BioXam System
User Manual

AnX Robotica Corporation

Warranty
AnX Robotica Corporation assures that all parts in the BioXam System are well-designed, manufactured, packed and tested for prevention of defects, and assumes no responsibility for any accident, loss, damage or cost increase directly or indirectly resulting from use of the platform. AnX Robotica Corporation will repair or replace parts within the warranty period, while customer is responsible for all other items including normal wear and tear or anything that is out of the control of AnX Robotica Corporation, including but not limited to operation, storage, cleaning, misuse, abuse, patient treatment or diagnosis. This warranty replaces any other warranties which may have been implied in verbal or documented form.

Modifications by User or Third Party
Any and all modifications to the product which are not expressly in writing approved AnX Robotica Corporation will void this warranty in its entirety.

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Rx Only **CAUTION:**US Federal law restricts this device to sale by or on the order of a physician.

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Chapter 1: INTRODUCTION

1.1 Important Information

A thorough understanding of the technical principles, clinical applications and risks associated with the BioXam System is necessary before using this product. Read this entire manual before using the system for the first time.

CAUTION

Failure to follow this instruction may result in damage to the equipment or pollution to environment

WARNING

Failure to follow instructions could result in injury or even death to operator, patient, or other personnel.
To avoid the risk of electric shock, this equipment must only be connected to a power supply that is properly grounded.

NOTE

If an event or information security issue is identified, immediately report it to AnX Robotica Customer Service

1.2 About BioXam System

The User Manual introduces the use of BioXam System (Model: BioXam-1). The BioXam System is a system to obtain pancreatic juice in the duodenum using the capsule endoscope as the technical core. This chapter introduces tip information involved in the quick guide and the User Manual.

The BioXam System allows the operator to collect pancreatic juice inside the duodenum. Guided by the Controller, the BioXam Capsule/Tether can reach the duodenal. The capsule endoscope and pH Sensor help the operator to find the appropriate position and complete the collection. The samples can be used for screening and diagnosis of pancreatic cancer or other diseases.

The BioXam System is comprised from the following components:

- **NaviCam® Xpress™ Controller (Model: NaviEC-2000) with NaviCtrl software (Catalog Number: MC-US-1002)**
- **Data Recorder (Catalog Number: MC-US-1006)**
- **BioXam Capsule/Tether (Catalog Number**
  - **BioXam Capsule with pH Sensor (Catalog Number**
  - **BioXam Tether (Catalog Number**

- **Locator (Catalog Number: SB-US-2006)**
- **BioXam Pump (Catalog Number**

A description of each component is provided below.

1.2.1 NaviCam® Xpress™ Controller（MC-US-1002）

	Length (mm)	Width (mm)	Height (mm)	Weight (kg)
NaviCam Xpress Controller (folded)	1210±50	780±50	2100±50	320±20
NaviCam Xpress Controller (unfolded)	2020±20	1330±20	1970±20	

The NaviCam® Xpress™ Controller (Figure 1-1) consists of a 5D motion system (3D linear motion and 2D rotation motion) where the robotic arms achieve three-axis translational motion of the magnetic head, and two-axis rotation motion of magnet in the magnetic head can generate magnetic fields in different directions. The magnetic head is a key component that drives the motion of the capsule endoscope and is rigidly attached to the front cantilever of the Controller through fasteners and covered by an outer casing.

The NaviCam® Xpress™ Controller is controlled by the NaviCtrl software. It is integrated and runs on the NaviCam® Xpress™ Controller, controlling the three-axis linear motion of the magnetic head and the two-axis rotation (in horizontal/vertical directions) motion of the magnet in the magnetic head.

Image transmission from a capsule to a recorder is through wireless transmission. Image transmission between the recorder and the NaviCam® Xpress™ Controller is through USB cable.

Note: An examination bed that meets the following requirements can be used with the NaviCam® Xpress™ Controller.

- Length (mm): 1850-2200
- Width (mm): 700-900, ＜1000 plus rails
- Height (mm): 720±10 (an adjustable height for bed surface)
- Weight (kg): ＜246
- Mattress thicknesses (mm): ＞30
- Rail height: No interference to the motion space of the magnetic head
- Bottom space (mm): ≥200, ≥350 is preferred
- Main body material: stainless steel, aluminum, plastics, etc.
- Ground wheels: no other requirements as long as they can fix the bed or brake.

WARNING

Relative distance of mattress support platform above ground: 720 mm.

WARNING

Do not touch the display and the patient body simultaneously.

WARNING

The NaviCam Xpress Controller can only be operated by well-trained operators.

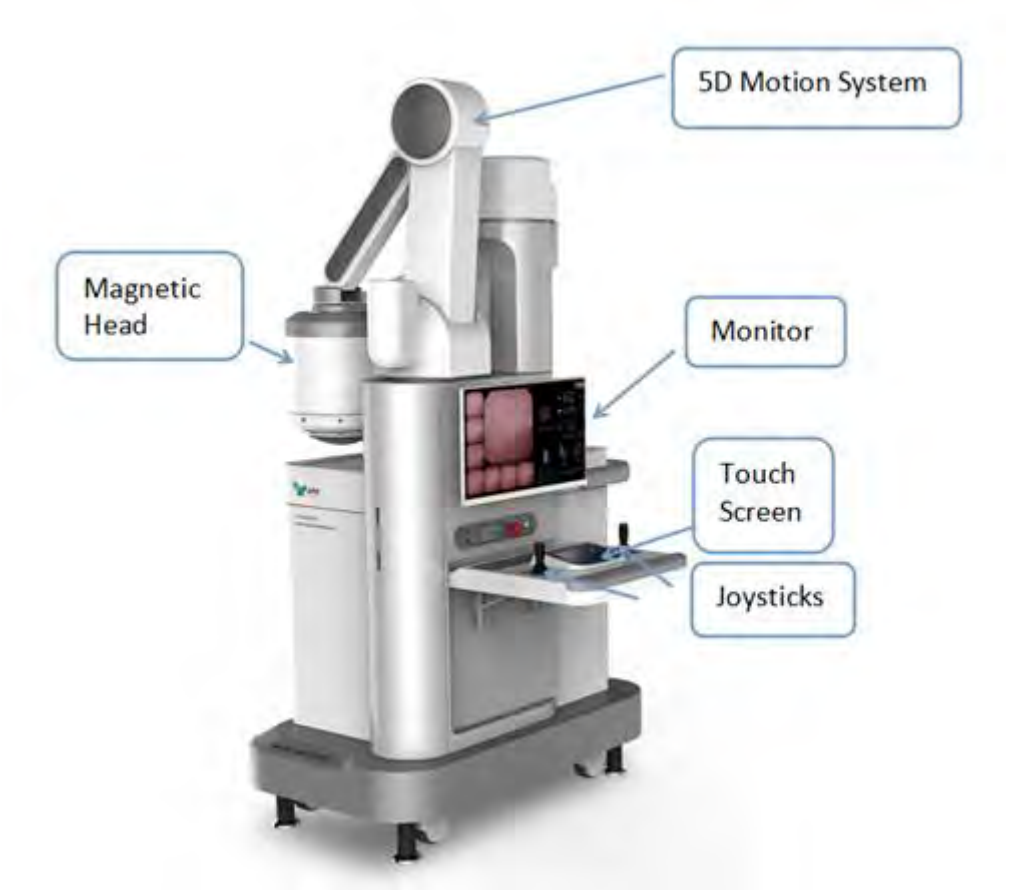

Figure 1-1: NaviCam® Xpress™ Controller

1.2.2 Data Recorder (MC-US-1006)

The Data Recorder, presented in Figure 1-2, is a portable data receiving unit with built-in rechargeable lithium battery and placed inside the examination cloth worn by the patient during examination. It is used for receiving image data wirelessly transmitted from the capsule endoscope. The Data Recorder is charged with an included charger when not in use.

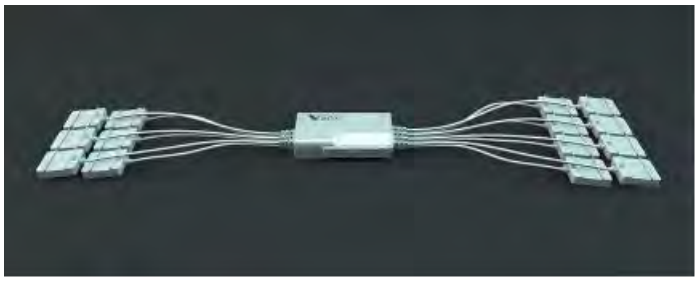

Figure 1-2: Data Recorder (AKR-1)

WARNING

Never charge the Data Recorder when it is in use by a patient.

1.2.3 BioXam Capsule/Tether (Catalog Number)

The BioXam Capsule/Tether (AKEB-31SW-PH) is consisted of a BioXam Capsule with pH Sensor and a BioXam Tether, and is sealed in a PETG package, as shown in Figure 1-3.

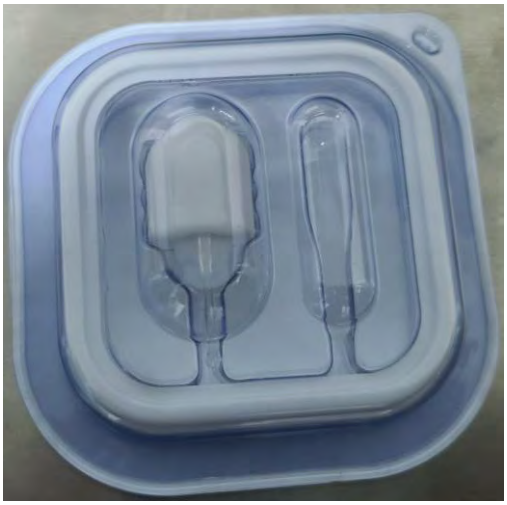

Figure 1-3: BioXam Capsule/Tether Sealed in PETG package

1.2.3.1. BioXam Capsule with ph Sensor (Catalog Number)

The BioXam Capsule (AKEM-31SW), presented in Figure 1-4, is a capsule endoscope capable of capturing images inside the stomach and duodenum. The BioXam Capsule composes of a built-in camera, wireless receiving and transmitting unit, LED lights, battery, and a magnet. All components are sealed in a case made of bio-compatible materials. The pH Sensor consists of a poly-acrylic film and some dye is attached to it. The pH Sensor is glued on the front of the BioXam Capsule.

Figure 1-4: BioXam Capsule

WARNING

BioXam Capsule is MR unsafe.

Note: 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.

1.2.3.2. BioXam Tether (Catalog Number)

The BioXam Tether (hereinafter referred to as "Tether") is an accessory used to collect fluid from the duodenum. It's composed of a capsule cradle, a tube and a syringe connector. All the parts are made of bio-compatible silicone. A combination of the BioXam Tether and the BioXam Capsule with pH Sensor forms the BioXam Capsule/Tether, which is packaged together under micro-biological control. The structure and packaging of the BioXam Capsule/Tether are presented in Figure 1-5.

TBD

Figure 1-5: Structure and Packaging of BioXam Capsule/Tether

1.2.4 NaviCam® Locator (Catalog Number)

The NaviCam® Locator (hereinafter referred to as "Locator"), presented in Figure 1-6 is used to turn the capsule on. The Locator is charged with an included charger.

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Figure 1-6: NaviCam® Locator

WARNING

- Never charge the Locator when it is in use by a patient.
- For patient who needs to undergo an MRI test before the expulsion of the capsule has been confirmed, Locator scan should not replace an X-Ray to confirm the absence of capsule in the body.

1.2.5 BioXam Pump (Catalog Number)

The BioXam Pump (hereinafter referred to as "Pump") is customized based on the LINZ 8A syringe pump. During the collection process, the Pump pulls the piston of the syringe to create a negative pressure, allowing the liquid to be drawn into the syringe. See Figure 1-8 for BioXam Pump. For details about BioXam Pump usage, see its user manual.

Figure 1-8: BioXam Pump

1.3 Summary of Clinical Studies

TBD

TBD

TBD

TBD

Chapter 2: INDICATIONS, CONTRAINDICATIONS AND WARNINGS

2.1 Indications

The BioXam System is intended for collection of pancreatic juice of adults (≥22 years) with BMI < 38. The system can be used in clinics and hospitals, including ER settings.

2.2 Contraindications

BioXam System is contraindicated in the following circumstances:

- Patients without surgical conditions or who refused to undergo any abdominal surgery.
- Patients with known or suspected gastrointestinal obstruction, stenosis or fistula.
- Patients implanted with electronic device or those containing ferromagnetic foreign matter (propose screen form is provided in Annex 5)*.
- Patients with allergies to medical polymer materials.
- Patients with persistent cough.
- Patients with dysphagia.
- Pregnant women.

*** Note: Certain implantable medical devices are labeled by their manufacturers as "MR Conditional". For such devices, this general contraindication may not be applicable in its entirety: It is the responsibility of the MCE operator to ensure that the conditions of the "MR-Conditional" set by the manufacturer of such implant are strictly adhered to.**

WARNING

- For a patient with an implant which its MR status is unknown, the model of the implant should be retrieved and its MR status verified.
- Please consult the MCE Technician or GI physician if you have any question or concern BEFORE you enter the MCE system room.

Patient with an implant that is labeled "MR Safe" or "MR Conditional" with conditions permitting MR scanning in a maximum static magnetic field > 0.3T (3000 gauss) and a maximum magnetic spatial field gradient >10T/m can undergo the NaviCam Xpress Stomach Procedure.

2.3 Adverse Events

Potential adverse events associated with the use of BioXam Capsule/Tether include injury to a patient caused by unexpected rupture of Tether and partial Capsule/Tether retention. It could be necessary to remove the Capsule/Tether by intervention.

2.4 Warnings

Warning is used to suggest risks that may cause damage to patient or operator.

⚠Patient should fully understand the requirements for use of this product and instructed by the Physician.

⚠Individuals implanted with electronic devices or ferromagnetic implants should remain at least 2 meters from the Controller and at least 5 centimeters away from the torso of patients who have ingested a BioXam Capsule.

⚠BioXam System can be used only in the presence of authorized personnel.

⚠Before examination, make sure that all clothes with metal wire or metal parts and all other metal objects such as watch or coins are removed from the patient.

⚠Before using the BioXam Capsule/Tether, check the capsule for rough surfaces, sharp edges, or bumps.

⚠BioXam Capsule/Tether is a sealed package. Do not use it if the package is open or damaged.

⚠If there is any concern about the integrity of the BioXam Capsule/Tether, it should not be used until an authorized representative of AnX Robotica Corporation is consulted. BioXam Capsule/Tether should be turned off and put back in the holder and then placed in the package. A new BioXam Capsule/Tether should be used.

⚠Do not use an expired BioXam Capsule/Tether.

⚠Please check whether the pH Sensor on the capsule is off. If it is off, do not use it.

⚠BioXam Capsule can be swallowed and BioXam System used for examination only after the physician has determined that the patient does not have any other camera capsules in their digestive tract.

⚠Please connect the Tether to the syringe correctly, and make sure that the syringe is correctly installed on the Pump.

⚠Patient should avoid biting BioXam Capsule and BioXam Tether at all time.

⚠The product is rigorously designed, and the strength of the Tether is strictly tested from production to inspection. Under normal use, it is not easy to break. However, if the Tether is bitten or broken by other forces, the inspection should be terminated immediately, and the part in vivo should be discharged naturally or taken out by other means.

⚠Patient should not to approach any strong magnetic field source, such as the magnetic field generated by a magnetic resonance imaging device, during the examination until the BioXam Capsule is pulled out.

⚠The BioXam Capsule/Tether should be kept away from DC electromagnetic fields or static magnetic fields.

⚠Patient should be instructed to immediately inform the physician if he/she has any abdominal pain, nausea or vomiting after swallowing the Capsule/Tether.

⚠The BioXam Capsule/Tether must be stored in a safe place and kept out of reach of children.

⚠If a child accidentally swallows any unused or used capsule, a physician must be consulted.

⚠Patient's dietary instructions must be followed as directed by the physician.

⚠The BioXam Capsule/Tether is for single use only.

⚠When installing the system, ensure that there is no strong magnetic field device such as MRI device within 5 meters of the installation room.

⚠When the patient wears metal dental braces, avoid close contact between the tube and the dental braces. If the tube is attached to the dental braces, remove the tube from the dental braces device before continuing the examination.

⚠When the examination is end, shut off the BioXam Capsule in time

⚠To reduce influence from electromagnetic interference, keep a proper distance from other medical electronic devices when using the BioXam System.

⚠To reduce influence from electromagnetic interference, do not expose the equipment to or locate it closely to RF source (for example, a device working in 2.4GHz radio band).

⚠Even if other devices meet corresponding national emission standards, the system may still be interfered.

2.5 Emergency Stop Procedure

In the event of an emergency while using the system, press the emergency stop button. If appropriate, move the patient away from the area.

2.6 Disposal of the BioXam System

When the BioXam System is to be disposed, contact the local qualified solid waste disposal company to dispose the magnetic head. Disposal of all other parts is done according to local regulations regarding electronics waste.

2.7 Wiring of Console

The NaviCam® Xpress™ Controller is connected to an external 120VAC 60Hz socket via a power cable.

Interfaces for connecting 120VAC 60 Hz socket (seen in Figure 2-1) are visible on the lower left side of the Controller after the cover is removed.

The potential equalization conductor is only be operated in medical facilities where supplementary equipotential bonding has been installed and tested according to country- specific regulations.

