



# **User Manual**

## **iVation Tracking System**

V1.0

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# 1 General

## 1.1 Introduction, Principle of Operation

The iVation system is a close range single use optical tracking system. The system is designed to determine the 6DOF position of a target relative to the camera position. The system transmits the tracking data wireless to a host computer. The iVation System comprises two components:

- iVation Camera
- iVation Target

A host computer is also required to operate the iVation tracking system and associated tracking software. The host computer must support connection to a Bluetooth LE (> 4.0) device. Other system requirements are defined by the application that integrates the tracking system.

## 1.2 Warnings and cautions

### **Modifications to the system**

The user or manufacturer that integrates the iVation is not permitted to modify the iVation system

### **Modifications/additions to the software**

The user or manufacturer that integrates the iVation system should communicate with the system using the defined wireless API calls. The software on the host computer must check compatibility with iVation system firmware.

### **Host computer, wireless connection**

The user is responsible to select a appropriate host computer to guarantee safe and robust connection with the iVation tracking system.

### **Functional and accuracy test**

To verify accurate functionality, the system should be checked before use using a verification tool.

### **Recycling/Disposal**

Electronic equipment must be disposed separately and may not be included in the regular domestic waste. Alternatively, the unit can be handed over to Medivation AG for correct recycling. If the devices are contaminated, they must be disposed as clinical waste.

### **Instrument mounts**

The instrument mounts must be designed according to the specification/drawings of Medivation AG. Damaged mounts or remaining dirt/residuals in mounts may lead to inaccurate results or may damage the iVation devices.

### **Danger of damage, direct impact**

The devices may be damaged on direct impact with a instrument or surgical tool. The instruments mounts shall be designed to prevent direct impact forces on devices. The glass on the camera may break on impact with sharp tool.

### **Sunlight, ambient light tolerance**

The system operates in the IR range and may be disturbed by sunlight or ambient light (surgical lamps). Direct sunlight or lamps shining into the camera optics must be avoided.

### **Reflective material, metal object**

The presence of reflective material like metal objects close to the optical path may lead to inaccurate measurements. The system will indicate if measurements are disturbed.

### **Residuals, fluids on optical system**

The optical parts of the iVation system must stay free of any residuals or fluids on it. Residual fluids, fat on the camera optics may impair measurement accuracy. Also avoid condensating water on optical parts.

### **Impaired optical system/glass mask**

The optical mask of the iVation system must stay scratch free and should not be touched with sharp objects.

### **IR Radiation**

The system emits IR light with center wavelength of 850nm to perform the measurements. The device may disturb other devices working in the same IR range or may be disturbed by other devices.

### **Ingress of fluids/water**

Avoid any ingress of water or fluids into the housings. Do not submerge the devices. In case of fluid ingress or immersion immediately replace the device. Avoid situations where water may condensate on/inside device.

### **Second iVation system**

Do not operate the iVation system within 10m of another running iVation system. The user must ensure that the host computer connect to the correct iVation camera. IR communication between camera and target may interfere if the systems are used in the same room.

**NOTE:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

## 2 System Components

### 2.1 iVation Camera



#### Camera Components

- On-Off Switch/Status-LED
- Camera with Glass Mask
- IR-LED/IR-Receiver
- Tactile Button

**Note** The camera connects wireless to a host computer using a Bluetooth LE wireless connection.

**Note** The camera can be mounted on instruments using the snap-in mechanism. The reference coupling design must be used to ensure proper and accurate mount.

**Note** If the camera is mounted on a medical instrument. The camera has to be treated like an applied part type B.

**Warning** The camera glass must always be kept clean and scratch free to ensure system accuracy.

### 2.2 iVation Target-18 / Target Small



#### Target Components

- On-Off Switch/Status-LED
- Camera with Glass Mask
- IR-LED/IR-Receiver

**Note** The target must be paired with a camera before use. The camera communicates via IR link to the target.

**Note** The target can be mounted on instruments using the snap-in mechanism. The reference coupling design must be used to ensure proper and accurate mount.

**Note** If the target is mounted on a medical instrument. The target has to be treated like an applied part type B.

**Warning** The target LED must be kept clean during operation to ensure

system accuracy

## 3 System Setup and Operation

### 3.1 System Setup

The following components are used for a typical system setup where one instrument can be tracked relative to another instrument or reference body.

