NAVIGATØR®

BioNavigation™ System

Operator's Manual

VIASYS®
HEALTHCARE
MEDSYSTEMS

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INTRODUCTION

The NAVIGATØR® BioNavigation™ System is designed to aid in the placement of central venous catheters (CVCs) by indicating the position of the catheter tip inside the body during the catheter insertion procedure.

Note: Prior to catheter use, confirm catheter tip position with x-ray.

The NAVIGATØR BioNavigation System consists of:

1. NAVIGATØR Instrument - a hand-held, battery–powered, electronic locating instrument.

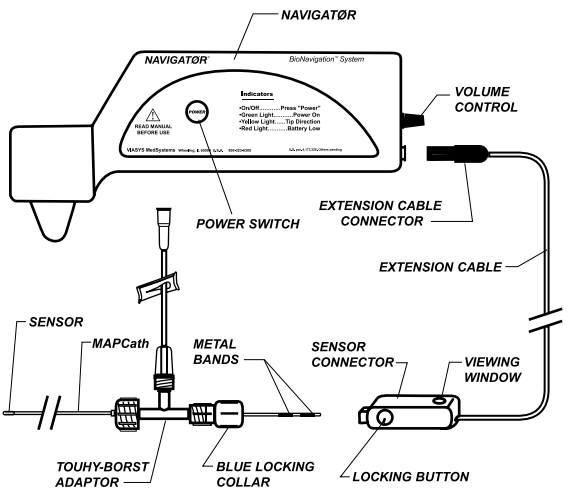
2. MAPCath® - a sterile, disposable, closed-end plastic stylet with a miniature, magnetically activated positioning (MAP) sensor in its tip. The MAPCath is supplied assembled with a Tuohy-Borst Adaptor in a sterile pouch.

3. Extension Cable - an electrical cable to connect the NAVIGATØR Instrument to the banded end of the MAPCath stylet.

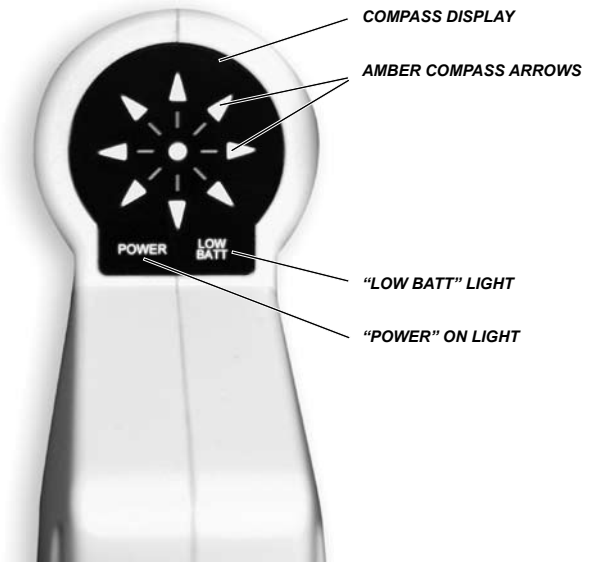
The NAVIGATØR Instrument emits a low level, high frequency electromagnetic field that is detected by the sensor in the tip of the MAPCath stylet. The position of the MAPCath stylet tip inside the patient is indicated externally by the position shown on the NAVIGATØR display. Audible and visual indicators signal the operator when the NAVIGATØR is positioned directly over the sensor in the MAPCath stylet tip.

The NAVIGATØR Instrument is packaged in a carrying case with an Extension Cable and an additional 9-volt battery. Included in the carrying case, is a built-in Test Sensor Stylet. The Test Sensor Stylet is used to confirm that the NAVIGATØR Instrument and the Extension Cable are functioning properly. The MAPCath stylet is sold separately as a single use, sterile product.

