ICam 5 System IFU – U.S.A Version

1 Introduction

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 5 System. Before initial use of the Imetric ICam 5 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 5 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:

Hardware		
ICam 5 Camera	The ICam 5 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 5 Camera. Both the Power Connector on the Cable Bundle and the Power Cord must be plugged into the Power Supply.	

Power Cord	This cable plugs into the Power Supply and into the wall outlet to supply the ICam 5 Camera with power.	
Calibration Plate and Calibration Plate Holder	This is used to calibrate the ICam 5 Camera before every measurement. This calibration verifies that the ICam 5 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 5 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 5 Camera during the measurement process

3 Compatibility

The ICam 5 System is compatible with a set of separately packaged devices from Imetric (ICamBodies, ICamRefs, ICamBody Screws, ICBD-Torx-8-11), which are also required for the process of determining implant locations.

The following compatible devices are supplied by Imetric:

ScanBodies	Screws	Drivers
ICamBodies	ICamBody Screws	ICBD-Torx-8-11
ICamRefs		

4 Intended Use

The Imetric ICam 5 System is intended to obtain and output the 3D coordinates of endosseous dental implants, either directly from the patient's mouth or from models.

5 Indications for Use

The ICam 5 System is indicated for use when finding the 3D coordinates of endosseous dental implants for bridges spanning two or more implants.

6 Contraindications ⚠

It is contraindicated to use the ICam 5 System in the following situations:

- If the patient is medically unfit for oral surgery.
- If the number, size, or position of implants is not sufficient to support the forces exerted by the prosthesis.
- If accessories, such as Scanbodies, that are not Imetric products are being used

7 Cautions ⚠

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

- Do not use the ICam 5 System if it is damaged in any way.
- Do not allow liquids to come in contact with the ICam 5 Camera or Calibration Plate.

- Do not allow any liquids or cleaning agents to come in contact with the ICam 5 Camera lenses or Calibration Plate.
- Do not touch the ICam 5 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 5 System until the calibration cycle is complete.
- Do not take measurements with the ICam 5 Camera before the 20-minute warm-up period is complete.

Damage to the ICam 5 System may lead to decreased accuracy of measurements or a complete system outage. To avoid damaging the ICam 5 System, please consider the following:

- Do not drop, toss, or roughly handle the ICam 5 System.
- Do not exert excessive force or twisting on the Cable Bundle or ICam 5 Camera ports.
- Do not store the ICam 5 System on soft or uneven surfaces when not in use.
- Do not store the ICam 5 System in a humid environment when not in use.
- Do not expose the ICam 5 System to sharp objects or liquids.
- Do not mechanically or electrically modify any component of the ICam 5 System.

8 Sterility and Reusability Information ⚠

The ICam 5 System is a reusable device that is delivered non-sterile. The ICam 5 System does not come in contact with patients. The ICam 5 System cannot be sterilized.

9 Handling Procedure

1 Unbox and Assemble

1.1 Choose a clean and steady workspace to set up the ICam 5 System. Ensure your workspace is close enough to both the patient and a power outlet so that you have sufficient cable length to reach both.

1.2 Remove each component and set on a clean and steady workspace.

1.3 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.

1.4 Plug the USB-B connector end of the provided Cable Bundle into the back of the ICam 5 Camera.
1.5 Plug the provided Power Cord into the provided Power Supply, then plug into a standard socket.
1.6 Connect the Cable Bundle into the Power Connector.

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

1.7 Connect the circular Power Connector end of the Cable Bundle to the back of the ICam 5 Camera and gently tighten the cuff.
1.8 Press the power button on the back of the ICam 5 Camera to power it on. The power button should light up blue and the ICam 5 Camera should project “Heating Up”.
1.9 Allow the ICam 5 Camera to heat up for at least 20 minutes prior to taking measurements. When the ICam 5 Camera is fully heated, it will project a blue light.

2 Setting Up a Project in IScan3D Dental Software
2.1 Open the IScan3D Dental software on your computer.
2.2 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.
2.3 On the tooth diagram, select the tooth position numbers that correspond to the implant sites.

2.4 In the ICamBody Selection Window, select the exocad ™ implant library you plan to use in the restoration design process.

