SOPHYSA
At the heart of the **brain**

EN

POLARIS® VALVES ELECTRONIC READING INSTRUMENT

Add-on to Adjustment Kits for Polaris® valves

Instructions for Use

CE

NT174_EN_US
Rev001_2024-10

Table of Contents

WARNING
Read the Instructions for Use carefully before adjusting the valve operating pressure.

CAUTION
Federal (USA) law restricts the sale, distribution or use of this device to medical professionals, or by order of medical professionals.

NOTE
These Instructions for Use only describe the operation and the use of the Electronic Reading Instrument.

For more information on the other components of the adjustment kit, see the specific Instructions for Use *Polaris® Adjustment Kit-2 (PAK2)*.

NOTE
Availability of the products mentioned in these Instructions for Use may vary according to country.

1. Intended use

Designed for reading the operating pressure of a Polaris® valve in order to adapt to the clinical evolution of the patient.

2. Indications

Refer to the Instructions for Use of Sophysa's neurological valves.

3. Patient populations

The device can be used on patients of all ages, including pre-term infants.

4. Environment of use

The Electronic Reading Instrument and compatible adjustment kits are intended for use on patients in a hospital setting (operating rooms, patient rooms, intensive care units, and consultation rooms).

Post-operative follow-up is done at the hospital (consultation, imaging service, emergency room), clinic, or doctor's office.

It must only by used by a neurosurgeon. It is not intended for use in a patient's home. Patients are never expected to use the device by themselves.

5. Contraindications

This device is not intended for any use other than those indicated in these Instructions for Use.

6. Description

The rotor of the Polaris valves is fitted with a patented magnetic locking system made up of two mobile micro-magnets.

Changing the operating pressure of the Polaris valves is performed through the skin via a magnetic field using the Electronic Reading Instrument (hereinafter referred to as Compass) and the following components from a compatible adjustment kit:

– Locating instrument (hereinafter referred to as Locator),
– Setting instrument (hereinafter referred to as Magnet).

For simplicity, for the rest of these Instructions for Use, the “operating pressure of the valve” will be referred to as “pressure”.

The Compass is sold and packaged by itself in non-sterile cardboard packaging.

It fits into the shielded case of the PAK2 adjustment kits, fitting directly into the Locator.

WARNING
The Compass must not be used near an MRI machine or in any adjoining rooms.

If there are any electromagnetic disturbances, indications relating to centering and reading may be compromised.

NOTE
It is not made with natural or synthetic latex.

NOTE
All of the information needed to properly use the Compass is provided in these Instructions for Use. They are the primary training document. Using the Compass, therefore, does not require any specific training.

6.1. Compass

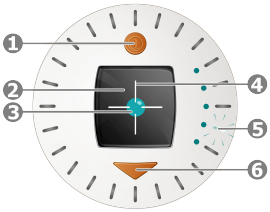
The Compass was designed to precisely identify the position and orientation of Polaris valve rotors using a set of magnetic field sensors.

When in use, the Compass carries out an automatic magnetic calibration to cancel out any ambient magnetic fields. These fields, (and especially the Earth's magnetic field) can create centering and/or reading errors.

WARNING
Avoid exposing the Compass to magnetic objects, such as metallic surfaces, magnets, motors, speakers, telephones, etc. This can provoke reading errors.

NOTE
The magnetic field cancellation must be done just before use, but far enough away from the valve to not cancel out the magnetic fields it emits. That is why there is an automatic magnetic calibration phase.

Once the calibration is complete, the magnetic field must remain stable in the area where the device is being used.



[1] ON/OFF Button.

[2] Screen.

[3] Dot to align with the target.

[4] Target for centering the position of the Compass over the valve.

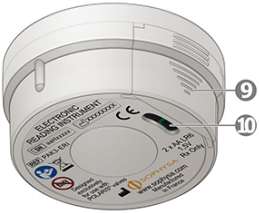
[5] Indicator light displaying the orientation of the valve rotor.

When the Compass is inserted into the Locator, and when the Locator is correctly positioned, the indicator light allows you to read the valve adjustment pressure on the Locator.

[6] Arrow indicating the CSF flow direction, to be aligned with the Locator direction.

[7] Fool-proofing device to correctly orient the Compass in the Locator during insertion.

[8] Insertion sensor.



[9] Battery hatch.

[10] Magnetic calibration assistance sensors.

6.2. Screens

The Compass has two color themes available: blue and gray.

The blue theme is used with any action specific to finding, centering and adjusting the Polaris valve.

The gray theme is used with any generic action, when the Compass needs to be inserted into the Selector or calibrated.

6.2.1. Welcome and automatic calibration

When the Compass is turned on, a welcome screen appears, displaying the software version and battery level.