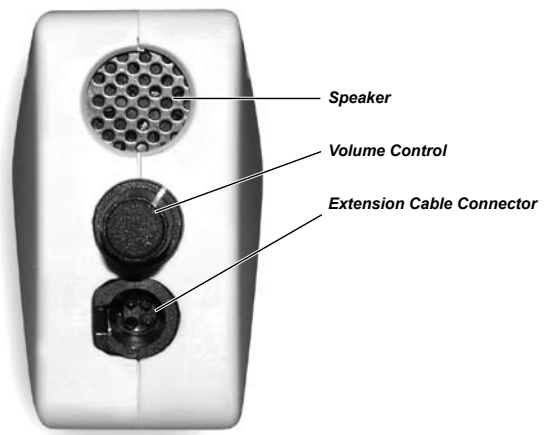
System Components with MAPCath



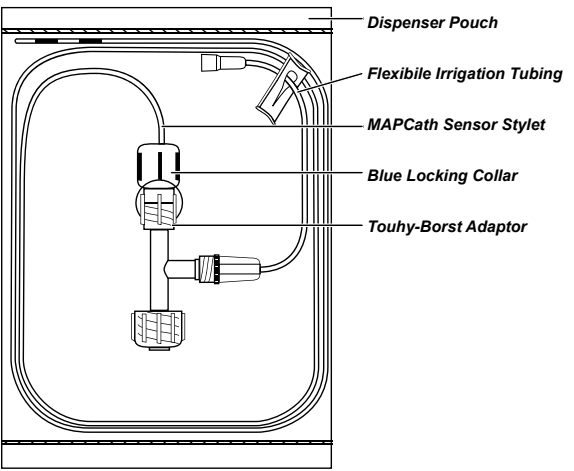
NAVIGATØR Information Displays



NAVIGATØR Rear Panel



Packaged MAPCath



INDICATIONS FOR USE

The NAVIGATØR BioNavigation System is designed to aid in the placement of central venous catheters (CVCs) by providing information as to the position and direction of the CVC distal tip inside the body during the catheter insertion procedure.

CONTRAINDICATIONS

DO NOT USE the NAVIGATØR System for patients with implanted medical devices that may be affected by electromagnetic fields.

CAUTIONS

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

DO NOT submerge any components of the NAVIGATØR BioNavigation System in water or other fluids, or attempt to sterilize.

DANGER: Possible explosion risk if used in the presence of flammable anesthetics.

POTENTIAL COMPLICATIONS

Potential complications are similar to those normally associated with CV catheterization. These include:

vein puncture	right atrial puncture
pneumothorax	hemothorax
air embolism	thromboembolism
cardiac arrhythmia	cardiac tamponade

Note: Placement of CVCs should only be performed by persons knowledgeable of the risks involved and qualified in the procedures.

INSTRUCTIONS FOR USE

Note: Prior to use of the NAVIGATØR BioNavigation System, the operator must read the NAVIGATØR BioNavigation System Operator's Manual, the MAPCath Instructions For Use and be thoroughly familiar with the NAVIGATØR Instrument's operation.

I. Functionality Test Using the Test Sensor Stylet

Note: Complete this functionality test prior to use on each patient. This assures you of a functional device for use during your sterile procedure.

1. Connect one end of the Extension Cable to the NAVIGATØR Instrument.

2. Depress the Locking Button found on the Extension Cable's Sensor Connector and insert the gold-banded tip completely into the Sensor Connector.

3. Verify that the gold-banded tip can be seen through the viewing window and is flush with the far wall of the connecter.

4. Release the button to lock the Test Sensor Stylet into the Sensor Connector.

5. Briefly press “POWER” switch on side of NAVIGATØR Instrument to activate. During start-up, all amber compass arrows and the “LOW BATT” light will flash, and an audible “BEEP” sound is made. The green “POWER” light will remain lit to show that the instrument is “ON”. If the “LOW BATT” light remains lit, battery power is low and battery should be replaced prior to use (see instructions for changing battery on page 19). The NAVIGATØR Instrument should be able to function for another 10-20 minutes after the “LOW BATT” light has illuminated. Please replace battery as soon as possible.

   NOTE: Once turned “ON”, the NAVIGATØR Instrument will remain “ON” as long as it senses a signal from the MAPCath stylet. If a signal has not been received for 60 seconds, the NAVIGATØR Instrument will automatically turn off to conserve battery power. If a signal is present, but no audio “BEEPS” occur, the NAVIGATØR will turn off after 5 minutes. To turn the instrument back “ON”, briefly press the “POWER” switch.

