

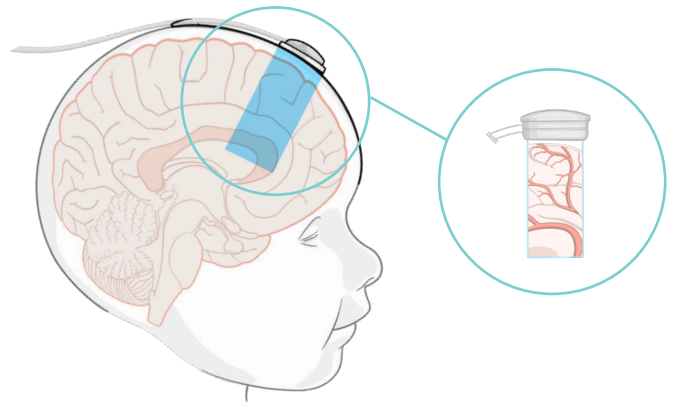


NeoDoppler Quickstart Guide

NeoDoppler is a Doppler ultrasound system that is intended for monitoring cerebral blood flow (CBF) in infants.

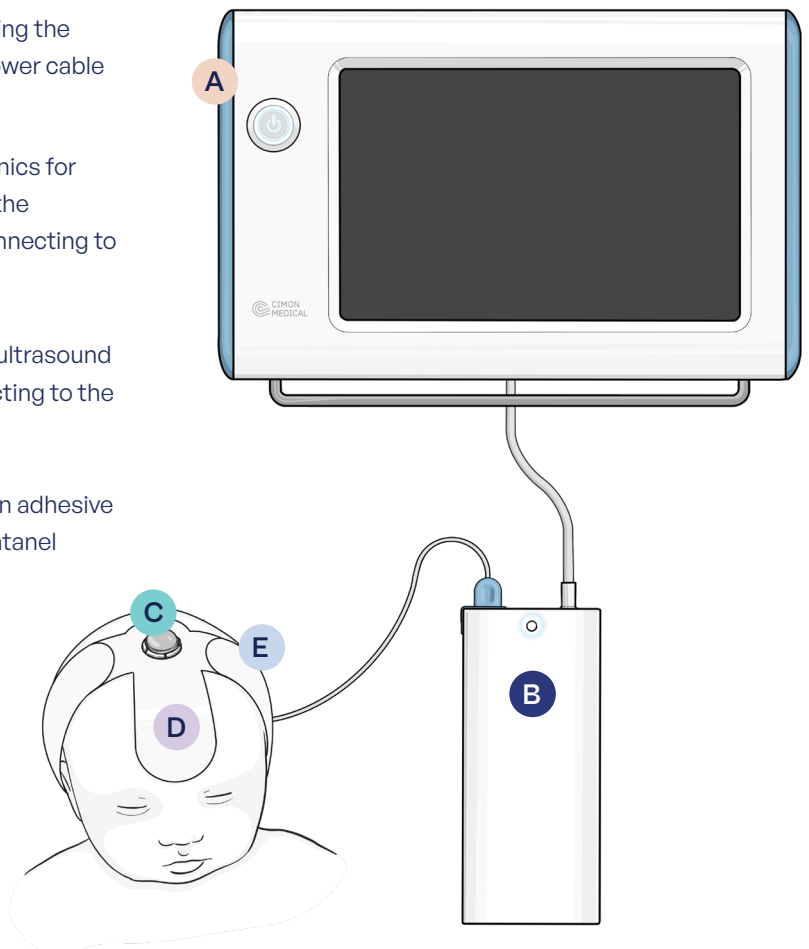
The Doppler measurements rely on a small, lightweight ultrasound sensor constructed as a single element transducer that can be gently affixed over an infant's anterior fontanel.

Because the ultrasound beam is unfocussed, brain tissue heating is reduced significantly compared to conventional Doppler ultrasound, and safely within recommended limits allowing NeoDoppler use for continuous monitoring of CBF.



