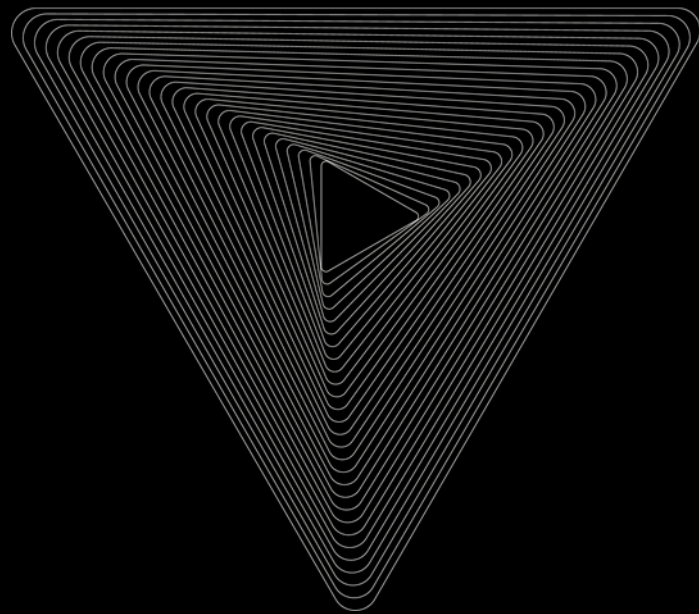


VERSO
BIOSENSE



IRIS Performance Check Instructions

1. Introduction

These instructions describe a test protocol that is run on the IRIS product prior to insertion of the IRIS to ensure that the system provided operates as intended.

2. Items required for the test

- The IRIS selected for the insertion procedure.
- The Receiver kit with the correct size garments
- A Hydration Stand (to be provided by Verso Biosense)

Important Note:

- The IRIS will have been hydrated for at least 2 hours and no more than 48 hours prior to inclusion in this procedure.

3. Performance Procedure

Important Note:

- Take care to ensure that all the following steps are carried out on a surface that has been wiped clean.



3.1. Place the garment onto the hydration stand

- Remove one of the bagged garments from the Receiver Kit.
- Remove the garment from the plastic bag, keep the plastic bag as it will be used once the checks have been completed.
- Place the garment onto the work surface, with the waistband facing up.
- Place the Hydration stand with the hydrating IRIS inside the garment.
- Carefully pull the waistband of the garment up, securing the waistband onto the hydration stand, using the images above for reference.

Important Note:

- Ensure that the contents of the hydration pocket inside the sterilisation bag does not spill into the sterilisation bag.

Critical:

- **If hydration saline leaks outside of the hydration pocket, please DO NOT USE the IRIS.**

3.2. Connecting the receiver

- Ensure that the receiver you are going to use is switched off.
- Connect the receiver to the garment.
- Locate the “on” switch on the bottom of the receiver and switch the receiver on.
- The blue, red and green LEDs on the receiver should illuminate for approximately 20 seconds. The green LED is located close to the red LED and may be difficult to see.
- The receiver will then have a green LED flash twice, and then vibrate twice to indicate successful connection.
- The blue LED will flash continuously indicating clinician mode has been entered.
- Leave the receiver connected to the garment for 10 minutes, slotting it into the pocket, ensuring the LEDs are still visible.
- The blue LED should light up continuously to indicate success.
- Remove the receiver from the garment, it will vibrate three times. The blue LED will remain on for 5 minutes, or until a garment is connected again.
- Switch the receiver off.

Critical:

If the red LED on the receiver illuminates continuously, this indicates that the IRIS has failed communication and should not be used.

If continuous vibration occurs, the receiver has failed.

3.3. Boxing up the product

- Remove the garment from the hydration stand and return the garment to the garment bag.
- Return the bagged garment to the Receiver Kit.
- Wipe down the hydration stand with a non-alcohol detergent wipe.
- The IRIS is ready for insertion and must be inserted within 24 hours. Refer to the “IRIS Kit Physician Instructions for Use” (0300-IFU-02) for insertion instructions.

Important Note:

- Please ensure that the Receiver Kit is not damaged during this process and that the surfaces of the box are not marked.
- Ensure that the contents of the hydration pocket inside the sterilisation bag does not spill into the sterilisation bag.

4. Technical Support

Technical Support at Verso Biosense Limited can be reached on:

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This IFU can also be found at: <https://versobiosense.com/product-docs/>