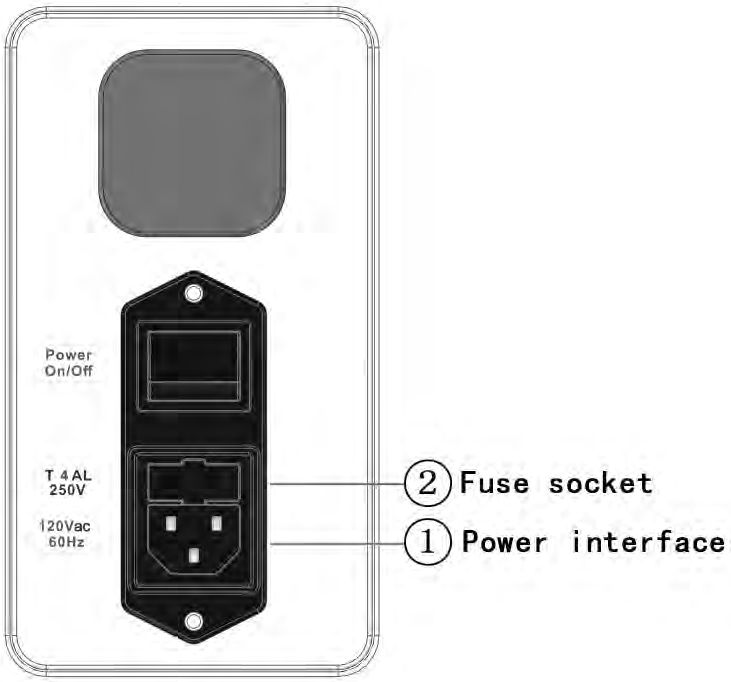


Figure 2-1: Socket Interface

WARNING

- **Do not step on the connection cable.**
- **Unplug if not used for a long time to safely terminate the operation of the device.**

2.8 Control Panel of Console

The control panel on the NaviCam® Xpress™ Controller is provided with power switch and emergency stop switch as shown in Figure 2-2.

Figure 2-2: Control Panel

If the NaviCam® Xpress™ Controller fails during operation, the BioXam System can be immediately stopped by applying the brake and pressing down the emergency stop switch.

Chapter 3: OPERATING THE NAVICAM XPRESS CONTROLLER

3.1 Operation Steps

Figure 3-1 illustrates the work-flow of the procedure of BioXam System examination.

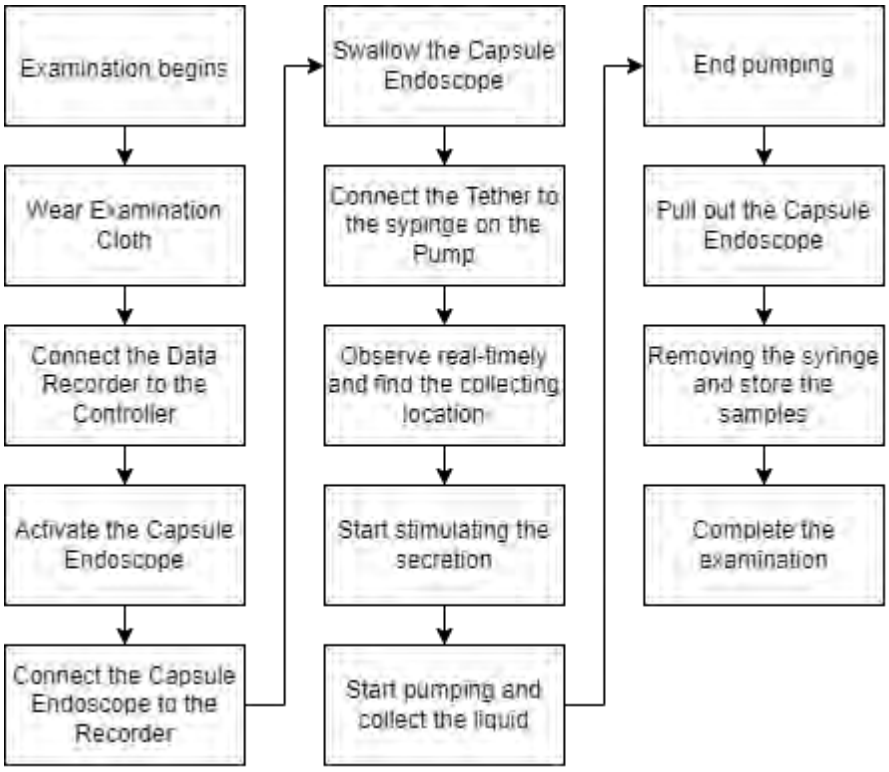


Figure 3-1: System Work-flow Illustration

1. Open the Data Recorder and connect it to the Controller. Then the NaviCtrl software on the Controller automatically connects to the Data Recorder.
2. Activate the BioXam Capsule using the Locator.
3. When the BioXam Capsule is activated, it will connect to the Recorder automatically. The images the BioXam Capsule capturing and the SN number of the BioXam Capsule are displayed on the software interface. Check if the image display and the SN number are correct and if the capsule voltage meets the examination requirements.

Note: If the BioXam Capsule does not connect to the Recorder automatically, check if the channel of the Recorder is 5. The channel of the Recorder can be changed in the touch screen of the Controller.

Note: Check if the SN number displayed on the recorder is the same as that of the BioXam Capsule. If it is different, it is necessary to remove the wrong BioXam Capsule, such as keeping it away from the Recorder, or closing it, and then using the "Scan and pair a capsule endoscope" to connect with the needed BioXam Capsule.

4. Help the patient swallow the BioXam Capsule. Attach the syringe to the Pump and connect the Tether to the syringe.
5. Use the joysticks and the touch screen to control the motion and the posture of the BioXam Capsule to observe real-time images and to reach the collecting location. (See Section 3.2 for detailed basic operation).
6. When the BioXam Capsule reaches the collecting location, start stimulation the secretion and turn on the Pump to collect the liquid. (See Chapter 9 for details.)
7. End pumping and pull out the BioXam Capsule. (See Chapter 9 for details.)
8. Remove the syringe from the Pump and store the samples under appropriate conditions (See Chapter 9 for details.)

Note: Recommend that relevant information about the patient and examination be recorded on the sample.

9. Complete the examination.

Caution

If an event or information security issue is identified, immediately report it to AnX Robotica Customer Service.

3.2 Basic Operation

Section 3.2 is about the basic operation of the Controller. It is suitable for any capsule endoscope and data recorder which can be adapted to the Controller. Therefore, in this section, **"capsule" means any model of capsule endoscope which can match the Controller**, not only AKEB-31SW. **"Data recorder" means any model of data recorder which can match the Controller**, not only AKR-1.

3.2.1 Power On/Off

There is a power on/off switch on the power input module of the NaviEC-2000 (see Figure 2-2), which is used to power on/off the NaviEC-2000.

3.2.2 Power On

Press the power on button on the operation panel and then the NaviCtrl software will automatically start and the monitor and touch screen will display the following power-on screen.

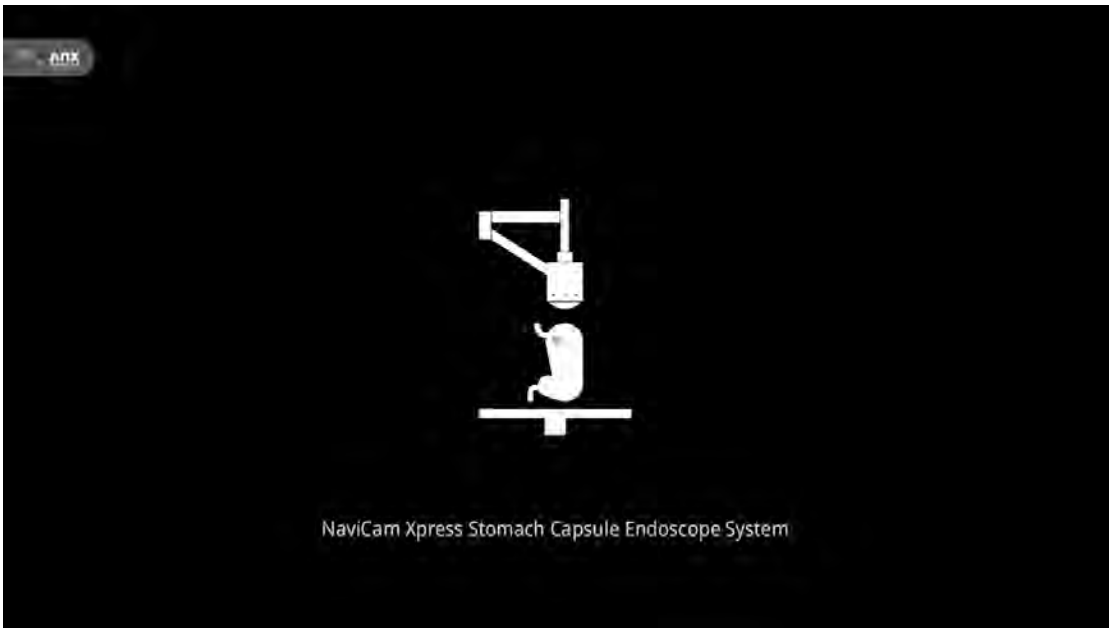


Figure 3-2: Monitor Power-on Screen

Figure 3-3: Touch Screen Power-on Screen

3.2.3 User Interface

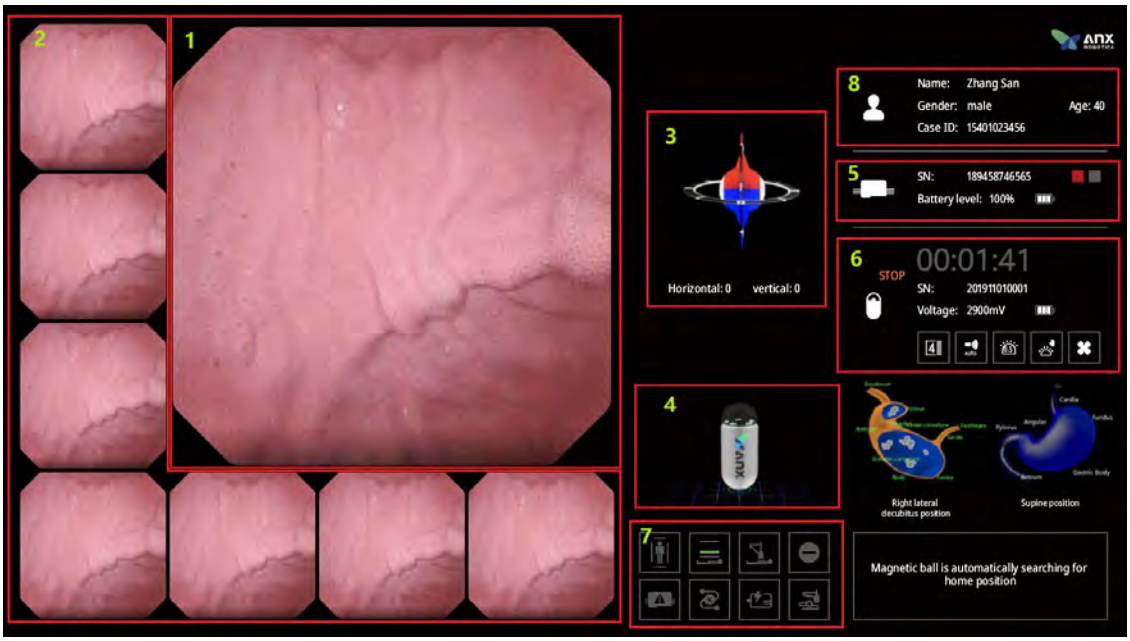


Figure 3-4: Monitor Screen

Figure 3-5: Operation Screen 1

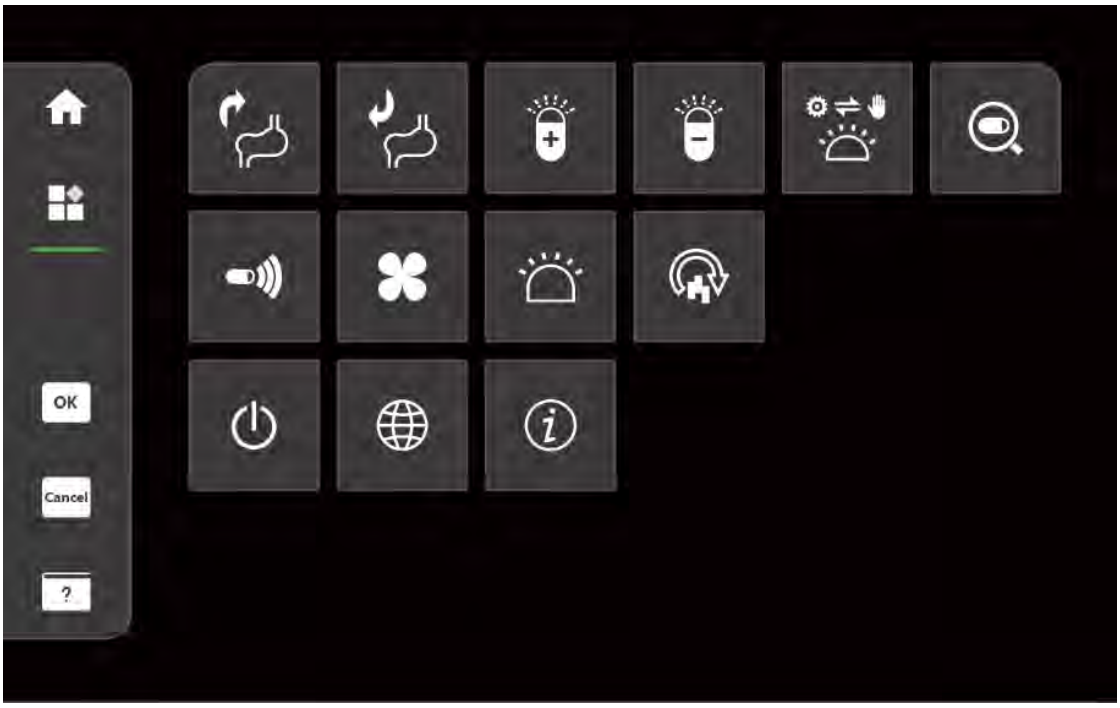


Figure 3-6: Operation screen 2

1. The monitor screen is mainly used to display real-time information of the Controller, the capsule, and the data recorder, including the following contents:

No.	Displayed content
1	Real-time image taken by the capsule endoscope
2	Recently captured images
3	Magnetic head posture model
4	Capsule posture model
5	Data recorder status display; when the data recorder is not connected, displayed as 
6	Capsule status display; when the data recorder is connected while the capsule is not connected, displayed as 
7	Controller exception warning message
8	Patient information

2. The operation screen is mainly used to adjust the working status of the capsule endoscope and control the equipment.

3. Before starting examination, the data recorder must be connected to the Controller via USB. When the data recorder is not properly connected, the connection status display area in the recorder status monitor screen will display "Data recorder not connected. Please connect the Data recorder properly." At this time, the images taken by the capsule endoscope cannot be displayed in real time. When the data recorder is connected to the computer via USB properly, the information of the rata decorder and the patient will be displayed on the screen.

3.2.4 Button Functions

The button functions are detailed in Table 3-1 below.

Table 3-1: Operation Screen Buttons and Their Functions

Icon	Function
	Switch to Common Functions page (Home page).
	Switch to More Functions page.
	Unfold the device
	Fold the device
	Reset magnetic head orientation
	Search capsule location • The magnetic head will stops right above the capsule (head up) • Only available for capsules in the stomach
	Camera point facing down (Capsule head facing down)
	Camera point facing sideways (Capsule head facing sideways)
	Camera point facing up (Capsule head facing up)
	360-degree horizontal scan
	Set/clear safety height limit
	Tilt the capsule vertically 45 degree
	Clear alarm
	Clear patient access.

Icon	Function
	Turn off the data recorder.
	Turn off the capsule
	Set the wireless channel
	Increase exposure.
	Reduce exposure.
	Switch exposure mode (auto/manual)
	Set frame rate
	Set transmission rate
	Adjust image quality.
	Scan and pair a capsule
	Restore default settings.
	About (Show software info)
	Power off.
	OK button
	Cancel button
	Show the functions of individual buttons
	PH measurement

3.2.5 Joystick Operations

3.2.5.1. Three-axis Motion

Use the right joystick to control up, down, left, right, front, and back motions (X, Y, Z) of the magnetic head, as shown in Figures 3-7 to 3-13.

Figure 3-7: Three-axis motion

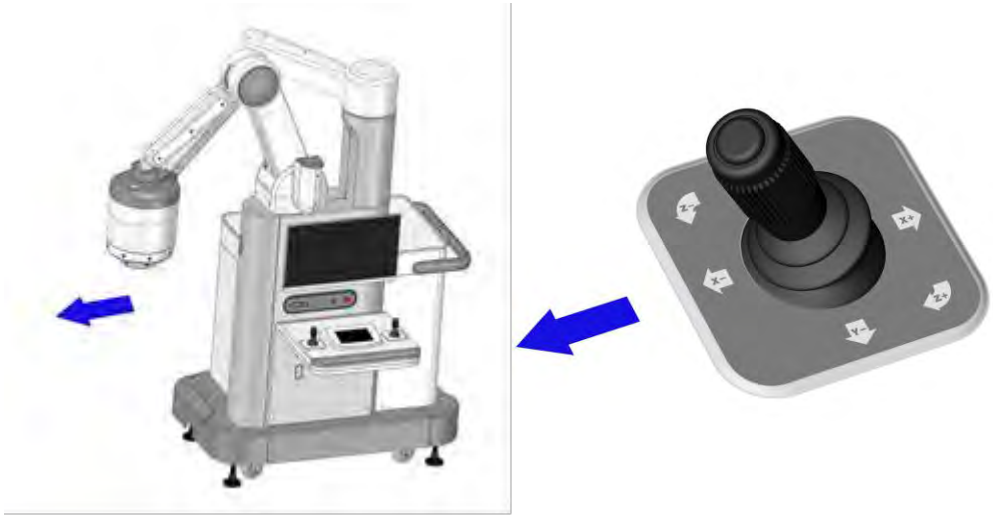


Figure 3-8: Move in direction along X- axis

Figure 3-9 :Move in direction along X+ axis

Figure 3-10: Move in direction along Y+ axis

Figure 3-11: Move in direction along Y- axis

Figure 3-12: Move in direction along Z- axis

Figure 3-13: Move in direction along Z+ axis

3.2.5.2. 2D Rotation Motion

Use the left joystick to control the rotation motors for horizontal and vertical rotation motion of the magnetic head (counterclockwise push of the vertical rotation motor, to make the capsule roll forward; clockwise push of the vertical rotation motor, to make the capsule roll backward), as shown in Figures 3-14 to 3-17.