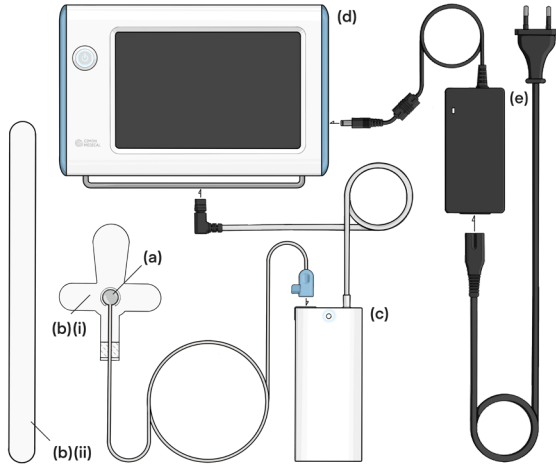
System Components

- A** Display Unit with proprietary software for displaying the acquired signal and providing a user interface (power cable not shown)
- B** Ultrasound Scanner Module with custom electronics for transmitting the ultrasound beam and receiving the reflected echoes (includes attached cable for connecting to the Display unit)
- C** Single-patient, disposable Sensor containing an ultrasound transducer (includes attached cabling for connecting to the Scanner Module) the Display Unit);
- D** Single-patient, disposable Adhesive Patch with an adhesive backing for fixing the Sensor in place over the fontanel (provided with the Sensor already attached)
- E** Accompanying Strap that wraps around the back of the infant's head to secure the Adhesive Patch.



Equipment

⚠ WARNING: Before putting the system into operation, always inspect all the system components, connecting cables and power cords carefully to ensure that they are in correct working order and operating condition. Do not attempt to use the system if any component appears damaged or unclean.



Multiple-Use Cimon Medical equipment

d & e: Display Unit and power supply/cable

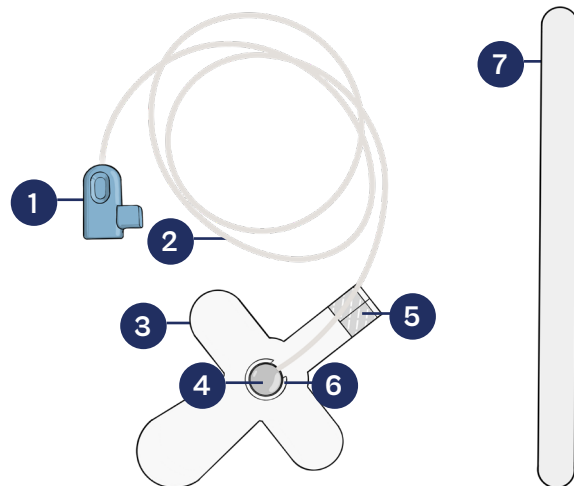
a - c: Scanner Module and connector cable

Multiple-Use third party equipment

Trolley

75mmx75mm VESA bracket pivoting arm

- 1 Scanner connector**
Plugs into the Scanner Module
- 2 Sensor Cable**
Connects the Sensor to the Scanner Module
- 3 Adhesive Patch**
Adheres to the scalp to hold the Sensor in place over the fontanel
- 4 Sensor**
Houses the Ultrasound transducer
- 5 Fishtail tabs**
Used for securing the Sensor cabling on the Patch
- 6 Attachment ring**
Used for attaching the Sensor to the Patch
- 6 Strap**
Wraps around infant's head for additional securing of the Patch



