



Instructions for Use (version 14.0)

SaMD version 1.21.4





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1.0 General

1.1 Using this manual

These instructions for use are written for users of the SONDA Hub Class I medical device and, for users with the diagnostic module activated, for the interpretation of the output of the diagnostic report (SONDA Class IIa Software as Medical Device - SaMD).

The users include healthcare professionals and opticians. Before using any SONDA device, you must read, understand, and follow the instructions provided in this manual and take specific note of the warnings and cautions provided herein. The safety information is provided for your and your patients' benefit.

Paper copies of these instructions for use are available upon request at no cost and are dispatched within 7 calendar days.

1.2 Disclaimer

Reyedar assumes no liability for the use of this document if any unauthorized changes to the content or format have been made. Every care has been taken to ensure the accuracy of the information in this document. Neither Reyedar nor anyone else who has been involved in the development, production, or delivery of the documentation can be held liable for any special, incidental, or consequential damages, whether based upon breach of warranty, breach of contract, negligence, strict liability in tort, or any other legal concept.

This document is continuously updated. Always refer to the latest published version, which will be provided to you by Reyedar B.V.

1.3 User Responsibility

SONDA Hub and the diagnostic SONDA SaMD are regulated medical devices. The manufacturer and the users of the device share responsibilities regarding the post-market reporting of incidents according to the regulatory framework.

An incident is defined as any malfunction or deterioration in the characteristics or performance of the SONDA Hub and/or the diagnostic SaMD, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by Reyedar and any undesirable side-effect stemming from clinical use of the device.

A serious incident involves the death of a user or other person; the temporary or permanent serious deterioration of a user's or other person's state of health; and a serious public health threat. In the context of the SONDA Hub device, serious incidents are considered extremely unlikely, also including the diagnostic functionality of the Class IIa SaMD.

It is of utmost importance that users are aware of their responsibility to report any incidents, serious incidents, or adverse events associated with the SONDA Hub and diagnostic SaMD devices. If a serious incident occurs, users and patients should specifically notify the manufacturer, Reyedar B.V., at support@reyedar.com within 2 calendar days. In addition, users need to use the SONDA Hub and diagnostic SaMD only within the scope described in this document. Any use outside the scope of this document in any way constitutes a violation. Any deviation from the normal expected performance of the device, as described during user training, as well as any event fitting the description of an incident, still needs to be reported to the manufacturer for investigation as soon as possible. In addition to reporting to the manufacturer, users must report serious incidents to the competent authority of the Member State

in which the user and/or patient is established. A list of competent authorities is available on the European Commission website under 'Contact points':

https://health.ec.europa.eu/medical-devices-sector/contacts_en

Regardless of the above definitions, any event that is related to the SONDA Hub device and that causes or has the potential to cause harm to the health of the user or the patient requires the user to immediately discontinue the use of the device.

User Manual Icons

The following symbols are used throughout the user manual:

	Warning
	Consult Instructions for Use
	Manufacturer
	Warning: risk of electric shock
	Mandatory action
	No pushing

2.0 Intended Use

2.1 Intended Purpose – SONDA Hub (Data Acquisition and Visualization)

The SONDA Hub is a functional vision assessment tool. Its intended purpose is to collect and visualize eye-tracking data to help professionals objectively observe an individual's functional vision and oculomotor behavior. The SONDA Hub provides visual representations of eye-tracking data and its quality metrics; it does not serve a diagnostic purpose on its own.

2.2 Intended Purpose – SONDA SaMD (Diagnostic Module)

The SONDA SaMD (Software as a Medical Device) processes the oculomotor behavior data to obtain clinically relevant metrics. It is intended to be used by healthcare professionals as an aid in the diagnosis and staging of functional vision disorders, specifically glaucoma.

NB: SONDA SaMD is not active by default and has to be purchased separately. Throughout this manual can be referred to as “diagnostic module”.

2.2.1 Clinical benefit

SONDA (SaMD) supports the earlier and more accessible detection of glaucomatous functional vision loss by providing an objective, patient-friendly functional vision assessment, enabling qualified professionals to make timely referral and management decisions. SONDA is a diagnostic aid and does not provide a standalone diagnosis.

2.3 Intended User

The intended users are healthcare professionals trained in eye care testing, for example, opticians, optometrists, technical ophthalmic assistants, and ophthalmologists.

To ensure effective and safe use of the device, Reyedar will provide training covering its operation, features, and applications.



Warning: Make sure that only authorized personnel use the device.

2.4 Intended patient target group

The patients cannot control or influence the device. The intended patient population is all individuals above 18 years of age.

2.5 Contraindications for Use

- SONDA Hub: There are no known contraindications to the use of the SONDA Hub.
- SONDA SaMD: There are no known contraindications to the use of SONDA SaMD. No undesirable side effects have been identified.

2.6 Product Performance

2.6.1 SONDA Hub

SONDA Hub has no essential performance. If the network connection is lost, the test will not start or will stop safely. No results will be shown, and the test can be restarted once the connection is restored.

2.6.2 SONDA SaMD (Diagnostic Module)

Based on clinical validation, the SONDA SaMD diagnostic algorithm achieves sensitivities of 63%, 97%, and 100% for early, moderate, and severe glaucoma, respectively, with a specificity of 95%. This is the output of a version-locked machine learning model.

2.6.3 Declared Limits of Accuracy

NB: these limits apply when the device is used within the conditions of use specified in this document.

Dimension	Parameter	Declared limit
Diagnostic	Sensitivity, early glaucoma	$\geq 50\%$ at 95% specificity
Diagnostic	Sensitivity, moderate glaucoma	$\geq 90\%$ at 95% specificity
Diagnostic	Sensitivity, advanced glaucoma	$= 100\%$ at 95% specificity
Diagnostic	Specificity	$= 95\%$ (fixed threshold)
Diagnostic	Clinical validity	$ r > 0.50$ versus HFA mean sensitivity
Stability	Test-retest reliability	No significant learning effect ($p > 0.05$)
Stability	Reproducibility across hardware	Diagnostic performance maintained across all compatible configurations
Technical	Gaze estimation accuracy (median, uncalibrated)	$\leq 3.0^\circ$ per-subject median at ~ 0.6 m working distance, $\geq 80\%$ of population
Technical	Gaze precision (RMS-S2S)	$\leq 0.5^\circ$

2.7 Intended Environment

SONDA Hub device is intended to be used in a low-light environment suitable for vision or ophthalmic tests, with ambient illumination not exceeding 11 lux, and with no direct light sources illuminating the display.

SONDA Hub device must be stored in temperatures between -20°C and $+40^\circ\text{C}$ and used between $+5^\circ\text{C}$ and $+25^\circ\text{C}$. The humidity levels for storage must be between 5% and 95%, non-condensing, and for the use environment, a humidity level between 20 % and 80 %, non-condensing, is recommended.