Device	Description
Host Computer with tracking Application that uses Bluetooth API - Windows, Linux Operating System - Bluetooth LE Module > 4.0	Manages wireless connection to iVation camera.  Communication over Bluetooth LE Services: <ul style="list-style-type: none"><li>• Button Service</li><li>• Battery Services</li><li>• Serial Communication Service (API-Commands, Tracking Data)</li></ul>
iVation Camera	Camera mounted on first instrument or fixed to reference body
iVation Target-18	Camera mounted on first instrument or fixed to reference body
First instrument/reference body with reference coupling for camera	Instrument with defined coupling for iVation camera
Second instrument/reference body with reference coupling for target	Instrument with defined coupling for iVation target-18

Example for a typical surgical setup:

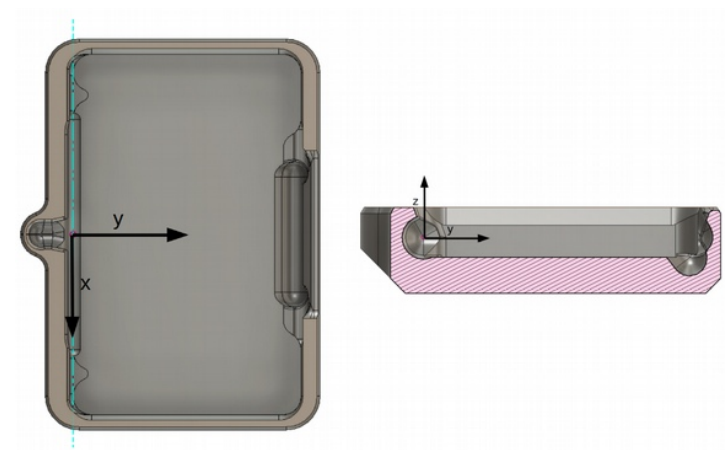
- Host Computer: Medical grade Panel-PC
- Bone mount with coupling for iVation target-18 (Reference of bone structure)
- Instrument with coupling for iVation camera (Moving Instrument)

In the described setup the application can track the position of a instrument relative to a anatomical structure.

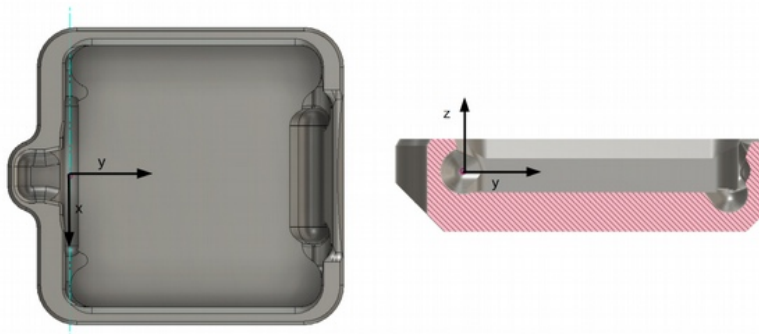
### 3.2 Coordinate systems

The iVation system uses the following coordinate system definition for the camera and target devices. The system reports the 6DOF position of the target reference frame relative to the camera reference frame. The 6DOF transformation is encoded as translation component (x,y,z) and rotation in angle axis representation (rx, ry, tz, ra). All instrument offsets have to be defined in the coordinate frames shown below.

#### 3.2.1 Camera reference frame



### 3.2.2 Target reference frame



### 3.3 Instrument mounts

To ensure proper mount in the couplings the instruments must implement the coupling defined.

Drawings for the reference coupling are available from Medivation on request.

For proper functionality the couplings must be designed according to the reference drawings. The accuracy of the couplings must be tested for each application.

The following important notes should be considered when designing the instrument mounts:

- The position of the coupling on the instrument should prevent from a direct impact with surgical instrument.
- The position on the instruments should avoid contamination of the devices
- The coupling should be kept clean during to allow accurate placement of the camera and target
- The position on the instrument should avoid possible reflections on metal surfaces in the optical path

### 3.4 System Operation

The following steps describe the procedure to operate the system. For more information Medivation can provide the iVation Bluetooth API reference and a example implementations for different platforms (Windows 10, Ubuntu 18.04)

#### 3.4.1 Turn on target and camera

Turn on the camera and target using the slide switch on top of the devices.

The LED is blinking slowly (approx. 1 blink/s)

If the LED blinks fast there is an error with the camera on target on startup or the battery is almost empty. Try turn off/on again the system or if the problem persist the devices must be exchanged.

#### 3.4.2 Mount target and camera on instruments

Mount the camera and target to the instruments with the reference couplings.

#### 3.4.3 Connection to host computer

The camera must be connected to the host computer and wireless connection established.