Figure 3-14: Horizontal and clockwise rotation

Figure 3-15: Horizontal and anticlockwise rotation

Figure 3-16: Vertical and clockwise rotation

Figure 3-17: Vertical and anticlockwise rotation

3.2.5.3. Capsule Coupled Movement

When the capsule is directly under the magnetic head, capsule coupled movement can be realized by clicking the left joystick button: 360-degree rotation in the capsule head direction, and the magnetic head moves at the same time to ensure the capsule endoscope is still right under the head after 360-degree rotation. When using capsule coupled movement, first control the magnetic head close to or away from the human body in the Z-axis direction, and ensure the capsule is located on the upper/lower wall of the stomach, otherwise the capsule coupled movement cannot be realized.

3.2.5.4. Capture Image

Click the right joystick button to capture the current image.

3.2.6 3D Model Display

1. Capsule Model Display: displays the current orientation of the capsule when connected, as shown in Figure 3-18 and Figure 3-19.

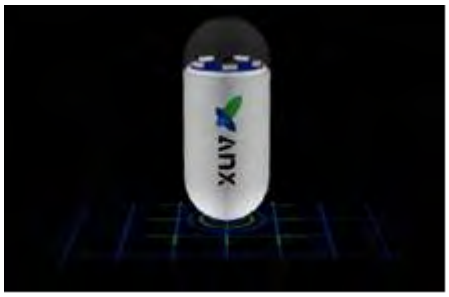


Figure 3-18: Initial state of the capsule model

Figure 3-19: Actual posture of the capsule after connection

2. Magnetic Head Posture Display: displays the posture and angles of the magnetic head in real time.

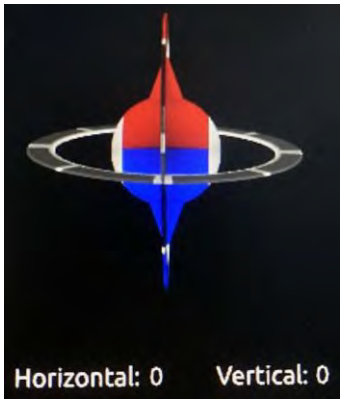


Figure 3-20: Magnetic head model

3.2.7 Power Off

Soft shutdown operation:

1. Press "More" →"Power"→ "Power off" on the touch screen, the prompt "Prepare to shutdown device, confirm to fold device?" will pop up. If you select "YES", the device will first fold up and then shut down; if you select "NO", it will shut down immediately
2. Press and hold the power button on the operation panel for two seconds, the prompt "Prepare to shutdown device, confirm to fold device?" will pop up on the touch screen. If you select "YES", the device will first fold up and then shut down; if you select "NO", it will shut down immediately.

Hard shutdown operation:

Press the power button on the operation panel of the Controller for five seconds to immediately power off the controller.

Note: To restart the system, wait for 30 seconds before powering back on.

3.2.8 TOF Collision Avoidance

The infrared TOF sensor comes with two parts: the surrounding detection part and the bottom detection part.
The surrounding detection part of the sensor detects obstacles in horizontal movement area of the magnetic head in real time. When the magnetic head is detected near an obstacle, it will automatically slow down until it stops.

The bottom detection part of the sensor detects obstacles in downward movement area of the magnetic head in real time. When the magnetic head is detected near an obstacle, it will automatically slow down until it stops.

Chapter 4: USING THE BIOXAM CAPSULE/TETHER

4.1 Composition

The BioXam Capsule/Tether consists of the BioXam Capsule with pH Sensor and the BioXam Tether. The pH Sensor is attached to the front end of the BioXam Capsule. The BioXam Capsule can be guided by the Controller so that the pH Sensor can touch the liquid that needs to be measured. The pH Sensor measures the pH of a liquid by showing different colors depending on its pH. Figure 4-1 shows the color of the pH sensor under different pH values.

TBD

Figure 4-1: Different colors of pH Sensor with different pH

The Tether is composed of the capsule cradle, the tube, and the syringe connector (see Figure 4-2). During manufacturing, the capsule cradle has been wrapped tightly around the BioXam Capsule. The tube is used for hauling the capsule cradle, and transporting liquid or gas. One end of the tube is flush with the tip of the capsule cradle, and the other end is in the syringe connector. The tube has marks printed on it. In the relaxed state, the distance between the marks and the front end of the Tether are 500 mm, 600 mm, 700 mm, 800 mm.

TBD

Figure 4-2: Structure of the Tether

4.2 Package Removal and Activation

The BioXam Capsule/Tether is packed in a sealed package. It can be removed from the package and activated as shown in Figure 4-3. The protective cover is used as a fixture and protects the BioXam Capsule/Tether, facilitating its storage and handling before operation.

TBD

Figure 4-3: Schematic diagram of activation of the BioXam Capsule/Tether

1. Tear off the paper cover of the package box.
2. Remove the BioXam Capsule/Tether with fixture from the cup and remove the upper part.
3. Take out the BioXam Capsule/Tether.
4. Face the lens of the BioXam Capsule to the IR window on the Locator, press the INIT button on the Locator to activate it with IR light.

WARNING

- **The BioXam Capsule/Tether must be removed and activated before ingestion and operation.**
- **The BioXam Capsule/Tether should only be stored in the original package before ingestion.**
- **Do not use a BioXam Capsule/Tether if package is damaged.**

Chapter 5:USING THE DATA RECORDER

5.1 Installation and Use

The Data Recorder is equipped with 14 sensor arrays, as presented in Figure 5-.

Figure 5-1: Data Recorder (AKR-1)

When in use, the Data Recorder and sensor arrays are embedded into the corresponding examination vest as shown in Figure 5-2. As tested, the working temperature of the data recorder can reach 42℃ tested under 40℃ ambient temperature. Since the data recorder does not contact patient skin directly, the temperature will not cause burn or other hazard to patients and operators, and the contact duration can be longer than 10 minutes.

Figure 5-2: NaviCam® Data Recorder Vest

5.2 Operation Instructions

5.2.1 Composition of Data Recorder

Related marks and position of power switch, USB interface, LED, keys on the Data Recorder are shown in Figure 5-3.

Figure 5-3: Data Recorder (AKR-1)

① Alarm indicator
② Running indicator
③ Battery capacity indicators
④ Battery capacity indicators
⑤ Battery capacity indicators
⑥ Charge indicator
⑦ Power switch
⑧ USB interface
⑨ Charging port

5.2.2 Operation before Real-time Examination

1. Embed the Data Recorder correctly into the examination cloth. Usually, there's no need to remove the Data Recorder from the examination cloth after the examination, so this step can be skipped.
2. Ensure that the Data Recorder has sufficient power, and if the power is insufficient, please refer to 5.2.5 for charging

WARNING

Charging can only be performed by the physician/operator. Patients shall not have access to the adaptor.

3. To turn on the Data Recorder, press and hold the power switch until all five indicators (marked as ①②③④⑤ in Figure 5-3) are on.
4. Help the patient wear the examination cloth.

5. Connect the Data Recorder to the Controller.

5.2.3 Real-time Display

1. The BioXam Capsule captures images which are transmitted to the Data Recorder in real-time. These images are displayed on the NaviCtrl interface.
2. The green running indicator (② in Figure 5-3 with the word "run" beneath it) lights up and goes off quickly upon receiving an image from the BioXam Capsule. It lights up again upon receiving the next image information and then goes off again.
3. The yellow alarm indicator (① in Figure 5-3 with the word "alarm" beneath it) stays on if no capsule is detected. If the indicator continues to flash, it means that the BioXam Capsule is present, but the upper-level software (such as NaviCrtl in the Controller) has not yet issued a command to capture images using the BioXam Capsule.

5.2.4 Shut down

If the Data Recorder cannot detect the BioXam Capsule for 15 minutes and cannot connect to the NaviCtrl via USB port, it would be automatically power off to save power.

5.2.5 Battery Capacity and Charging

1. The green battery capacity indicators (③④⑤ in Figure 5-3 with a battery capacity icon beneath them) indicate the current battery capacity. When all three indicators (③④⑤) are lit up, the battery capacity is more than 90%. When only indicators ④⑤ are lit up, the battery capacity is between 70% and 90%. When only indicator ⑤ is lit up, the battery capacity is between 40% and 70%. If only indicator ⑤ is flashing, it means that the remaining battery capacity is very low.
2. To charge the Data Recorder, connect it to a powered PC or a special charger. While charging, the white LED charge indicator (⑥ in Figure 5-3) will remain lit up. If the Data Recorder is also turned on, the indicators ③④⑤ will flash in a cycle. The white LED will automatically turn off when the Data Recorder is fully charged.

WARNING

- **Charging can only be performed by the physician/operator. Patients shall not have access to the adaptor.**
- **The USB interface should only be connected to the NaviCam Xpress Controller.**

Chapter 6: USING THE NAVICAM® LOCATOR

6.1 Operation Panel

Figure 6-1 shows functional keys and indicators of the Locator.

Figure 6-1: Keys and Indicators of NaviCam® Locator

① Scanning indicator, yellow
② Working indicator, green
③ Infrared light source
④ INIT Key
⑤ Power Switch
⑥ Charging port
⑦ Power switch indicator, white
⑧ Label plat

6.2 Usage

6.2.1 Activation of the BioXam Capsule/Tether

1. Press the "Power Switch" to turn on the Locator. Once the Locator is on, the working indicator will flash.
2. Place the photosensitive sensor (see Figure 6-2) of the BioXam Capsule opposite to the start infrared light source of the Locator.
3. Press and hold the "INIT Button" activate the BioXam Capsule. The LED in the BioXam Capsule will start blinking after the BioXam Capsule is activated normally.

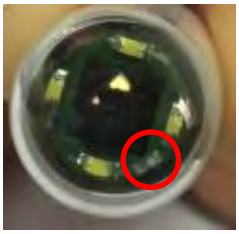


Figure 6-2: Photosensitive sensor (circled in red)

6.2.2 Turn off the NaviCam® Locator

Press and hold the "Power Switch" for more than 5 seconds and the Locator will be shut down. All the indicators will be off after the shutdown. The Locator will be shut down automatically after 10 minutes without any operation.

6.2.3 Charge the NaviCam® Locator

The Locator uses a battery to supply power. When the battery voltage is low, the flashing frequency of the working indicator will get lower. When the flashing changes to one time per three seconds, the Locator needs to be charged through the power port. During the charging process, the charging indicator is always on, and is automatically turned off after being fully charged.

WARNING

- **The Locator can only be charged using a charger that comes with the unit.**
- **Charging can only be performed by the physician/operator. Patients shall not have access to the adaptor.**

Chapter 7: USING THE BIOXAM PUMP

7.1 External Characteristics

The external characteristics of the Pump are shown in Figure 7-1 (front side) and Figure 7-2 (back side).

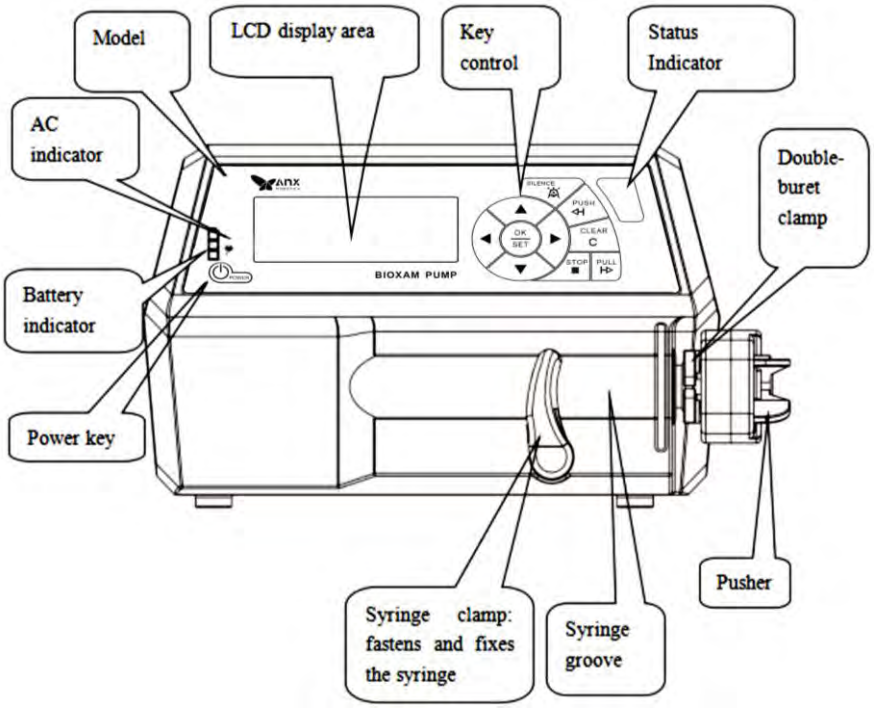


Figure 7-1: External composition of the front side

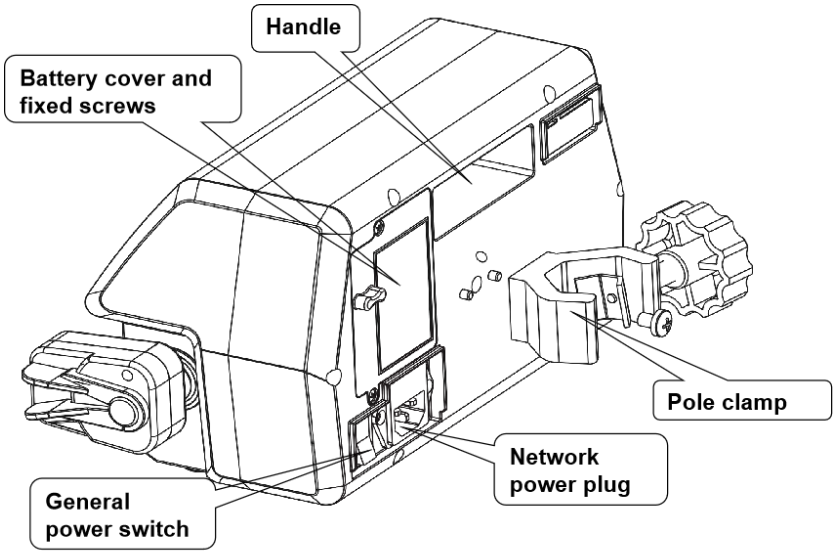


Figure 7-2: External composition of the back side

7.2 Device Location

The Pump should be placed on a level surface near the patient, such as a table or examination bed.

If a suitable surface is not available, the Pump can be attached to an infusion rack or another suitable shelf. To attach the Pump, follow these steps (refer to Figure 7-3): Attach the pole clip to the device, and then fix the pole clip onto the infusion stand. Secure the screws on the pole clamp to prevent any sliding.

