

	NGS User Manual Module I: Hardware	Document No.	LB-0194-00 RL
		DCO-000197	Rel. Date: See Arena

Neocis Guidance System (NGS) User Manual

Module I: Hardware



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1 General Information for the User

1.1 Explanation of Warning Symbols Provided in the Accompanying Documents



Safety warnings appearing through this User Manual are marked with this symbol.

1.2 Important Information



The NGS may only be used in accordance with local regulations and by qualified practitioners (user's) who fully observe the operating instructions and have the required technical training.



Rx Only: Federal law restricts this device to sale (or use) by or on the order of a qualified practitioner (user) (Per 21 CFR 801.109 Prescription Devices).

1.3 Safety Measures



This manual shall be followed to ensure the protection of the patient.



The safety, reliability and performance of the equipment can be assured only if:

- Installation, adjustment, maintenance, modification, and service are performed by Neocis Inc. personnel, or persons authorized by Neocis Inc.
- The electrical installation of the facility where the device is installed meets the appropriate regulatory requirements.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- The Equipment is used as specified in the User Manual.
- Where specified in the User Manual, only Neocis supplied spare parts and accessories are to be used.

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1.4 User Assistance Information

For any inquiries associated with the Neocis Guidance System, or to report any problems or issues, please email support@neocis.com, or contact the following customer assistance line: 855-9NEOCIS.

1.5 Cleaning and Disinfection Methods

All external parts of the system such as monitors, laptops and cart should be cleaned by wiping with an EPA registered disinfectant wipe such as Sani-Cloth®AF3 Germicidal Disposable Wipes (EPA# 9480-6). Excess cleaning liquids should be wiped off with a soft cloth.

Cleaning, disinfection, and sterilization methods are described in greater detail in Section 7



Avoid spilling liquids into the surface of the device during cleaning/disinfecting. This may cause damage to the device. Always use proper draping.

1.6 Explanation of Figures, Symbols, Warning Statements and Abbreviations on the Equipment

I/O	Mains switch ON / OFF
	Safety Warning! Consult the accompanying documents.
	Degree of protection against electric shock - Applied Part Type BF
	Manufacturer / Date of Manufacture
	Consult Instructions for Use
	Refer to Instruction Manual / booklet
	Keep dry
	To ensure that the user is aware of a potential pinch hazard.

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Ensure safe movement of NGS over a threshold.



Do not use for more than one patient.



Catalog Number or Reference Number



Batch Code or Lot Number



Serial Number



Indicates a medical device that has not been subjected to a sterilization process.



Do not use if package is damaged



Federal (USA) law restricts this device to sale by or on the order of a physician.

Caution: Valence Warning

Despite having wheels, this equipment is not intended to be moved throughout building as part of its normal operation. As such this device may not be able to pass over thresholds or obstacles greater than 20 mm. The wheels are generally intended to facilitate movement of the device to position it at the patient and move away from the patient when operation of the device is completed, within the room where therapy is provided.

Despite having wheels, this equipment is not intended to be moved throughout a building as part of its normal operation. As such this device may not be able to pass over thresholds or obstacles greater than 20 mm. The wheels are generally intended to facilitate movement of the device to position it at the patient and move away from the patient when operation of the device is completed, within the room where therapy is provided.



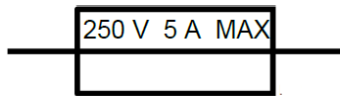
Transport Only In Stowed Position

Transport Only in the Stowed Position



Applied Part

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Fuse rating shall not exceed 250 Volts and 5 Amps



Tipping Hazard

WARNING!
Tip over hazard



Emergency Stop



Do Not Push



Push

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2 Connection To Specified Compatible Equipment

The NGS shall only be coupled with an Aseptico Drill Motor (Aseptico Part # AEU-7000LNE-70V), and the 20:1 Mont Blanc Implant Handpiece (Aseptico Part # AHP-85MBFO-CX). Please refer to LB-1007 NGS User Manual Module III: YomiPlan 2.4 Surgical Technique for instructions regarding use of the Aseptico motor with the NGS. Please refer to Aseptico's website (<https://aseptico.com/resources/aseptico-manuals/>) for further instructions regarding the cleaning, sterilization, and use of the Aseptico equipment.

3 Technical Specifications for Hardware

Technological Characteristic	Neocis Guidance System
Supply Voltage	120 V
Phases	1
Type of Current	AC
Rated Frequency (Hz)	60 Hz
Rated Power Input (VA)	600 VA
Types of Ratings and of external accessible fuses	5.0 A for 240 V
Type of Protection against Electric Shock	Class I Equipment
Degree of Protection against Electric Shock	Type BF
Equipment Suitable for use in the presence of Flammable Mixtures	No
Fluid Ingress	IPX0
Mode of Operation	Continuous Operation
System Lateral Accuracy	RMS < 1mm
System Depth Accuracy	RMS < 1mm
System Angular Accuracy	RMS < 6.0°
CT Scan Requirements	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512x512, Full 13 cm 21 sec, Multi 2 DICOM format.
F/T Sensor Force Measurement Range	+/- 30 N
F/T Sensor Torque Measurement Range	+/- 2 Nm
F/T Sensor Single Axis Force Overload Limit	200 N
F/T Sensor Axis Torque Overload Limit	20 Nm
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s
Storage Requirements	Store powered at Room Temperature (68°F to 76°F or 20°C to 24.4°C) and standard ambient humidity (5% to 95%) in a dust free, clean environment.

F/T indicates force/torque

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3.1 Storage Instructions and Environmental Conditions for Transport and Storage

The NGS is portable and is capable of being stored.

- Ensure that the patient tracking arm is in the proper rest position.
- Ensure that the Guidance Arm is in the proper rest position.
- Return all supporting cart components (Monitor Arm, Lap Top Base) to the proper rest position.
- Store the system with the wheel brakes engaged.
- Store and operate the system in room temperature, standard ambient humidity (5% to 95%) and a dust free, clean environment.
- Transport the system in a temperature range between 0°C and 46°C (32°F and 115°F).
- The system cannot be transported from facility to facility without notification of Neocis Inc. Please notify Neocis Inc. for transfer of the system from facility to facility.

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4 Information For Clinician Concerning the NGS

4.1 Indications for Use

The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

4.2 Contraindications

- The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Neocis YomiLink rigidly throughout a surgical procedure (refer to LB-0191 and LB-0253 User Manual Addendums for additional information on the indications, contraindications, warnings, and instructions for the YomiLink's).
- The Neocis YomiLink Teeth should not be attached to patients that exhibit:
 - Periodontal disease to include loose teeth and inflamed tissue
 - Fixed orthodontic appliances, bridges, and/or dental implants
 - Patients with a history of jaw or TMJ pain
 - Patients with allergies to methyl methacrylates
- The YomiLink Bone should not be used in patients with insufficient bone quality for fixation of the YomiLink Bone and patient tracker loading.
- The YomiLink Bone should not be used in patients with a history of jaw or TMJ pain.

