

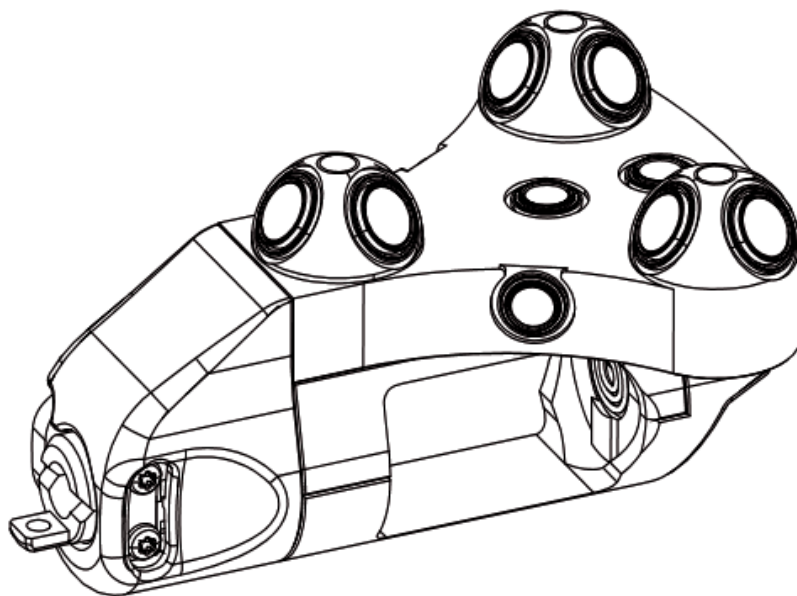
# nGenius Universal Tracker

REF 6000-014-000

# stryker<sup>®</sup>

## Instructions for Use

**CPT Use Only**



## Intended Use

The nGenius Universal Tracker is part of the Stryker Navigation System. It is used in combination with the Navigation System camera to track the position and orientation of instruments or rigid anatomical structures to which the nGenius Universal Tracker may be attached via a pin or mechanical adapter.

The medical purpose is determined by the application modules. Refer to the intended use of the relevant application module for detailed information.

## User/Patient Safety



### WARNINGS:

- Read and understand this information. Familiarization with the Stryker Navigation System prior to use is important. Only trained personnel are to use this system.
- The instruments should only be used in accordance with the instructions for use contained in this manual by authorized persons who have been fully trained in their safe and effective use. The failure to follow these instructions will void your warranty.
- Prior to each use, instruments should be operated and inspected for any loose components, damage or malfunction. DO NOT use if any of these conditions exist. Contact Stryker Navigation Service immediately in such case. *See contact information in the address field.*
- Do not service instruments. They contain no parts that the user can service. If service is required, contact Stryker Navigation Customer Service.
- Performing procedures with instruments other than those specified in these instructions or outside of their intended use compromises navigation accuracy.
- The health care provider performing any procedure is responsible for determining the appropriateness of the instruments and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.
- Clean and sterilize the nGenius Universal Tracker before first and every use as instructed in this manual.
- This equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Use Instrument Battery REF 6000-006-000 only. Load a new battery before first and every use as instructed in this manual. Have several new batteries available.
- Remove Instrument Battery before storing or sterilizing the nGenius Universal Tracker.
- Prior to surgery, this equipment should be checked with the Stryker Navigation System to ensure that it is functioning properly.
- During surgery, if fluids such as saline solution enter the battery holder, the electronics can fail and communications with the system will cease.

### Manufactured and Distributed by:

Stryker Leibinger GmbH & Co. KG  
Bötzinger Straße 41  
79111 Freiburg, Germany  
t: +49 761 4512-0

### Distributed by:

Stryker Navigation  
4100 East Milham Avenue  
Kalamazoo, MI 49001 USA  
t: +1 269 323 7700  
t: 800 253 3210 (toll-free within the US)