Single-use Cimon Medical equipment

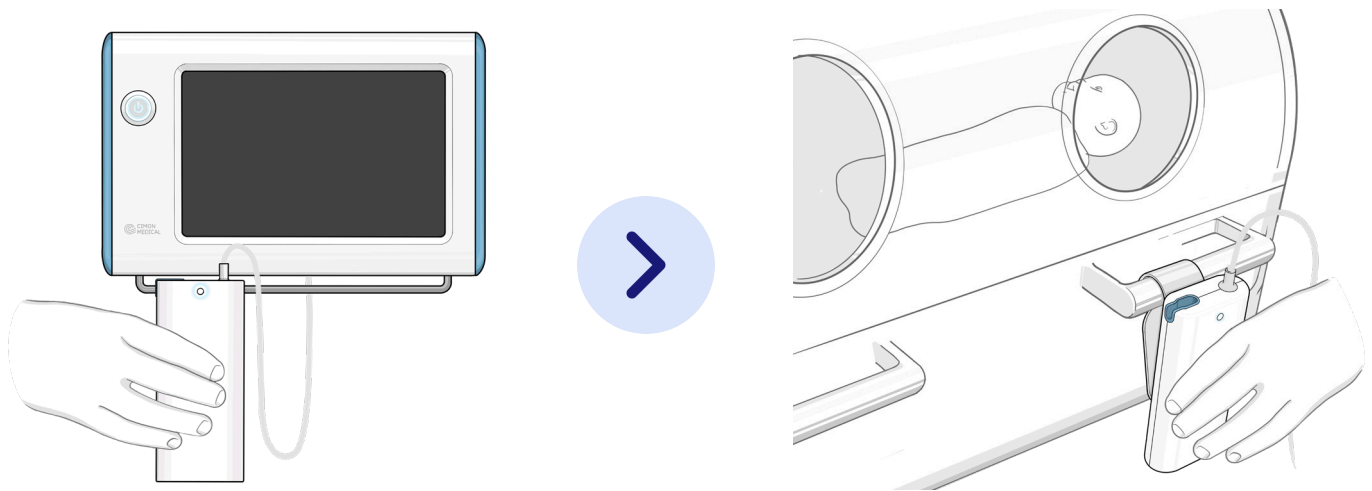
1-6: Single-patient, disposable Adhesive Patch with attached sensor and cabling for connecting to the Scanner Module.

7: Strap (Large and Small straps included for different infant sizes)

1. Startup

1.1 – Positioning the Scanner Module

Remove Scanner Module from the Display Unit and position it on the incubator exterior. Find a handle, edge, or other suitable feature on the incubator where the Scanner can hang securely.

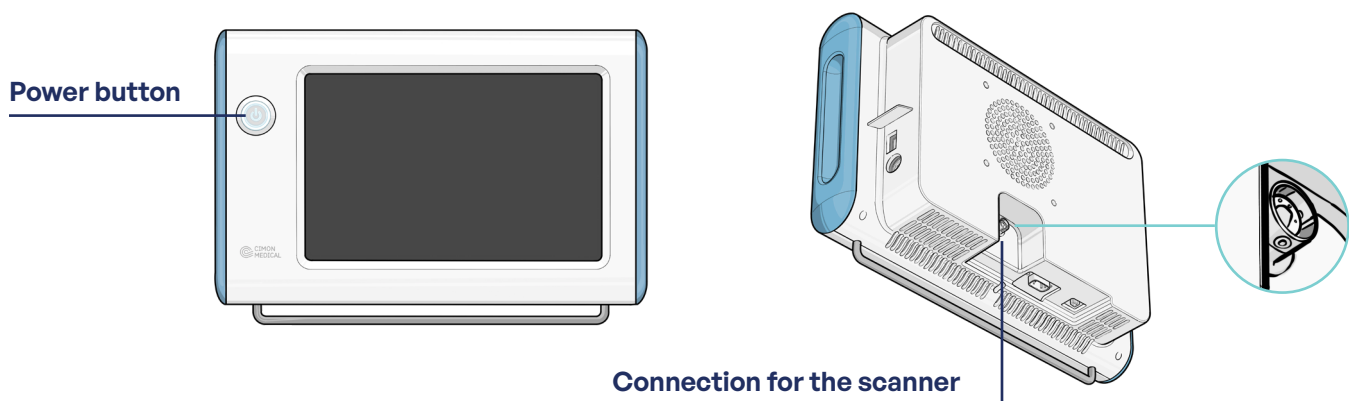


⚠ WARNING: Do not position the scanner unit inside a closed incubator or in the infant warming area of a radiant warmer. Doing so may overheat the scanner unit, making the examination end abruptly

1.2 – Connecting the Scanner

If the system is not already powered ON, press the Power Button on the Display Unit. The Power Button will illuminate when the system is powered ON, and the Cimon software startup screen will be displayed.