4.3 Caution

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in procedural complications or patient harm.

4.4 Warnings

- Neocis Inc. has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the Neocis Guidance System (NGS) in applications other than the preparation of sites for placing dental implants.
- Sufficient teeth and underlying bone are necessary for rigidly maintaining a link in the patient's mouth. Any movement of a link relative to the rest of the mouth may lead to inaccurate preparation of the implant site.

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- The NGS is intended only to be used following installation qualification by a trained Neocis Inc. professional. The device is not to be used in an unqualified manner.
- All users must be properly trained, following approved Neocis Inc. training materials, prior to use.
- All assembly, adjustment, modification, or repairs associated with the NGS shall only be performed by a trained Neocis Inc. representative.
- Do not touch the patient and other electrical equipment simultaneously when operating the device.
- Preplanning cases with the NGS requires verification of the plan upon uploading to the NGS planning station prior to performing the procedure on the patient. Always use best clinical judgement.
- Corrupted or inaccurate plans should be discarded and replanned.
- Only the dental materials listed in the Neocis User Manual Addendums for the selected YomiLink should be used (refer to LB-0191 and LB-0253)
- Dental material may flow into undercuts.
- Refer to the specific Neocis User Manual Addendums for each YomiLink for additional warnings (refer to LB-0191 and LB-0253)



The NGS is not intended for use in an MR environment, and has not been evaluated for use with RF emitting devices such as diathermy, RFID and electromagnetic security systems (metal detectors and EAS systems).

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4.5 Precautions

- The Neocis Guidance System (NGS) should only be used by qualified practitioners trained in the placement of dental implants at facilities properly equipped for such procedures.
- Prior to using the NGS to guide drilling, check the integrity of the system by using anatomical landmarks for verification. Touch the drill tip to a distinct anatomical landmark and verify that the visualization on the screen matches.
- The device is intended to be used with a single phase 120VAC 60 Hz Mains power source. Do not attempt to use the device with any other power source.
- The device is not designed to protect against ingress of solid foreign objects, or liquids (IPX0). Do not attempt to spray or wipe the device with any liquid or wet media.
- The device is only designed to be used on a hard, flat, stable surface.
- When transporting and stowing the system, use proper handles.
- Ensure that the device is positioned in such a manner that the Device Power Cord is accessible during normal operation.

4.6 Adverse events

The following adverse events are possible:

- Inaccurate implant site preparation, resulting in suboptimal tooth placement or patient harm.
- Injury to user or patient due to uncontrolled or unintended motion of the system.
- Electric shock to user or patient due to electric malfunction.
- Misuse or off label use of the system that leads to manual manipulation of the osteotomy, resulting in patient injury or hazard to the user.

Neocis Inc. risk analysis documents reflect a complete description of potential adverse events. Although the system has been designed to mitigate all reasonably foreseeable risks, there is the possibility that unknown risks exist.

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5 Device Description and Workflow

The Neocis Guidance System (NGS) is a dental stereotaxic instrument that guides qualified practitioners during dental implant surgery. The system allows the user to plan the surgery virtually in software using a CT Scan of the patient, and the plan is used by the NGS to provide physical and visual feedback to the surgeon during the implant site preparation. The device includes a Neocis YomiLink that is placed on the patient prior to the CT Scan, and a fiducial array with fiducial markers that is placed on the YomiLink prior to the CT Scan so the virtual plan can be linked to the physical space of the system. The Guidance arm grips a standard dental drill from the back end, allowing the surgeon to grip the drill as normal. The Guidance arm does not move unless the surgeon applies a manual force to the drill. The arm will constrain the surgeon to drill according to the prescribed surgical plan, preventing deviation. The surgeon is constantly in control of the drilling. The system has a mechanical feedback system that is connected to the YomiLink on the patient, which relays information to the control software in order to track patient movement. If patient movement occurs during the surgical procedure, the system will respond by altering the prescribed surgical cutting angle and position to accommodate the patient movement, which will maintain the accuracy of the drill placement.

The NGS will include components such that the reusable portion of the system will be modular and self-contained. Disposable components of the system are single patient use only and are designed to maximize surgical accuracy and ensure patient comfort.

The NGS can be used for flapless dental implant procedures, which is a type of minimally invasive surgical approach.

5.1 Stepwise Process Overview

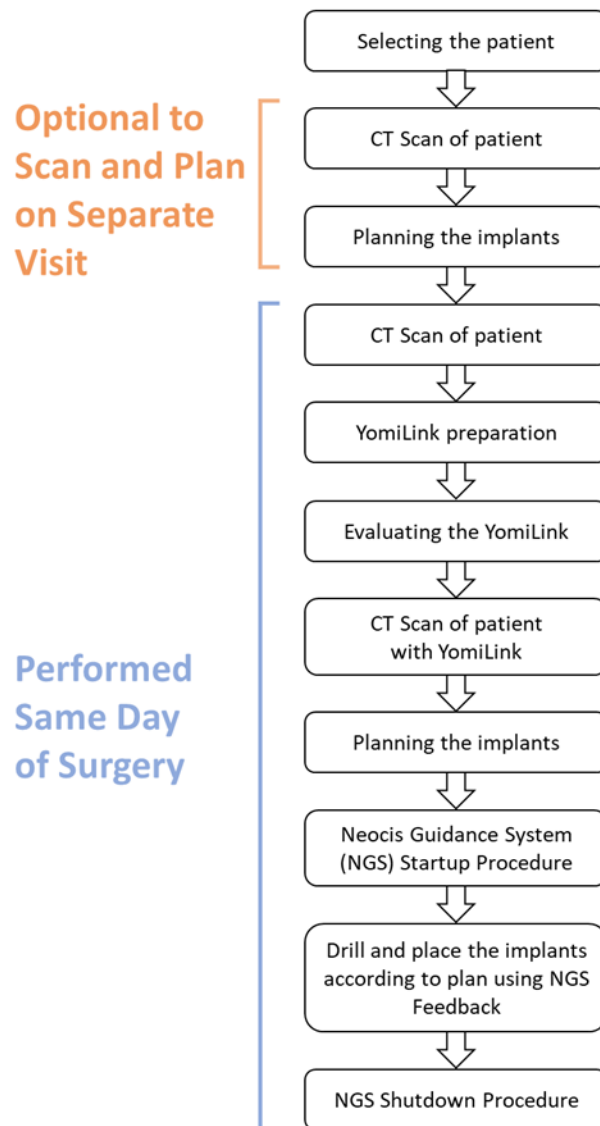


Figure 1: NGS Workflow

- Patient is examined by a trained qualified practitioner to ensure that the patient is eligible for dental implant surgery. The surgeon then determines if the patient has sufficient anchoring (teeth or bone) and if the patient's bone is sufficiently dense to provide a rigid fixation for the YomiLink. Select the appropriate YomiLink for the procedures so access to the surgical site is not blocked and ensuring the YomiLink is stable. The procedure may be planned ahead of time using the NGS planning station laptop.