**stryker**<sup>®</sup>

- Use only Stryker approved components and accessories, unless otherwise specified. Other accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system. DO NOT modify any component or accessory. Failure to comply may result in patient and/or health care staff injury.
- Ensure the line of sight between the tracker and the camera is NOT blocked. The infrared Light Emitting Diodes (LEDs) and photodiodes must be in view of the camera for the Navigation System to function properly.
- Excessive infrared radiation from external sources can influence localization of the instruments by the Navigation System. *Refer to the Navigation System II-Camera Instructions For Use.*
- Mount and detach the tracker as instructed in this manual.
- Attach the nGenius Universal Tracker only to devices with a generic interface pin (see figure 3). Refer also to the NavLock Instructions for Use REF 6000-999-700.
- In case of the slightest suspicion of incompatibility or risks, do not use the nGenius Universal Tracker.
- Ensure the generic interface pin is fully inserted into the tracker's notch and snaps into position.
- Take special precautions regarding electromagnetic compatibility (EMC) when using this medical electronic equipment. Install and put the equipment into service according to the EMC information in the EMC Specifications Manual REF 6000-005-760. This medical equipment meets all requirements in the EN/IEC 60601-1-2 standard and can be installed in a normal environment. The equipment must not be placed or installed close to strong electromagnetic sources which may influence the function of this equipment.
- Prior to proceeding, verify that the nGenius Universal Tracker is firmly attached to the instrument with no movement after attachment, as instructed in this manual. If the tracker moves relative to the instrument, navigation is inaccurate. Fixate the tracker again, recalibrate and re-validate the instrument.
- To prevent incorrect treatment, regularly perform landmark tests.
- Use the nGenius Universal Tracker only with instruments which have less than 250 mm tip offset.
- Always validate the instrument after calibration.
- Remove any NavLock / NavLock Lite adapter from both tracker and instrument before cleaning and sterilization.
- Recalibrate the instrument, if the tracker with the instrument has been subjected to a shock.
- Avoid placing fingers on or near the LED domes and keep other objects at least 25 mm away from the LED domes when tracking.



## CAUTIONS:

- DO NOT apply any physical impact to the tracker, especially with a mallet or similar tool. Any impact will cause product damage or operational failure due to battery movement.
- To avoid malfunction, DO NOT scratch or damage the LEDs or photodiode covers in any way.

## ***Troubleshooting Guidelines***

### **Green status light does not come on when battery is inserted:**

- Battery installed in wrong orientation. Reinstall.
- Battery power low. Replace battery.
- Tracker damaged. Return for service.

### **Green status light flashes rapidly when battery is inserted:**

- Tracker defective. Return for service.

### **Green status light illuminates continuously:**

- Battery power low. Replace battery.

### **Tracker cannot be initialized:**

- LEDs are not facing Navigation System camera. Ensure that LEDs are facing Navigation System camera. Retry.
- Battery power low. Replace battery.
- LEDs or photodiodes damaged. Return for service.

### **Navigated Instrument cannot be validated using the nGenius Universal Tracker:**

- LEDs are not facing Navigation System camera. Ensure the LEDs are facing Navigation System camera. Retry.
- Instrument tip damaged or bent. Replace by another instrument. Return the broken instrument for service.
- Incorrect instrument selected. Compare the reference number displayed on the monitor with the number on the selected instrument.

### **Communication with the system fails after Navigation software is restarted:**

- Remove and reinsert battery. Reinitialize tracker.

### **Sporadic electrical interference is experienced:**

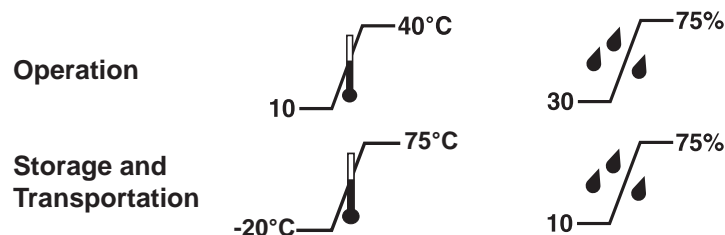
- Electrical noise present. Turn off all electrical equipment not used in the operating room. Relocate electrical equipment; increase spatial distance. Plug equipment into different operating room outlets.

### **Line of sight between tracker and camera is interrupted:**

- Message on the system monitor: - NOT VISIBLE - Remove obstruction and system will resume communication.

## Specifications\*

**Model:** REF 6000-014-000 nGenius Universal Tracker  
**Size:** 74.2 mm [2.92 in] length, 46.2 mm [1.82 in] width, 36.1 mm [1.42 in] height  
**Weight:** 49 g [1.73 oz] without Instrument Battery  
**Material:** Titanium (electronics housing), PPSU (battery holder, front cover, SELECT button), stainless steel (interface release button)  
**Power supply:** 3V  $\equiv$ , internally powered (lithium battery)  
**Enclosure protection:** IPX0 Ordinary Equipment  
**LED classification:** Class1, IEC 60825-1 Edition 1.2 2001-08, Safety of Laser Products Part 1: Equipment Classification Requirements and User's Guide



**RF-ID operating frequency:** 125 kHz

## Cleaning and Inspection Instructions      Sterilization Instructions\*

Only use the manual cleaning method. *Refer to the Guide for Cleaning and Steam-Based Sterilization REF 6000-005-750 for cleaning safety and caution notes, cleaning equipment as well as detailed cleaning and inspection instructions.*

Only use the Sterrad® Sterilizer. Follow the Sterrad® protocol instructions.

Do not steam sterilize.