Excessive bright lighting conditions close to the device can negatively impact the quality of the test results.

3.0 Safety Requirements

SONDA Hub and the diagnostic module SONDA SaMD have been designed, developed, and manufactured as part of a risk management system. Hazards and risks associated with the use of the devices have been identified and controlled. As a result of this process, the overall residual risk to the user and the patient associated with the use of the devices is deemed low and acceptable when weighed against the benefits to the patient. Nevertheless, some risks remain that cannot be reduced further. This is expressed in the current section in the form of warnings and mandatory actions that must be complied with during the use of the devices.

3.1 Hardware & Operational Safety (SONDA Hub)

	This device is heavy. To prevent physical injury, do not push the device or lean on the device in any way. Do not step on the device. Do not use this equipment in locations where children are likely to be present.
	SONDA Hub is classified as a Class I medical electrical equipment according to IEC 60601-1. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	Do not disassemble or modify the device in any way. Only Reyedar B.V. service personnel are allowed to assemble, disassemble and move the device, once installed. Modifying the device in any way may invalidate the test results and/or result in personal injury or electric shock.
	Do not connect any external devices such as a mouse, keyboard, or any other USB peripherals to the service (USB-A) port of the device. Doing so constitutes a violation, may invalidate the test results and compromise the safety of the user. Only Reyedar personnel are authorized to use the service port.
	Only the supplied eye tracker must be connected to the eye tracker port. Do not connect other eye trackers or any external devices such as a laptop, smartphone, charger or any other USB-C peripherals to the eye tracker (USB-C) port of the device. Doing so constitutes a violation, may invalidate the test results and compromise the safety of the user.
	Do not connect the supplied eye tracker to any other device such as a laptop, smartphone or any device, other than the SONDA Hub. Doing so may compromise the safety of the user or patient.
	The eye tracker part of the device contains cameras and sensitive electronic components, DO NOT rinse or wet-clean. The glasses' lenses must be cleaned with the provided microfiber cloth.
	The SONDA Hub eye-tracker uses a fixed, non-detachable cable. Always route the cable safely away from walkways and ensure the patient remains seated during the test. Cable tension or tripping may pull the eye-tracker from the patient's face or cause them to lose balance, leading to facial and head injuries, or falls.
	For any incident that results or has the potential to result in harm to the patient or the user in any way, please discontinue use of the device immediately and notify Reyedar B.V. of the incident providing as much detail as possible.
	Do not use unsupported web browsers with the device. Doing so may invalidate the test results.
	Do not change the screen settings of the device. Doing so may invalidate the test results.
	Do not use the device for any purpose other than what is described in this document. The device is not intended to be used as a personal computer. Any usage outside the scope described in this document constitutes a violation, can compromise its correct functioning and invalidate the test results.
	Only trained personnel are allowed to use the SONDA Hub device.

	The eye tracker included in SONDA Hub has been tested and found to comply with the radiated emission limits for a Class B device in accordance with EN 55032:2015/A11:2020, and with radiated electromagnetic field immunity and electrostatic discharge immunity requirements in accordance with EN 55035:2017. Class B limits are designed to provide reasonable protection against electromagnetic interference in residential and clinical installations. Nevertheless, electromagnetic interference between the device and other nearby electronic equipment cannot be fully excluded. To minimize the risk of interference: keep adequate separation between SONDA Hub and other electronic devices; if interference is observed, contact Reyedar B.V. for assistance.
	Only execute a test using the device in a light-controlled environment, as described in this document. Using too bright light conditions may invalidate the test results.
	Ensure that appropriate corrective lenses are present in the eye tracker during the test to guarantee optimal vision for the patient being tested.
	The mains supply plug is the disconnection device for SONDA Hub. Ensure that the mains plug and the socket outlet are accessible at all times and are not obstructed, so that the device can be quickly disconnected from the supply mains if required.

3.2 Clinical & Diagnostic Warnings (SONDA SaMD)

	For any incident that results or has the potential to result in harm to the patient or the user in any way, please discontinue use immediately and notify Reyedar B.V. of the incident providing as much detail as possible.
	The accuracy of the diagnostic output relies on correct hardware setup. Do not change the screen settings of the device, and do not use unsupported web browsers, as doing so may invalidate the test results.
	Do not use the device with patients who cannot keep their eyes fully open. During the test, the entire pupil must be visible to the cameras in the eye tracker. The test may also yield inaccurate results in patients with severe nystagmus or conditions that prevent stable gaze fixation.
	Do not perform the test if the eye-tracker does not fit the patient correctly. An ill-fitting eye-tracker — including a frame that is too loose, slips during use, or cannot be positioned so that both eye cameras have a clear, unobstructed view of the patient's eyes — will produce unreliable gaze data and may lead to invalid screening results. If a proper fit cannot be achieved, abort the test, and do not interpret any partial results.
	Do not use the device for any purpose other than what is described in this document. Any usage outside the scope described in this document constitutes a violation, can compromise its correct functioning and invalidate the test results.
	Only trained personnel are allowed to use SONDA SaMD.
	SONDA (SaMD) is a software device which can produce undetectable software errors. While all precautions have been taken by the manufacturer to minimize the chance of this

	occurrence, in the unlikely event of such an error, potential delayed provision of care and visual loss progression may result. Consequently, SONDA SaMD is intended strictly as a diagnostic aid; final diagnostic decisions must be made by a qualified healthcare professional in conjunction with other clinical findings, as dictated by clinical guidelines. It must never serve as the sole basis for clinical decision-making or therapeutic intervention.
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4.0 IT Requirements

The minimum internet speed for the correct functioning of the SONDA Hub device is 20 mb/s download and 20 mb/s upload.

To access and operate the SONDA Hub user interface, the client computer must meet the following minimum specifications:

- **Processor:** Intel Core i3 or equivalent
- **Memory (RAM):** 8 GB
- **Graphics:** Integrated graphics equivalent to Intel UHD Graphics 615
- **Display:** Minimum 10-inch screen

Supported web browsers for SONDA Hub are Google Chrome and Microsoft Edge. Always use the latest updates.

To access the eIFU, use the PDF viewer of the aforementioned supported web browsers with a network connection.

Network changes must be communicated to Reyedar B.V. before implementation. Any changes to the network configuration — including changes to IP addresses, firewall rules, proxy settings, VPN configuration, or network infrastructure — may affect the correct functioning of the SONDA Hub device. Contact Reyedar B.V. at support@reyedar.com prior to making such changes to ensure continuity of service.

Network and cloud-service dependency: SONDA is a cloud-based device and requires a continuous, stable internet connection to operate. During use, the device must be able to reach the manufacturer's cloud services for user authentication, upload and retrieval of test data and results, and software updates. The network and firewall must permit outbound HTTPS (TLS) connections to these services. If internet connectivity or the required cloud services are unavailable, or if the firewall blocks the required outbound HTTPS connections, SONDA becomes temporarily unavailable: a test cannot be started or its results cannot be processed, and no risk indication is produced. In this condition the device fails safely, producing no result rather than an unreliable one; the operational consequence is a delayed clinical evaluation. Repeat the test once connectivity and the required services are restored, and report persistent unavailability to Reyedar B.V. at support@reyedar.com.