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- The YomiLink is prepared chairside. The surgeon can prepare the YomiLink, using one of the dental materials cleared for use with the selected YomiLink. Apply the YomiLink to a section of the arch away from (or contralateral to) where the surgery is going to be performed prior to acquiring the CT Scan.
- The YomiLink is mounted on the patient at the proper location on the dental arch and evaluated.
- A Fiducial Array is mounted on the YomiLink and the patient undergoes a CT Scan.
- The CT Scan images are loaded into the YomiPlan application. The surgeon uses the anatomical images to plan the surgery.
- The NGS is started when the surgeon is ready to perform surgery.
- The NGS guides the surgeon through a series of modes that provide mechanical restriction and assists them in performing the osteotomy.
- Once the surgery is complete, the Patient Tracker is detached from the YomiLink and the YomiLink is unmounted from the patient. The NGS is then shutdown and returned to its storage location.

5.2 Use of the YomiLink Teeth

For patient's with sufficient anchoring (teeth) that are healthy and supported by bone sufficiently dense to provide a rigid fixation, the YomiLink Teeth is recommended. Please refer to LB-0253 YomiLink Teeth User Manual Addendum for additional instructions and information on the indications, contraindications, warnings, and use of YomiLink Teeth.

5.3 Use of the YomiLink Bone

Depending on the clinical situation, the YomiLink Bone may be used instead of the YomiLink Teeth. Please refer to LB-0191 YomiLink Bone User Manual Addendum for additional instructions and information on the indications, contraindications, warnings, and use of YomiLink Bone.

5.4 Use of the IntraOral Fiducial Array (IOFA)

Depending on the clinical situation, the IntraOral Fiducial Array (IOFA) may be used. Please refer to LB-0364 IntraOral Fiducial Array User Manual Addendum for additional instructions and information on the indications, contraindications, warnings, and use of the IOFA.

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6 Device Components, Controls and Indicators

6.1 Hardware Components



Figure 2: Neocis Guidance System Setup

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1. **Monitor:** Provides visibility of the NGS Software Application for the user during a procedure.
2. **Planning Station:** Used to execute the NGS Software Application for planning and surgery.
3. **Horizontal Stage:** Supports the Guidance Arm and is used to adjust the position of the Guidance Arm
4. **Cart:** Supports the NGS, provides mobility and locks in position with the foot brake lever.
5. **Guidance Arm:** Used to assist the surgeon in performing the surgery.
6. **Patient Tracker Arm:** Attached to YomiLink in order to track the patient position in real-time throughout the surgery. Includes a counter mass to minimize forces experienced by the patient due to the weight of the Patient Tracker after attachment to the YomiLink.

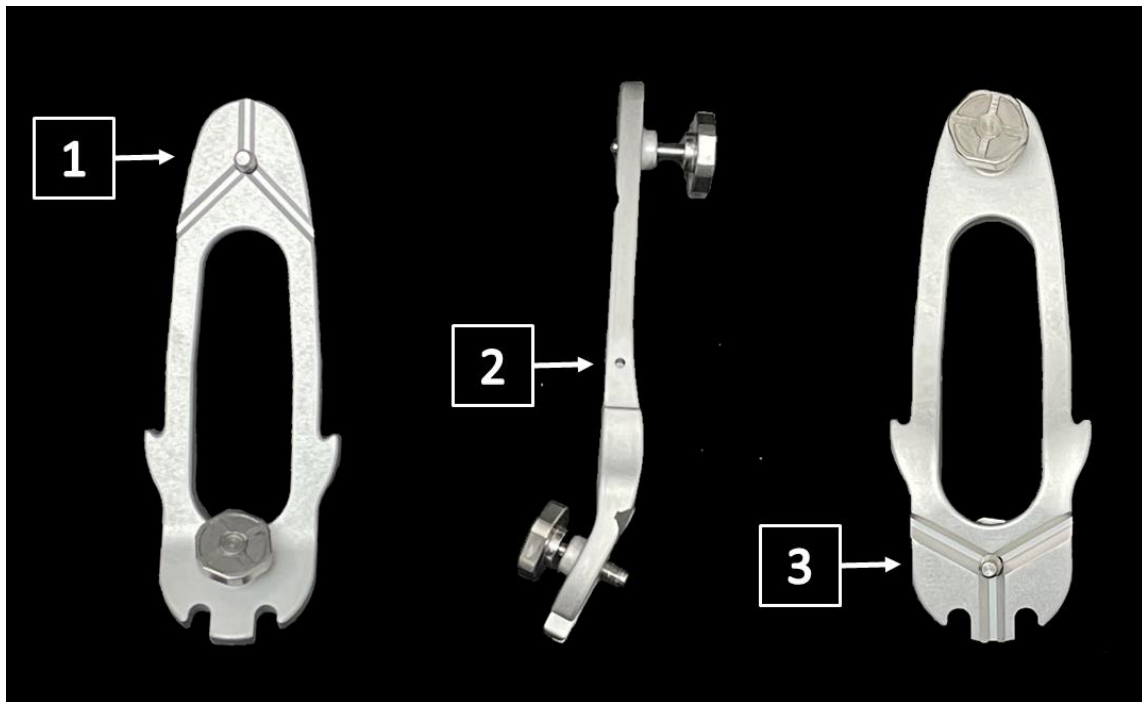


Figure 3: Patient Tracker End Effector

1. **End Effector Mount:** Used to properly orient the Patient Tracker End Effector to the YomiLink during surgery.
2. **Drill Face Calibration Divot:** Used while performing the Drill Face Calibration in combination with the Calibration Drill Bit.
3. **Tracker Mount:** Used to properly orient the Patient Tracker End Effector to the Patient Tracker during surgery.

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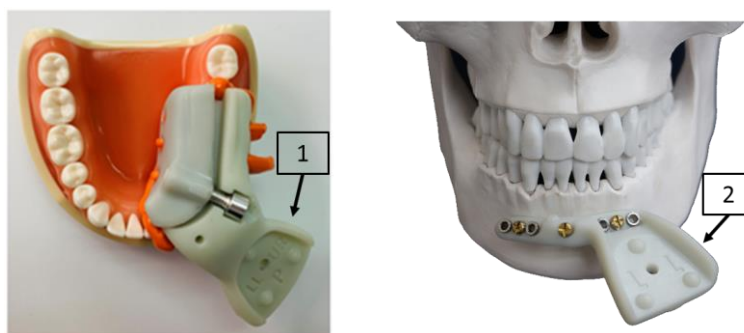


Figure 4: Patient Models with Mandibular YomiLinks

1. **YomiLink Teeth:** Mounts to the upper or lower patient arch in the posterior (shown) or anterior regions. Patient Tracker attaches to the YomiLink to monitor patient position.
2. **YomiLink Bone:** Mounts to the upper or lower patient arch. Patient Tracker attaches to the YomiLink to monitor patient position.