**For the nGenius Universal Tracker follow the procedure for *Manual Cleaning and Disinfection of Instruments with Electronics* as described in section 5.**

The nGenius Universal Tracker is a Cleaning Group IV instrument as defined in the *Guide for Cleaning and Steam-Based Sterilization*.

\* Specifications listed are approximate and may vary slightly from unit to unit.

## **Function and Features**

### **SELECT Button**

- Press for tracker initialization or software function selection when tracker is initialized.

### **Validation Disk**

- Use to validate other navigated instruments.

### **Interface**

- Use to attach the tracker to devices fitted with a generic interface pin.

### **Release Button**

- Press to attach devices to the interface and detach from the interface.

### **Green Status Light**

- Flashes rapidly during tracker initialization.
- Flashes every few seconds during normal operation.
- Illuminates continuously if battery power is low.

### **Battery Holder**

- Designed to hold the Instrument Battery REF 6000-006-000.

### **Infrared Light Emitting Diodes (LED)**

- Emit infrared signals that are received by the Navigation System camera for position tracking and wireless communication.

### **Photodiodes**

- Receive infrared signals sent from the Navigation System camera for wireless communication.

### **Automatic Device Identification**

- The interface contains a sensor for automatic identification of devices with generic interface pins equipped with an RF-ID transponder.

## **Regulatory Compliance (US and Canada)**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

### **FCC Statement**

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.

*Please also refer to the Declaration of Conformity in accordance with the Radio and Telecommunications Terminal Equipment Act (FTEG) and Directive 1999/5/EC (R&TTE Directive) provided with this device.*

## Instructions

### 1 Install Battery

- Remove Instrument Battery REF 6000-006-000 from the sterile package.
- Just prior to surgery, load the battery into the battery holder, pressing in the negative end first **(1)** and then the positive end **(2)** against the spring. See *figure 2*.
- The green status light lights up for 2-3 seconds to indicate that the tracker is operative. Then, the light turns off.

### 2 Initialize Tracker

- Align the tracker in such a way that the LEDs are facing the camera.
- Once in system setup mode and prompted by the software interface, press the SELECT button **(3)** to initialize the tracker (see *figure 2*).
- The status light flashes rapidly during initialization. When initialization is complete, the light stops flashing.
- Release the SELECT button.
- Once initialized, verify that the status light flashes every 2-3 seconds and the software recognizes the tracker.

### 3 Attaching the nGenius Universal Tracker to a Device with Generic Interface Pin

The nGenius Universal Tracker is compatible to devices fitted with generic interface pins with **(a)** and without **(b)** an RF-ID transponder as shown in *figure 3*.

To attach or detach the tracker follow the visual instructions in *figure 4*.

### 4 Using the nGenius Universal Tracker to Validate Navigated Instruments

- Initialize both the nGenius Universal Tracker and the navigated instrument.
- Aim the LEDs of both the nGenius Universal Tracker and the navigated instrument towards the Navigation System camera and follow the instructions in *figure 5*.

## Symbol Definitions



**Precautionary  
Information**



**Type BF**

**Applied  
Part**



**Battery**

**+ Positive Terminal**



**CSA International**

CAN/CSA-C22.2 No. 601.1-M90

UL 60601-1

IEC 60601-1



In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste. The product should be collected separately. Refer to your local distributor for return and/or collection systems available in your country.

