorized representative in the European Union		For prescription use only
	Keep dry		CE sign		Distributor
	Symbol for the separate collection of electrical and electronic equipment				