6. Confirm proper operation of NAVIGATØR Instrument and Extension Cable by the following:

   a. Place tapered cone of NAVIGATØR Instrument 5-10 cm above Test Sensor wire.
   b. Move NAVIGATØR Instrument towards the end of Test Sensor.

c. As the NAVIGATØR Instrument is moved towards the end of the Test Sensor, the audible tone should increase in pitch. Adjust volume control on the rear panel of the instrument to your personal preference.

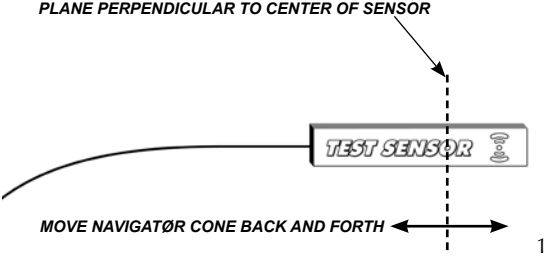
d. While passing over the Test Sensor, the NAVIGATØR Instrument will produce an audible beep and one compass arrow light will flash as the plane perpendicular to the sensor is crossed. Move the NAVIGATØR Instrument back and forth slowly (5-10 cm per second) across plane to trigger the display repeatedly.

e. The compass arrow should indicate correct direction of the Test Sensor tip.

7. Press "POWER" button to turn instrument "OFF".

Note: Refer to "Troubleshooting" Section of manual if instrument is not functioning properly.

8. Press and hold button on Sensor Connector to disconnect Test Sensor from Extension Cable.



II. CVC Placement

9. Open CVC kit CSR wrap to create sterile field and expose contents for use per hospital protocols and procedures.

10. Place NAVIGATØR Instrument, with Extension Cable connected, into sterile, plastic sleeve and lay on sterile field. The sterile sleeve should be long enough to cover the full length of the Extension Cable.

11. Refer to MAPCath stylet Instructions for Use supplied with the individual product for CVC preparation and insertion. Position the catheter with the MAPCath stylet in the desired location within the superior vena cava.

III. Tip Position Determination

12. Depress the Locking Button on the Sensor Connector and insert the gold-banded tip of the MAPCath stylet completely. The end of the MAPCath stylet should be visible through the viewing window and be sitting flush against the far wall. Release button to lock it inside the Sensor Connector.

Note: A sterile 4 x 4 or drape can be placed over Sensor Connector to maintain sterility of gloved hands.

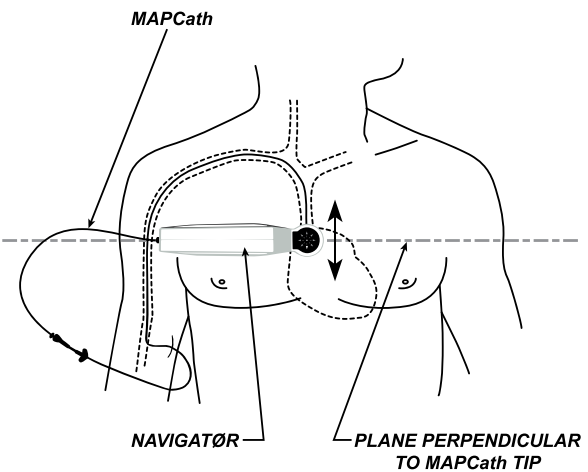
13. Press "POWER" switch to turn NAVIGATØR Instrument "ON".

14. While holding the NAVIGATØR Instrument parallel to patient, place tapered cone near patient's skin (approx. 3 cm) and follow estimated path of MAPCath stylet beginning at patient's chin moving towards the expected final tip position.

15. Slowly advance NAVIGATØR Instrument toward MAPCath tip. As it nears the tip, the pitch (frequency) of the audible tone will increase. The volume of audible tone can be adjusted by the volume control knob on the NAVIGATØR Instrument's rear panel.

16. When the NAVIGATØR crosses the plane perpendicular to tip, it will beep and an amber compass arrow will briefly light, indicating the direction of MAPCath stylet tip (tip direction is indicated from center of display outward to perimeter arrows).