2.5 In the ICamBody Selection Window, select the ICamBody Set to be used in the measurement.

2.6 Click apply and close the ICamBody Selection Window.

2.7 You are now ready to begin calibrating the ICam 5 Camera.

3 Calibration

3.1 Ensure the 20-minute warmup period has completed prior to calibrating the ICam 5 Camera.

3.2 Set the Calibration Plate on a flat surface next to the ICam 5 Camera.

3.3 Position the screen of your computer so you can see it during the measurement process.

3.4 Once the project is set up in the IScan3D Dental software, the software will transition to Calibration Mode and the ICam 5 Camera will project a light.

3.5 Pick up the ICam 5 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.

3.6 While keeping the six large targets in the middle of the live camera view, slowly move the ICam 5 Camera towards the Calibration Plate until the green plane of disks appears above the red square on the left side of the calibration window.

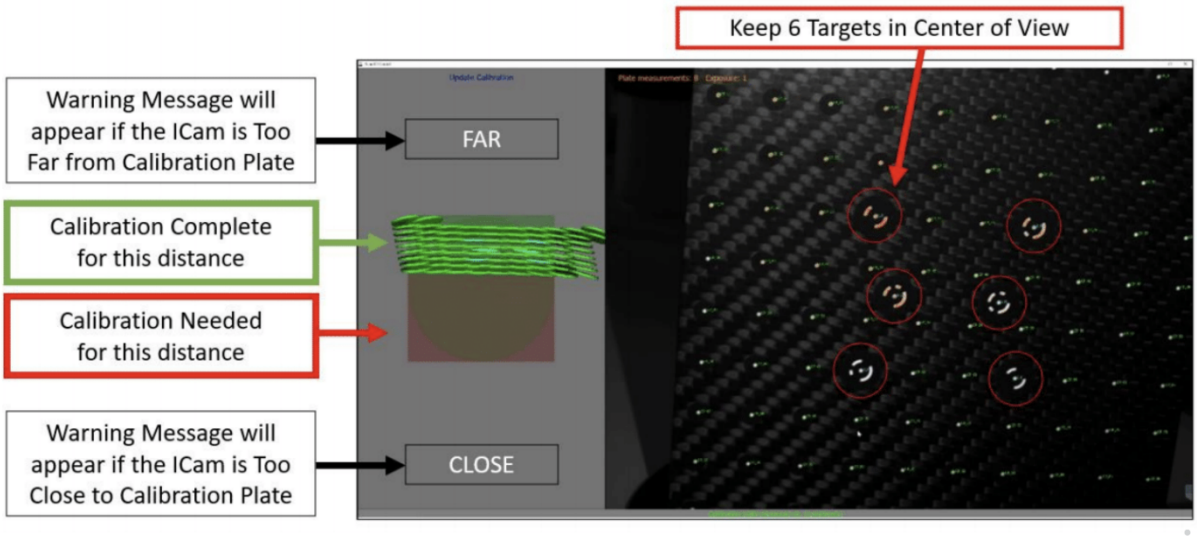

Figure 3: Calibration of the ICam 5 Camera

3.7 Continue slowly moving the ICam 5 Camera towards the Calibration Plate until the green plane of disks has passed to the opposite side of the red square.

3.8 Once the square is completely green, the calibration process is complete.

4 Measurements

4.1 Once the calibration is complete, the IScan3D Dental software will automatically transition from Calibration Mode to ICamBody Measurement Mode.

4.2 Start on one side of the patient's mouth and position the ICam 5 Camera so that the ICamBodies are in the center of the live camera view.

4.3 Move the ICam 5 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 5 Camera and the ICamBodies, as seen on the left side of the IScan 3D Dental software

4.4 While maintaining the distance between the ICam 5 Camera and the ICamBodies, slowly orbit the ICam 5 Camera around the patient's mouth so that two faces of the ICamBodies are captured.