Warning: Do not use unsupported web browsers. If in doubt, contact a representative of Reyedar B.V. for assistance.

4.1 IT Security Requirements

The security measures that the operating environment and its users are required to observe:

- unique named user accounts, with credentials not shared, and account creation, permission assignment, and deactivation performed by the designated administrator;
- password requirements applicable to user accounts, the requirement to log out on completion of use, and the automatic session timeout applied;

- operation only with a supported operating system and supported web browsers, kept current with security updates, with security features of the operating environment not disabled and no unauthorized software installed on it;
- TLS-protected communication with the manufacturer's servers, and the prohibition on operating over untrusted or public networks;
- restriction of physical access to the computing platform to authorized personnel;
- prompt installation of software updates provided by the manufacturer, obtained only through the manufacturer-controlled distribution channel;
- reporting to Reyedar B.V. without delay any suspected security incident, unauthorized access, or loss of credentials.

5.0 Product Description

The SONDA products are designed to assess eye movements in response to visual stimuli. This is achieved by displaying standardized visual stimuli on a calibrated screen while simultaneously recording eye movements.

This assessment utilizes two distinct medical devices:

- **SONDA Hub:** A standalone medical device that collects, formats and visualizes the eye-movement data and its quality metrics. Includes a database for the secure storage and retrieval of patient information. When SONDA SaMD is available, SONDA Hub functions as its accessory for data collection.
- **SONDA SaMD (Diagnostic Module):** Software as a Medical Device that processes the collected data to generate clinical reports with diagnostic indications. N.B. not included by default, must be purchased separately.

SONDA Hub is delivered in a pre-assembled state and is installed by an authorized representative of Reyedar B.V. SONDA Hub consists of two components: the stimulus display hub and the eye tracker. The stimulus display hub consists of a medical-grade monitor with photometric calibration, integrated with a processing unit (See Figure 1).

The eye tracker component consists of a wearable frame with integrated eye-tracking sensors and a metal suitcase containing 2 eye occluders and 1 set of 32 pairs of corrective lenses ranging from -6 to +6 diopters. These lenses can be easily attached to the eye tracker using magnetic clips. The eye tracker is connected to the stimulus display hub through a USB-C cable. A microfiber cloth for cleaning the eye tracker lenses is provided. The wearable eye tracker is the only applied part of the SONDA Hub medical electrical equipment, as it comes into physical contact with the patient during normal use. SONDA Hub is intended for continuous operation.

SONDA Hub emits infrared (IR) radiation via the built-in IR LEDs of the wearable eye tracker (LED type SFH4053, peak wavelength approximately 850 nm). These LEDs are used solely to illuminate the eye region for tracking purposes. The measured IR irradiance at 200 mm distance is $0.037 \text{ W}\cdot\text{m}^{-2}$, well below the Exempt Group limit of $100 \text{ W}\cdot\text{m}^{-2}$ defined by EN 62471:2008. The device has been assessed and classified as Exempt Group for all photobiological hazards; no special control measures or user precautions are required regarding optical radiation.

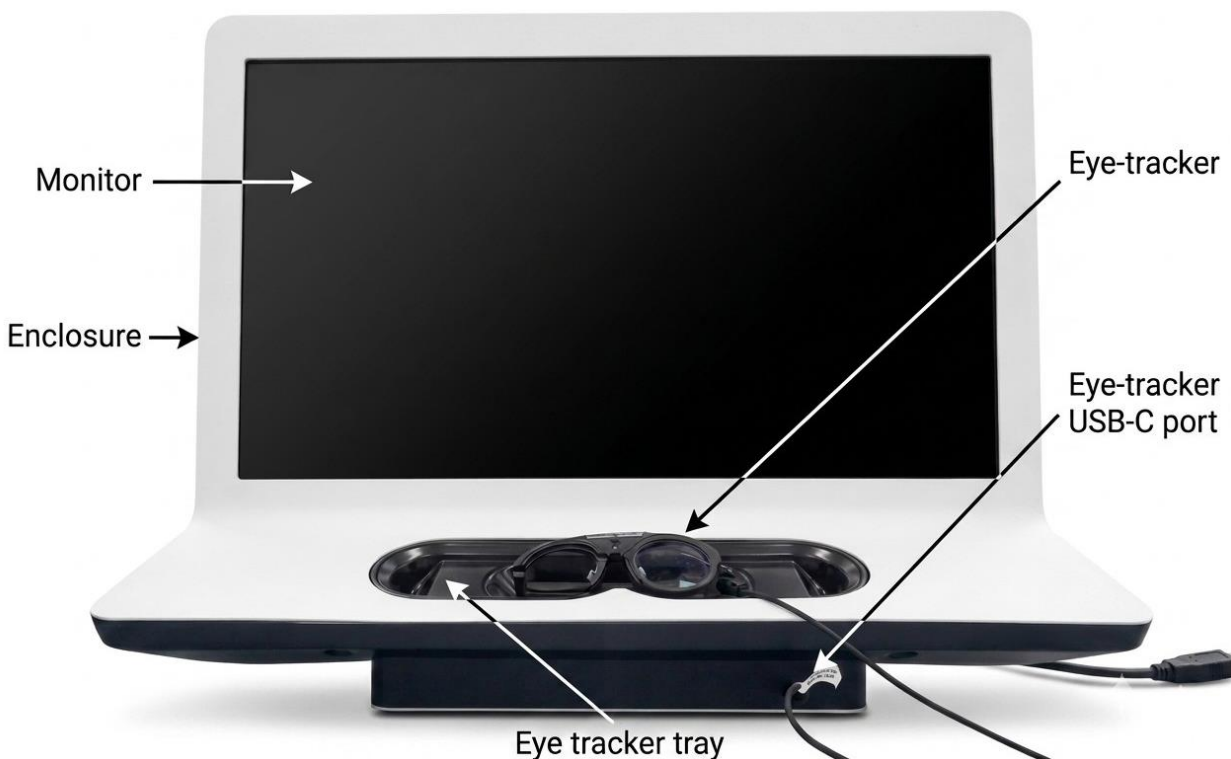


Figure 1: The stimulus display hub with the wearable eye tracker accommodated in the hub tray.

The wearable eye tracker is shown in detail in Figure 2.