	Welcome screen

Whenever the Compass is inserted into the Locator, the Compass must be calibrated. The different steps are displayed on the screen, to help the user carry out the calibration.

	Insert the Compass into the Locator.
	Move the Compass vertically. The bar on the right-hand side of the screen indicates how much further you need to go.
	Step complete

6.2.2. Finding the valve

When the Locator-Compass assembly is too far from the center of the valve, the Compass screen will display an arrow, indicating where you need to move the assembly to position it above the valve.

	Example of the screen when the Locator-Compass assembly is too far from the center of the valve. The Compass can indicate 8 different movement directions.

6.2.3. Centering

When the Locator-Compass assembly is close enough to the magnetic center of the valve, the screen will display a dot.

- When a cross is displayed over the dot, the Compass is still too far from the magnetic center of the valve to provide a reliable reading.
- The cross will disappear when the Compass is close enough to the magnetic center of the valve.

The size of the dot corresponds to the implantation depth of the valve:

- A larger dot indicates a shallow implantation.
- A smaller dot indicates a deeper implantation.

	Searching for the magnetic center. Shallow valve. Locator not centered on the valve.

	Searching for the magnetic center. Deep valve. Locator not centered on the valve.
	Compass centered. Shallow valve.
	Compass centered. Deep valve.

6.2.4. Correcting the orientation of the Locator in extreme positions

This display only appears when:

- the position indicated by the Compass is one of the two extreme positions of the valve (position 1 or position 5),
- and the Locator-Compass assembly is not properly aligned with the two valve connectors that determine the axis of the CSF flow.

The following screens indicate how to correct an alignment error (of less than 7 degrees) between the Locator-Compass assembly and the valve axis. The arrow that appears on the screen indicates the direction towards which the Locator-Compass must be turned to correct its positioning.

	Compass centered over the valve. Locator not aligned with the valve axis. Locator must be rotated to the left.
	Compass centered over the valve. Locator not aligned with the valve axis. Locator must be rotated to the right.
	Compass centered over the valve. Locator oriented correctly.

6.2.5. Low battery indicator

When the batteries are run down, an indicator will flash in the lower right of the screen. This indicator means that the batteries should be replaced as soon as possible.

	*Examples of screens with the low battery indicator.*

7. Cleaning

7.1. Introduction

While the risk of infection is low (no contact with the skin, either healthy skin or scar tissue), clean the Compass before first use and between each patient, as described in this section.

CAUTION

Do not sterilize or immerse the Compass. Irreversible alterations to the markings, distortion of the plastic parts and/or damage to the electronic components risk rendering the adjustment device unusable.

CAUTION

The Compass is not sterile and must not be sterilized. Risk of explosion when exposed to ethylene oxide.

NOTICE

Do not use solvents or cleaning agents which could damage the Compass (surfaces, glass, or general appearance):

- phenol-based cleaning agents,
- cleaning by boiling,
- cleaning with hot air/steam,
- acetone, ammonia, benzene, bleach, chlorine, chlorinated water, water above 60 °C, paint thinners, trichloroethylene.

For more information, contact Sophysa Customer Service at contact@sophysa.com, or contact your local distributor.

If the cleaning procedure is carried out as preventive maintenance, fill out the “Electronic Reading Instrument preventive maintenance traceability form” (See *Section 22. Electronic Reading Instrument preventive maintenance traceability form (p. 18)*).

7.2. Prerequisites

1. Turn off the Compass.
2. Put on gloves, and keep them throughout the procedure.
3. Take pre-soaked wipes with 70% isopropyl alcohol (IPA).

7.3. Cleaning procedure

The purpose of this procedure is to remove any soiling and visible residue from the external surfaces of the Compass.

1. Take the Compass in your hands.
2. Clean the surface of the Compass for at least 1 minute using pre-soaked wipes, to remove any visible residue.
   a. Clean the screen carefully, without exerting too much pressure on it.

      NOTICE

      Do not use cloth or abrasive paper. There is a risk of damaging the screen.

   b. Clean the external surfaces of the Compass carefully.

CAUTION
Do not rinse.

Do not pour liquid directly onto the Compass, and prevent any liquid from entering the Compass.

If the Compass is exposed to liquids, dry it with care and send it to the **biomedical engineering** department for evaluation, before any attempt to turn it back on.

3. Once the Compass has been cleaned, leave it to dry completely in the open air for 1 hour.
4. Inspect the Compass visually. If there is any remaining residue:
   a. Take a new wipe, and clean the Compass again.
   b. Leave it to dry again completely in the open air for 1 hour.

7.4. Inspection

After each cleaning procedure, check the Compass visually to ensure that it has not been damaged.