17. Move the NAVIGATØR back and forth slowly (5-10 cm per second) across plane to trigger display. If tip is shown as reversed or pointing in an unexpected direction, reposition catheter and repeat steps 2-6 under “Tip Position Determination”.



18. Move the NAVIGATØR perpendicular to the direction indicated by the compass arrow (along plane perpendicular to MAPCath tip) and find position where highest pitch tone is heard.

19. At this position, move NAVIGATØR slowly back and forth across plane (approx 5-10 cm/sec) to trigger the compass display. The position where the compass display is activated and highest pitch tone is heard corresponds to exact position of the MAPCath / MAPWire tip. Be sure NAVIGATØR is kept parallel to the patient.

    Note: If the MAPCath stylet "Instructions For Use" are followed, the CVC tip position will be approximately 0.5-1.0 cm forward of the position indicated by the NAVIGATØR Instrument. Typically, catheter tips positioned under the third rib parasternally, will be located in the lower third of the superior vena cava.

    If the MAPCath tip cannot be found, it may have followed an alternate venous path. Check other venous positions (e.g., jugular veins, etc.) and reposition. Repeat steps 13-19. (See "Troubleshooting" section for more information).

20. After correctly positioning the MAPCath, press the locking button on the Sensor Connector and remove the MAPCath per "Instructions for Use" and discard. Do not re-use the MAPCath stylet.

21. Turn the NAVIGATØR Instrument off to conserve battery power.

22. Prepare the CVC per supplied instructions and institutional procedures.

23. Confirm the CVC position with x-ray prior to use.

TROUBLESHOOTING

1. If the Green "POWER" light on / amber compass lights will not turn on:

   - **The MAPCath stylet may have followed an alternate venous path.**
     If the amber compass display cannot be activated, the MAPCath may have followed a branching vein. Repeat steps 13-19 following the path from the venipuncture site along potential alternate pathways (e.g., jugular vein, etc.). Reposition tip as necessary and repeat steps 13-19.

- **The MAPCath stylet may not be properly connected to the NAVIGATØR Instrument.** Check that the double-banded end of the MAPCath stylet is fully inserted into the sensor connector.

- **The MAPCath stylet may be positioned too deep in the patient.** The NAVIGATØR will detect the MAPCath stylet tip at a depth of up to 15-20cm. Typically, the superior vena cava is located in the anterior chest at a depth of 1/3 the distance from sternum to spine. Therefore, the NAVIGATØR can be used on patients with sternum to spine dimensions as large as 45-60cm. In large patients, keep the NAVIGATØR cone as close to the skin as possible.

- **The Extension Cable may be damaged.** Replace Extension Cable and retry.

- **The MAPCath stylet may be damaged.** The MAPCath stylet may have been damaged during insertion. Withdraw the catheter assembly and replace with new product and repeat placement procedure.

2. If the Green “POWER” light will not turn on:

   Press POWER switch again. If green “POWER” light does not turn on, the battery may be completely drained. Replace the battery and retry. If the NAVIGATØR Instrument will not turn on, call for service.

3. If there is no audible signal:

   Check the volume control knob setting on the rear panel and adjust to a higher level. Test the NAVIGATØR Instrument with the Test Sensor or a new or known “good” MAPCath stylet. If still no audible signal call for service.

4. If one or more amber compass arrows do not light:

   If any of the amber compass arrows do not light, call for service.

MAINTENANCE

Service

Servicing of the NAVIGATØR BioNavigation Device must be performed by authorized service personnel only. There are no user serviceable components in the instrument or any of its accessories.

The NAVIGATØR BioNavigation Device must be calibrated annually. Please contact authorized service personnel to return to the manufacturer for annual calibration.

Changing the Battery

The battery compartment is located on the bottom of instrument under the indicated label. Slide the battery door open, remove the battery and replace with a 9-volt alkaline battery (Eveready 522, Duracell MN 1604 or equivalent). Do not use non-alkaline batteries. Close the battery door. Press POWER switch. Green "POWER" light and audible signal should be activated.

Warning: Do not dispose of battery in fire or recharge – the battery may explode or leak and cause personal injury.

Cleaning

The NAVIGATØR Instrument may be cleaned with a soft, damp cloth and mild detergent.