Check that the Scanner connector cable is connected to the back of the Display Unit. If necessary, connect it.



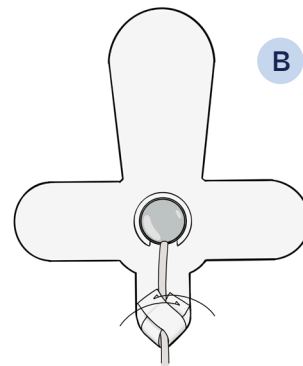
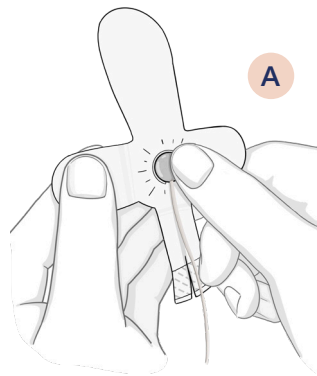
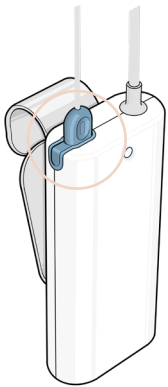
2. Preparing the sensor

2.1 – Inspect the equipment

Being careful to maintain cleanliness, carefully remove the Single-Use components from their packaging. Inspect all the components including the transducer face and connecting cables for damage, and do not attempt to use the system if any components show signs of damage.

⚠ WARNING: Always carefully inspect sensors before using. Do not use a sensor that has scratches or other damage. Use of a damaged sensor may result in injury to the patient or user, inaccurate measurements and/or damage to the device.

2.2 – Secure the sensor to the Adhesive Patch



A Ensure that the Sensor is attached securely in the attachment ring on the Adhesive Patch. If necessary, press on the Sensor to snap it into the attachment ring.

B Secure the Sensor cable to the Adhesive Patch by folding the fish tails on the Adhesive Patch over the cable and gently pressing down on them.

2.2 – Connect the Sensor to the Scanner Module

Plug the Sensor cable into the Scanner Module. Make sure that the connector is fully depressed in the socket.

The system software will now display this message on the screen:

“Sensor connection detected”