Figure 5: Instrument kit and small sterilize-before-use components

1. **Instrument Kit Box:** contains the smaller components for NGS usage. All these components, before their usage, must undergo pouched sterilization per the instructions provided in Section 7.2.3. The box is intended only for storage.
2. **Calibration Drill Bit:** used with the handpiece (Figure 9, #1), to collocate it with respect to the Drill Face Calibration Divot (Figure 3, # 2)
3. **Depth Gauge:** used to measure the depth of the drill bit currently put into the handpiece

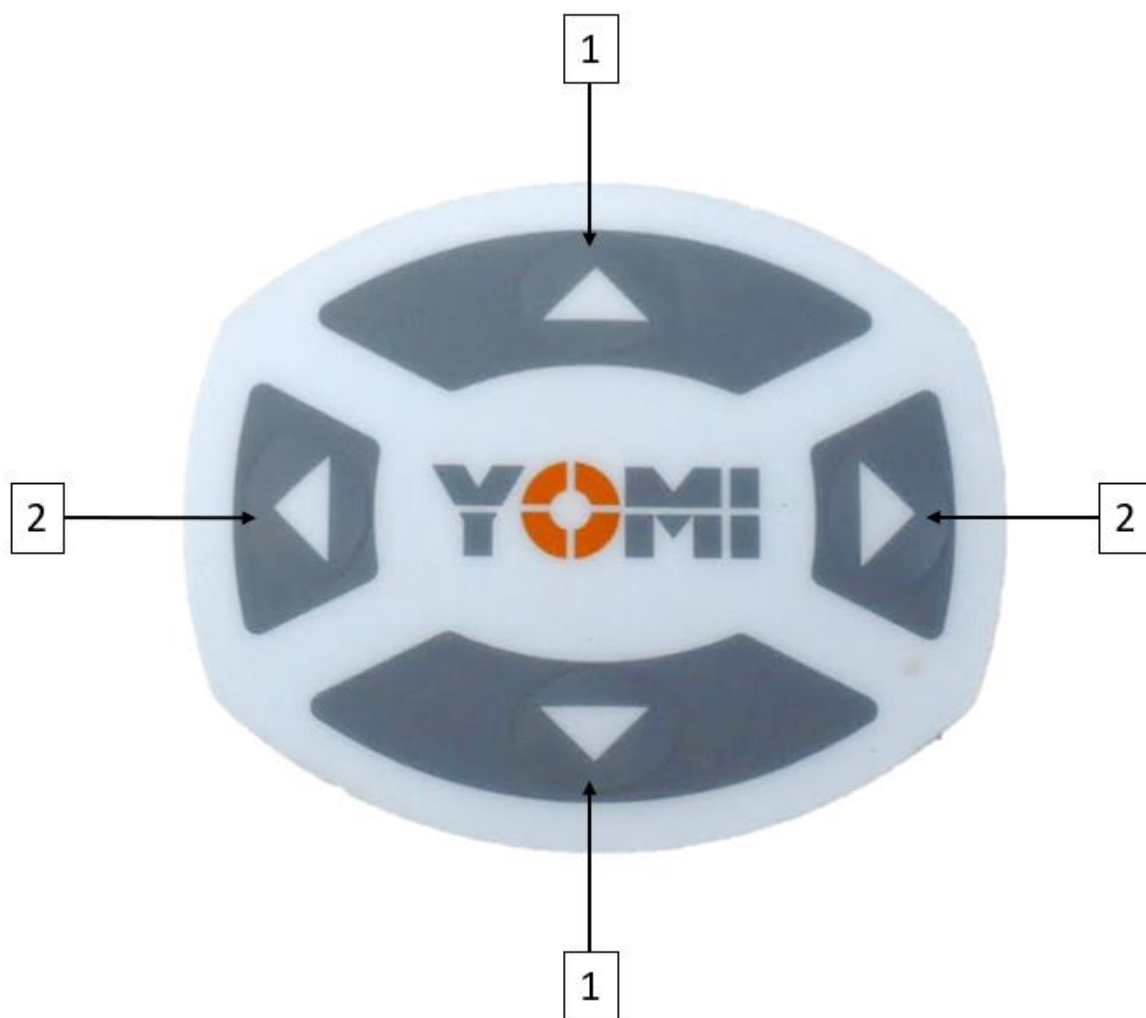


Figure 6: Switch pad used to adjust the position of the Guidance Arm with respect to the patient

1. **Vertical Buttons:** Buttons control the vertical motion of the Horizontal Stage.
2. **Horizontal Buttons:** Buttons control the horizontal motion of the Horizontal Stage.

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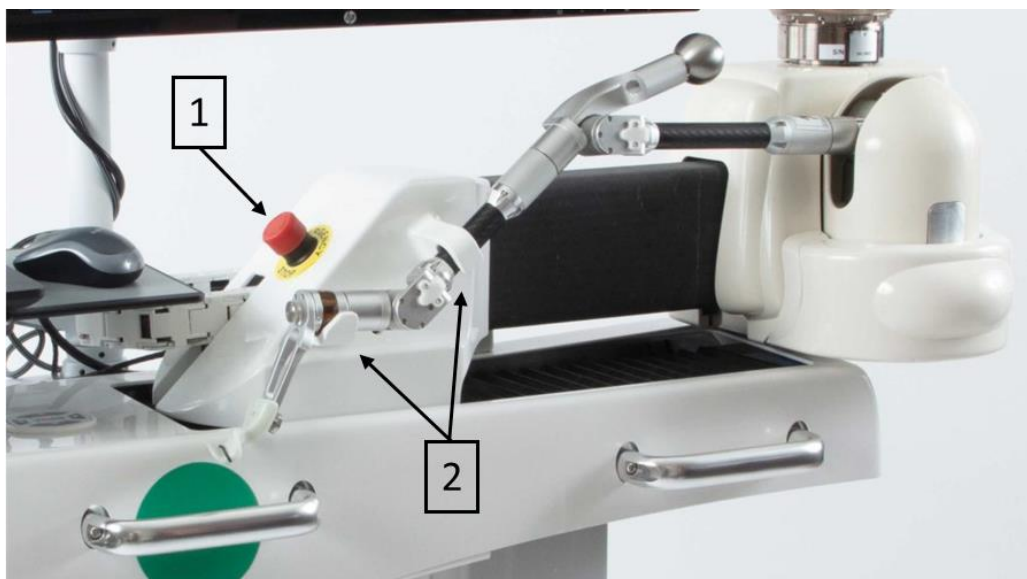


Figure 7: Neocis Guidance System Horizontal Stage and Emergency Stop Button

1. **Guidance Arm Emergency Stop (E-Stop):** Button to be pressed in the case of a robot-related emergency. Pressing the E-Stop will cut all power to the Guidance Arm, ceasing its motion.
2. **Patient Tracker Cradle:** Designed to support the tracker from both the top and bottom directions, and steady its position to prevent potential injury or damage to the system. Because the Patient Tracker is near “weightless,” when the Patient Tracker End Effector is attached the Patient Tracker may float if not stowed in cradle or if left unsecured to a YomiLink.
 - It is recommended to properly stow the Patient Tracker Arm into the cradle any time it is not in use.
 - Match the two flat white surfaces of the cradle and Patient Tracker to properly position (Figure 4a and 4b).