When the connection is established the LED

- Discovery of Bluetooth LE Devices (ID: iVation Camera)
- Service Discovery
- Device connection

#### 3.4.4 Target Pairing

To track a target the target must be paired with the camera and the target must send it's calibration data (LED geometry) to the camera. For pairing the target should be at approx. distance of 10 cm from the camera to transmit the calibration data.

- Probe for available targets
- Pair with target and read calibration data

#### 3.4.5 Target Tracking

If the target is paired the camera is able to track the target and report its position to the host computer. Tracking a target is possible with a frame rate up to 15 Hz.

The system reports the following 6DOF transformation and warning/error flags for each frame measured:

Translation (x,y,z)	Translation components x,y,z of 6DOF transform
Rotation (rx, ry, rz, ra)	Rotation component of 6DOF transform in angle axis format rx, ry, rz: Rotation axis ra: Rotation angle (in radians)
Sensor error	Average re-projection error of all LED ray to image sensor in mm
Space error	Average distance from LED position of rigid body fit to measured LED position.
Measurement Flags*	0: OverExposure (LED too bright) 1: UnderExposure (LED too dark) 2: Interpolation Overrun (No temporal interpolation of measurement data possible) 3: Background Light: High level of background light in the IR range 4: NoShadow: At least one LED was not detected, no valid shadow on sensor 5: VolumeLimitZ: Target is out of defined volume in z 6: VolumeLimitXY: Target is out of defined volume in x,y 7: VolumeLimitCone: Target is out of defined measurement cone (opening angle) 8: TargetLimitTilt: Target tilt is too high, above limit 9: TargetLowBattery: 10: SensorError: Sensor error above threshold 11: SpaceError: Space error above threshold

\*The application that integrates the iVation tracking system is responsible to handle the reported measurement errors and flags. Depending on the required application accuracy the software can ignore the flags or limit the measurements. The limits for the warning ranges can be defined by the application.

## 3.5 Wireless API and Documentation

### 3.5.1 API Documentation

The documentation for the wireless bluetooth LE API V1.0 is available on request from Medivation AG. This documentation describes all the commands used to communicate with the iVation tracking system.

### 3.5.2 Reference Implementation

A example implementation of an application the bluetooth LE API is available on request from Medivation AG for Windows and Linux platforms.

### 3.5.3 API compatibility

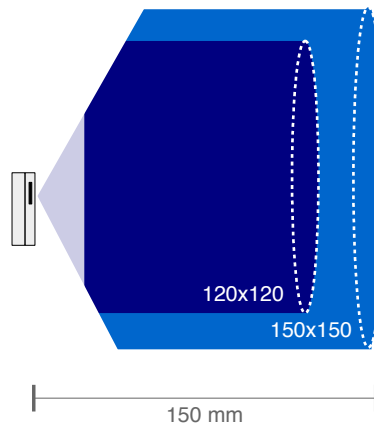
The iVation Devices with Firmware V1.0 are compatible with all API versions V1.0. The application software that implements the communication with the iVation devices has to check for a valid API version of the iVation camera.



## 4 Measurement volumes and accuracy

### 4.1 Measurement volumes

The following measurement volumes has been tested with the two target sizes (18/36). Measurements outside the defined volumes are possible but accuracy is not defined. The volume is defined by the opening angle of 120° and a cylinder with defined diameter and depth. The maximum tilt of the target relative to the view axis is 45°.



### 4.2 Relative System accuracy

Measurement results of one camera and target 18 on coordinate measurement machine (sampling grid 10x10x10 mm). All values have been rounded up to the next 1/10°, 1/10 mm.

	Volume 120x120 mm	Volume 150x150 mm
<b>Accuracy (RMS):</b>		
Rotations (x,y)	0.4°	0.5°
Rotations (z)	0.3°	0.3°
Translation (tx,ty)	0.3 mm	0.3 mm
Translation (z)	0.5 mm	0.6 mm

### 4.3 Absolute System accuracy (including instrument mounts)

This sections lists the accuracy in a typical setup including instrument mounts have been measured for 9 reference positions in the measurement volume with different orientations of camera and target. The measurements have been made in a 3D printed reference coupling design. Based on the measurement the following absolute system accuracy is expected.

	Volume 120x120 mm	Volume 150x150 mm
<b>Accuracy (RMS):</b>		
Rotations (x,y)	0.6°	0.7°
Rotations (z)	0.5°	0.5°
Translation (tx,ty)	0.5 mm	0.5 mm
Translation (z)	0.7 mm	0.8 mm

Note: The reported values are reference values for a typical setup, the total system accuracy has to be determined together with the real instruments and instrument offsets by the application that integrates the iVation tracking system.