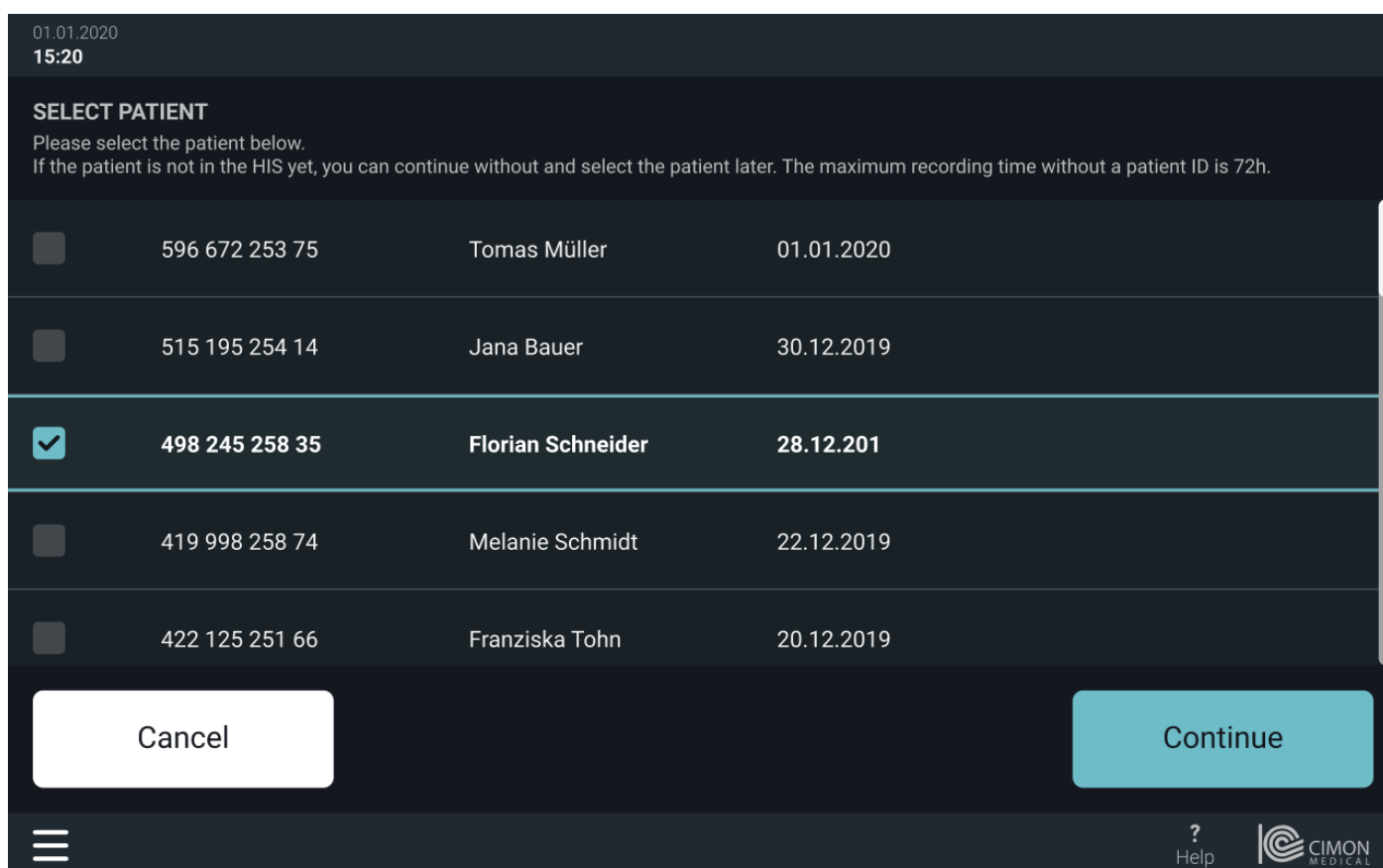
You are now ready to start the patient exam!

3. Selecting the Patient

3.1 – Advance to patient selection screen

Tap on the Activate the Sensor button on the screen to advance to the patient selection screen.

3.2 – Select the correct patient from the displayed list



01.01.2020
15:20

SELECT PATIENT
Please select the patient below.
If the patient is not in the HIS yet, you can continue without and select the patient later. The maximum recording time without a patient ID is 72h.

| | | | |
|-------------------------------------|----------------|-------------------|------------|
| <input type="checkbox"/> | 596 672 253 75 | Tomas Müller | 01.01.2020 |
| <input type="checkbox"/> | 515 195 254 14 | Jana Bauer | 30.12.2019 |
| <input checked="" type="checkbox"/> | 498 245 258 35 | Florian Schneider | 28.12.201 |
| <input type="checkbox"/> | 419 998 258 74 | Melanie Schmidt | 22.12.2019 |
| <input type="checkbox"/> | 422 125 251 66 | Franziska Tohn | 20.12.2019 |

Cancel Continue

Help CIMON MEDICAL

Scroll through the patient list using the scroll bar on the right side of the screen to find the correct patient. The patient ID, name and birthdate are displayed.

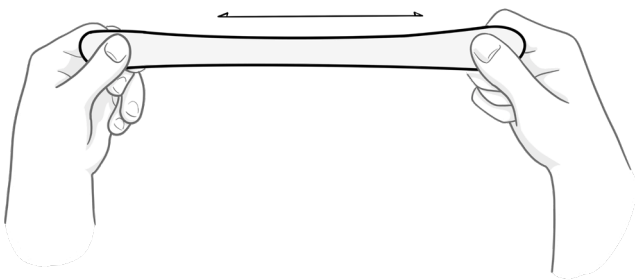
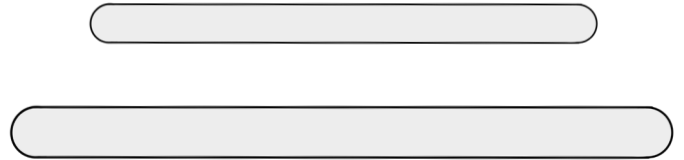
When you have found the correct patient, click the box to the left of the patient ID. Note that the selected patient will be highlighted.