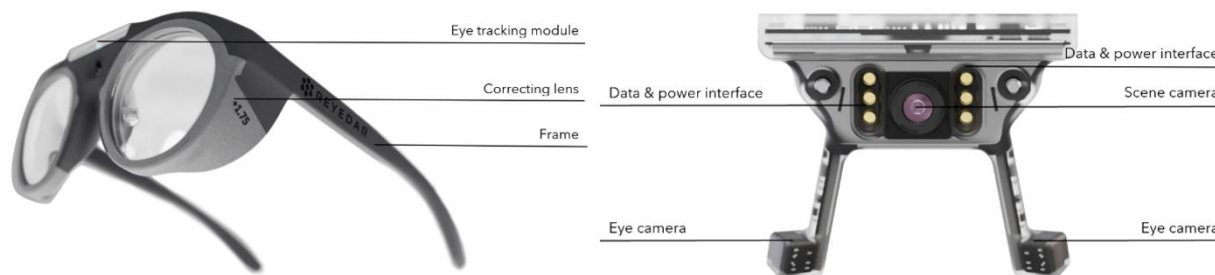


Figure 2: Details of the wearable eye-tracker.

6.0 Use of the SONDA devices

This section covers the operational use of SONDA Hub to conduct a full data collection and the interpretation of the reports (separately for SONDA Hub and SaMD as the latter contains diagnostic output).

6.1 Switching on the device

To switch on the SONDA Hub device, ensure that it is plugged in, then push the power button on the right-hand side of the device. Make sure the eye tracker is connected to the dedicated Type C USB in the front.

6.2 Logging in

The device can be accessed from a personal computer connected to the internet. Both the internet connection and the personal computer are set up at the time of the installation of the device. If you want to access the interface of SONDA Hub from an additional personal computer, please follow the instructions in 6.8.2.

To log in, open the internet browser on the pre-configured personal computer and navigate to the web address www.sonda.reyedar.com. Enter your username and password that have been provided via e-mail to you. If you have forgotten your password, an option to reset the password is available on the login page, shown in Figure 3.

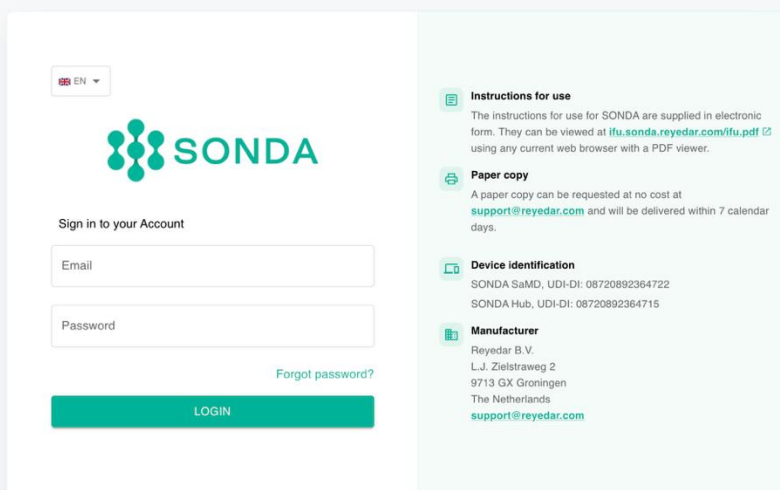


Figure 3: SONDA Hub login page.

6.3 Sign out, restart, and switch off SONDA Hub device

To **sign out**, click on the avatar symbol on the top right of the web page and click on “*sign out*”. The menu is shown in Figure 4.

To **reboot** the device, click on the avatar symbol and then click on “*reboot*”. It is advised to allow some time for all services to resume normal operation after a reboot.

To **shut down** the device, click on the avatar and then click on “*shutdown*”.

Please, do not switch off the device using the power button on the device itself.

When rebooting or switching off the device, system updates could be installed. The device could take some time to complete the operation.

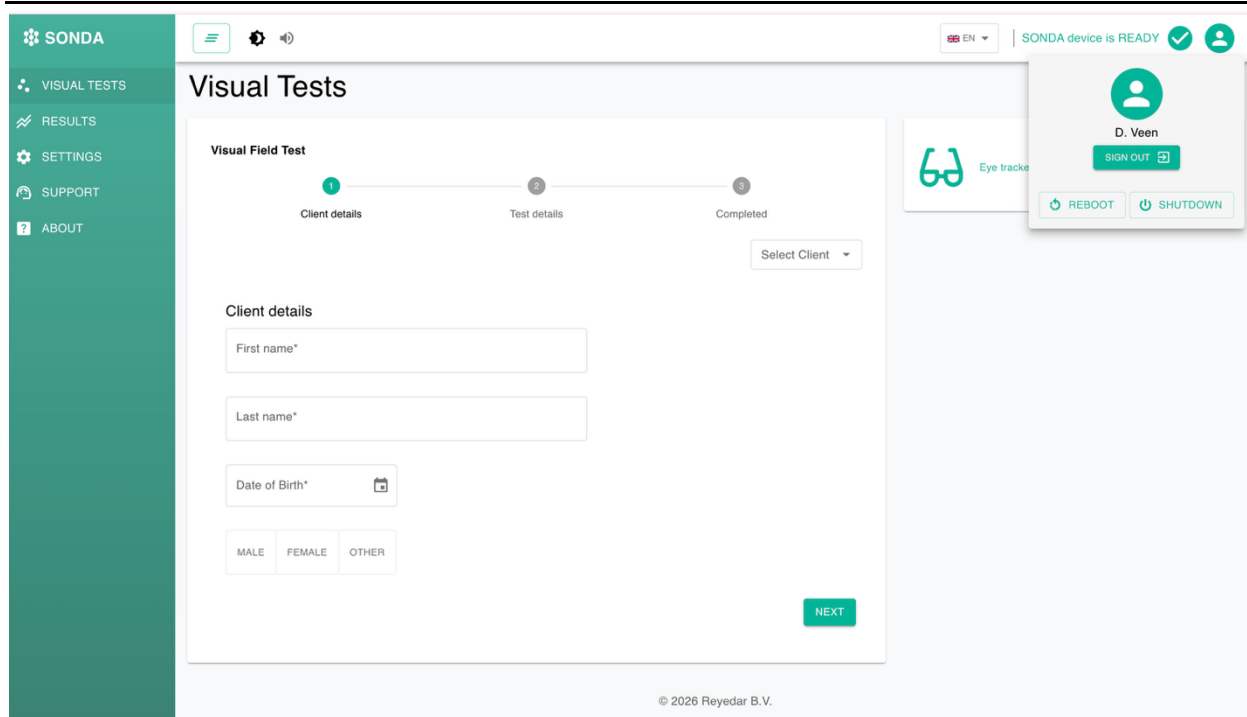


Figure 4: Sign out, reboot and switch off menu available on the top right of the screen.

6.4 Preparing for a Visual Test

A trained user is required to execute a visual test with the device. The user will receive training by Reyedard B.V. specialized personnel at the time the device is installed.



Warning: Only trained users are allowed to interact with the SONDA Hub device.

To prepare for a visual test, click on “VISUAL TESTS” on the left menu. The page will appear as shown in Figure 5.