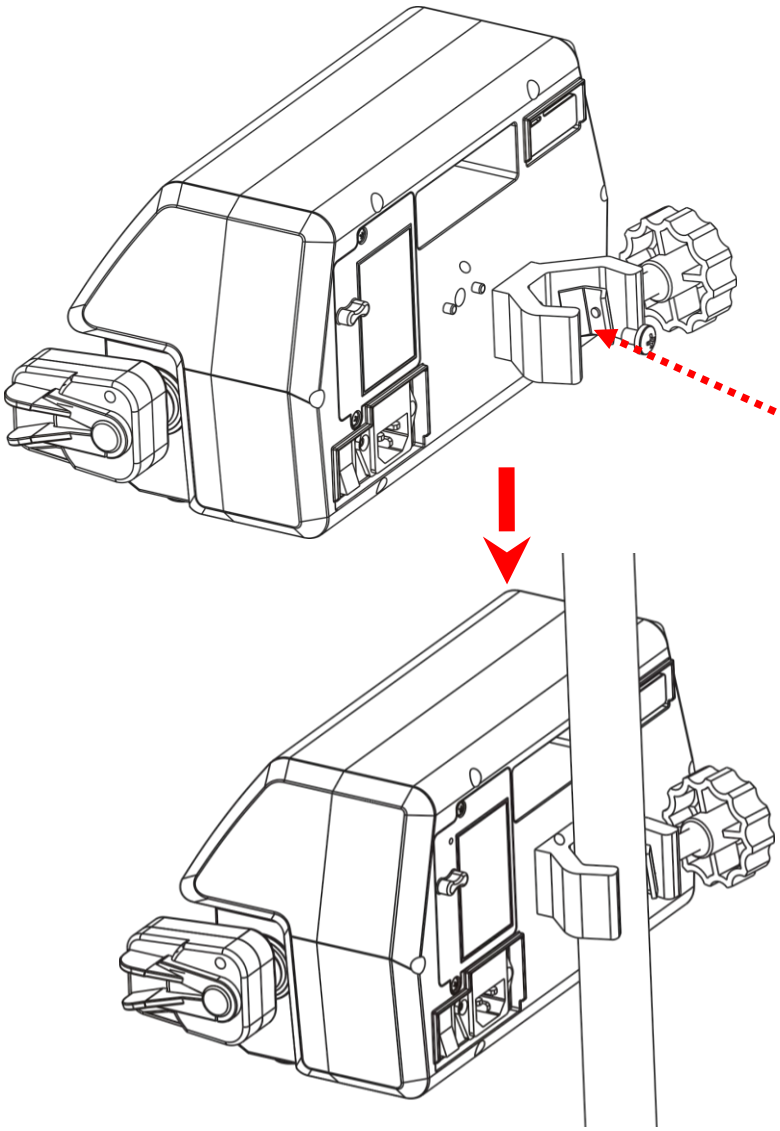


Figure 7-3: Fixing the Pump vertically

7.3 Assembly of the Syringe and BioXam Tether

The Pump can be used with the syringe that meets the ISO 7886-1:2017 standard. The procedure for assembling the syringe is as follows (See in Figure7-4):

1. Press and hold the pusher button of the double-buret clamps.

2. Pull the pusher to the far end, then release it
3. Raise the syringe clamp to the top position, but do not lower it.
4. Rotate the syringe clamp counterclockwise to the 90-degree position and release it.
5. Properly place the syringe into the groove, making sure to align the finger guard of the syringe with the installation groove.
6. Rotate the syringe clamp 90 degrees clockwise, release it, and clamp the syringe.
7. Press and hold the pusher button, then open the double-burette clamp.
8. Slowly push the syringe to the leftmost end, and then release the pusher button

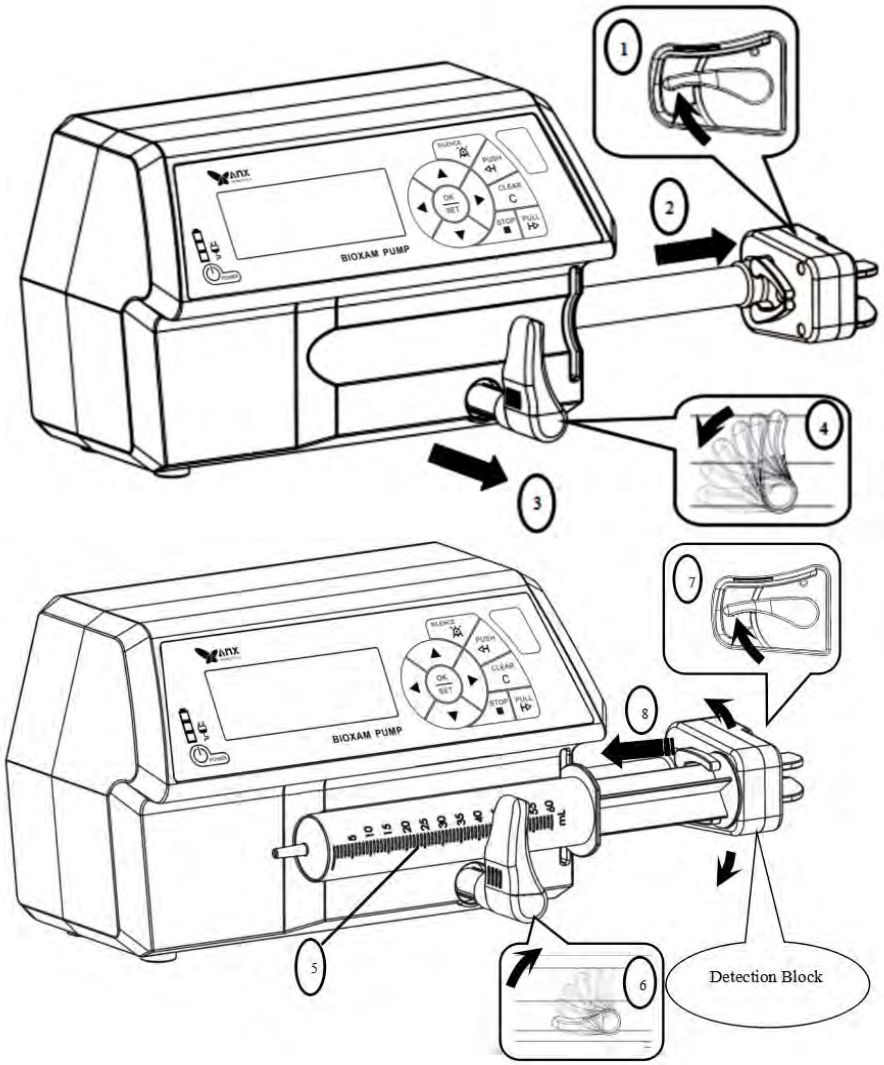


Figure 7-4: Steps of assembling the syringe

The Pump assembled with syringe is shown in Figure 7-5.

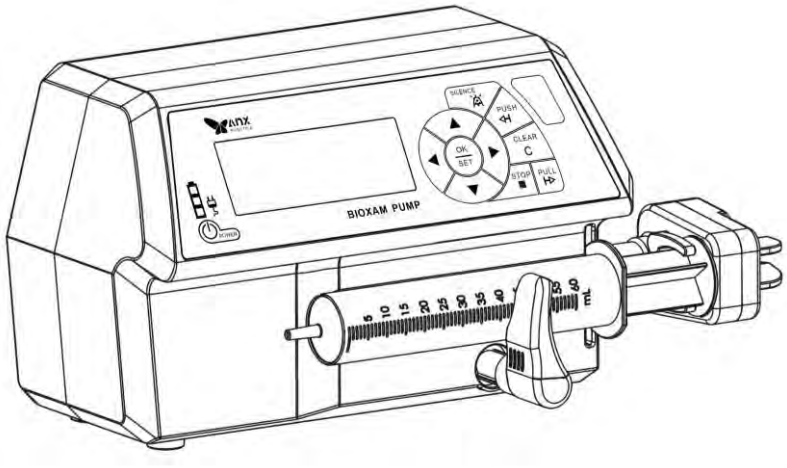


Figure 7-5: Pump with assembled syringe

After assembling the syringe on the Pump, connect the Tether to the syringe(shown in Figure 7-6):

1. Align the syringe connector of the Tether with the nozzle of the syringe.
2. Slowly and forcefully rub the syringe connector until the nozzle of the syringe is completely inside the cavity of the syringe connector

TBD

Figure 7-6: Connect the Tether to the syringe

7.4 Collection Operation

The procedure of pumping is shown in Figure 7-7.

1. Place the pump on a suitable surface, such as a flat table or shelf.
2. Assemble the syringe and the Tether according to step 7.3
3. To perform a self-diagnosis of the internal circuit, press and hold the "Power" key for at least one second. When you hear a beep, the syringe pump will be in standby mode, and the Pump needs to be pre-charged or charged.
4. Use key controls to set the flow rate of pulling (pumping) in the working interface. The left and right keys move the cursor, and the up and down keys increase or decrease the number (as seen in Figure 7-8). The default flow rate is 100 mL/h, and the maximum flow rate can be set to 400 mL/h.

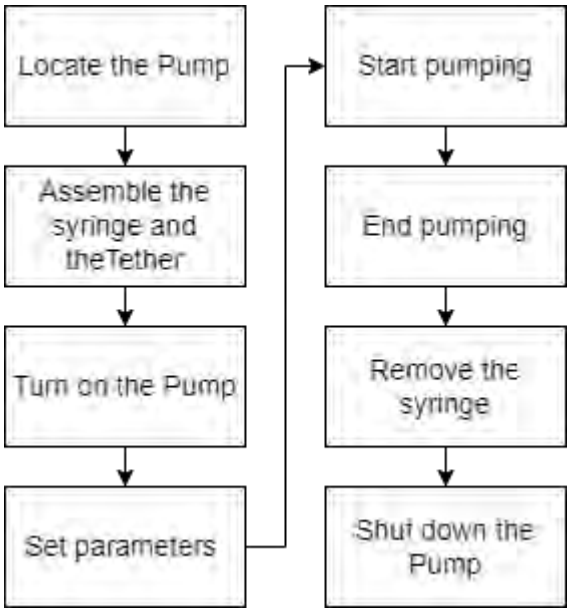


Figure 7-7: Procedure of pumping

TBD

Figure 7-8: Interface of setting flow rate

5. If the flow rate is less than 400 mL/h, press the "PULL" key to start pumping. If it reaches 400 mL/h, press the "PULL" key, and "Exact?" will be displayed on the screen. Then, press "PULL" again to start pumping.
6. To stop pumping, press the "STOP" button. When the plunger of the syringe is pulled to the farthest or the pump reaches the set max pumping amount, it will stop pumping automatically.
7. To remove the syringe, follow these steps: Raise the syringe clamp to the top and rotate the syringe clamp counterclockwise to the 90-degree position, then release it. Press and hold the pusher button of the double-burette clamps and remove the syringe.
8. To shut down the Pump, press and hold the "Power" button for one second.

Note: The procedure should be performed in a quiet and bright room.

7.5 Charging

The Pump can be charged using wires that comply with local electrical safety regulations.

While charging, the battery indicator will flash with different lights indicating the corresponding electric quantity and turn off when fully charged. When the battery is supplying power, the battery indicator light will remain on (with different lights indicating the electric quantity, but without flashing), and the AC indicator light will be off. During the use of AC

power, the AC indicator light will be on. The battery indicator will flash with different lights indicating the electric quantity. When the battery has low voltage, only one battery indicator light will be on, and the remaining two will be off. When the battery is empty, all three indicator lights will be off. In the event of a failure in the battery circuit, all three battery lights will flash simultaneously.

It is possible for the Pump to work normally even while being charged.

7.6 Supplement information

7.6.1 Applied part

The BioXam Pump is CF type, and the applied part is the BioXam Capsule/Tether except the syringe connector (shown in Figure 7-9).

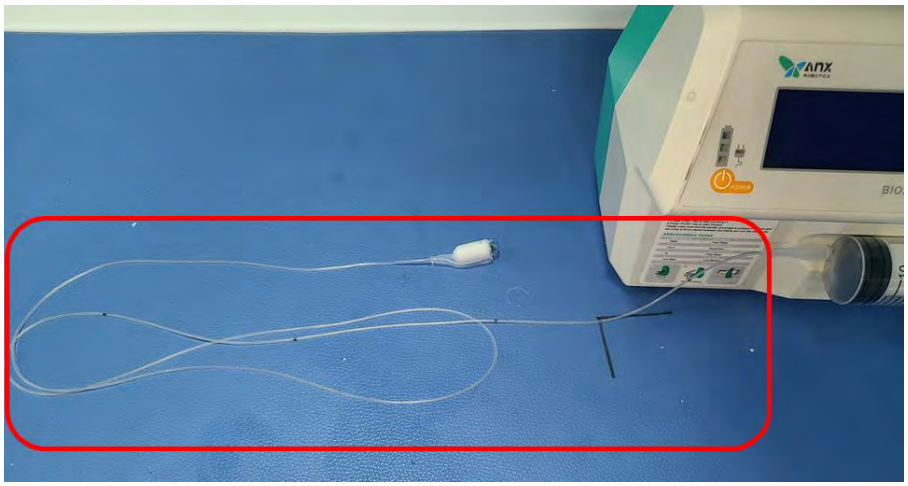


Figure 7-9: Applied part of BioXam Pump

7.6.2 Other Information

Please refer to the user manual of the Pump for more information.

Chapter 8: INSTALLATION AND TRAINING

8.1 Requirements

The System requires the following space, power and environment conditions before installation.

WARNING

Installation, handling and adjustment of the System should be completed by AnX authorized personnel.

8.1.1 Space Requirements

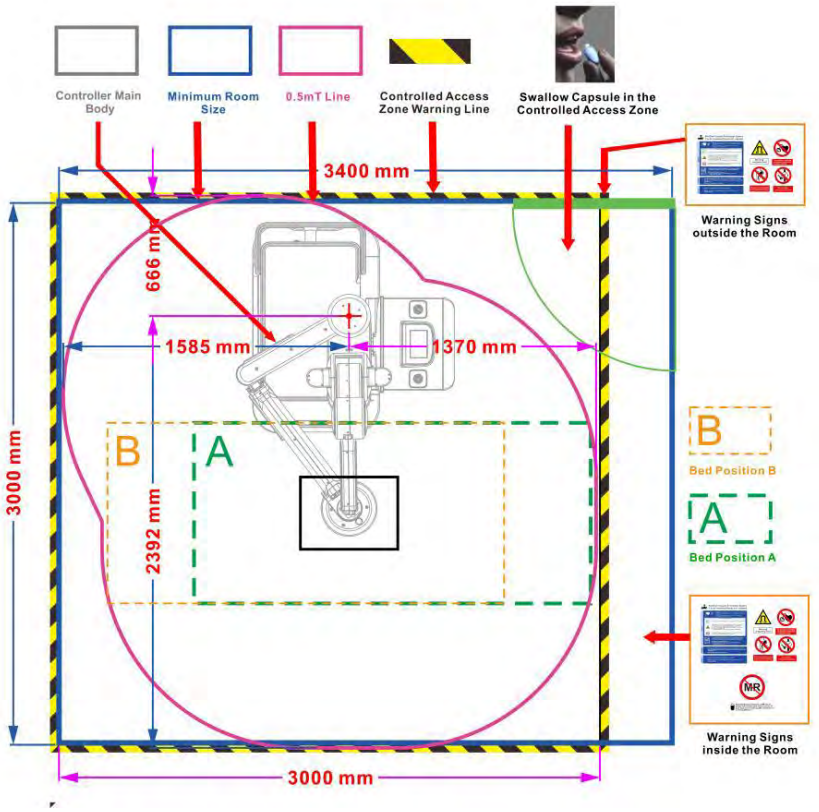


Figure 8-1: Equipment installation schematic diagram

Ensure required space for maintenance and servicing. Consider heat dissipation of the System. The installation requirements are:

- Area coverage: 3.00 m × 3.15 m (9.84 ft × 10.33 ft) (according to the bed position as Figure 8-1)
- Floor height: 2.5 m (8.2 ft) or above

- Flat solid ground with an inclination of no more than 1 degree.
- Determine the boundary in accordance with the requirements of Figure 8-1. It is advised to put warning tape at the boundary but refer to the facility specific requirements..

In bed position A, the patient lies down with the feet toward the NaviCam operator. In bed position B, the patient lies down with the head toward the NaviCam operator.

MR unsafe poster can be placed in front of the door or outside wall of the examination room, and MR unsafe sign can be placed behind the door and/or walls inside examination room.

WARNING

- **Only qualified personnel should enter the boundary.**
- **Take capsule within the warning line.**
- **Do not position the device so that it is difficult to operate the disconnect.**

8.1.2 Power Requirements for the Controller (model: NaviEC-2000)

Voltage	Frequency	Input power	Fuse
120 VAC±12 V	60 Hz±1 Hz	≤300 VA	T 4AL 250 V

WARNING

- **The equipment must be properly grounded.**
- **The maintenance personnel should only use specified fuse.**
- **Make sure that the input voltage meets the equipment requirements.**

8.1.3 Working Condition Requirements

- Ambient temperature: 5 °C~40 °C / 41 °F~104 °F.
- Relative humidity: ≤85%.
- Air pressure: 86 kPa~106 kPa.
- The environment should be free of dust, with no mechanical vibration, no significant noise nearby and be free of power interference.
- Within 5 m^2 area coverage of the installed equipment, there should be no magnetic resonance imaging equipment or strong electromagnetic interference.

8.2 Installation and Adjustment Instruction

8.2.1 General

Installation, movement, or modification of the location of the System should be completed by a qualified maintenance technician or by AnX Robotica personnel.

WARNING

Do not move the equipment without authorization. If necessary, contact AnX Robotica Corporation

8.2.2 Use of Examination Bed

Examination bed should meet the following requirements:

- Maximum Length: 86.6" (2200 mm).
- Maximum Width 39.4" (1000 mm) with side rails.
- Height: Adjustable up to 28.4" (720 mm), side rails no more than 8.7" (220 mm) above bed level under normal operation.
- Maximum Weigh 542 lb. (246 kg).

Adjust the height of the examination bed to its lowest level, as shown in Figure 8-1, by placing it at position A or position B next to the controller, and then slowly adjust the height of the bed flush with the corresponding height line on the controller.

WARNING

Before installing or adjusting the examination bed, switch the Controller to folded state.

8.3 Training

8.3.1 Equipment Operation Training

The equipment operator should be trained by AnX Robotica Corporation personnel before start using the system. The facility may designate a trainer to train additional personnel, as applicable.

8.3.2 Clinic Use Training

It is strongly recommended by AnX Robotica that the equipment be used only by well-trained physician or health professional with clinical operational experience with this System.

WARNING

The equipment operator should be well trained before performing clinical operations with patients.

Chapter 9:BIOXAM SYSTEM PROCEDURE

9.1 Procedure Before Examination

9.1.1 Screening patients

The physician/practitioner screens the patient for eligibility to undergo the BioXam System procedure (see Annex 5 for proposed screening form), and confirms that the patient has no contraindications, then gives the patient an Informed Consent (referred to Annex 3) and instruction for the procedure (referred to Annex 4).

9.1.2 Diet remind

Remind the patient of the diet and lifestyle before the examination (referred to Annex 4).