8. Preparing the Compass

8.1. Inserting batteries

1. Press on the ridged part of the battery hatch and push it in the direction indicated by the arrow.

2. Insert the batteries that have been provided.
   Be sure to follow the battery directions indicated on the product.
3. Close the battery hatch and make sure that it has been completely reinserted, in order to not prevent the Compass from fitting correctly into the Locator.

8.2. Visual inspection

A visual inspection of the Compass must be made after each use.

This visual inspection includes the following checks:

- all markings, labels, and safety information on the Compass are perfectly legible and complete.
- the Compass is in perfect working order.
- the Compass does not have any traces of contamination (traces of liquids).

If all of these conditions have been met, the Compass can be used.

NOTE
Do not use the Compass if you detect any problems. Contact Sophysa to arrange to return the product for repair.

9. Reading and adjusting the valve

WARNING
Do not use the Compass without previously identifying the valve model and making sure that the adjustment kit Locator and pressure range shown on the Locator correspond to this model. The Compass is not compatible with Sophy® valves or the Sophy® Adjustment Kit (SAK).

Overdrainage or underdrainage can result from a reading and/or adjustment with a pressure range on the Locator different from that of the implanted valve model.

WARNING
Changing the valve pressure must only be done by a neurosurgeon.

WARNING
When reading or adjusting the pressure, make sure that the Magnet, or any other ferromagnetic object, is located more than 65 cm away from the Compass so that this reading cannot be falsified by the influence of magnetic fields.

CAUTION
Do not use the Compass in the operative field. As the Compass cannot be sterilized, using it during the operation would cause a high risk of infection for the patient.

NOTICE
Do not use the Compass in the presence of any flammable anesthetics. Risk of explosion.

9.1. Adjusting the pressure prior to implantation

The Compass can be used to adjust valves in their packaging. However, we recommend that you continue to use the PAK2-RI mechanical Compass for a faster adjustment of a valve in the operating room before implanting.

See the Instructions for Use *Polaris® Adjustment Kit-2 (PAK2)*.

9.2. Reading and/or changing the valve pressure after implantation

CAUTION
The operation scar and/or post-operative edema can make positioning the Locator painful and inaccurate. This could then cause difficulties in adjustment or even make it temporarily impossible.

9.2.1. Identifying the valve model

1. In the patient's file, check the model and pressure range of the Polaris valve to be adjusted.
2. Check under the Locator that it is compatible with a Polaris valve (PAK2-LI).

9.2.2. Displaying the correct pressure range on the Locator

1. Check that the pressure range displayed in the Locator reading area corresponds to the previously identified valve model.
2. If this is not the case, display the pressure range corresponding to the implanted valve model.

For more information, see the Instructions for Use *Polaris® Adjustment Kit-2 (PAK2), section "Displaying the correct pressure range on the Locator"*.

9.2.3. Positioning the patient

Position the patient, ensuring that:

– the implantation site is readily accessible,
– the patient is in a position that is comfortable enough for them to stay still throughout the adjustment.

The Compass can be used no matter the patient position.

9.2.4. Positioning the Locator

1. Palpate the valve implantation site in order to determine both the location and orientation of the valve.
   First find the inlet and outlet connectors, at each end of the valve, and the reservoir (if fitted). These are the easiest components to locate.
2. Place the Locator above the valve, with its axis aligned with that of the valve connectors, and with the arrow of the Locator pointing in the direction of the CSF flow.
3. Center the Locator as well as possible over the valve.
4. Press the Locator against the valve so as to center and immobilize it above the valve.

WARNING
Properly positioning the Locator depends on identifying the valve axis by its connectors. If you have any doubts at this stage, the procedure to be followed once the Compass is inserted into the Locator is described in *Section 10.1. Stop method (p. 11)*.

WARNING
If the dot on the screen is significantly small, it means that the valve is implanted deeply. Thus, positioning the Locator can be less accurate and extra care should be taken in locating and aligning the orientation of the valve. See *Section 6.2.3. Centering (p. 6)* and *Section 6.2.4. Correcting the orientation of the Locator in extreme positions (p. 7)*.

When in doubt, check the valve adjustment with an X-ray examination.

For more information, see the Instructions for Use for each model:

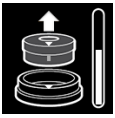
– *Polaris® Adjustment Kit-2 (PAK2), "Positioning the Locator"*,
– *Polaris® Adjustment Kit-4 (PAK4), "Positioning the Locator"*.

9.2.5. Reading the pressure

1. Hold the Locator with one hand.
2. Press the ON/OFF button to turn on the Compass.
   The Compass will then run an automatic test, during which all of the indicator lights will come on one after the other.
3. Insert the Compass fully into the Locator, aligning the arrow on the Compass with the one on the Locator.

CAUTION
Do not cover the Compass sensors when inserting it into the Locator. This could cause the calibration to fail.