Tap the Continue button to continue to the next screen.

4. Placing the Strap

1 Select Strap length

Based on the child's head circumference, select the Large or Small Strap. Provide recommendation of which one to choose based on head

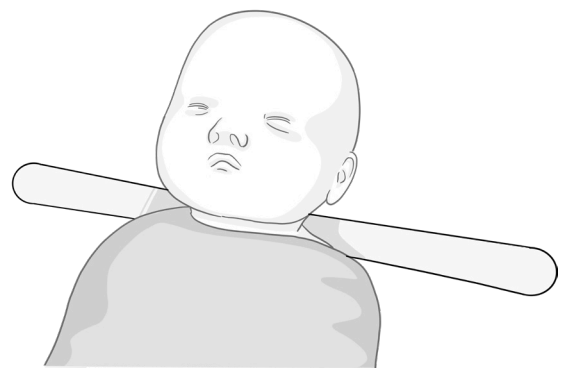


2 Length adjustment (if necessary)

If needed, stretch the Strap to the appropriate length.

3 Place Strap under infant's neck

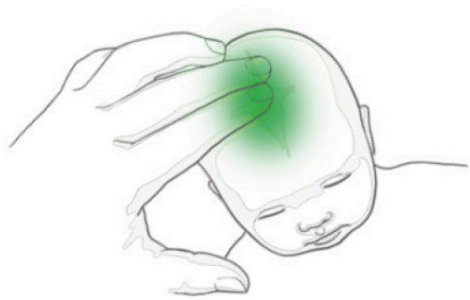
Carefully lay out the strap below the infant's neck with the textured side facing up.



5. Positioning the Sensor

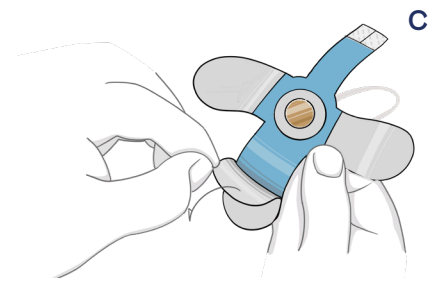
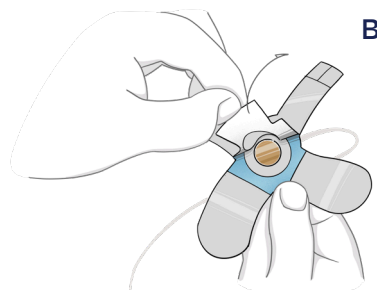
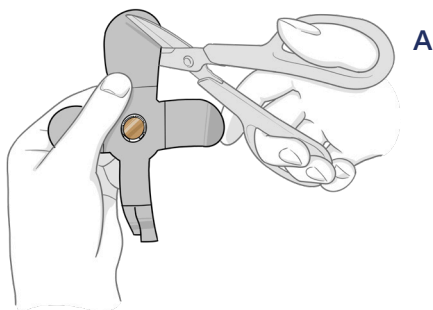
5.1 – Locate the Fontanel

Locate the Fontanel by palpating the scalp. Apply a small amount of Ultrasonic Gel to the center of the fontanel and to the transducer surface. Using only enough gel to ensure good acoustic contact between the transducer and the Skin. Too much gel will prevent the Adhesive Patch from sticking to the skin.



! CAUTION: The NeoDoppler sensor should not be affixed to broken or infected skin. It is meant for use on healthy, intact skin surfaces only.