9.2 Equipment Test Before Examination

9.2.1 Start-Up Process – Equipment Test

Turn the NaviEC-2000 switch on:

Press the power-on button on the operation panel to turn on the Controller. The NaviCtrl software will be automatically started.

9.2.2 Check Items

Equipment start-up and operation:

1. Check the Xpress Controller turn on normally and work properly.
2. Check the Controller joysticks work properly to control the equipment for five-dimensional movements.

Software running:

1. Check the NaviCtrl software are successfully initialized and work properly.

Examination the NaviCam® Data Recorder:

1. Verify the Data Recorder has enough power.
2. Check the connection cable of the Data Recorder for damage.
3. Verify the connection between Data Recorder and computer is normal.

Examination the NaviCam® Locator:

1. Check the Locator can be turned on and off normally.

2. Verify the Locator has enough power

Examination the BioXam Pump:

1. Verify the Pump has enough power.
2. Verify the Pump can work normally.

9.3 Conduct Examination

9.3.1 Preparatory Procedure

1. Confirms that the checklist (see Annex 1 or Annex 2) issued by the physician is consistent with the information of the patient, and again informs the patient of the contraindications and takes back the signed Informed Consent.
2. Remove any metal material from patient (e.g., keys, cell phone, etc.). Confirm the power of the Data Recorder.
3. Help the patient wear the examination cloth correctly. Confirm that the examination vest with the Data Recorder fits the patient well.
4. Turn on the Data Recorder and connect the Data Recorder to the Controller.

Note: If the Recorder is shown to be connected to another capsule endoscope, that is, the SN number of the other capsule endoscope is displayed on the Monitor Screen, and no abnormality is indicated, the capsule endoscope connected to the Recorder shall be found and kept away from the inspection environment. Turn off the Recorder and restart it.

5. Measure the approximate *distance* from the mouth to the stomach.
6. Open a new BioXam Capsule/Tether from the package, and check it according to the warnings. Make sure the tube of the Tether is not knotted.
7. Activate the BioXam Capsule with the Locator. When activated, it will connect to the Recorder automatically. The images the BioXam Capsule capturing and the SN number of the BioXam Capsule are displayed on the software interface.

Note: If the BioXam Capsule does not connect to the Recorder automatically, make sure the channel of the Recorder is 5, then use the "Scan and pair a capsule" on the Operation Screen 2 to connect with the BioXam Capsule.

Note: When the capsule endoscope has been linked to the recorder, but the SN number of other capsules is stored inside the recorder, a pop-up prompt will be displayed on the controller screen. At this time, click "OK" on the operation screen to continue the inspection.

8. Wait for 2 minutes then check the image quality, capsule voltage, and image capturing-related parameters, and switch channels as required.

Note: The capsule voltage may not be in right range within less than 2 minutes after activated.

9.3.2 Swallow the BioXam Capsule

1. Let the patient sit on the examination bed.
2. Wrap part of the tube (usually less than 5 cm) around the capsule cradle (see Figure 9-1).

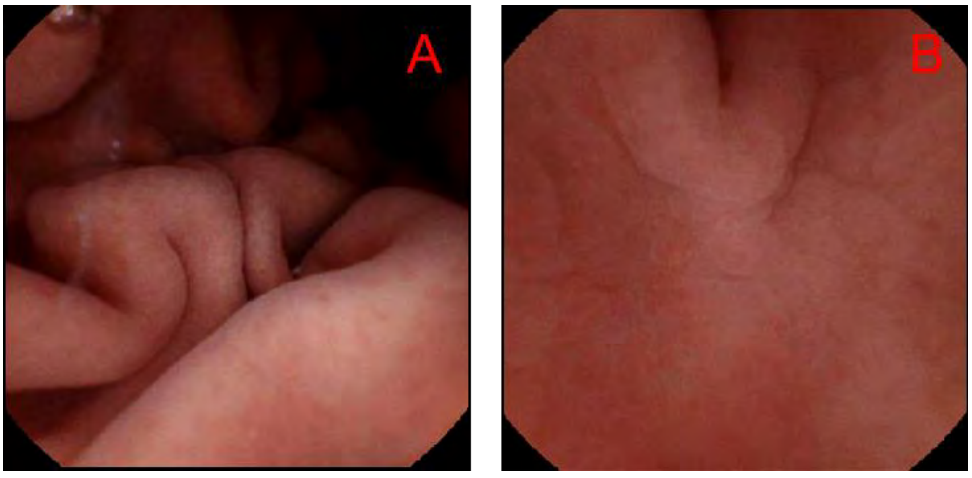
TBD

Figure 9-1: Sketch image of tube around the capsule cradle

3. Put the BioXam Capsule (in the capsule cradle) into the patient's mouth and ask the patient to swallow it in sitting position. If the patient has problem of swallowing the capsule, let the patient drink some water. Instruct the patient to avoid scratching or even biting the BioXam Capsule with teeth and to drink water slowly.

Note: If the patient spit the BioXam Capsule from the mouth due to coughing, etc., it should be confirmed that the BioXam Capsule has not been contaminated by the environment (such as falling on the ground). If contamination occurs, it should be considered to disinfect the BioXam Capsule with ethanol or replace it with a new BioXam Capsule.

4. Slowly release the tube. Make sure the length of the tube in vivo is approximate *distance+15* cm, that is, the length in vitro is approximate *105-distance* cm, which the *distance* is the approximate distance from the mouth to stomach. The length can be judged by the marks on the tube.
5. Observe whether the capsule falls in the greater curvature of the stomach near the antrum (see Figure 9-2), otherwise continue to slowly release the tube, and observe the image simultaneously. Drinking water can speed up the process, but not to much.



Figrure 9-2: A. Image of the BioXam Capsule not reaching the greater curvature of the stomach. A large range of gastric tissue can be seen. B. Image of the BioXam Capsule reaching the greater curvature of the stomach. The camera is near the gastric wall.

6. When the BioXam Capsule is the greater curvature of the stomach near the antrum, let the patient lie on the back.
7. During all process, make sure there's long enough tube in vivo. The other end of the Tether should be kept outside the mouth, and the tube kept loose.
8. As the BioXam Capsule moves, it drags the tube through the mouth and pharynx, and the patient should be guided to accommodate the tube movement (see Annex 4).

Note: If the patient feels nausea due to the moving of the tube, let the patient drink water to release the nausea. When drinking, take care to keep the patient lying on the back and drink through a straw. If the patient really needs to sit up and drink, keep the other end of the Tether outside the mouth.

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.3.3 BioXam Capsule into the Duodenum

1. When the patient lay on the back, identify the location of the BioXam Capsule in time. Normally the BioXam Capsule should fall into the greater curvature of the stomach near the antrum. But if the length of the tube in vivo is insufficient, or the stomach is severely contracted, the BioXam Capsule may not be in the proper location.
2. The method to drag the BioXam Capsule to the greater curvature of the stomach:

(1) Move the magnetic head over the patient's left shoulder and lower it to the appropriate height (as low as possible without affecting the patient or without reaching the lower limit).

(2) Drag the magnetic head to move to above the left chest and the left side of navel in sequence (see Figure 9-2 for the movement route), and push the left joystick forward or backward to the full. Or point the camera to the the greater curvature of the stomach and use the Capsule Coupled Movement function to move the BioXam Capsule.

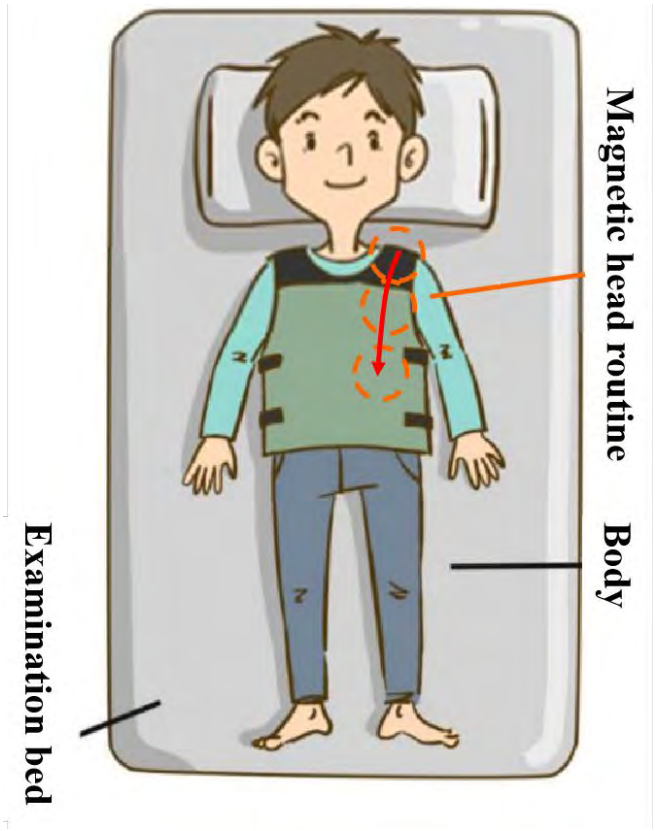


Figure 9-2: Movement routine of step 2

(3) When the magnetic head stops, release the left joystick and observe the environment of the BioXam Capsule.

(4) Or point the camera to the the greater curvature of the stomach and use the Capsule Coupled Movement function to move the BioXam Capsule.

(5) If it is not in the proper position, move the magnetic head above the left shoulder and repeat the process until the BioXam Capsule reaches the proper location.

3. Drag the BioXam Capsule from the the greater curvature into the gastric antrum:

(1) Lower the magnetic head above the left side of the patient's navel (this is where the magnetic head should stay if it has gone through step 2), and move the magnetic head to the right side of navel (see Figure 9-3 for the movement route).

(2) At the same time, push the left joystick forward or backward to the full.

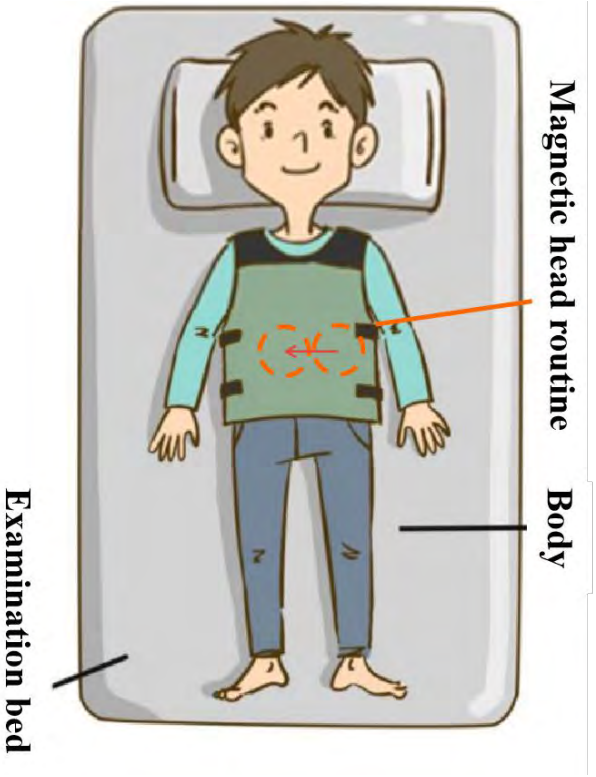


Figure 9-3: Movement routine of step 3

(3) When the magnetic head stops, release the left joystick and observe the BioXam Capsule's environment. At this time, the BioXam Capsule should be in the antrum.

(4) Alternatively, starting with step 3(1), point the camera towards the gastric antrum and then use the Capsule Coupled Movement function to move the BioXam Capsule.

(5) If the BioXam Capsule cannot enter the antrum, repeat step 3(1)-(4). Or raise the magnetic head and let the patient lie on the right side, observe the BioXam Capsule in the gastric antrum and then let the patient lie on the back again, while the magnetic head is lowered to the right side of the navel.

4. Move the BioXam Capsule near the pylorus:

(1) Adjust the camera of the BioXam Capsule to see the pylorus.

(2) If the BioXam Capsule is far from the pylorus, repeat the step 3 and stop the magnetic head further to the right.

(3) If it is close to the pylorus, raise the magnetic head directly. Move the camera towards the pylorus. The BioXam Capsule should be near the pylorus.

5. The pylorus opens and closes regularly and waits until the BioXam Capsule is pushed through it. If you haven't pushed through the pylorus for a long time, repeat step 3 or Step 4 to change

the BioXam Capsule's position relative to the pylorus and continue to wait. Usually 10 minutes is considered a long wait.

6. When the BioXam Capsule passes through the pylorus, do not operate the joystick to control the capsule immediately. Do not operate the joystick until the BioXam Capsule does not move obviously (usually wait 5 seconds).
7. To ensure long enough tube in the stomach during all processes, do not pull the tube outward, and allow the patient to swallow the tube if the BioXam Capsule cannot be dragged by the magnetic head
8. The other end of the Tether should be kept outside the mouth, and the tube kept loose.

Note: Drinking water can relieve the patient's nausea and promote stomach movement, improving the likelihood of the BioXam Capsule passing through the pylorus. When drinking, take care to keep the patient lying on the back and drink through a straw. If the patient really needs to sit up and drink, keep the other end of the Tether outside the mouth,and identify the location of the BioXam Capsule again.

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.3.4 Finding Collecting Location

The major duodenal papilla (MDP) in the duodenum is the ideal location for collecting liquid. MDP is usually within 7-10 cm of the pylorus (see Figure 9-4) and hidden in the folds of the duodenum.

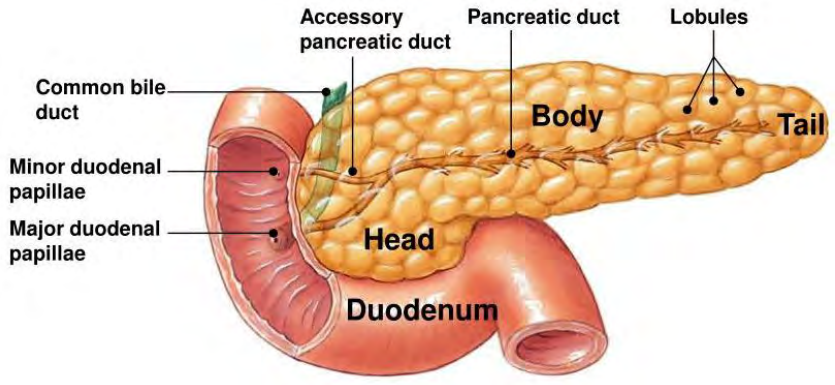


Figure 9-4: Location of MDP and minor duodenal papilla

The optimal location of liquid collection is near MDP. The methods for finding MDP are as follows:

1. After the BioXam Capsule enters the duodenum, slowly release the tube for 5-6 cm.
2. Let the patient lay on the right.
3. Observe the location of the BioXam Capsule and determine if MDP is visible. If it is, move the BioXam Capsule towards the MDP. If it is not, repeat the following steps to find MDP:

1) Release the tube for 1-3 cm gradually and observe.
2) Pull the tube outward for 1-3 cm gradually and observe.
3) Move the left and right joystick to adjust the orientation of the camera.

After finding MDP, use the magnetic head to adjust the position of the BioXam Capsuleas close to the MDP as possible, as shown in Figure 9-5. Once in place, hold the BioXam Capsule stable (no tube length changes, no joystick moves) and proceed to the next step.

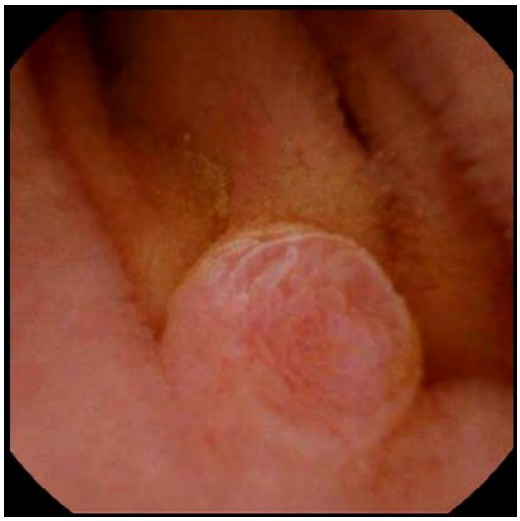


Figure 9-5: Image of MDP in proper location

The minor duodenal papilla is present in the duodenum in most patients (about 77%), and it should be distinguished from the MDP. The minor duodenal papilla is usually closer to the pylorus than the MDP, about 2 cm away from the MDP. They can be distinguished by morphology and position (see Figure 9-6 for morphology).

TBD

Figure 9-6: Morphology difference of MDP and minor duodenal papilla

Note: If the MDP has not been found after a long period of searching (e.g., more than 30 minutes), or if the conditions for further searching are not available (e.g., the voltage of the BioXam Capsule is too low and the patient is seriously uncomfortable), the liquid needs to be collected in the passive collection position. Keep the length of the tube in the incisor at 750 mm and collect liquid.

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.3.5 Collecting Liquid

When the BioXam Capsule reaches the collecting location, the following steps can be followed for the liquid collection:

1. Install a 50 mL syringe correctly on the Pump, connect the syringe connector to the syringe correctly, and be careful not to pull the tube excessively when connecting. This step can be performed after the patient has swallowed the capsule.
2. It is highly recommended to promote the secretion of pancreatic juice by simulated chewing with the following assitant methods:

(1) Watch videos of food.

(2) Smell the spicy food.

(3) If the patient is unable to secrete pancreatic fluid naturally, the patient should be injected with drugs such as cretin to stimulate secretion.