   The Compass screen will change and guide you through an automatic magnetic calibration.
4. Without moving the Locator, lift the Compass a few centimeters vertically without rotating it.
   The bar to the right of the screen indicates how much further you need to go.



   Once the Compass is far enough from the valve, the magnetic calibration will run automatically and a confirmation screen will appear.

5. Once the magnetic calibration is complete, return the Compass to the Locator, making sure to align the arrows.

> **NOTE**
> A new automatic magnetic calibration will be run each time the Compass is inserted into the Locator, or whenever the Compass detects an anomaly.

6. If the Locator is not positioned properly over the valve, move the Locator-Compass assembly in the direction indicated on the Compass screen to reposition it correctly.

Example screen

7. Center the dot in the central target by sliding the Locator-Compass assembly over the skin until it is above the valve.
   When the dot is correctly centered on the target, an indicator light will come on, indicating the orientation of the valve rotor.

> **CAUTION**
> If the valve is implanted too deeply, it may not be possible to take a pressure reading.
>
> This is the case when the Locator-Compass assembly is close to the valve and when:
>
> – the dot is very small, does not appear at all, or is flashing,
> – the Compass does not indicate a direction to move the Locator.

> **NOTE**
> If there is any doubt about the orientation of the valve during palpation:
>
> – if the initial pressure is known: turn the Locator-Compass assembly slightly so that the indicator light corresponding to the initial pressure comes on,
> – if the initial pressure is unknown: turn the Locator-Compass assembly slightly so that one of the two indicator lights goes off, and follow the stop method described in *Section 10.1. Stop method (p. 11)*.

Possible indicator light behaviors

– Indicator lights will only turn on when the Compass is sufficiently centered over the valve and close enough to it to reliably display the rotor orientation (the cross disappears from the dot). In this position, the centering is also sufficient to properly unlock the Polaris valve with the adjustment Magnet (up to a depth of 8 mm).
– When two indicator lights turn on and off one after the other, this means that the valve rotor is between two Locator positions.
  – If the initial pressure is known: turn the Locator-Compass assembly slightly so that the indicator light corresponding to the initial pressure turns on.
  – If the initial pressure is unknown: turn the Locator-Compass assembly slightly so that one of the two indicator lights goes off, and follow the stop method described in *Section 10.1. Stop method (p. 11)*.

8. On the Locator, read the pressure value indicated by the Compass indicator light.

Under the recommended implantation conditions, X-ray examination is optional as the pressure can be read directly via the adjustment kit.

However, since X-ray examination provides absolute proof of the valve adjustment, it is especially recommended in the following cases:

– If there is a disparity between the pressure read and the value listed on the Patient Identification Card (PC-SPV) and/or on the X-ray used to identify the valve model.
– If the valve was implanted deeply (dot on the screen is significantly small), refer to *Section 10.1. Stop method (p. 11)* first, or opt to use X-ray examination.
– If the user is not familiar with the use of Polaris adjustment kits or in case of any doubt.

9.2.6. Setting a new pressure

1. Remove the Compass, recording the pressure that it indicates.
2. Insert the Magnet, aligning the mark with the recorded pressure, then set a new pressure.

For more information, see the Instructions for Use *Polaris® Adjustment Kit-2 (PAK2), Section "Setting a new pressure"*.

9.2.7. Checking the pressure setting

Verification is performed using the Compass in accordance with the procedure described previously.

If you have any difficulties with the adjustment, make sure that the device is properly centered. This is an essential requirement for the adjustment to work properly.

If such difficulties persist, see *Solutions in case of difficult adjustment*.

Once the pressure adjustment has been successfully made, press and hold the ON/OFF button (for about 2 seconds) to turn off the Compass.

NOTE
X-ray examination may be necessary for patients with scalp thickness greater than 3 mm.

9.2.8. Recording the new pressure

Note the pressure value read during verification on the Patient Identification Card (PC-SPV).

9.2.9. Post-adjustment monitoring

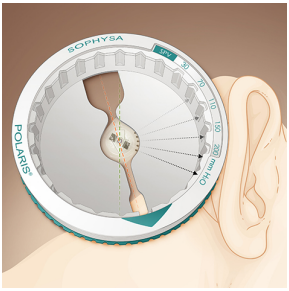
It is advisable to monitor the patient carefully for 24 hours following any change in pressure setting.

10. Solutions in case of difficult adjustment

10.1. Stop method

The correct alignment of the Locator in relation to the valve flow path is essential for an accurate reading of the Compass.

Under thick skin, the connectors are sometimes difficult to locate, which makes it difficult to accurately determine the optimum orientation of the Locator.