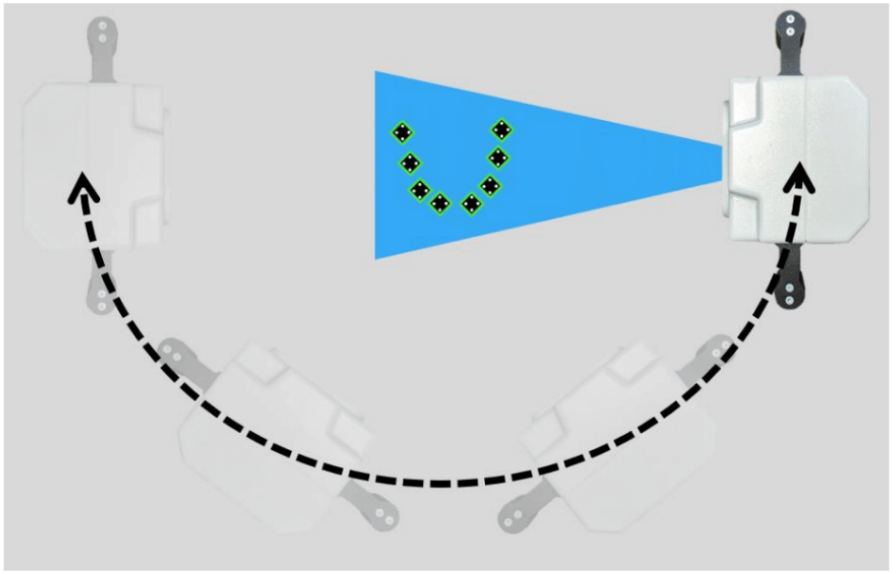

Figure 5. Example of the ICam 5 Camera orbiting motion as viewed from above

4.5 Once all ICamBodies are green, continue slowly orbiting the ICam 5 Camera from side to side to reach at least 50 views for optimum accuracy.

4.6 When you are done measuring, click anywhere on the screen to stop the ICamBody Measurement Mode.

4.7 Select the green check mark button at the bottom of the screen to accept the adapter labeling for the ICamBodies.

4.8 If the green check mark is greyed out, please see section 10.5 of the troubleshooting section.

4.9 In the next window, click the save button. If you do not select the save button, your measurement data will not be saved.

4.10 The ICam 5 Camera measurement process is now complete. The ICam 5 Camera can now be turned off and stored.

10 Troubleshooting

If problems occur while operating the ICam 5 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 to account for the damaged ICamBody

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)
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 5 Camera Too Quickly	Stop the measurement, click the Delete Measurement button, and retry the measurement. Make sure to move the ICam 5 Camera in a slow and steady orbit

10.3 No Cameras Found

Cause	Action
No Cameras Found	Power cycle the ICam 5 Camera
	Check all physical connection points between your ICam 5 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 5 Camera

10.5 Adaptor Labeling Error

Cause	Action
The ICam 5 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

ICam 5 Camera	Depth of Field: 70 – 250 mm
	Dimensions: 160 x 136 x 146 mm Handles: 114.3 mm Height with 30 mm Diameter
	Weight: 2097.86 g
Calibration Plate	Dimensions: 100 x 100 x 13 mm
	Weight: 164 g (With Holder) 48 g (Without Holder)
Cable Bundle	Cable Length: 3.6 m
Power Cable	Cable Length: 2.1 m
Power Supply	Input: 100-240 V ⎓ 1.62-0.72 A 47-63 Hz
	Output: 12 V ⎓ 5.25 A
	Max Power Output: 63 W
	Model: MPU64-105
	Weight: 595 g
Super Speed Hub	Dimensions: 97 x 68 x 23 mm
	Weight: 82.21 g

Computer System Specifications

- A computer (not supplied by Imetric) with the following system specifications is necessary to operate the ICam 5 System:

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

12 Cleaning, Disinfection, and Maintenance ⚠

- **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.
- **ICam 5 Camera:** Disinfect the outer casing and handles with disinfectant wipes. Do not touch the ICam 5 Camera lenses. If the lenses were accidentally touched or become soiled, contact your distributor. Do not attempt to clean the lenses. Do not use any sprays on the ICam 5 Camera.
- **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.
- **IScan3D Dental Software:** Ensure all updates for the IScan3D Dental software are completed.

13 Storage, Handling, and Transportation

The ICam 5 System must not be dropped, tossed, or roughly handled. The device(s) may be stored at room temperature. When finished using the ICam 5 System, place the ICam 5 System components and related accessories in a protective case.

14 Disposal ⚠

The ICam 5 System components should not be disposed of by the user. To dispose of any ICam 5 System components, please contact Imetric or your local distributor, who will accept the ICam 5 System components free of charge.

15 Serious Incidents ⚠

Every serious incident that has occurred in connection with the ICam 5 System must be reported to the manufacturer (complaints@imetric4d.com) and the competent authority in the respective country.

16 Signs and Symbols

REF	**Catalogue number**		**WEEE**		**Caution**
	Manufacturer		**Consult instructions for use**		**Keep away from sunlight**

	Unique Device Identifier		Non-sterile		Medical device
	Date of manufacture		Prescription Only		Serial Number
	Keep dry		Authorized representative in the European Union	Signs and Symbols	

17 Manufacturer

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