Check that the SONDA Hub device detects the eye tracker: on the right of the page, the prompt “Eye tracker connected” must appear.

If any of the above steps are taken and SONDA Hub does not detect the eye tracker, try disconnecting and reconnecting the eye tracker. Always allow a couple of minutes for SONDA Hub to be able to detect the eye tracker again.

When the device is ready to perform a visual test, a green circle will appear on the top right of the screen with the prompt “SONDA device is ready”. Insert the patient’s name, surname, date of birth, and gender.

If you have the SONDA diagnostic module active, ensure that the entered date of birth is accurate, as the patient’s age is a key parameter in calculating the risk score.

If a patient has already been tested, you can automatically fill their details in by clicking "Select Client" and either scrolling through the list, which displays patients in order of their last test, and selecting their name, or by typing their name to trigger a search, then clicking on the correct name.

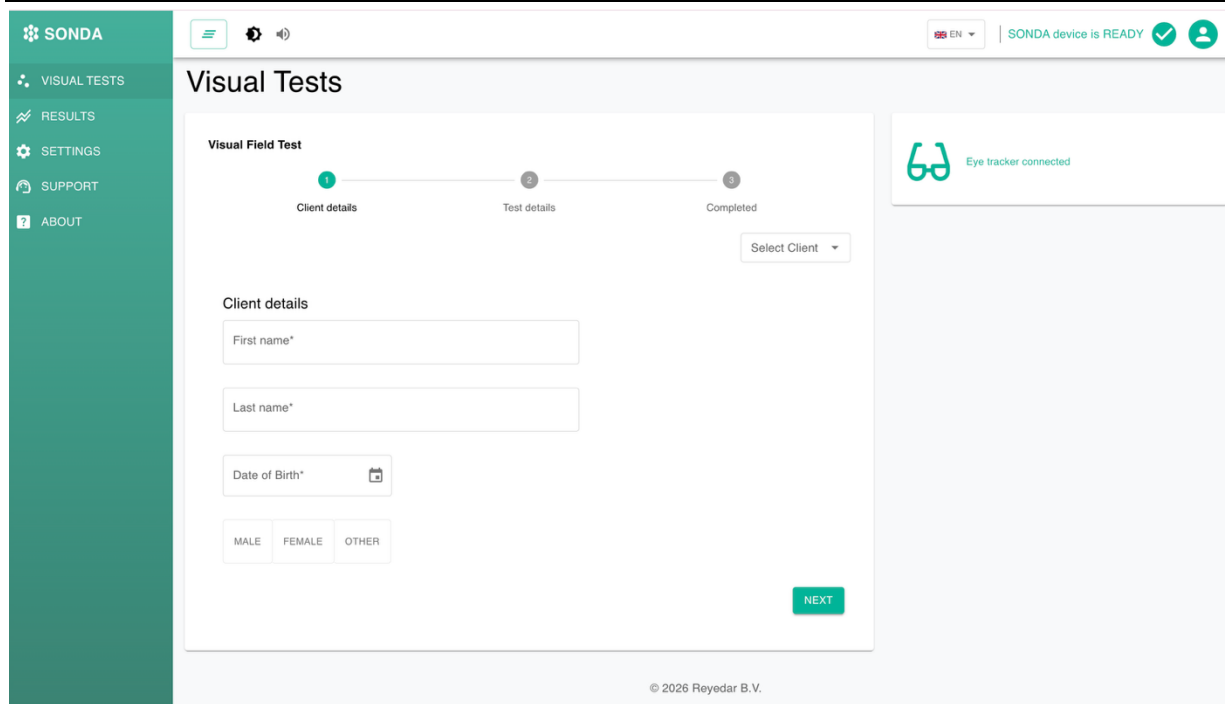


Figure 5: Conducting a Visual Field Test - client details page.

Click on the button “NEXT” to continue. On the next page, which is shown in Figure 6, you will be asked to fill in the test details.

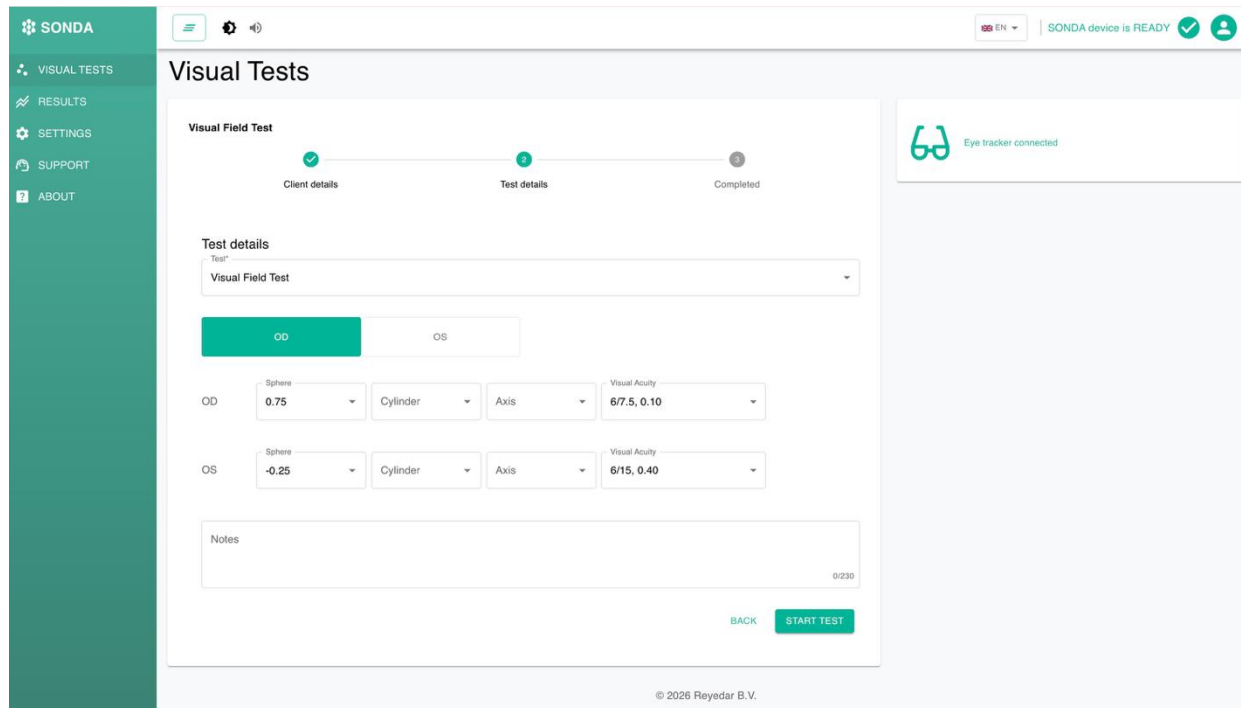


Figure 6: Conducting a Visual Field Test - test details page.