Example of an incorrectly oriented Locator

In this case:

1. If the current pressure of the valve is known (up to date Patient Identification Card or recent X-ray): correct the orientation of the Locator when the Compass is taking a reading, by turning the Locator-Compass assembly slightly so that the indicator light corresponding to the known valve pressure turns on.
2. If the current pressure is not known with certainty: perform the stop method described in *Section 10.1.1. Adjusting the valve in a stop position (p. 11)* below to ensure a correct reading. This makes it possible to correct the orientation during the reinsertion of the Compass.

10.1.1. Adjusting the valve in a stop position

NOTE
The stops referred to in this section are the extreme positions of the valve (minimum and maximum values). The valve cannot be mechanically adjusted beyond these extreme positions, that is why they are called “stops”.

After an initial reading, the Locator is centered and an indicator light is on next to a pressure.

Adjust the valve in a stop position by following the steps below:

1. Without moving the Locator:
   a. remove the Compass,
   b. align the mark on the Magnet on the pressure read and insert the Magnet vertically in the Locator.
2. Turn the Magnet until it reaches the selected stop.

   NOTE
   The maximum position is usually selected as the stop so as to favor the reduction of drainage during handling.
3. Then move two positions past stop.
4. Remove the Magnet vertically.
5. Place the Magnet more than 65 cm from the valve.
6. Insert the Compass fully into the Locator.
7. Carry out the magnetic calibration.

If the stop adjustment is correctly performed, the Compass indicator light will indicate the direction corresponding to the selected stop.

If this correctly matches the indication of the Locator, it is correctly oriented and the initial reading was correct.

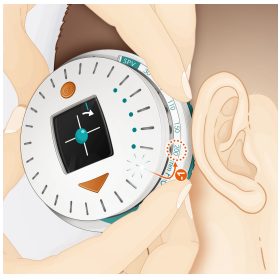
Otherwise, as described in the following section, it is possible to correct the Locator orientation and to determine what the real initial pressure actually was, based on the model of the implanted valve.

10.1.2. Correcting the orientation of the Locator and the initial reading

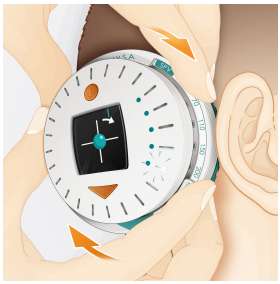
On the Locator, count the number of positions between the previously selected stop (real valve position) and the position indicated by the Compass (position read by the Compass because of the incorrect alignment with the valve connectors axis, which represent the CSF flow).

– If the indicator light comes on downstream of the selected stop, it means that the Locator-Compass assembly has been rotated too far counterclockwise by the number of positions previously counted.
  In this case, to correct the positioning of the Locator-Compass assembly: rotate the assembly clockwise, by the number of offset positions until the indicator light comes on over the selected stop value. See *Section 6.2.4. Correcting the orientation of the Locator in extreme positions (p. 7)*.
  Example
  In this example, the selected stop is the maximum value (position 5).
  However, the indicator light indicates a position downstream of position 5.

This means that the indicator light is shifted one position clockwise from the actual position.

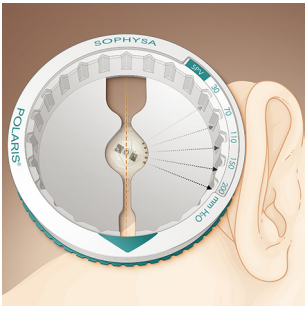


Rotating the assembly one position clockwise will move the indicator light to position 5, where the valve is now actually positioned.



– If the indicator light comes on upstream of the selected stop, it means that the Locator-Compass assembly has been rotated too far clockwise by the number of positions previously counted.
  In this case, to correct the positioning of the Locator-Compass assembly: rotate the assembly counterclockwise, by the number of offset positions until the indicator light comes on over the selected stop value. See *Section 6.2.4. Correcting the orientation of the Locator in extreme positions (p. 7)*.

From this point forward, the Locator is perfectly positioned in relation to the valve, which makes final adjustment possible.



10.2. Reading of valves implanted in conditions other than those recommended

The implantation of a valve not performed under the recommended conditions may lead to a Compass reading of a pressure value inconsistent with the patient's medical record or clinical status.

See the Instructions for Use for the *Polaris® Valve*, *section "Implantation technique"* for more information.

In this case, X-ray examination will dispel any doubts as it provides absolute proof of the correct adjustment of the valve and the correct direction of its implantation.

10.3. Electromagnetic and electrostatic disruptions

The Compass may be disrupted by ambient electromagnetic or electrostatic fields.

– If there is an electrostatic discharge, the Compass may interrupt its current operation and restart.
– In cases of electromagnetic disruption:
  – the Compass may have difficulty locating the valve,
  – the pressure reading may be less stable,
  – the Compass may report that there is too much ambient disruption to provide a reliable reading, while displaying the following symbol:

If any electromagnetic and electrostatic disruptions are detected, try one of the following solutions:

1. Turn the Compass off and then on again, then carry out a magnetic calibration.
   If the Compass does not turn off:
   – Restart the Compass by pressing and holding (for around 5 seconds) the ON/OFF button.
   – If the problem persists take out the batteries.
2. Have the patient rotate their position by 90°.
3. Move to another consultation room.