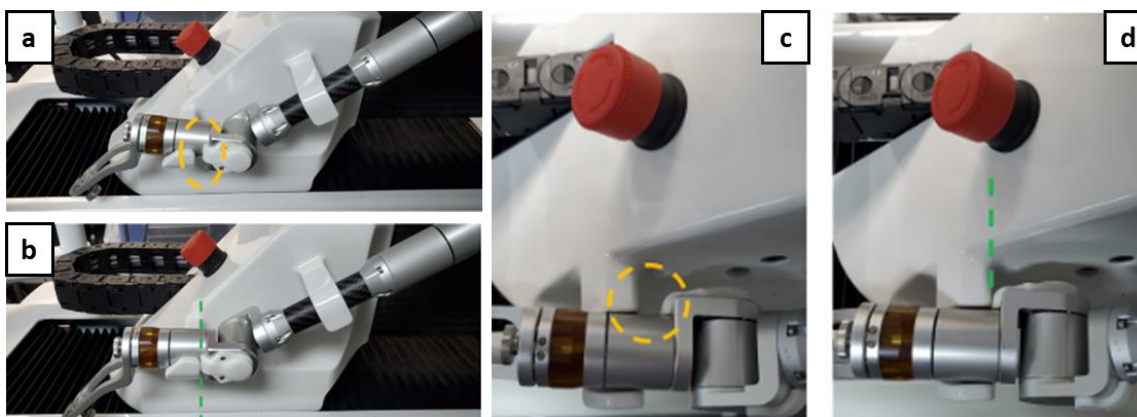


Figure 8: a) Side view illustrating the Patient Tracker not fully stowed in cradle; b) Side view illustrating the Patient Tracker correctly stowed in cradle. c) Top view showing incorrect stowage (note the two white pieces are not resting beside one another). d) Top view showing correct Patient Tracker stowage.

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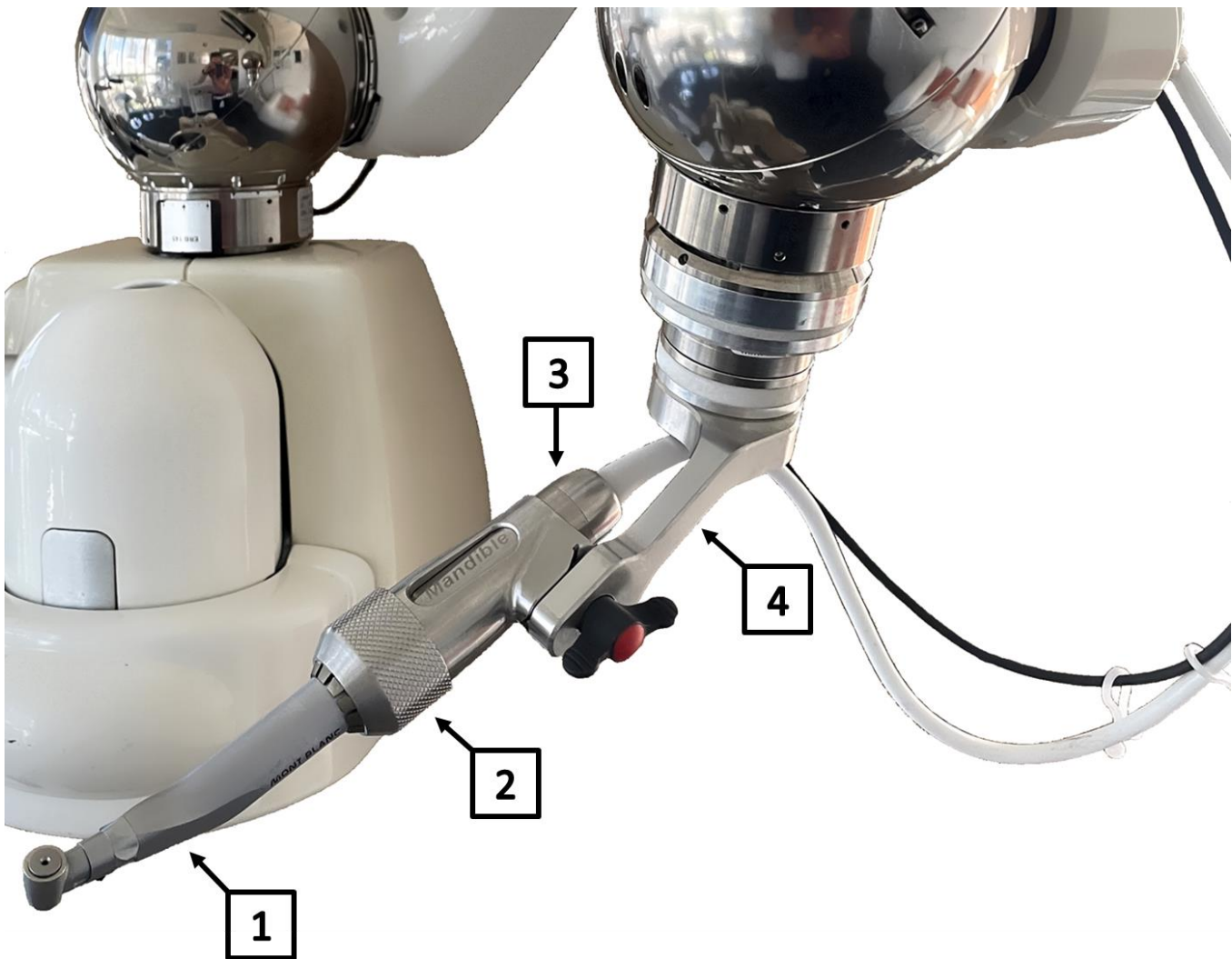


Figure 9: Guidance Arm End Effector

1. **Drill Handpiece:** Holds the Drill Bit and is used by the surgeon to perform surgery.
2. **Drill Collar:** Used to secure the handpiece to the Drill Collar
3. **Drill Motor:** Powers the motion of the Drill Bit for surgery. The Drill Motor is housed in the Drill Collar which is mounted to the Drill Bracket.
4. **Drill Bracket:** Connects the Drill Motor to the Guidance Arm.