Click on the drop-down menu to select the visual test to perform, e.g. ‘Visual Field Test’. Tests that will become available with future releases will be displayed here. Then select the eye to be tested: “OD” (right

eye) or “OS” (left eye) and fill in the refractive correction needed for each eye (sphere, cylinder, axis, visual acuity). It is possible to write notes in the bottom box that will appear printed on the final report (this option will be available at the end of a test as well). Finally, select the appropriate lens from the set provided with SONDA Hub (Item F in Figure 1) and insert it in the corresponding slot on the eye-tracker frame, then insert the eye occluder in the appropriate slot for the eye that is not being tested

The next step is the correct positioning of the patient in front of SONDA Hub. Ask the patient to sit in front of the device’s screen and to wear the eye tracker. Check that the patient’s **line of sight is aligned with the center of the device screen** and that the **distance between the patient and the device screen is correct, roughly 60 cm**. The distance can be adjusted in the next step. Click on the button “START TEST” to proceed to the next step.

Figure 7 shows the monitoring feature of the SONDA Hub. This page displays a window with two video streams: one from the patient's point of view and another showing the patient’s eyes. **Ensure that the eyes are fully open and fully visible within the camera image, with no part cut off by the image frame. Patients who cannot keep their eyes open are not eligible for the test. Cropped eye images may result in invalid or unusable measurements. This is valid for both standalone SONDA Hub and the SaMD diagnostic module.**

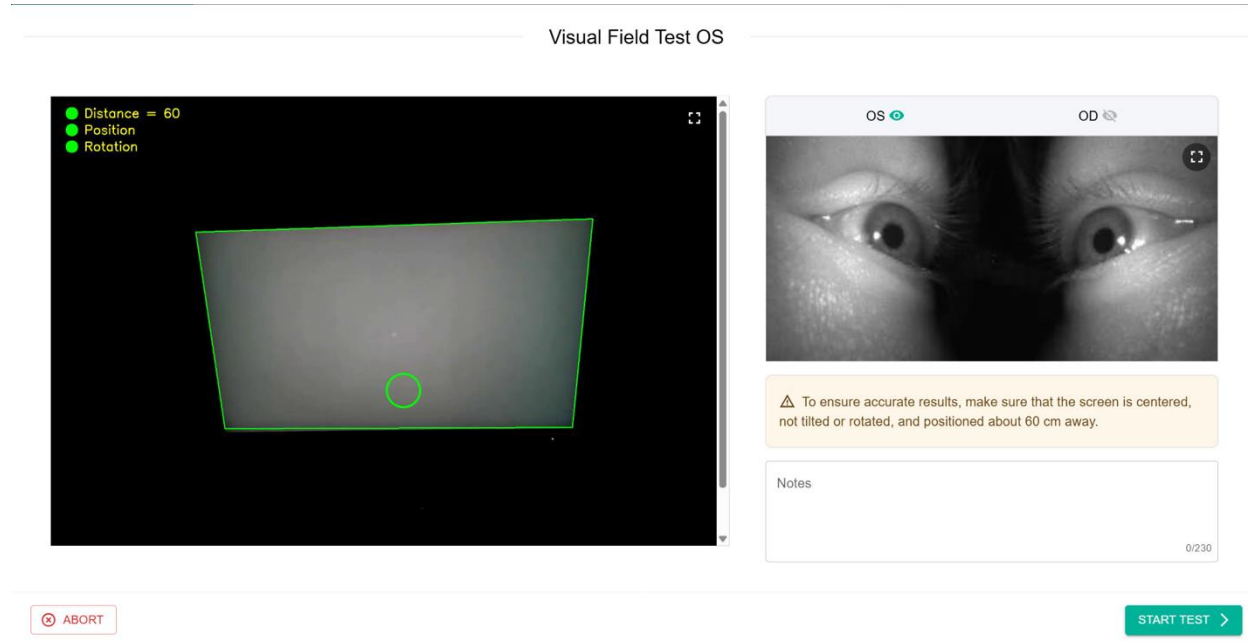


Figure 7: Conducting a Visual Field Test; monitoring window.

The screen detection is shown as a **rectangle around the screen border**, which will **change colors to indicate the correct distance**. If the rectangle is correctly shown around the device screen border, it means that the screen detection works correctly. Please use the color indication in order to position the patient at a correct position with respect to the screen. The rectangle will turn **green** if the screen is centered, it is not rotated, and if the patient is at the **optimal** distance from the screen (roughly 60 cm away from the screen). Otherwise, it will turn **orange** when the distance is **suboptimal** but still usable for analysis, and it will turn **red** when the distance is **not suitable** for obtaining reliable test results. **It is crucial**

to check that the screen is correctly detected during a visual test, as a wrong screen detection may result in unreliable test results.

Then, instruct the patient to follow with their gaze - while avoiding head movements and staying still - a moving stimulus that initially appears on the center of the screen as a white blob on a grey background.

When the patient is ready, click "START TEST" on the bottom right corner to start the visual test.

6.5 Executing a Visual Test

During a visual test, a window showing the patient's viewpoint is displayed, as before which includes the same indicators. The window is shown in Figure 8. Within this window, it is possible to **assess real-time factors** such as proper screen detection, correct distance, and accurate tracking of the stimulus by the patient. The patient's gaze is visually represented by a red circle for the left eye and a green circle for the right eye. This feature aids reliable data collection, allowing to verify the patient's adherence to instructions, the accuracy of the distance from the screen, and proper screen detection. Furthermore, it allows to monitor the patient's gaze to determine if they are effectively tracking the stimulus with their eyes. **It is important that the patient consciously tracks the stimulus for the entire duration of the test to ensure reliable results.** If the patient is not tracking the stimulus as expected, it suggests non-compliance with instructions or difficulty in doing so. The operator monitor's dashboard integrates a dynamic progress bar that advances through every stage of the test and a stimulus map that highlights saccadic jumps of the stimulus as they occur. This visualization is purely used to provide an intuitive overview of test progression and stimulus visual field coverage, it does not reflect the patient's behavior and does not contain any diagnostic information, even when used in the context of the diagnostic module.