11. Environmental conditions, storage and shipping

11.1. Environmental conditions

The Compass has been designed for use in the following environmental conditions:

– Temperature: between +10 °C (50 °F) and +40 °C (104 °F).
– Relative humidity without condensation: between 15 % and 85 %.
– Altitude: between -500 m and +3,000 m (which corresponds to flights up to 12,000 m in a pressurized cabin). This is equal to pressure between 700 hPa and 1,075 hPa.

11.2. Storage

Store the Compass in the case of the PAK2 adjustment kit, directly inside of the Locator.

NOTICE
Remove the batteries when storing the Compass for prolonged periods.

The Compass has been designed for the following storage conditions:

- Temperature: -20 °C (-4 °F) to +60 °C (140 °F).
- Relative humidity: between 10 % and 85 %.
- Altitude: between - 500 m and +4,600 m (which corresponds to flights up to 12,000 m in a pressurized cabin). This is equal to pressure between 570 hPa and 1,075 hPa.

11.3. Shipping

The Compass has been designed for the following shipping conditions:

- Temperature: -20 °C (-4 °F) to +50 °C (122 °F).
- Relative humidity: between 10 % and 85 %.
- Altitude: between -500 m and +4,600 m (which corresponds to flights up to 12,000 m in a pressurized cabin). This is equal to pressure between 570 hPa and 1,075 hPa.

12. Maintenance

12.1. Preventive maintenance

WARNING
The Compass does not contain any parts that can be repaired by the user.

No modifications of the Compass are authorized.

CAUTION
Do not clean the Compass while using it on a patient.

CAUTION
If the Compass must be repaired, do not try to do so on site.

Contact Sophysa to arrange to return the product.

At least once a year, perform the inspection described below, and fill out the “Electronic Reading Instrument preventive maintenance traceability form” (See *Section 22. Electronic Reading Instrument preventive maintenance traceability form (p. 18)*).

- Perform the visual inspection described in the *Section 8.2. Visual inspection (p. 8)* section.
- Open the Compass battery hatch to check on the batteries:
  - If the batteries are oxidized, or if they seem to be leaking electrolyte, change the batteries.
  - If the battery contacts are oxidized, contact Sophysa to arrange to return the product for repair.
- Check the integrity of the case and of the screen:
  - If there are any cracks or depressions, do not use the Compass and contact Sophysa to arrange to return the product for repair.
  - Check that there are no traces of liquids in the Compass.
- Insert new batteries and turn on the Compass to verify the autotest procedure:
  - The screen should light up and display the Sophysa logo, the battery level, and the software version.
  - The Compass will let out an audible beep.
  - The 24 white LEDs will light up one after the other.
  - No error message should appear.

  If one of the above checks reveals a problem, contact Sophysa to arrange to return the product for repair.
- Clean the Compass by following the procedure described in the *Section 7. Cleaning (p. 7)* section.
- Check the interior of the Locator, it must be clean and gray-colored.

  Clean in the inside of the Locator with a pre-soaked wipe with 70% isopropyl alcohol, if needed. The interior of the Locator must stay clean and the background or circle color must remain unchanged, so that the Compass can properly identify the Locator.

12.2. Maintenance

When the “Change batteries” screen appears on the Compass, change the batteries as described in the *Section 8.1. Inserting batteries (p. 8)* section.

For any other maintenance or repair operations, contact Sophysa to arrange to return the product.

13. Processing of the products after use

13.1. Product returns

To return a faulty product, contact a Sophysa representative to obtain the explanatory return form to be provided.

Do not do anything to the product so that its condition during analysis is as representative as possible.

Return the Compass in its original packaging.

13.2. Product elimination

Clean the Compass carefully (see the *Section 7. Cleaning (p. 7)* section).

Remove used batteries from the Compass and dispose of them according to the manufacturer's instructions and in line with local regulations.

Send the Compass back to Sophysa, in its original cardboard packaging, so that it can be destroyed properly.

The electrical and electronic components and circuit boards may contain material which is hazardous and harmful for the environment, such as capacitors. They should be recycled or destroyed in compliance with electronic waste regulations.

14. Monitoring of the product safety

As part of its continual improvement program, Sophysa asks its customers to inform it and the legal authority of the country of any unexpected and serious problems that occur with the product.

15. Warranty

The performance and safety of the Compass is ensured only with the Polaris ranges of valves, designed, tested and manufactured by Sophysa.