Warning: Do not submerge NAVIGATØR in water or other fluids or attempt to sterilize.

SPECIFICATIONS

1. NAVIGATØR BioNavigation System Model #60-3020

2. Power source: 9 volt alkaline battery (Eveready 522, Duracell MN 1604 or equivalent)

3. Usable battery life under continuous use: 2 hrs. minimum. Usable time after "LOW BATT" first comes on: 10-20 minutes.

4. Controls:
   "Power" – Turns NAVIGATØR on/off.
   "Volume" Knob – Adjusts sound level.

5. Indicators:
   a. Green "POWER" light indicated that the unit is turned on.
   b. Red "LOW BATT" light indicates low battery life.

c. MAPCath stylet tip position:

- Visual signal:
  Amber arrows indicate direction of the catheter tip and that the NAVIGATØR Instrument has crossed the plane perpendicular to the catheter tip.
- Audible tone:
  An increasing pitch indicates NAVIGATØR is moving closer to the MAPCath stylet tip.

An audio “Beep” indicates that the NAVIGATØR has crossed the plane perpendicular to the MAPCath tip.

6. Connectors:
   a. NAVIGATØR Cable connector (on rear panel).
   b. Sensor Connector (Part of Extension Cable).

7. NAVIGATØR Size:

a. Height	11 cm
b. Width	4 cm
c. Length	24 cm
d. Weight	0.5 Kg

8. Electrical Safety:
   Battery powered. Leakage current is well below AAMI/ANSI, CSA, and IEC limits. Patient is electrically isolated from circuitry.

9. Magnetic field frequency: 62.5 khz

10. Flux density: 2.0 gauss maximum (measured at patient’s skin).

11. Materials in contact with fluid path
    a. MAPCath stylet – Medical grade hydrophilic coating.
    b. Touhy-Borst Adaptor – medical grade plastic and silicone, DEHP-free PVC.

FCC COMPLIANCE STATEMENT

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.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

LIMITED WARRANTY

VIASYS MedSystems Inc. ("VIASYS") warrants to the original purchaser ("Customer") of NAVIGATØR BioNavigation System (the "Product") which accompanies this document that Product shall be free from material defects in materials and workmanship under normal use for a period of 12 months from the date of purchase. In the event of a breach of the foregoing warranty reported to VIASYS within 30 days after such breach is discovered, Customer's sole and exclusive remedy, and VIASYS' sole and exclusive obligation, shall be for VIASYS to, at its option, either (i) repair the non-conforming Product (or part thereof) at no charge, using new or refurbished replacement parts, (ii) exchange the non-conforming Product (or part thereof) with replacement Product (or part thereof) that is new or which has been manufactured from new or serviceable used parts and is at least functionally equivalent to the original Product, or (iii) refund the purchase price of the non-conforming Product.

LIMITED WARRANTY (cont.)

When a refund is given, the Product for which the refund is provided shall become VIASYS' property upon the issuance of the refund and must be returned to VIASYS. With respect to Product returned to VIASYS for warranty service, Customer shall bear the cost of sending the Product back to VIASYS and VIASYS shall bear the cost of returning the repaired or replaced Product back to Customer. The party shipping the Product shall bear the risk of loss and damage until the Product is delivered to its destination. The warranty set forth above does not apply to any non-conformity, damage, condition, or improper functioning or operation caused by, relating to, or based in anyway on: (a) a failure by Customer or its agents to follow specifications, instructions, warnings, documentation, guidelines, guidance, or recommendations furnished by VIASYS, (b) misuse or abuse of the Product by Customer or its agents, (c) use of any Product in combination with equipment, software, or other items not supplied by VIASYS, (d) use of the Product in an application or environment for which they were not designed, (e) service or modification of the Product by anyone other than VIASYS without VIASYS' prior written approval or authorization, (f) storage or handling of the Product other than as set forth on such Product or in documentation accompanying such Product, (g) damage caused by flood, fire, earthquake, or other external causes beyond VIASYS' control, or (h) damage that is covered by insurance. In addition, the warranty set forth above does not apply to any Product on which VIASYS' serial number or other markings has been removed, defaced, or obscured.

LIMITED WARRANTY (cont.)

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