3. Turn on the Pump immediately after starting the stimulation. Set the rate as 400 mL/h, and then press the "PULL" twice to start collecting. The Pump can work using the power or using the internal battery.
4. When the piston of the syringe is pulled to the farthest end, the syringe pump will automatically stop working. In most cases, the volume of liquid in the syringe chamber cannot meet the subsequent demand at this time. Keep the position of the syringe piston unchanged, and use the negative pressure in the syringe to continue collecting liquid until enough liquid is collected. Be careful not to wait more than 15 minutes.

Note: After stopping working for 90 seconds, the Pump will emit a warning sound, click "SILENCE" to temporarily eliminate the warning sound, or temporarily turn off the syringe pump.

5. After collecting enough samples, the syringe should be removed from the Pump following the steps bellow:

(1) Press and hold “POWER” to turn off the Pump.

(2) Remove the Pump from the syringe rod, place the Pump upright and keep the syringe facing up (see Figure 9-6), hold the syringe connector firmly and pull it up to separate it from the syringe.

(3) Remove the syringe from the Pump.

Note: Residual liquid in the Tether may flow out of the syringe connector in small amounts and needs to be disposed of in accordance with relevant regulations

6. Complete the liquid collecting process. The obtained samples can be used for subsequent tests.

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.3.6 Measuring PH of Liquid

The pH sensor film is glued to the front of the BioXam Capsule. When the pH sensor is in contact with the liquid, it will show different colors, and by observing the color change, the pH value of the contacted liquid can be obtained.

The pH sensor has a measurement range of 5-9 with an accuracy of ±1.

The color development of the pH sensor observed from the camera at different pH is shown in Figures 9-8. For liquids with pH less than 5 or greater than 9, it is not possible to accurately measure their pH by color. The new pH sensor, which has not been in contact with other liquids, appears yellow. The steps for measurement are as follows:

1. Operate the joystick to fully contact the pH sensor with the liquid to be tested
2. After waiting for more than 15 seconds for the color of the pH sensor to stabilize, judge the pH according to the color.

The fluid in the duodenum can be distinguished using a pH sensor. The pH of MDP secretion is usually around 9. If the pH of the contact fluid is much lower than 9, it is possible that the sample is not needed.

TBD

Figure 9-8 The colors shown by pH sensor in different pH

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.3.7 Pulling the BioXam Capsule out of the Patient

After obtaining sufficient samples, and unloading the syringe, the BioXam Capsule needs to be pulled out of the patient to complete the examination process. Here are the steps:

1. Raise the magnetic head as high as possible and away from the patient, or use “Fold the device” function to fold the device.
2. Let the patient sit on the examination bed.
3. Pull out the BioXam Tether by slowly pulling the tube outward.
4. When the patient feel discomfort, let the patient bend over and lower his head, open his mouth and say "ah" to relieve discomfort. Drink water is also helpful.

WARNING

If the BioXam Capsule falls off from the capsule cradle or Tether breaks due to accident, please stop the inspection immediately and refer to Chapter 11 for treatment

9.4 Post Examination

9.4.1 Operations at the End of the Examination

1. Turn off the BioXam Capsule

(1) Click the "Turn off capsule endoscope" button on the operation screen (Figure 9-9).

(2) A prompt to close the capsule will appear on the monitor screen. Select "Yes" (Figure 9-10).

(3) When the "Capsule Not Connected" icon appears on the monitor screen, the capsule is successfully turned off (Figure 9-11).

Figure 9-9: "Turn off capsule endoscope" Button

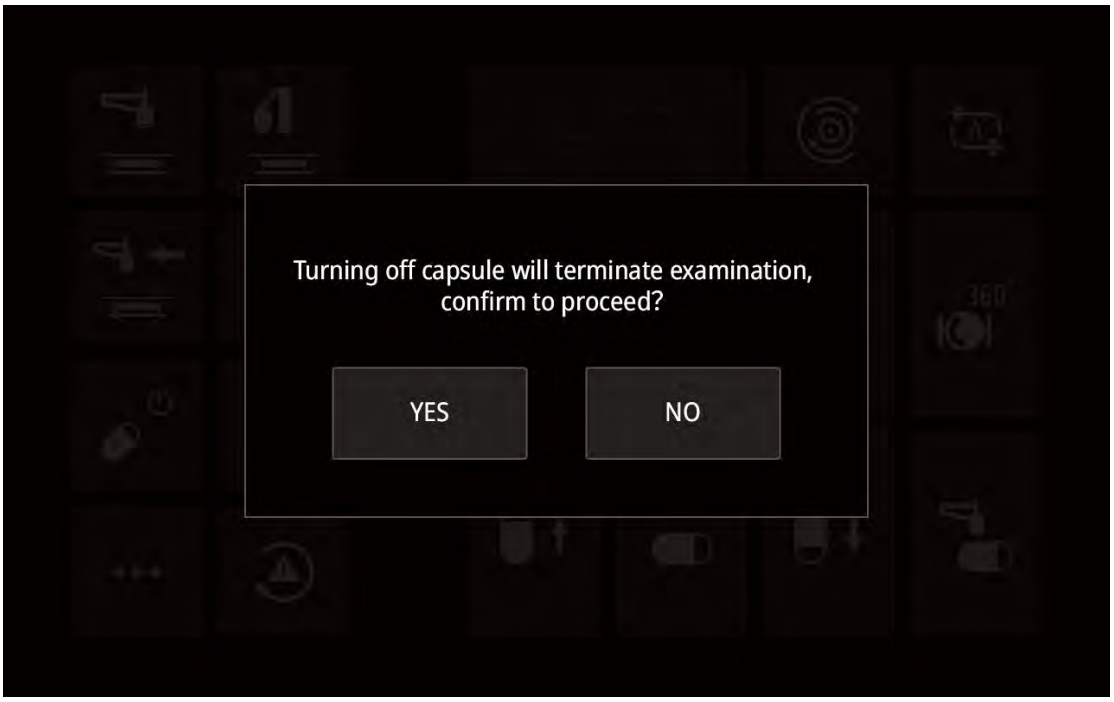


Figure 9-10: "Turn off Capsule" Prompt

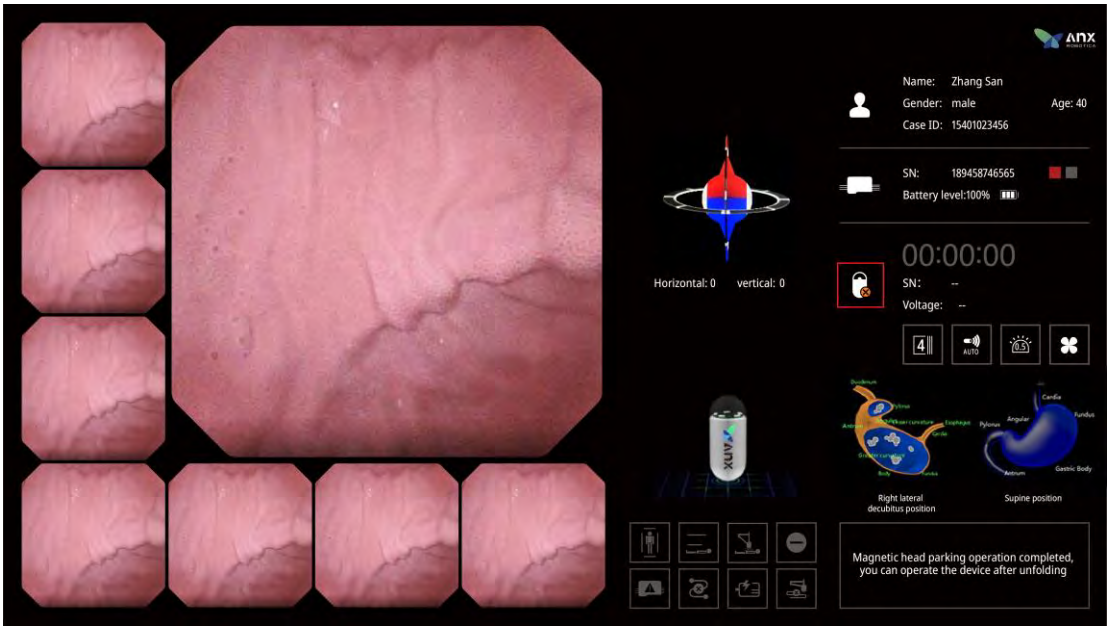


Figure 9-11: Capsule Not Connected Icon

2. Press  to make the Controller to folded state, and let the patient get off the examination bed.
3. Let the patient take off the examination vest.

9.4.2 Post Examination Instructions for Patient

Inform patient to eat and drink normally.

9.4.3 Processing and Storage of Samples.

It is recommend that relevant information about the patient and examination be recorded on the sample

The processing and storage of samples can be handled independently according to the needs, and the recommended steps are provided here:

1. It is recommended to centrifuge the samples: centrifuge at 3000 rpm for 10 min and store the supernatant and bottom separately.
2. Recommended sample storage conditions: the sample should be sealed and frozen at -15℃. If more tests are involved, it can be stored in multiple tubes.
3. Recommended sample storage time: according to the type of sample storage time, the loss of activity of most enzymes after 1 week of frozen storage is still within an acceptable range, and other proteins can be frozen and stored for 1 month while keeping their activities basically unchanged, but the same sample should not be frozen and thawed repeatedly.

9.5 Abnormal Cases Handling

9.5.1 Handling of Turbid Liquid in Stomach

Due to bile reflux, food residue retention and other factors, a few patients will appear turbid liquid in the stomach. The turbidity of the liquid in the stomach will interfere with the camera and pH sensor of the BioXam Capsule, and the turbid liquid will also enter the duodenum from the pylorus and pollute the environment in the duodenum. Therefore, it is necessary to treat the turbid liquid before continuing the examination. The treatment method can be referred to the following:

- Wait for the patient's turbid liquid in stomach to gradually empty before instructing the patient to drink an appropriate amount of water.
- Drinking water should be avoided until the patient has emptied the turbid liquid
- Walking around can accelerate gastrointestinal emptying, which is conducive to subsequent examination. During walking, the patient should be patient to keep the length of the tube in vitro unchanged
- If the lack of gastric dynamics of the patient is noted on interrogation, let the patient drink water and walk around for a longer period of time before the examination begins.

Note: There is a chance that the BioXam Capsule will enter the duodenum during walking, so locate the Capsule Endoscopy shortly after the patient returns to the examination bed. If the after the patient returns to the examination bed enters the duodenum, go on to find collecting location.

9.5.2 Nausea and vomiting

Because of the continuous contact of the tube with the base of the tongue and pharynx, it is normal for the patient to have some feeling of nausea, which is usually tolerable. However, if the patient's nausea is aggravated due to the movement of the tube, it is necessary to stop pulling or releasing the tube immediately, let the patient lie on his back, and drink an appropriate amount of water to relieve the nausea.

If the patient has vomiting, the examination should first be paused so that the patient can rinse his mouth and drink water to relieve discomfort. After the patient is relieved, whether to continue the examination should be determined according to the situation: if the patient can tolerate it, the examination can continue (pay attention to whether there is vomit glued to the surface of the capsule endoscope lens, which needs to be treated in time), otherwise the examination should be terminated and the capsule endoscope should be removed.

Note: Use a straw when drinking water.

9.5.3 Mucus Handling

There is mucus in the stomach, and in some cases, mucus will affect the examination. Different treatment schemes are used according to different situations.

Mucus stuck to lens:

1. Lower the magnetic head to bring the capsule up to the anterior gastric wall.
2. Turn the Capsule Endoscopy over several times to rub the camera lens on the gastric wall.

Mucus bubbles floating in the stomach:

Lower/lift the magnetic head to control the Capsule Endoscopy to be above/ below fluid level to avoid mucus when observing

9.5.4 Tube hooked by dental braces

For patients with metal dental braces, there is no need to remove the braces during the examination. However, during the process of releasing or pulling the tube, take care that the tube is not caught by the braces. Once hooked, pause releasing or pulling the tube immediately, and remove the tube from the braces. Check the tube for breakage, and if it is not, continue the examination.

9.5.5 Tube released too long

If the tube is released too long, the BioXam Capsule may pass through the descending part of the duodenum and enter the horizontal part, ascending part, or even the jejunum and ileum. The environment of the BioXam Capsule can be judged by the image or the estimated length. Usually, the descending part has velvet-like villi with a finer ring of creases. The jejunum has relatively long villi and peony petal-like creases, as shown in Figs. 9-12.

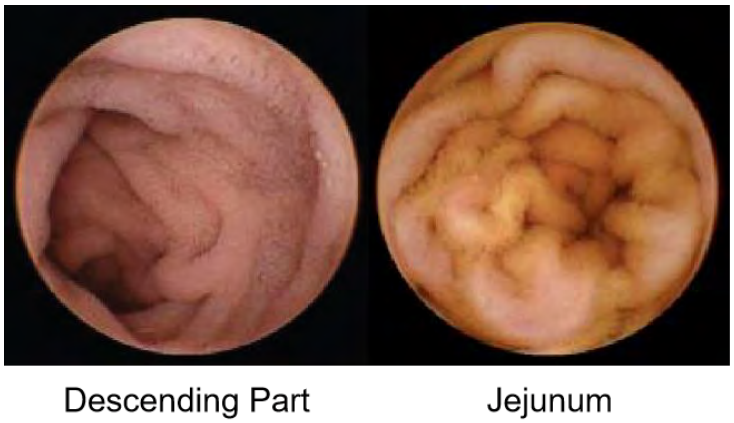


Figure 9-12: Typical images of the descending part and jejunum

After the tube released too long, it was necessary to pull the tube slowly and push the left rocker at the same time to avoid the BioXam Capsule getting stuck in the fold.

If the BioXam Capsule is still stuck in a certain position even after the above operations, the magnetic head can be elevated until it has no effect on the BioXam Capsule, and then the tube can be pulled to the BioXam Capsule to escape.

Note: When the BioXam Capsule is stuck, because the material of the BioXam Tether has good elasticity, the tube will be significantly extended when being pulled. At this time, there is a certain misjudgment in judging the position by the length, so it is necessary to observe the image at any time to understand the situation of the BioXam Capsule.

Chapter 10:MAINTENANCE

Maintenance of the equipment should be completed by qualified AnX Robotica personnel or designated by AnX Robotica at least once a year. Do not attempt to make any modifications to the device. Any modification during the actual service life requires acceptance testing to ensure OEM standards are met.

For scheduling routine maintenance and servicing of your device please contact AnX Robotica at Toll-free: +1 855.777.0020.

Routine inspection and maintenance activities are detailed below.

10.1 Power Inspection

Regularly check power supply of the System for damage, cracking or wear. Do not use the equipment when power voltage is out of specified range for the equipment 120 V±12 VAC, 60 Hz±1 Hz.

10.2 Replacement of Fuse

There are two fuses with fast-acting and high breaking capacity features. Each specified as T 4AL 250V, and the dimension is Φ5 mm in diameter, 20 mm in length.

The two fuses are located near the power input terminal of the equipment (see Figure 10-1). Please use a fuse removal tool to remove the fuse caps and replace the related fuse. AnX Robotica recommends that the fuses by replaced annually.

Figure 10-1: Fuse Replacement

WARNING

- **Replacing of the fuse can only be done by qualified personnel.**
- **Improper replacement of the fuse can induce harm to both the**

personnel and the device.

- **Please follow the fuse replacing instruction to safely replace the fuse.**

10.3 Inspection of Magnet strength

The service life of the Controller's magnetic head is 6 years.

Check that the maximum magnetic field value at the lowest 30 mm. of the magnetic head is 189.8±55.0 mT. If it does not meet this value, the magnet of the NaviCam Xpress Controller may need to be replaced or serviced.

10.4 System Cleaning

The facility should provide a bed cover that meet medical standards. To avoid cross contamination between patients, please replace with a new cover for each patient.

Once a month wipe the examination bed surface with cleaning cloth lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes.

Once a month, in power off condition, wipe the instrument surface with cleaning cloth lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes. If cleaning of internal parts of the equipment is required, only qualified personnel may clean the inside panels. ALWAYS make sure it is powered off. Outer casing may be cleaned by air blower to remove dust.

Preventive inspection and maintenance of the examination bed surface, frame and electric equipment should be conducted at least once a year. Check for loose fasteners or other conditions that may cause injury to patients or operators.

10.5 Cleaning of Data Recorder and Locator

The Data Recorder and NaviCam Locator should be manually cleaned after every use by wiping the equipment surface gently with a cotton ball lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes.

10.6 Maintenance of BioXam Pump

Refer to BioXam Pump User Manual

10.7 Handling Package Damage of BioXam Capsule/Tether

The BioXam Capsule/Tether is provided in a clean package and should not be used if its package is open, torn, or damaged.

Disposal of the BioXam Capsule/Tethers should be done in accordance with local regulations regarding the disposal of electronic products.