Sophysa warrants the performance and safety of this medical device under the normal conditions of the intended use of the device, adapted to its intended purpose and use, and in accordance with these Instructions for Use.

The medical device must be stored and transported in an environment and under conditions that also comply with the

information in these Instructions for Use. These storage and transport conditions have been tested and validated by Sophysa. Thus, Sophysa does not grant any other express or implicit guarantee as for the good conservation and the safety of the product in other premises than its own which would not respect these conditions. Likewise, no express or implicit guarantee is granted by Sophysa as to the suitability of the product for the use which will be made of it, or its adaptation to a particular use, except within the indications and the intended purpose of the product, or when it has been transformed, modified or repaired except within the instructions of Sophysa.

Under no circumstances, Sophysa can be held responsible in case of damages, for any incident and/or complication, resulting from damage or prejudice arising directly or indirectly from the unsuitable use of the device and/or a use of the device which fail to conform or the non-respect of its conditions of maintenance, cleaning, storage or transport.

16. Symbols

REF	Catalogue number
SN	Serial number
MD	Medical Device
UDI	Unique Device Identification
	Manufacturer
	Date of manufacture
	Consult Instructions for Use
	Compass ON/OFF button
	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation: between 570 hPa and 1,075 hPa.
	Humidity limitation: between 10 % and 85 %.
	Temperature limits: -20 °C (-4 °F) to +60 °C (140 °F)
	MR Unsafe
	Discarding this type of product with other waste is prohibited.
Rx only	By prescription only
CE	CE conformity marking

17. Error codes

The following table contains all of the error codes you may encounter:

	E00: General error Software or hardware issue
	E20 to E24: Calibration memory error
	E31: Change batteries
	E40: Magnetic sensor saturated or defective
	E50: Presence of an electromagnetic field disrupting the reading

18. Technical specifications

The Compass complies with the standards and regulations described in this chapter.

General specifications		
Name	Electronic Reading Instrument	
Reference	PAK3-ERI	
Dimensions	Ø 70 mm Height: 37 mm	
Mass	150 g (5.3 oz)	
Power supply	Batteries	2 AA/LR06 1.5 V batteries
	Consumption	210 mW
Case	Material	PBT-GF30 (PBT 30 % glass fiber)
Screen	Type	1.50" OLED

	Resolution	128 x 128 pixels
Glass	Material	Makrolon 2207 (Polycarbonate)
Measurement method	Hall effect sensors	
Magnetic field orientation indicators	24 indicators	
	White LEDs	
Compatible valves	Polaris®	
Maximum reading depth	12 mm (Polaris)	
Compatible accessories	PAK2-LI	

Battery operated	
Battery life	Over 6 hours
Energy saving	Automatic shutoff after 15 minutes of continuous reading, with no action from the user

Safety specifications	
Class	Internal electric energy source
Applied part	No
Type of device	Portable
Operation mode	Continuous
Protection index	IP00

Frequently used features
Turning on/off
Automatic calibration
Finding the valve
Centering
Pressure reading

Benefit/risk ratio summary
The greatest risk associated with using the Compass is the risk of not being able to read the existing pressure, or of not being able to set a new pressure. The direct consequence is needing to restart the adjustment.

The Compass meets the following standards:

- IEC 60601-1-2:2014/A1:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1:2005/A1:2012/AC1:2014/A2:2020: General requirements for basic safety and essential performance
- IEC 60601-1-6/A1:2013/A2:2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62366-1:2015/amd:2020: Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304: 2015: Medical device software - Software life cycle processes
- US National standard ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

19. Agreement rates quantitative information

The following table shows the quantitative information regarding the overall agreement rates between the Compass and the actual valve position.

The agreement rates are based on non-clinical testing with readings of 15 valves by 14 clinical users under simulated use conditions, yielding a total of 210 readings with the Compass.

	-2 position	**-1 position**	**0 position**	**+1 position**	**+2 position**
Grand total	**0.5 %**	**4.8 %**	**82.4 %**	**11.9 %**	**0.5 %**
2-mm skin	0 %	1.8 %	91.9 %	6.3 %	0 %
8-mm skin	1.0 %	8.1 %	71.7 %	18.22 %	1.0 %

20. Electromagnetic compatibility

WARNING

Using the Compass near or stacked with another device should be avoided, because this could result in improper functioning. If this cannot be avoided, the proper functioning of the Compass and of other devices must be verified.

WARNING

The use of accessories, transducers or cables other than those specified or provided by the manufacturer of this device may cause increased electromagnetic emissions or decreased electromagnetic immunity of this device and may lead to improper functioning.

Directives and manufacturer declaration - electromagnetic emissions		
The Compass is intended to be used in the electromagnetic environment specified below. The customer or Compass user must ensure that it is used in this type of environment. Deviations from emission and immunity environment for this device may affect its expected service life.		
Emission tests	**Compliance**	**Electromagnetic environment guidelines**
RF Emissions CISPR 11	Group 1	The Compass uses RF energy only for its internal functions. Consequently, its RF emissions are very low and are not likely to cause interference in nearby electronic devices.