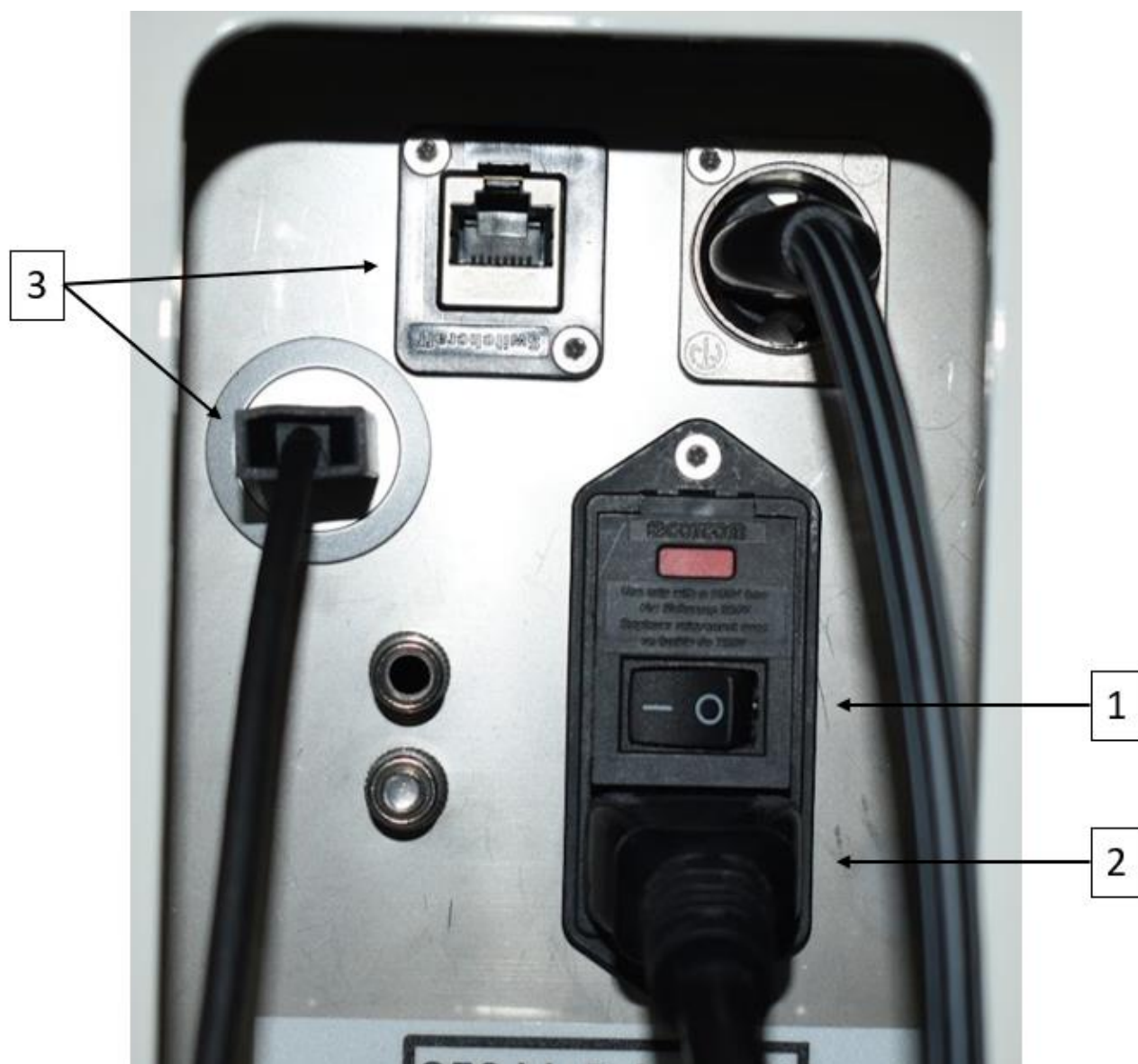


Figure 10: Electrical Panel

1. **Power Entry Module Power Switch:** Switches off external power from the outlet to the system
2. **Power Entry Module Power Cord:** Connects the system to an external 120 V/60 Hz power outlet
3. **Diagnostic service ports:** Ethernet and directional HDMI for service use only

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6.2 Initial Preparations

Following patient selection, a Neocis YomiLink must be prepared and a CT scan must be performed. For instruction for YomiLink selection, mounting and evaluation prior to scan, refer to the individual YomiLink User Manual Addendum. Below are instructions for selecting the fiducial array and performing the CT scan.

6.2.1 Selecting and mounting the appropriate Fiducial Array

The Fiducial Array is a fixture that is used to accurately locate patient anatomy in the CT Scan image. It defines the frame of reference in the DICOM image that is used to register the location of the patient anatomy. The Fiducial Array corresponds directly to the type of YomiLink being used; a LLUR YomiLink requires an LLUR Fiducial Array, and an LRUL YomiLink requires an LRUL Fiducial Array.

The Fiducial Array has built-in kinematic mount features to attach to the YomiLink and therefore has only one correct orientation. The YomiLink has a saddle that accommodates the Fiducial Array, and provides guidance for correct attachment.

1. Ensure the Fiducial Array that corresponds to the rigidly mounted YomiLink is selected.
2. Orient the Fiducial Array so the rollers on Fiducial Array line up with spheres on the YomiLink mount. This will ensure the thumbscrew lines up with threaded hole on the YomiLink. See Figure 11 for reference.

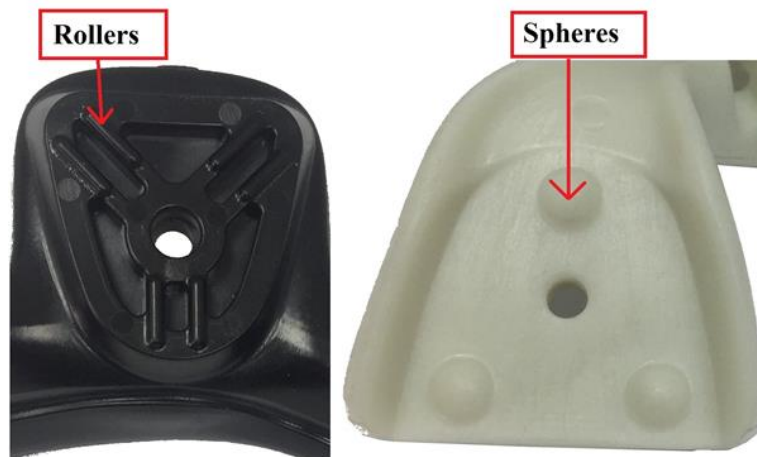


Figure 11: [Left] Rollers on Fiducial Array kinematic features. [Right] Spheres on YomiLink kinematic features

3. Tightly secure thumbscrew until there is no play between the Fiducial Array and the YomiLink.
4. The Fiducial Array sits outside of the patient's mouth and allows for acquisition of the fiducial markers in the CT Scan as shown in Figure 12.

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It is important that the Fiducial Array is properly mounted and there is no movement between the YomiLink and Fiducial Array. Failure to properly attach the Fiducial Array can result in a loss of system accuracy.



Figure 12: [Left] LRUL Fiducial Array on Anterior YomiLink Teeth. [Right] LLUR Fiducial Array on Anterior YomiLink Teeth.

6.2.2 CT Scan



Take a CT Scan of the patient following the instructions provided in Section 6.3.