5.2 – Preparing the Adhesive Patch

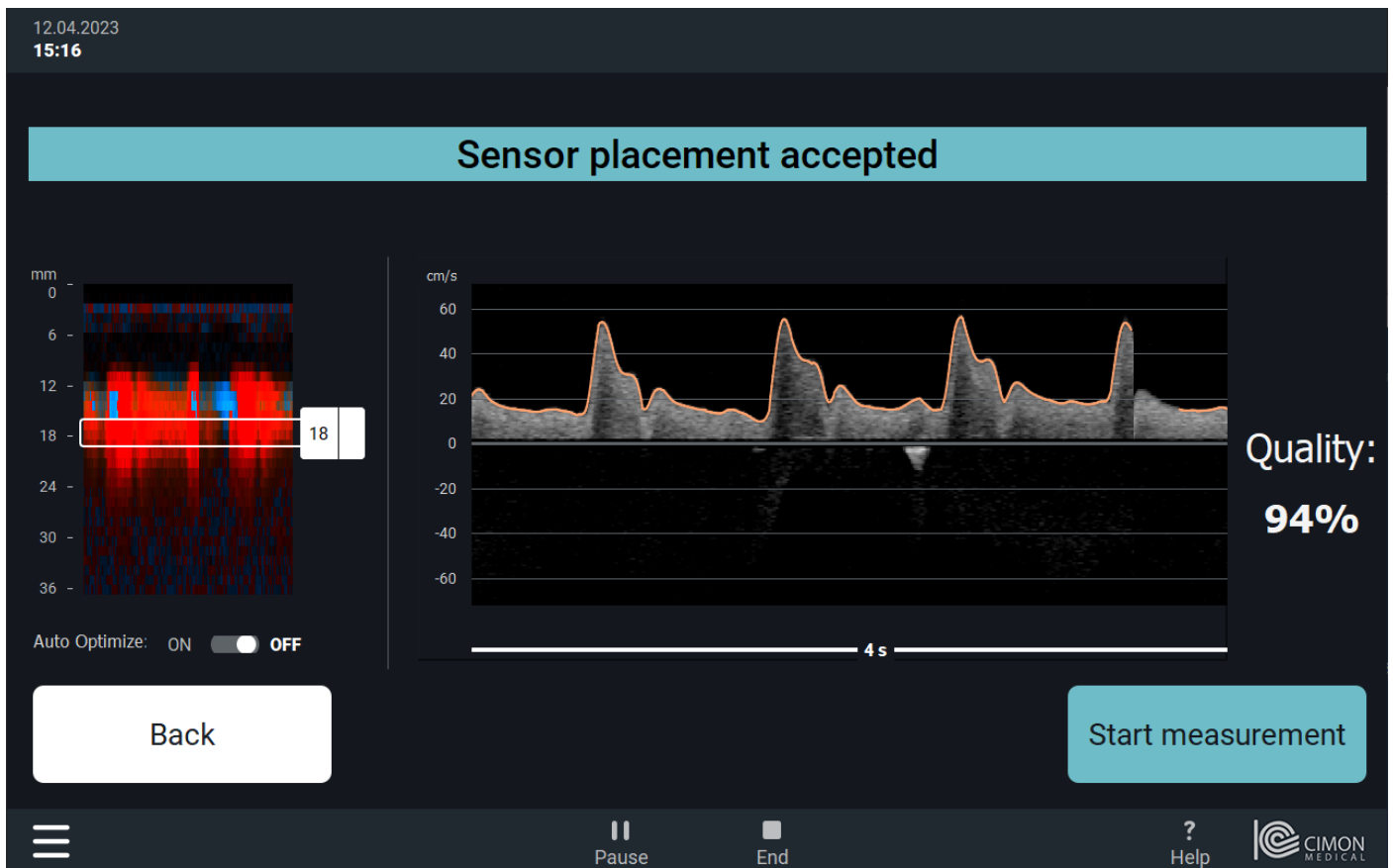


A If the Strap is too large, the frontal wing of the Strap can be cut to size using scissors.

B Remove the backing from the central portion of the patch exposing the adhesive.

C Remove the backing from the front tab of the patch exposing the adhesive.