RF Emissions CISPR 11	Class A	The Compass is suitable for use in all premises other than domestic premises and those directly connected to the public supply network for low voltage electricity supplying buildings for domestic use. **NOTE** This device's emissions characteristics allow it to be used in industrial zones and hospital settings (Class A defined in CISPR 11). When it is used in a residential environment (for which CISPR 11 Class B designation is normally required), this device may not be adequately protected against radio frequency communications. The user may need to take corrective steps, such as repositioning or reorienting the device.

Directives and manufacturer declaration - electromagnetic immunity			
The Compass is intended to be used in the electromagnetic environment specified below. The customer or Compass user must ensure that it is used in this type of environment. Deviations from emission and immunity environment for this device may affect its expected service life.			
Immunity tests	**Test level CEI 60601-1-2**	**Conformity level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) CEI 61000-4-2	± 8 kV on contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	±8 kV on contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	The floor surface should be wood, concrete, or tiling. If the floor is covered with a synthetic material, the relative humidity must be at least 30 %.
Electromagnetic fields RF radiation CEI 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	**WARNING** No mobile or portable RF communications equipment (including peripherals such as antenna cables and external antennas) may be used within 30 cm (12 inches) of the Compass, including cables specified by the manufacturer. Otherwise the performances of these appliances could be altered. There may be interference near equipment containing RF emitters, which will be marked

Proximity fields emitted by wireless RF communications devices CEI 61000-4-3	Frequency/ Test level 380 - 390 MHz / 27 V/m 430 - 470 MHz / 28 V/m 704 - 787 MHz / 9 V/m 800 - 960 MHz / 28 V/m 1 700 - 1 990 MHz / 28 V/m 2 400 - 2 570 MHz / 28 V/m 5 100 - 5 800 MHz / 9 V/m	Frequency/ Test level 380 - 390 MHz / 27 V/m 430 - 470 MHz / 28 V/m 704 - 787 MHz / 9 V/m 800 - 960 MHz / 28 V/m 1 700 - 1 990 MHz / 28 V/m 2 400 - 2 570 MHz / 28 V/m 5 100 - 5 800 MHz / 9 V/m	with the following symbol: 
Magnetic field at the assigned industrial frequency CEI 61000-4-8	30 A/m 50 Hz to 60 Hz	30 A/m 50 Hz to 60 Hz	The magnetic fields at the frequency of the electricity network must have levels characteristic of a representative location situated in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz Pulse modulation 2.1 kHz, 65 A/m	134.2 kHz Pulse modulation 2.1 kHz, 65 A/m	N.A.
	13.56 MHz Pulse modulation 50 kHz, 7.5 A/m	13.56 MHz Pulse modulation 50 kHz, 7.5 A/m	

21. References

21.1. References covered by this IFU

Table 1. Device for reading the operating pressure of the Polaris® 24 valve

PAK3-ERI	Polaris® Valves Electronic Reading Instrument

21.2. References of compatible products

This device is only compatible with the products listed in this table.

Table 2. Compatible devices

PAK2-LI	Polaris® Locating Instrument-2 Available in the Polaris® Adjustment Kit-2 (PAK2)

Technical specifications and list of product references may be modified without notice.

Year of first CE marking: 2022

22. Electronic Reading Instrument preventive maintenance traceability form

Copy and fill out this document at least once a year, when performing preventive maintenance on the Electronic Reading Instrument.

Electronic Reading Instrument preventive maintenance	
Model	PAK3-ERI
Serial number	
Software version	

Visual inspection			
Step number	Action	OK	NOK
1	Open the battery hatch and check the status of the batteries (oxidation, electrolyte leak, battery contact status).		
2	Check that all markings, labels, and safety information on the Compass are perfectly legible and complete.		
3	Check the integrity of the case and of the screen: no cracks or fissures, no traces of liquid in the Compass.		
If one of these steps is “NOK”: return the device to Sophysa. No repairs are authorized.			

Start-up tests			
Step number	Action	OK	NOK
1	The screen should light up and display the Sophysa logo, the battery level, and the software version.		
2	The Compass will let out an audible beep.		
3	The 24 white LEDs will light up one after the other.		
4	No error message should appear.		
If one of these steps is “NOK”: return the device to Sophysa. No repairs are authorized.			

Cleaning	
Action	Done
Carry out the cleaning procedure as described in the instructions.	

Technician identification					
Name:		Date:		Company/Department:	
Notes					

End result		
Result	OK	NOK
The PAK3-ERI Electronic Reading Instrument is compliant.		

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