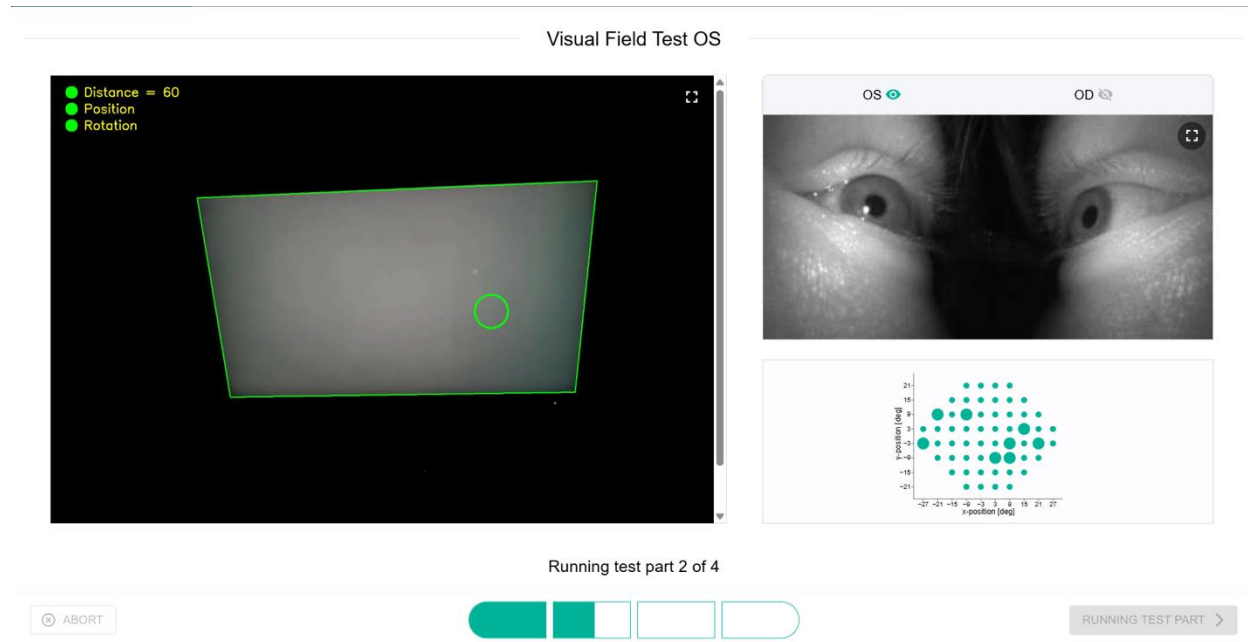


Figure 8: Conducting a Visual Field Test; running part 2 of the test.

A visual test is divided into multiple parts. After completing each part, a prompt, shown in Figure 9, will appear in the popup window, indicating "Test part X of Y completed", where X represents the finalized test part and Y represents the total number of parts in the test. At this point, it is possible to either proceed to the next part of the visual test by clicking the "Start test part X of Y" button or choose to abort or repeat the test by selecting the "ABORT" or "REPEAT PART" button.

Once all test parts are completed, a prompt appears: "Test is completed". On this screen, you can write additional notes that will appear in the final report. By clicking on the button "SAVE", the analysis of the test will commence automatically. If no action is taken at the end of the test, the analysis will commence automatically after 10 seconds (a countdown appears on the "SAVE" button, and the countdown will stop if you click on the notes box).

The status of a test analysis can be viewed on the RESULTS page, shown in Figure 10. The analysis will take a couple of minutes to finalize. During that time, it is not possible to perform a visual test and the device will appear as not ready.

6.5.1 Audio notifications

During use of the SONDA Hub device, audio notifications are used to indicate test progress and system status:

- **Test part finished:** a short sound is played when a test part is completed.
- **Success:** a confirmation sound is played when a visual test analysis or a system update is completed.
- **Failure:** an alert sound is played if a visual test analysis fails.

N.B. test "success" or "failure" and their respective sound indications are merely technical information related to test completeness, they are not related to the patient behavior.

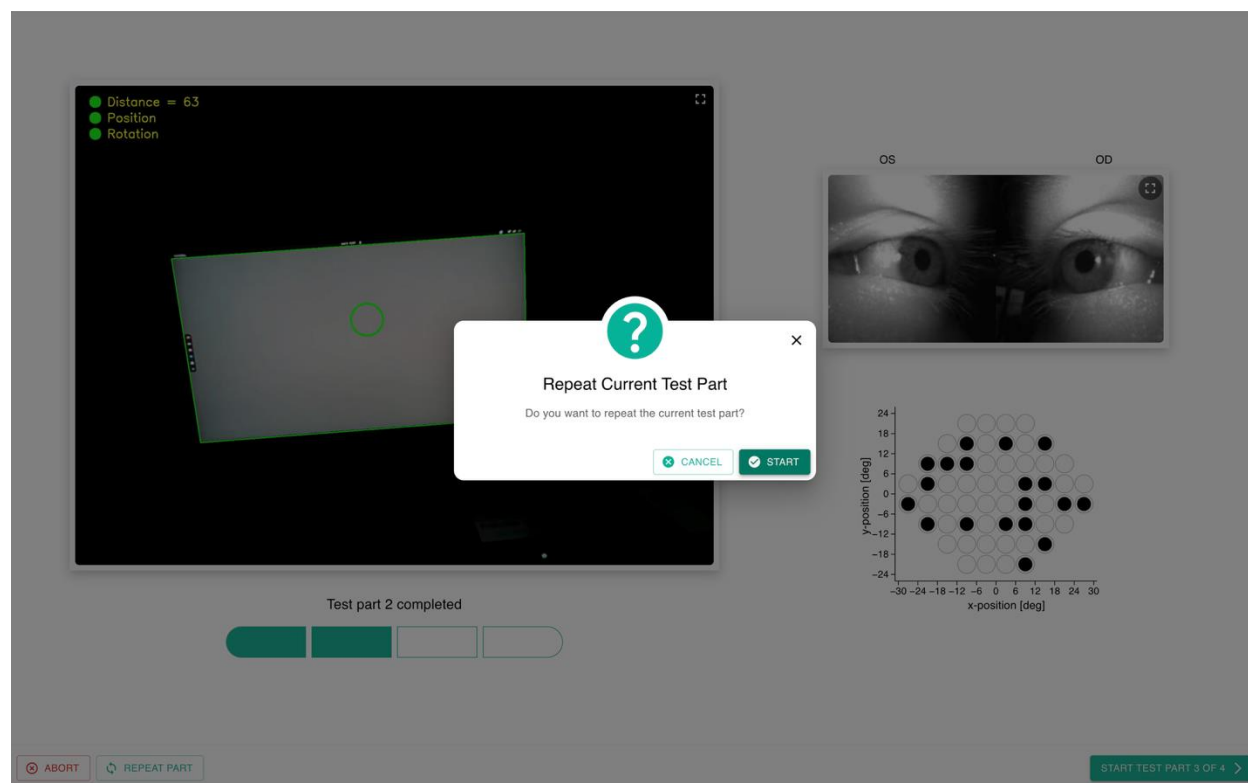


Figure 9: Conducting a Visual Field Test – test part repeat prompt.