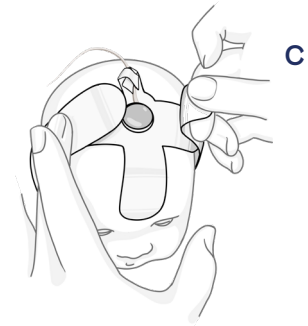
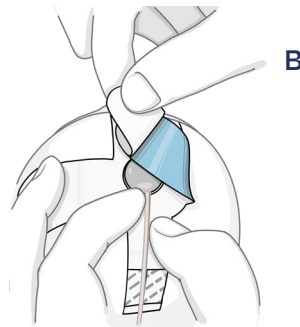
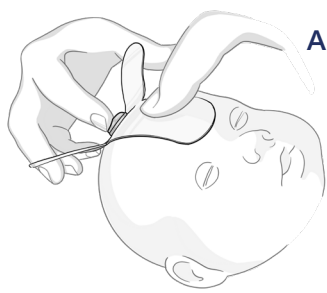
5.3 – Finding a Signal



Pinch side flaps with your thumb and middle finger, placing your index finger lightly pressing down on the Sensor. Place the sensor directly over expected fontanel location.

Gently search for a reliable Doppler signal until the Quality Indicator on the right side of the screen is greater than 80% and the Start Measurement button becomes active.

5.4 – Securing the Sensor

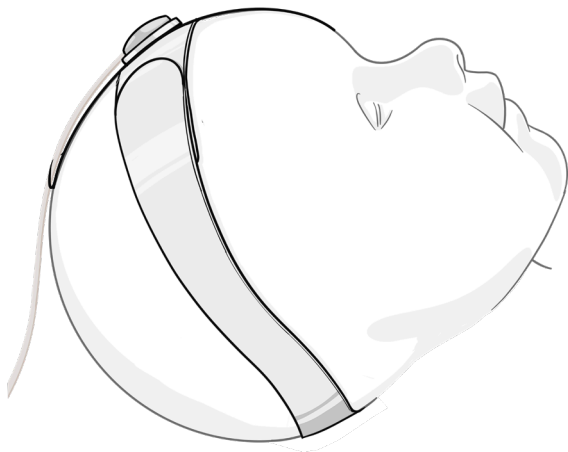


⚠ CAUTION: Do not apply additional pressure to the NeoDoppler sensor. Applying pressure may result in inaccurate measurements and/or injury to the patient. Do not apply pressure bandages or other wrappings over the sensor that apply pressure.

A To secure the sensor in place, gently press down on the Adhesive Patch around the sensor, moving outward to secure the front and back tabs.

B Remove the backing from the left and right tabs. Lightly press down on the left and right tabs until the Adhesive Patch is attached to the skin everywhere.

C Attach the strap ends to the Adhesive Patch to fully secure the Sensor.



The Sensor is now securely attached and you are ready to begin monitoring.

6. Monitoring

Tap the Start Measurement button to advance to the next screen, which is the main monitoring screen. This screen is divided into two sections. The left side of the screen displays the Doppler waveform and the RI with the expansion of the Doppler waveform, from EDV to PDV, displayed as an area, and the Vmean as a blue line over a longer time period.



Zooming into the waveform itself, allows the visualisation of the Doppler waveform and the RI in a higher resolution and for a shorter time period.

The right part of the screen shows the last 2 seconds in a higher time resolution. Additionally, the average velocity of the waveform (Vmean) and the RI (averaged over the last Heartcycle) are displayed and updated regularly.

Tapping on the trend, will display the trendmenu. Here, the scale of the timeline can be adjustet to the predefined timeframes of 4 hours or 30 minutes, Additionally, the plus (+) and minus (-) buttons can be used to manually adjust the displayed timeframe.

Tapping the arrow buttons left (<) and right (>) will move the trend accordingly, the button „Display now“ will bring you back to the most recent value in the graph.

Summarized reports from the monitoring period are automatically sent to either a HL7-compatible patient journal system or a connected USB thumb drive, dependent on the local configuration.



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