#### 4.4 Tracking performance

<b>Framerate:</b>	15 Hz
<b>Operating Temperature:</b>	15 - 30° C
<b>Measurement Volumes:</b>	Cylindrical volumes 120mm – 300mm in diameter and depth, see graphic section 4.1. Cone cutoff with opening angle 90° or 120° Volume can be selected according to accuracy requirements of the application
<b>Tilt of target:</b>	Max. tilt of target to view axis 45°

#### 4.5 Accuracy limitations

- The measurement volume size must be selected together with the target geometry for a defined system accuracy.
- The system uses IR light for measurements. Sunlight or lamps with high IR light radiance may impact system accuracy. Avoid direct light into the camera optics.
- Reflective material in the measurement volume or close to the iVation devices may disturb the measurements and lead to inaccurate results, avoid reflective object close the the tracking volume.
- Dirt or fat residuals may on the camera optics may lead to inaccurate measurements. If the glass mask is dirty it may be cleaned with a wipe. Residual liquid on the glass mask may also impair measurements.
- The measurements show that tracking accuracy of measuring the targets 6D position in the sensor coordinate system and does not account for any errors of calibration to the housing/snap-in attachment.
- Depending on the application and instruments geometry that are used in combination with the devices accuracy in surgical application may be lower than specified.
- The measurement system is not suited for tracking of fast moving objects. For most accurate measurements instruments must be held in a stable position to provide accurate measurements. During freehand movement of instruments motion artifacts may limit tracking accuracy.

## 5 Integration in a medical device

The iVation System is not a medical device, the manufacturer that integrates the iVation tracking system in a medical device is responsible for the validation and documentation of the complete system.

### 5.1 Intended use

The intended use must be defined by the manufacturer that integrates the iVation tracking system in its medical device. The iVation system is designed to be a intra-operative localization system in orthopedic, spine, trauma and sports medicine surgeries where accurate measurement of instrument positions are required.

### 5.2 Indications, Contraindications

The indication and contraindications use must be defined by the manufacturer that integrates the iVation tracking system.

### 5.3 Training

Training must be defined by the manufacturer that integrates the iVation tracking system. The operating instructions must be fully read and understood as part of the training. If any part of the instructions is not clear, please contact your local representative. The manufacturer is responsible to add appropriate warnings from this manual in its operating instruction or user training.

### 5.4 Improper Use, Malfunction

As with all technical equipment, malfunctions may occur due to improper use or, more rarely, technical failure. To reduce the risks involved with such technical malfunction the manufacturer that integrates is reliable to reduce the risks related with device failure due to improper use or technical failure. It is recommended that the manufacturer implement a initial check of the system operation and accuracy where this is critical for the application.

The manufacturer should ensure that only unmodified equipment is used to guarantee safe operation of the iVation tracking system.

### 5.5 Patient Environment

The manufacturer that integrates the iVation tracking system must define the environment where the iVation devices are used and check that the usage of the devices is safe in the defined environment.

### 5.6 Cleaning

Optics can be cleaned with water or isopropyl alcohol, check to properly dry mask after cleaning.

### 5.7 Packaging and Sterilization

The manufacturer that integrates the iVation tracking system must ensure proper final packaging and sterilization of the devices. The iVation system is designed to be EO sterilized and withstand the stated storage and environment conditions. The iVation system is delivered non-sterile for final packaging and sterilization, the integrator must define and validate the packaging and sterilization of the devices.

The packaging must be designed to:

- Be safely opened and prevent damage or dropping of the devices
- Prevent the devices to be activated during shipment
- The package must keep the devices sterile in the defined storage and transport conditions.

The devices are designed to be EO-sterilized, the exact sterilization procedure must be defined and validated by the manufacturer of the medical system:

- The devices must not be damaged by sterilization
- The manufacturer must ensure that correct sterilization method and parameters are applied.

The package label and system manual shall fulfill the essential requirements and must bear the following information:

- The package label shall be well readable
- The package label shall indicate that the system is part of a medical device
- The package label shall indicate the shelf life of the devices
- The package label shall indicate information to identify the devices
- The package label shall supply information in the form of symbols (see section 9)

- The package label shall indicate “STERILE” and the sterilization method (if applicable)
- The package label shall indicate to read the instructions for use if sterile packaging was damaged.
- The package label shall indicate storage environment conditions.
- The system manual shall describe disposal of the devices
- The system manual shall indicate that the devices are single use
- The system manual shall indicate that the devices are sterile and the sterilization method.