Chapter 11:WARNINGS, CAUTIONS AND TROUBLESHOOTING

11.1 NaviCtrl Error Messages

Prompt Box	Warning Message/Dialog	Action
The voltage of BioXam Capsule is too low to meet the examination requirements	Low capsule voltage	Replace capsule
Warning prompt for low battery of data recorder	Low Data Recorder voltage	Recharge the recorder for 8 hours or use another recorder for the procedure.
Warning prompt for turning off the BioXam Capsule	Turning off the capsule will terminate the examination. Are you sure you want to continue?	If you do want to turn off the capsule, click OK, otherwise click Cancel to exit
Warning prompt for turning off the Data Recorder	Turning off the data recorder will terminate the examination. Are you sure you want to continue?	If you do want to turn off the data recorder, click OK, otherwise click Cancel to exit
TOF warning message There are obstacles around or close to the bottom of the magnetic head, and collisions may occur if the magnetic head continues to move.	Collision warning The collision alarm icon  lights up:	Remove the obstacle while manually clearing the lowest stop limit before operating the joystick to continue lowering the magnetic head
Communication anomalies between the components of the modules of the device.	Device communication anomaly The communication anomaly alarm icon  lights up:	Wait for a while, or power off and restart the device, if the anomaly still occurs, contact technical support
Emergency stop button is pressed down.	Emergency stop The emergency stop icon  lights up	Turn clockwise to release the emergency stop button, and then manually restore
Controller failure information	Controller exception	Contact AnX Robotica Technical Support
Device motor anomaly;	Device motor anomaly	Power off and restart the device, if the anomaly still occurs,

	The motor anomaly alarm icon  lights up.	contact AnX Robotica technical support
Device motion space anomaly.	Device motion space anomaly The motion space anomaly alarm icon  lights up	Contact AnX Robotica technical support.
Data Recorder anomaly.	Data Recorder anomaly The recorder anomaly alarm icon  lights up.	Replace Data Recorder
The magnetic head moves to a limit position.	The limit icon on the corresponding side lights up:  Front & back & left & right limits;  Upper & lower limits.	The magnetic head cannot be controlled to continue moving towards this limit, but it can be controlled to move in the not limited motion space.
The remaining storage space on the device is below the warning value.	Device needs maintenance, please contact maintenance personnel as soon as possible. The device may still by used.	Contact technical support for device maintenance.
The device storage space is used up.	The device cannot be used without maintenance. Please contact maintenance personnel immediately.	Contact technical support for device maintenance
Joystick initialization failed.	The left joystick/right joystick/left & right joystick has been disabled due to initialization failure, please try restarting the device and do not touch the joystick during the initialization; if the problem persists, please contact the maintainer.	Restart the device. During the starting process and a period of time after the device is turned on (the monitor displays the software interface), do not touch the joysticks, and observe whether this warning still exists, if yes, please contact AnX Robotica technical support to deal with it.

WARNING

If the solutions provided above do not address the problem, contact AnX Robotica Corporation for assistance.

11.2 Problems with NaviCam Xpress Controller

Problem	Cause	Action
The power switch is on but the system is not powered up.	Power cord is loose	Check power cord connection
	Fuse is blown	Check and replace the fuse
	Equipment malfunction	Contact technical support
The motion of the robotic arm is accompanied with noise or jamming.	Motor is overloaded	Reset the corresponding motor driver
	Equipment malfunction	Contact technical support
Emergency stop of robotic arm motor.	Motor error	Reset the corresponding motor driver
	Equipment malfunction	Contact technical support
Large position error in motion of the robotic arm end.	Motor error	Reset the corresponding motor driver
	Equipment malfunction	Contact technical support
Robotic arm end moves at over speed.	Motor error	Reset the corresponding motor driver
	Equipment malfunction	Contact technical support

11.3 Problems with BioXam Capsule/Tether

Problem	Cause	Action
When activating BioXam Capsule, LED light does not lit up	Battery has no power or BioXam Capsule damaged	Replace the BioXam Capsule **Warning:** replacement of the battery is prohibited.
	BioXam Capsule is not activated	Activate the BioXam Capsule again with the Locator
	Equipment failure	Contact technical support
Real-time image is not transmitted to computer	BioXam Capsule is not in working state	Issue operation commands through computer
	Problems with Data Recorder	See below actions

11.4 Problems with Data Recorder

Problem	Cause	Action
The power switch is on but LED and monitor does not light up	The battery has no power	Recharge the recorder for 8 hours and use another recorder for the procedure. **Warning:** replacement of the battery is prohibited.
	Equipment failure	Contact technical support
Real-time image is not transmitted to computer display monitor	BioXam Capsule is not activated	Activate the BioXam Capsule with the Locator
	BioXam Capsule is not in working state	Issue related operation commands through the computer
	Signal transceiver of the Data Recorder failure	Contact technical support

11.5 Problems with NaviCam Locator

Problem	Cause	Action
The power switch is on but LED and monitor do not light up	The battery has no power	Recharge the locator again for 8 hours and use another locator for the procedure **Warning:** replacement of the battery is prohibited.
	Equipment failure	Contact technical support

WARNING

If the actions provided above do not address the problem, contact AnX Robotica Corporation for assistance.

Chapter 12:TECHNICAL SPECIFICATIONS

12.1 NaviCam Xpress Controller

Mechanical characteristics:

Range of Rotation angle of the magnet:	0~360°
X-axis movement range:	400±20 mm
Y-axis movement range:	540±20 mm
Z-axis movement range:	300±20 mm
Noise:	<65 dB(A)

Geometry of patient’s space:

Length:	196 mm
Width:	820 mm
Height:	520 mm

Magnetic field characteristic:

Magnetic induction intensity:	0~300 mm

Operating performance:

Grade of waterproof:	IPX0
Ambient temperature:	5~40℃ / 41~104°F
Relative humidity:	≤85%
Air pressure:	86 kPa~106 kPa
Power supply:	120 VAC±12 V, 60 Hz±1 Hz

Note: Detachable power supply cord is used to supply or isolate its circuits electrically from the supply mains.

Controllable capsule:	Positioning capsule endoscope system

Storage environment:

Storage temperature:	0~50℃ / 32~122°F
Relative humidity:	≤80％

Transport environment:

Transport temperature:	-20~55℃ / -4~131°F

Transport Requirement:

- Vehicle is sealed and rain proof
- Do not transport with flammable, explosive, and corrosive objects
- Do not unload during transport

12.2 Data Recorder

Operating performance:

Recording time:	8 hours (2fps)
Storage capacity:	≥ 4 GB
Battery type:	Lithium battery,3.7-4.2 VDC,≥2500 mAh
Ambient temperature:	5~40℃ / 41~104°F
Storage temperature:	0~40℃ / 32~104°F
Safety type:	Built-in power supply type BF continuous running equipment
Grade of waterproof:	IPX0

RF Performance:

Frequency:	2400~2481 MHz
Bandwidth:	≤3 MHz
Modulation:	GFSK
Emission Power:	≤10 mW(EIRP)

Adaptor:

Part No.:	UE110725GWGQ01-P
Input:	110-240 Vac~50/60 Hz, 500 mA
Output:	5.2 V⎓ 2 A
Protection class:	class II, continuous duty

Note: The Data Recorder incorporates a built-in RF module, while the module is completely shut down by software during operation.

FCC ID: 2ATXZ-AKR-1

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.

CAUTION

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

WARNING

The user shall avoid using RFID technology near the device while it is operating.

12.3 BioXam Capsule/Tether

12.3.1 BioXam Capsule

Physical performance:

Length:	24.5±1.0 mm
Diameter:	9.5±0.5 mm
Weight:	3.0±0.5 g
Material:	Bio-compatible materials

Optical performance:

Illumination:	LED
LED flash frequency:	0.5~6 Hz adjustable
Camera:	1 piece
FOV:	120°±15%
DOF:	0 mm~30 mm
Resolving power:	≥6 lp/mm

Image performance:

Frame rate:	0.5~6 fps adjustable
Image resolution:	480*480 adjustable

Magnetic field performance:

Surface magnetic field strength: ≤2000 Gs

Capsule's non-optic bottom magnetic induction intensity:96 Gs~360 Gs

Operating performance:

Operating time: ≥8 hours

Battery type: Silver oxide cell≥35 mAh

Rated voltage: 3V DC

Safety type: Built-in power supply type BF continuous running equipment

Grade of waterproof: IPX8

RF Performance:

Frequency: 2403~2480 MHz

Bandwidth: ≤3 MHz

Modulation: GFSK

Emission Power: ≤ 8 mW(EIRP)

FCC ID 2ATXZ-AKEM31SW:
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.

CAUTION

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

WARNING

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.

12.3.2 BioXam Tether

Physical performance:

Length:	1200 ± 50 mm
Inner diameter of capsule cradle:	9.5±0.5 mm
Outer diameter of tube:	1.1±0.2 mm
Inner diameter of tube:	0.6±0.2 mm
Material:	Bio-compatible materials

Operating performance:

Fitting syringe:	50 mL sterile syringe conforming to ISO 7886-1:2017 with a Luer taper (L1)
Binding to BioXam Capsules:	⩾3.6N

12.3.3 BioXam Capsule/Tether

Operating performance:

Chemical safety:	Resistance to dissolve when pH ranges from 2-9
Operating temperature:	20~40℃ / 68~104° F
Storage temperature:	0~40℃ / 32~104° F
RH:	⩽100%

12.4 NaviCam Locator

Operating performance:

Battery type:	Lithium battery, 3.7-4.2 V DC,2600 mAh

Ambient temperature:	5~40℃ / 41~104° F
Storage temperature:	0~40℃ / / 32~104° F
Safety type:	Built-in power supply type BF continuous running equipment
Grade of waterproof:	IPX 0

Adaptor:

Part no.	UE110725GWGQ01-P
Input:	110-240 Vac~50/60 Hz, 500 mA
Output:	5.2 V⎓ 2 A
Protection class:	class II, continuous duty

12.5 NaviCtrl Software

NaviCtrl software runs on the NaviCam Xpress Controller Device

Operating system:	Ubuntu Linux
Network interface:	No network access is required
Access requirements:	Adequate registration code must be entered for first use
Security software:	No special requirements for security software Users can use a security software of their choice

12.6 BioXam Pump

See BioXam Pump User Manual for other technical specifications

12.7 Guidance and Manufacturer's Declarations

The BioXam System complies with the requirements of IEC 60601-1-2:2014/AMD1:2020.

12.7.1 NaviCam Xpress Controller

Guidance and manufacturer's declaration - electronic emissions		
The NaviCam Xpress Controller is intended for use in the electromagnetic environment specified below. The user of the NaviCam Xpress Controller should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Radiated emissions CISPR 11	Group 1	The NaviCam Xpress Controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class A	The NaviCam Xpress Controller 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.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The NaviCam Xpress Controller is intended for use in the electromagnetic environment specified below. The customer or the user of the NaviCam Xpress Controller should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	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 for power supply Lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 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	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NaviCam Xpress Controller requires continued operation during power mains interruptions, it is recommended that the NaviCam Xpress Controller be powered from an un-interruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the NaviCam Xpress Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the

			transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

12.7.2 Data Recorder

Guidance and manufacturer's declaration - electronic emissions		
The Data Recorder is intended for use in the electromagnetic environment specified below. The user of the Data Recorder should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Radiated emissions CISPR 11	Group 1	The Data Recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class A	The harmonic current test and The voltage fluctuation and flick test are not necessary because the Data Recorder is not intended to be connected to the PUBLIC MAINS NETWORK.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Data Recorder is intended for use in the electromagnetic environment specified below. The user of the Data Recorder should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	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 for power supply Lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 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	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Data Recorder requires continued operation during power mains interruptions, it is recommended that the Data Recorder be powered from an un-interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Data Recorder is intended for use in the electromagnetic environment specified below. The user of the Data Recorder should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Data Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance.
Conducted RF IEC 61000-4-6	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.
			Portable and mobile RF communications

Guidance and manufacturer's declaration - electromagnetic immunity			
			equipment should be used no closer to any part of the Data Recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

12.7.3 BioXam Capsule

Guidance and manufacturer's declaration - electronic emissions		
The BioXam Capsule are intended for use in the electromagnetic environment specified below. The user of the BioXam Capsules should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Radiated emissions CISPR 11	Group 1	The BioXam Capsules uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class B	The BioXam Capsules are suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The BioXam Capsules are intended for use in the electromagnetic environment specified below. The user of the BioXam Capsules should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	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	N/A	N/A
Surge IEC/EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input Lines IEC 61000-4-11	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles	N/A	N/A

	Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The BioXam Capsules are intended for use in the electromagnetic environment specified below. The user of the BioXam Capsules should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of a BioXam Capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

12.7.4 NaviCam Locator

Guidance and manufacturer's declaration - electronic emissions		
The Locator is intended for use in the electromagnetic environment specified below. The user of the Locator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Radiated emissions CISPR 11	Group 1	The Locator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11	Class A	The harmonic current test and The voltage fluctuation and flick test are not necessary because the Locator isn't intended to be connected to the PUBLIC MAINS NETWORK.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The user of the Locator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

Guidance and manufacturer's declaration - electromagnetic immunity			
Electrostatic discharge IEC 61000-4-2	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	±8 kV contact discharge ±2~15 kV air discharge ±8 kV Horizontal Coupling ±8 kV Vertical Coupling	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 for power supply Lines ±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 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	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Voltage dips: 0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° Voltage interruptions: 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Data Recorder requires continued operation during power mains interruptions, it is recommended that the Locator be powered from an un-interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Locator is intended for use in the electromagnetic environment specified below. The of the Locator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Locator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	3 V 150 KHz – 80 MHz 6 V in ISM bands between 150 KHz and 80 MHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

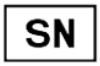
Guidance and manufacturer's declaration - electromagnetic immunity			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Mains power quality should be that of a typical commercial or hospital environment.

12.7.5 BioXam Pump

See BioXam Pump User Manual

Chapter 13:LABEL SYMBOLS AND DESCRIPTION

Followings are labels on system components:

Label	Description
	Serial Number
	Manufacturer
	Date of Manufacture
	CAUTION:US Federal law restricts this device to sale by or on the order of a physician.
	Type B Applied Part
	Type BF Applied Part
	Do not re-use
IPX8	IP Code(10m,2h)
	Batch Code/ Lot Number
	Use by/ Expiry Date
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged
T 4AL 250V	Fuse socket
Power On/Off	Power on/off

Working voltage

Protective grounding

Refer to instruction for use manual/booklet

Caution

General warning sign

Warning Mechanical injury

Warning, crushing hazard: hand

Warning, overhead obstacle

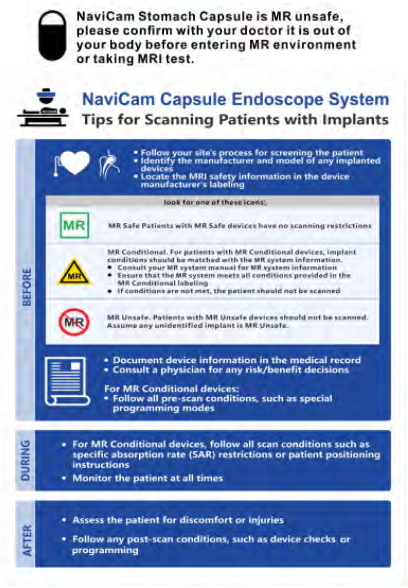
Keep Clean

No heavy load

Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please

recycle where facilities exist. Check with your local Authority or
retailer for recycling advice."

MR unsafe sign



MR unsafe sign

Warning, magnetic field

No access for people with active implanted cardiac devices

No access for people with ferromagnetic metallic implants

No metallic articles or watches

White logo

Product name identification

Chapter 14:SAFETY MANAGEMENT OF NAVIEC-2000 CONTROLLER

14.1 Safety Risks

The main safety risks of using the NaviEC-2000 controller include:

1. High magnetic field intensity attracts ferromagnetic objects, such as keys, mobile phones, watches, coins, etc.
2. Diseases or changes in anatomical structure (such as after a gastrointestinal surgery) may result in a failure of the capsule endoscope to be expelled out of the body.
3. An extreme case where the capsule is inhaled into the trachea may occur and cause asphyxia.
4. Patient may hit the magnetic head during lying down or getting up and may be injured.

14.2 Site Safety Zones Division

The three safety zones are illustrated in Figure 14-1.

1. Safety zone (Zone 1)

A safety zone is an area where people can move freely. However, for areas beyond the equipment installation room and within 0.5G line, which may include adjacent rooms, corridors, etc., although there are no safety restrictions on human body, some medical instruments that are very sensitive to magnetic fields should be subject to restricted installation areas according to installation manual. In addition, the installation distance from the adjacent NaviEC-2000 controller and the distance from the NaviEC-2000 controller to MRI devices should meet the requirements of installation manual.

2. Transition zone (Zone 2)

The transition zone is an area inside the installation room of the controller but outside the controlled access zone. In the exterior and inside of the door of the magnetic control capsule inspection room, the strong magnetic field warning signs, and "No Entry" signs for the patients with implanted cardiac devices should be hung outside and inside the magnetic capsule endoscopy room.

3. Controlled access zone (Zone 3)

The controlled access zone is an area where an operator or physician helps a patient wear the examination vest, activates a capsule, and guides the patient to swallow the capsule, and prepares for the examination. It is also an area where the operator or physician operates the capsule endoscopy system, and the physician reviews images taken by the capsule. In the controlled zone, the patient lying on an examination bed receives an examination. The magnetic capsule swallowed by the patient can be guided by the magnetic field in this area to complete the examination.

In bed position, the patient lies down with his/her feet toward the NaviCam operator.