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6.3 CT Scan Protocol

The CT Scan is to be performed with the YomiLink attached to the patient and the Fiducial Array mounted to the YomiLink. The following instructions provide the appropriate steps to ensure that the CT Scanned image has met the NGS CT Scan requirements.

Set up the CT Scanning Device with the following settings and acquire a CT Scan:

- 0.3 mm voxel (maximum setting)
- 0.3 mm slice thickness (maximum setting)
- Matrix 512 x 512
- 11 cm diameter FOV (minimum setting) - If using the IntraOral Fiducial Array (IOFA), refer to LB-0364
- Use multi-frame DICOM format for saving file

NOTE: All scanners are qualified by Neocis prior to acquiring patient scans for use with the NGS system. For optimal scan acquisition, use the same settings used during scanner qualification. Contact customer support for any questions regarding a specific scanner's qualification settings.

Verify that the CT Scan meets the following criteria:

- Full anatomy of interest is captured (upper and lower arches if desired).
- All Fiducial Markers are captured completely.
- Anatomy and fiducial markers are clearly rendered.



If the voxel size and slice thickness is not within the recommended resolution (0.3mm), the software will generate a warning. There are two issues related to this suboptimal setting:

- 1. Pre-operative planning may be compromised. It is up to the qualified practitioner's discretion to judge the quality of the CT image for procedural planning. If the anatomy is not clear enough in the image to properly plan the implant position, it is recommended to not proceed with the current scan.**
- 2. Accuracy of image registration may be compromised**

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7 Cleaning, Disinfection, and Sterilization

All system parts and components should be cleaned, disinfected, and/or sterilized in a timely manner following each procedure. All steps below need to be completed in full as applicable for each component and part of the system. Ensure steps are completed sequentially and without delay between each step.

- Note – Neocis, Inc. does not recommend using lubricating agents (silicone or oil-based) on any of the accessories.
- Note – Should the user have any questions related to the cleaning steps described above, please contact a Neocis Clinical Representative or call Neocis at 1-855-963-6247.
- Note – Additional education/clinical guidelines (but not in lieu of the validated cleaning instructions listed above) for cleaning/reprocessing of medical devices are available at CDC.gov.

7.1 NGS Cleaning

All external parts of the system such as monitors, laptops and cart should be cleaned by wiping with an EPA registered moist (not saturated) disinfectant wipe such as Sani-Cloth®AF3 Germicidal Disposable Wipes (EPA# 9480-6). Avoid excess cleaning fluids. Wipe off any excess cleaning fluid with a clean dry cloth immediately.



Avoid spilling of liquids onto the surface of the device, or any component of the device during cleaning / disinfecting. This may result in damage to the device.

7.2 Device Preparation and Accessory Decontamination

7.2.1 Device Preparation

As indicated in LB-0256 NGS Custom Drape User Manual and LB-1007 NGS User Manual Module III: YomiPlan 2.4 Surgical Technique, ensure that all surfaces have been appropriately draped prior to the procedure. Upon completion of the procedure, dispose of all draping materials.

7.2.2 Instruments and Accessory Cleaning

These cleaning instructions are applicable to the accessories listed below. These cleaning instructions are applicable to parts that require sterilization and must be completed prior to executing the sterilization instructions. Cleaning prior to sterilization is not required for single use components (i.e., the YomiLinks).

- Calibration Drill Bit
- Drill Collet
- Depth Gauge
- Patient Tracker End Effector (including thumbscrews)
- Fiducial Array (including thumbscrews)

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Instructions

Required Accessories for Cleaning:

- Enzol[®] enzymatic detergent
- Syringe
- Spectrum M16 soft bristle brush
- Sonication unit
- ValSure[®] Neutral detergent
- Disposable lint-free cloths
- Filtered pressurized air to thoroughly dry components

Cleaning Set-Up:

- Disassemble components which are comprised of multiple removable parts (thumbscrews from patient end-effector, fiducial array)
- At point-of-use as an initial cleaning step, remove any visible soil/organic components.
- Inspect any device for signs of degradation. Check for deterioration such as corrosion, discoloration, pitting, cracks, missing beads, and/or excessive wear. If you notice any degradation, contact a Neocis clinical representative and complete the necessary cleaning and/or sterilization steps. Any components that need to be replaced should be returned to Neocis and a replacement component will be provided.

Cleaning Steps:

1. Rinse the accessories under cold running tap water to remove gross soil and/or organic material.
2. Prepare Enzol[®] enzymatic detergent as per the manufacturer's recommendation at 1 oz/gal of lukewarm tap water.
3. Immerse the accessories into the prepared detergent solution and use a syringe to flush hard to reach areas (e.g. holes, crevices, recesses, etc.) with the detergent solution.
4. Soak the accessories for at least 1 minute.
5. Use a soft bristle brush (Spectrum M16) to clean each accessory thoroughly of any soil and/or organic material. Pay extra attention to hard to reach areas. Use a syringe to flush hard to reach areas with the detergent solution.
6. Remove the accessories from the prepared detergent solution and thoroughly rinse under running tap water for at least 1 minute per accessory. Use a syringe to flush hard to reach areas with tap water.
7. Prepare ValSure[®] Neutral detergent per manufacturer's recommendation at oz/gal of lukewarm tap water in a sonication unit.
8. Immerse the accessories together into the prepared detergent solution and sonicate for 10 minutes.
9. Remove the accessories from the sonication unit and thoroughly rinse under running tap water for at least 1 minute per accessory. Use a syringe to flush hard to reach areas with tap water.

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10. After sonication, dry the accessories thoroughly using disposable, lint-free cloths. Use filtered pressurized air to aid drying completely.
11. Visually inspect each accessory and repeat the previous steps if soil is visible on the accessory. If you notice any degradation upon inspection, contact a Neocis clinical representative and complete the necessary cleaning and/or sterilization steps. Any components that need to be replaced should be returned to Neocis and a replacement component will be provided.

7.2.3 Sterilization

Setup

Pouch the following accessories separately using Cardinal Health self-sealed pouch CAT #92510 - 510(k) K062704. All parts (excluding single use disposables such as the YomiLinks) must be cleaned prior to sterilization following the instructions in Section 7.2.2 above.

- Neocis YomiLink
- Calibration Drill Bit
- Depth Gauge
- Patient Tracker End Effector (including thumbscrews)
- Fiducial Array (including thumbscrews)

Sterilization Parameters

The following are the parameters to use while performing sterilization.

- Sterilizer Type: Prevacuum
- Preconditioning Pulses: 4
- Minimum Temperature: 132°C
- Full Cycle Time: 4 minutes
- Minimum Dry Time: 30 minutes

Due to the materials and form of the accessories, repeated Sterilization will have little to no effect on the intended function of the device. If the user notices a degradation of the intended performance of the accessory, contact a Neocis clinical representative and complete the necessary cleaning and/or sterilization steps. Any components that need to be replaced should be returned to Neocis and a replacement component will be provided.

The YomiLink is to be used for 1 patient only. Following completion of the patient's treatment, the YomiLink should be disposed. The YomiLink is composed of biocompatible materials and is provided non-sterile.