### **5.8 Measurement volume , accuracy**

The manufacturer that integrates the iVation tracking system is responsible to check that total system accuracy is appropriate for the intended application. The total clinical system accuracy depends on various factors like surgical setup, instrument mounts, ambient light conditions and other factors.

### **5.9 Instrument mounts**

The manufacturer that integrates the iVation tracking system is responsible that instrument mounts are according the the specified reference couplings. The manufacturer has to check that accuracy and stability of instrument mounts are appropriate for the intended application.

The integrator can get the drawings of the reference couplings (Z5004 and Z5005) on request.

The instrument design must avoid a direct impact on the iVation devices where such a situation may occur.

Application close to the surgical site or direct contact with wound must be avoided. The devices are only intended to be used in the defined reference couplings.

### **5.10 Instructions for use**

The manufacturer that integrates the iVation tracking system must provide a user manual and instructions for use for the complete system. In a system risk analysis a number of points have been defined that should be addressed in the system manual or instructions for use by integrator The information listed below must include the following points to guarantee safe use of the iVation tracking system. Where appropriate this information should be in the form of symbols where required (see section 9).

## 6 Troubleshooting

Issue	Steps to resolve the problem
The camera LED is not blinking or on	Check that camera is turned on  If camera LED does not turn on camera is defect must be replaced.
The target LED is not blinking or on	Check that camera is turned on  If camera LED does not turn on camera is defect must be replaced.
The camera does not show up as bluetooth/wireless device	Check that Bluetooth is enabled on host computer and device scan is working properly.  Check that camera is not already connected to another system.  Turn on/off camera, then try to reconnect to the camera
The camera does not connect to the host computer or unstable wireless connection	If the problem persists try to turn on/off the camera an reconnect.  Check for other devices that may disturb wireless connection.
Connected to the wrong iVation camera	If multiple iVation cameras are running the host may be connected to the wrong camera. Check that serial number listed on device is the same as in the software.  Disconnect and reconnect to the correct camera.
The camera does not detect/pair with the target	Check that target is turned on and blinking.  Hold the target approx 10 cm facing the camera to pair the target with the camera.  If the problem persists try to turn on/off the target and retry pairing.
The camera was paired with the wrong target	Reinitialize target detection and pairing procedure and hold correct target in front of the camera.  Check that no other target is running and is close to the camera.
The camera does not track the target	Check that target is tuned on and paired.  Check that target is in front of the camera.
Unstable or inaccurate measurements	Check system setup: No direct sunlight, bright lights directly in to camera optics. Check that camera optics/glass is clean and scratch free. Check that there are no reflecting/metal object close to the operating volume. Optics can be cleaned with water or isopropyl alcohol, check to properly dry mask after cleaning. Check battery status of camera and target.
Camera is blinking fast	During operation: Camera battery is very low On startup: Error in camera initialization Try to turn off/on again the camera. If blinking persists replace the camera.
Target is blinking fast	During operation: Target battery is very low, target must be replaced. On startup: Error in target initialization. Try to turn off/on again the target. If blinking persists replace the target.
Camera is blinking slow	The camera is on, but not yet connected to the host computer
Target is blinking slow	The target is on, but not yet paired with a camera.

## 7 Maintenance

The iVation tracking system is intended to be used single use. No maintenance is required.











## 8 Disposal

The devices must be disposed as electronic waste according to national regulations.

The manufacturer that integrates the iVation tracking system must define the disposal of the system. If the devices have been used in surgical or lab environment where they have been in potential contact with tissue or blood the devices must be disposed as medical waste in the hospital.

## 9 Glossary of symbols

The manufacturer that integrates the iVation tracking system must use the form of symbols in the user manual or on packaging were appropriate. The following symbols are recommended to be used on the packaging of the devices and in the instructions for use.

	Not for general waste
	CE mark
	Catalog number
	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Power on
	Power off
	Single Use

## 10 Technical Specification

<b>Battery</b>	Camera	3V, 1200 mAh
	Target	3V, 150 mAh
<b>Classification</b>	Humidity	No protection
	Explosion	No protection
	International Protection Marking	No protection
<b>Ambient conditions</b>	Temperature	15 - 30 °C
	Humidity	30 – 75% RH (non-condensing)
	Pressure	70 – 106 kPa
<b>Storage and transport</b>	Temperature	-10 - 55°C
	Humidity	10 - 90% RH (non-condensing)
	Pressure	70 – 106 kPa
<b>System</b>	Camera dimensions (D x W x H)	28 x 46 x 12 mm
	Camera weight	20 gr
	Target dimensions (D x W x H)	28 x 26 x 15 mm
	Target weight	8 gr