**CE** corresponds with the Directive 93/42/EEC  
corresponds with the Directive 1995/5/EC



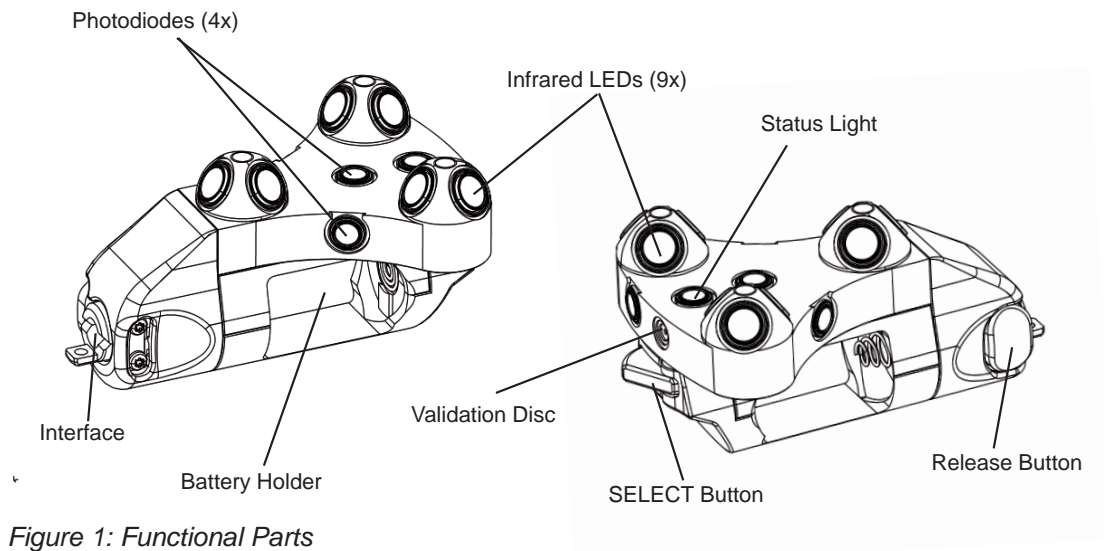


Figure 1: Functional Parts

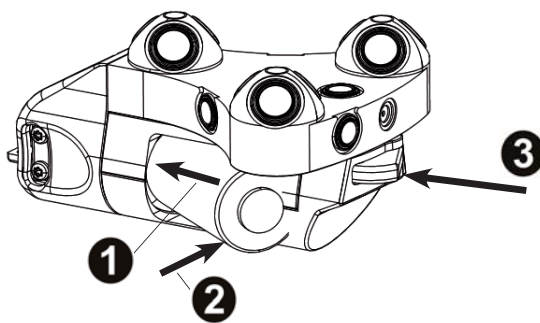


Figure 2: Battery Installation

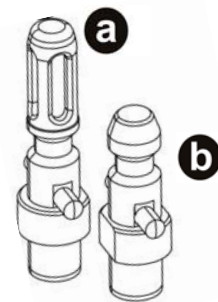


Figure 3: Generic Interface Pins

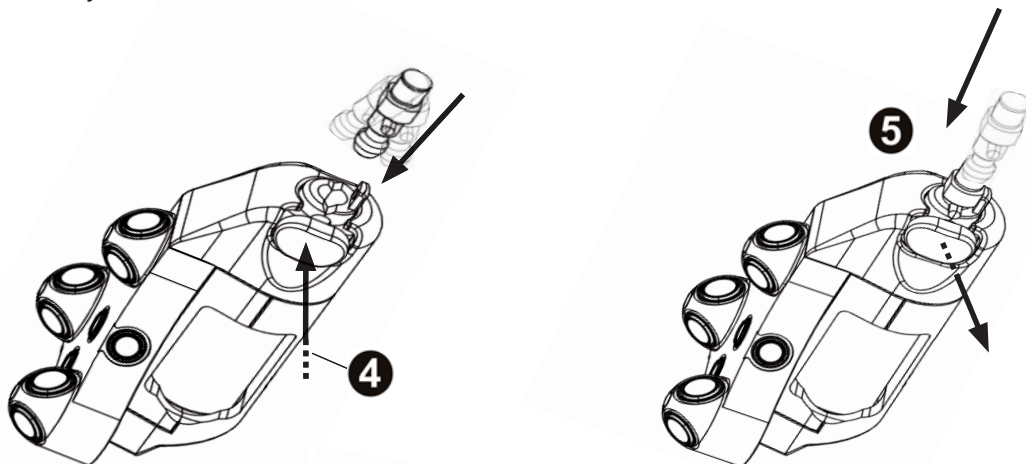


Figure 4: Attaching Tracker to a Device with a Generic Interface Pin

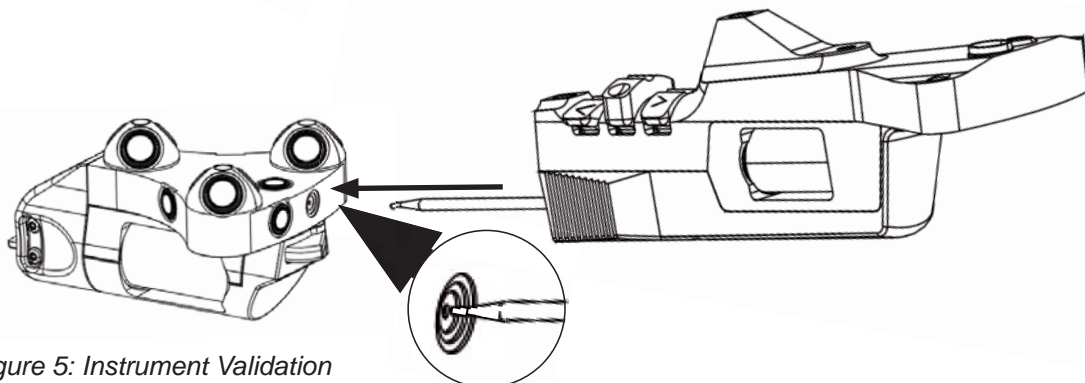


Figure 5: Instrument Validation