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Do not use a YomiLink for more than one patient.

7.2.4 Aseptico Equipment

For cleaning and sterilization of the Aseptico equipment Refer to the Aseptico AEU-7000L-70V and AEU-7000L Operation and Maintenance Instruction Manual for instructions on the proper cleaning, disinfection, and sterilization of the Aseptico Handpiece and the Aseptico Irrigation Tubing.

8 System Maintenance, Calibration, and Inspection

The user is not permitted to perform routine maintenance, preventive maintenance, or corrective actions on the system. All repairs, replacement, or preventive maintenance and calibration activities other than those explicitly described as part of the procedure in this document will be performed by a Neocis Inc. representative on a regularly defined interval. The following table provides instructions for user inspection activities, and intervals.

Inspection	Interval
Inspect connection between YomiLink and Tracker	Each Procedure
Inspect Patient Tracker End Effector for damage or dirt, clean if necessary.	Daily
Inspect Guidance Arm End Effector for damage or dirt, clean if necessary.	Daily
Verify System Accuracy by performing anatomical check	Each Procedure
Inspect the Guidance Arm end effector for rigidity/stability of drill bracket and drill handle mounting.	Each Procedure

9 Instructions on Related Devices

Only use the NGS system with the approved drill system. Follow all instructions for use provided with the drill system.

10 Definitions

Term	Definition
Application Software	Graphical User Interface (GUI) Application that is used for surgical planning and navigation of anatomical features during surgical execution.
Arch	Superior and inferior lines of permanent teeth curved in the row of the upper and lower jaw
Clipping Plane	A plane about which images can be removed.

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Control Software	Software intended to interface with the Application Software, Patient Tracking System, and Guidance System in order to coordinate movement
CT Protocol	CT Scanner settings that are optimal for use with Neocis Surgical Planning Application
DICOM	Digital Imaging and Communications in Medicine: A standard object oriented image and patient information file type.
Fiducial Marker	Standard Reference or measurement point accepted as a fixed basis of reference or comparison.
Guidance Arm	Arm used for providing mechanical guidance per surgical plan.
Mains Power	General purpose alternating current (AC) electric power supply for US / North America.
Patient Tracker	System intended to identify the location of the patient, relative to the Guidance Arm and surgical planning.
Spline	A series of points along the circumference of a 1/2 circle that is intended to be manipulated to fit the contour of the patient's arch.
YomiLink	A dental appliance secured to the patient, that is made stationary (by use of dental material adhesive or bone screw) and is intended to be a rigid support structure for placement of the Patient Tracker and Fiducial Array.
Stereotaxic	Surgical method for location of points within a patient anatomy using external, three-dimensional frame of reference usually based on the Cartesian Coordinate System
End Effector	Dental instrument and attachments connected to the Guidance Arm of the NGS used to perform dental implant procedures

11 Patents and Trademarks

This product and / or its use are covered by one or more of the following United States Patents: US 8,808,000 B2. Other U.S. patents pending. Foreign patents pending.

12 Electromagnetic Compatibility (EMC) Information

The following section provides details regarding the manner in which the NGS complies with EN 60601-1-2: Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests. The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The essential performance of the system is "maintain guidance during drilling for dental implant surgery."



Medical Electrical Equipment (NGS) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

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Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NGS YOMI. Including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



There are certain RF emitters which are not covered under the NGS compliance to IEC 60601-1-2 regarding EMC. These include radiofrequency identification (RFID) readers, electronic security systems, near-field communication (NFC) systems, wireless power transfer (WPT) and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. Do not use these RF emitters in the vicinity of the NGS as this may result in electromagnetic interference and impact the overall performance of the NGS. The user might need to take mitigation measures, such as relocating or re-orienting the equipment if this is not possible.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Neocis Guidance System (NGS) is intended for use in the electromagnetic environment specified below. The customer or the user of the Neocis Guidance System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The NGS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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Guidance and manufacturer's declaration – electromagnetic immunity			
The NGS is intended for use in the electromagnetic environment specified below. The customer or the user of the NGS should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 500 mS 70 % U_T (30 % dip in U_T) for 100 mS <5 % U_T (>95 % dip in U_T) for 5000 mS	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NGS requires continued operation during power mains interruptions, it is recommended that the NGS be powered from an uninterruptible power supply or a battery. The NGS comes equipped with a UPS internal to the system cart, and should be powered directly from the mains.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – electromagnetic immunity			
The NGS is intended for use in the electromagnetic environment specified below. The customer or the user of the NGS should assure that it is used in such an environment.			
Immunity test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the NGS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.33\sqrt{P} \text{ 800 MHz to 2,5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NGS is used exceeds the applicable RF compliance level above, the NGS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NGS.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the NGS			
The NGS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NGS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NGS as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

13 Wireless Coexistence

The wireless communication links for the NGS can coexist with an IEEE 802.11n network as the interfering network operating at maximum throughput and maximum transmit power when a separation distance of 5.6m is maintained between the NGS and the companion device. Wireless coexistence testing was successfully performed to ANSI C63.27-2017 and AAMI TIR69:2017.

The following section provides details regarding Wireless Coexistence and the wireless technology employed in the NGS.

- Wireless Technology:
 - 2.4 GHz ISM Band
 - Transmit power < 20dBm
 - Receiver Sensitivity Range for 11n: -74dBm/-94dBm
 - 5 GHz UNII and ISM Bands
 - Transmit power < 23dBm
 - Receiver Sensitivity Range for 11n: -73.5dBm/-94dBm
- Highest Frequency Generated or Used in NGS
 - 5 GHz
- Lowest Frequency Generated or Used in NGS
 - 60 Hz
- The NGS is a Class A Digital Device to be used in commercial, industrial, or business environments

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- Power source for the NGS:
 - AC: Single Phase, 120 V, 60 Hz
- Other wireless products able to connect to NGS wireless network:
 - Imaging scanners
 - Desktop computers
- Wireless Functions
 - The NGS wireless function is used to upload CT scanned images and surgery plans onto the NGS planning station. Uploads have no impact on the patient, but they can affect the user experience quality. If the upload is unsuccessful, a new attempt can be made.
- Intended Use Environment with Possible Wireless Devices in Co-channel and Adjacent Band
 - NGS is to be used in a dental office connected to a local network operating at 2.4 or 5 GHz.
 - Potential interferers include IEEE 802.11b/g/n networks (2.4 GHz and 5 GHz)
- Risk Management / Mitigations
 - A failure in wireless transfer will require the transfer of images from a CT scan to the planning station using a tethered connection (e.g., ethernet cable, USB flash drive).
 - Data transfer is performed manually, and a failure has no impact on NGS functionality. To be able to use the NGS, however, patient data (e.g., CT scan, patient plan) will need to be transferred to the NGS using a tethered connection.
 - Mitigation techniques when there is interference include moving the device causing the interference away from the NGS or moving the NGS away from the offending device.