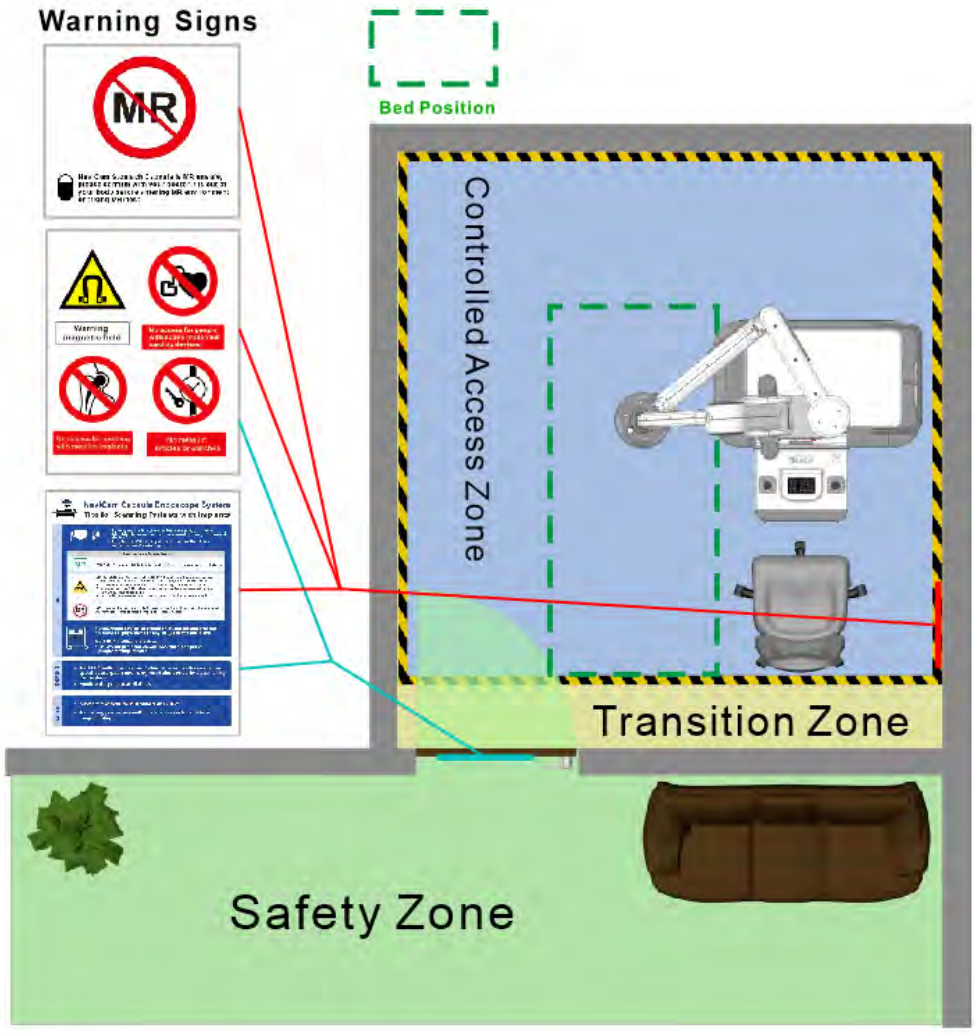


Figure 14-1: Zones Division

MR unsafe sign (see Figure14-2) should be placed behind the door and/or walls inside examination room.

Figure 14-2: MR Unsafe Sign

MR poster (Figure 14-3) should be placed in front of the door or outside wall of the examination room.

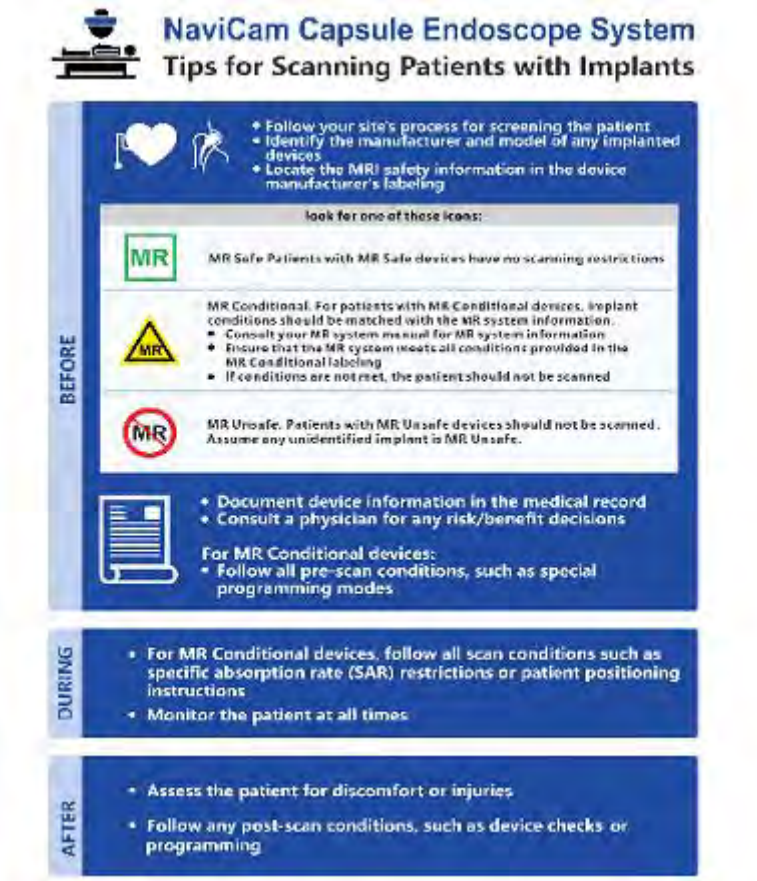


Figure 14-3: MR Poster

14.3 Roles and Responsibilities

1. Physician

Before examination: Strictly follows the indications and contraindications of BioXam System, determines if the patient meets the safety requirements of the examination, explains the examination process, and provides instructions to the patient.

After examination: Judge the patient's condition according to the detection indicators of the samples.

2. Operator

Before examination: Verifies patient's condition, past medical history, main symptoms and other relevant conditions affecting the examination results and, if there is anything unclear, verifies with the physician the eligibility of the patient to undergo the examination. Checks the items carried by the patient and ensures he/she removed all ferromagnetic items. Informs the patient of relevant matters on the examination, guides the patient to prepare for the examination, puts on the patient the examination vest, and guides the patient to enter the examination area.

During examination: Operates the equipment according to user manual, communicates with the patient throughout the examination to ensure the effectiveness of the examination, completes the examination.

3. Sample testers

Handle and store the samples in time, and test the samples correctly.

4. Hospital Equipment Management Department

Confirms that the equipment installation meets the requirements of installation manual, ensures that medical devices vulnerable to magnetic field interference are not within the 0.5G line of the NaviEC-2000 controller or makes necessary magnetic field shielding, arranges special personnel to do maintenance and troubleshooting, and regularly adjusts parameters to ensure normal and accurate operation of the equipment.

5. Relevant leader of the hospital

Checks and supervises the implementation of safety management of the NaviEC-2000 controller in the hospital.

ANNEX 1: BIOXAM SYSTEM PHYSICIAN SAFETY INSTRUCTIONS

Safety considerations before examination

1. Ask the patient whether meeting any of the contraindications for BioXam System procedure.
2. Ask the patient about the medical history: Suspected of having incomplete gastrointestinal obstruction, stenosis or fistula according to other imaging examinations or has received a gastrointestinal surgery. If the answer of any of these is yes, the risk of possible capsule retention should be explicitly explained.
3. Provide the patient with an explanation about the potential risks of the BioXam System procedure, including the use of a magnet during the procedure and ensure that the patient does not have any item that may put him/her in risk due to the magnetic forces.

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ANNEX 2: BIOXAM SYSTEM OPERATOR SAFETY INSTRUCTIONS

Safety considerations before examination

1. Remove all communication items and any ferromagnetic items from the patient, including watches, belts, mobile phones, keys, lighters, coins, knives, pens, hair clips, hairpins, glasses, dentures, earrings, metal ornaments, etc.
2. After turning on the real-time control program, ensure that the three-axis motors are returned to a safe position for the patient to get on and off the examination bed, and then help the patient to get on the bed to prevent collision against the magnetic head.

Safety considerations during examination

Set the minimum safety limit for Z axis before operating

Safety considerations after examination

Control the magnetic head to return to the clear bed access position and help the patient to get on the examination bed to prevent collision against the magnetic head.

ANNEX 3: PROPOSED TEXT TO PATIENT CONSENT TO UNDERGO BIOXAM SYSTEM PROCEDURE

The BioXam System Procedure is a safe and effective method to collect pancreatic juice.

Presented below is important information on the procedure and its risks:

1. The BioXam Capsule/Tether can be completely removed by pulling the tube during normal use, but in extreme cases (such as physiological lesions), the tube may need to be cut. The retained BioXam Capsule/Tether can be discharged naturally.
2. The product is rigorously designed, and the strength of the Tether is strictly tested from production to inspection.， Under normal use, it is not easy to break. However, in extreme cases, the Tether may be abnormally broken (such as excessive chewing), and after breaking, the retained BioXam Capsule/Tether in the body can be naturally discharged.
3. In the above two cases, if the retained BioXam Capsule/Tether cannot be discharged naturally, it may be necessary to take medicine to accelerate or to remove it by abdominal surgery.
4. In extreme cases, the BioXam Capsule may enter the trachea during swallowing.
5. Because of the continuous contact of the tube with the base of the tongue and pharynx, it is normal to have some feeling of nausea, which is usually tolerable. However, if you feel intolerable nausea, you need to notify the operator immediately.
6. During the inspection, it is necessary to replenish water in time, and if you can not drink a lot of water, inform the operator in advance. Toilet access is allowed, but communicate with the operator in advance
7. During the process of collecting liquid, it is necessary to stimulate the secretion of pancreatic juice by chewing. Do not bite the tube during chewing, and inform the operator in advance if it is inconvenient to chew.

ANNEX 4: PROPOSED PATIENT INSTRUCTIONS FOR BIOXAM SYSTEM

PROCEDURE

Before the procedure:

1. Fasting: Eat soft food with low fiber at dinner of the day before examination and fast after 8:00pm (if you have hypoglycemia, you can drink some sugar water).
2. Drinking: Drink purified water or colorless transparent liquid before examination, but do not drink any colored liquid (tea, cola, milk, soup, etc.).
3. It is best not to smoke and drink alcohol, and to avoid spicy food and non-digestible food such as beef, sticky cake, leeks in the day before examination.
4. Make sure to provide the physician or technician with all information regarding your medical history, in particular, your medical history related to the digestive system and any history of surgery.
5. Inform the physician or technician on any nonremovable implant/device you have.
6. Remove all communication items and any ferromagnetic items before examination, including watches, belts, mobile phones, keys, lighters, coins, knives, pens, hair clips, hairpins, glasses, dentures, metal ornaments, etc..

During the procedure:

Drinking water during examination: Drink water when feel nausea or listen to the operator.

After the procedure:

1. Eating immediately after the procedure is permitted if it does not conflict with other examinations, but it is highly recommended to avoid overeating.

ANNEX 5: PROPOSED PATIENT SCREENING FORM

BIOXAM SYSTEM PROCEDURE SCREENING FORM FOR PATIENTS

Date _____/_____/_____ Patient Number _____

Name _____ Age _____ Height _____ Weight _____

Last name First name Middle Initial

Date of Birth _____/_____/_____ oMale oFemale

MM DD YYYY

Address _____ Telephone (home) (_____) _____-_____

City _____ Telephone (work) (_____) _____-_____

State _____ Zip Code _____

Reason for MCE and/or Symptoms _____

Referring Physician _____ Telephone (_____) _____-_____

1. Have you had prior surgery or operation that included the introduction of a device/implant) of any kind? oNo oYes
   If yes, please indicate the date and type of surgery/operation:
   Date _____/_____/_____ Type of surgery _____
   Date _____/_____/_____ Type of surgery _____
2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? oNo oYes
   If yes, please list the most recent examination:

	Body part	Date	Facility
MRI	_____	_____/_____/_____	_____
CT/CAT Scan	_____	_____/_____/_____	_____
X-Ray	_____	_____/_____/_____	_____
Ultrasound	_____	_____/_____/_____	_____
Nuclear Medicine	_____	_____/_____/_____	_____
EGD/MCE	_____	_____/_____/_____	_____
Other_____	_____	_____/_____/_____	_____

3. Have you experienced any problem related to a previous MRI or MCE examination or MR procedure? oNo oYes
   If yes, please describe: _____
4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? oNo oYes
   If yes, please describe: _____
5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? oNo oYes
   If yes, please describe: _____
6. Are you currently taking or have you recently taken any medication or drug? oNo oYes
   If yes, please list:_____
   _____
7. Are you allergic to any medication? oNo oYes
   If yes, please list:_____
8. Did you recently have a GI surgery? oNo oYes
   If yes, which and when:_____
9. For female patients: Are you pregnant or experiencing a late menstrual period? oNo oYes

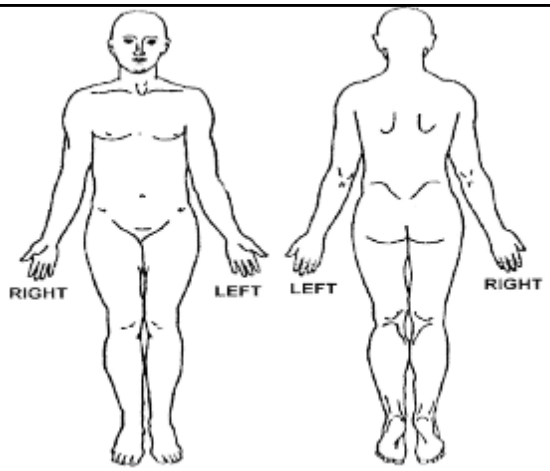
WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MCE procedure. Do not enter the MCE system room or MCE environment if you have any question or concern regarding an implant, device, or object. Consult the MCE Technologist or GI physician BEFORE entering the MCE system room. The MCE system magnet is ALWAYS on.

Please indicate if you have any of the following:

- ☐Yes ☐No Aneurysm clip(s)
- ☐Yes ☐No Cardiac pacemaker
- ☐Yes ☐No Implanted cardioverter defibrillator (ICD)
- ☐Yes ☐No Electronic implant or device
- ☐Yes ☐No Magnetically-activated implant or device
- ☐Yes ☐No Neurostimulation system

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.

☐Yes ☐No Spinal cord stimulator
☐Yes ☐No Internal electrodes or wires
☐Yes ☐No Bone growth/bone fusion stimulator
☐Yes ☐No Cochlear, otologic, or other ear implant
☐Yes ☐No Insulin or other infusion pump
☐Yes ☐No Implanted drug infusion device
☐Yes ☐No Heart valve prosthesis
☐Yes ☐No Artificial or prosthetic limb
☐Yes ☐No Shunt (spin al or intraventricular)
☐Yes ☐No Hearing aid (Remove before entering MCE system room)
☐Yes ☐No Other implant _____



IMPORTANT INSTRUCTIONS

Before entering the MCE environment or MCE system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.
Please consult the MCE Technologist or GI physician if you have any question or concern BEFORE you enter the MCE system room.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MCE procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date ____/____/____
Signature

Form Completed By: ☐ Patient ☐ Relative ☐ Nurse _____ _____
Print name Relationship to patient

Form Information Reviewed By: _____ _____
Print name Signature

☐ GI physician ☐ Nurse ☐ Other_____

ANNEX 6: PROPOSED NON-PATIENT SCREENING FORM

BIOXAM SYSTEM PROCEDURE SCREENING FORM FOR NON-PATIENTS*

The MCE system has a very strong magnetic field that may be hazardous to individuals entering the MCE environment or MCE system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MCE environment or MCE system room. Be advised, the MCE system magnet is ALWAYS on.

***NOTE: If you are a patient preparing to undergo an MCE examination, you are required to fill out a different form.**

Date _____/_____/_____ Name _____ Age _____
month day year Last Name First Name Middle Initial

Address _____ Telephone(home) (_____) _____-_____

City _____ Telephone(work) (_____) _____-_____

State _____ Zip Code _____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ☐No ☐Yes
   If yes, please indicate date and type of surgery: Date ____/____/____ Type of surgery_____
2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? ☐No ☐Yes
   If yes, please describe: _____
3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ☐No ☐Yes
   If yes, please describe: _____
4. Are you pregnant or suspect that you are pregnant? ☐No ☐Yes

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MCE procedure. Do not enter the MCE system room or MCE environment if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

☐Yes	☐No	Aneurysm clip(s)
☐Yes	☐No	Cardiac pacemaker
☐Yes	☐No	Implanted cardioverter defibrillator (ICD)
☐Yes	☐No	Electronic implant or device
☐Yes	☐No	Magnetically-activated implant or device
☐Yes	☐No	Neurostimulation system
☐Yes	☐No	Spinal cord stimulator
☐Yes	☐No	Internal electrodes or wires
☐Yes	☐No	Bone growth/bone fusion stimulator
☐Yes	☐No	Cochlear, otologic, or other ear implant
☐Yes	☐No	Insulin or other infusion pump
☐Yes	☐No	Implanted drug infusion device
☐Yes	☐No	Heart valve prosthesis
☐Yes	☐No	Artificial or prosthetic limb
☐Yes	☐No	Shunt (spin al or intraventricular)
☐Yes	☐No	Hearing aid
☐Yes	☐No	Other implant _____
☐Yes	☐No	Other device _____

IMPORTANT INSTRUCTIONS

Before entering the MCE environment or MCE system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MCE Technologist or GI physician if you have any question or concern BEFORE you enter the MCE system room

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MCE procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date ____/____/____

Signature

Form Information Reviewed By: _____

Print name Signature

☐ GI physician ☐ Other_____

FCC Warning statements in User Manual

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.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

FCC SDoC statement

FCC Supplier's Declaration of Conformity

BioXam Capsule (AKEM-31SW)
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.
AnX Robotica Corporation
6010 W Spring Creek Parkway
Plano, TX 75024

Tim Thomas
VP, Regulatory/Quality/Clinical
770-480-2911
Tim.thomas@anxrobotics.com