- VISUAL TESTS
- RESULTS
- SETTINGS
- SUPPORT
- ABOUT

EN

SONDA device is READY

Results

X

Rows per page 10

<

1

2

>

Name	Date Of Birth	Test Name	Test Date	Test ID	Eye	Risk	
Sarah Ergo	12-Feb-1967	Visual Field Test	1-May-2025 09:08	14	OD	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	1-May-2025 08:58	13	OS	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	30-Apr-2025 10:05	12	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:54	11	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:45	10	OD	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:38	9	OS	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:25	8	OD	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:18	7	OS	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:11	6	OD	2	SHOW REPORT
David van der Veen	3-Apr-2007	Visual Field Test	30-Apr-2025 09:03	5	OS	2	SHOW REPORT

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Figure 10: Accessing test results - results page

6.6 Test Results

The RESULTS page displays the list of test results for the user to review. Each test is represented as a row entry containing the following information: patient name, age, date of birth, test name, test date, test ID, eye, and - if the diagnostic module is present - risk indication. In this case, the risk indication values can be 0, 1, or 2, representing low, medium, and high risk, respectively. For a detailed explanation of the risk indication, refer to the SONDA risk indication score description in section 6.7.

To the left of each entry on the Results page is an edit button with a pencil icon, which allows modifying any inaccurately entered test information (see Figure 11). After saving the changes, a new report with the updated information will be generated.

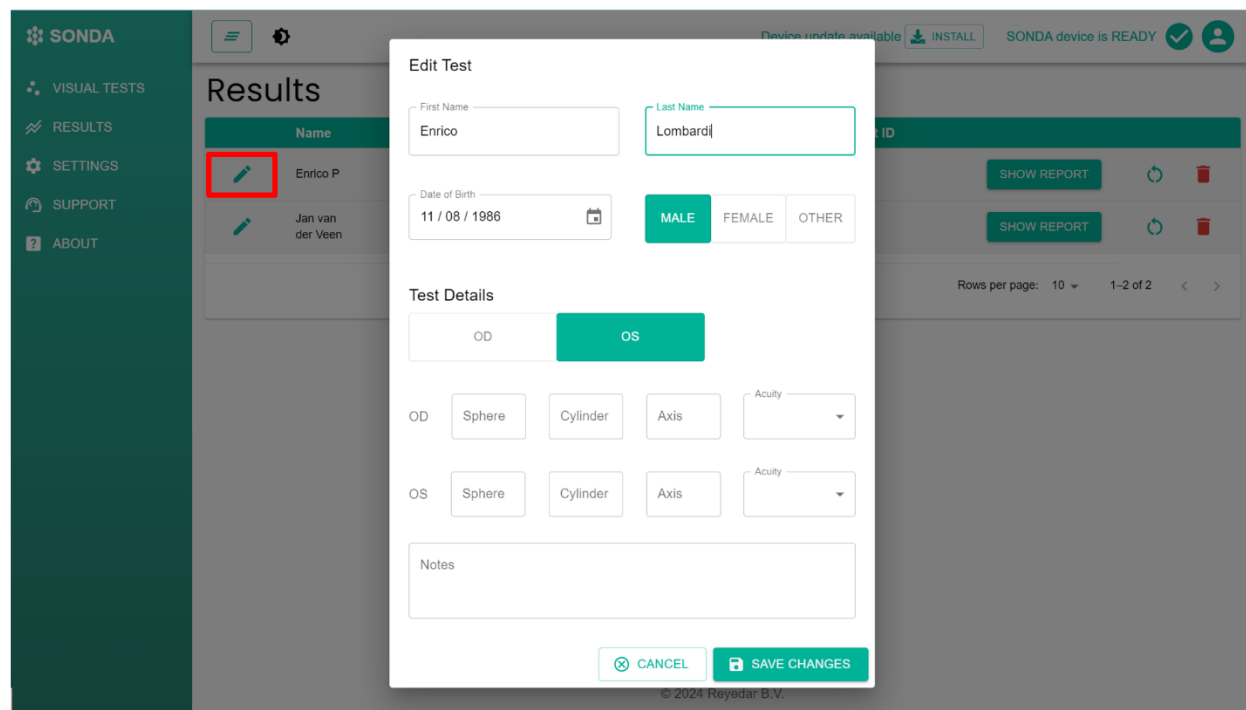


Figure 11: Accessing test results - edit test information

A trash bin icon is available on the right side of each entry to delete the corresponding test entry if needed. Adjacent to the trash bin icon, a button “SHOW REPORT” is displayed, as shown in Figure 12.

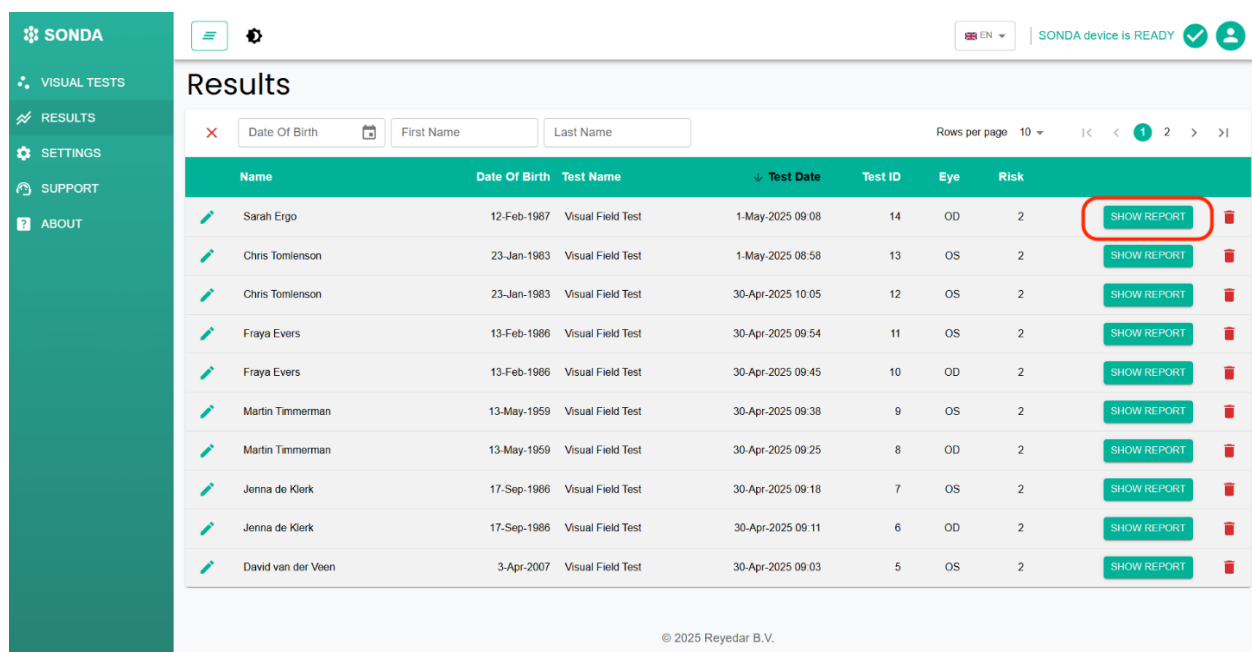
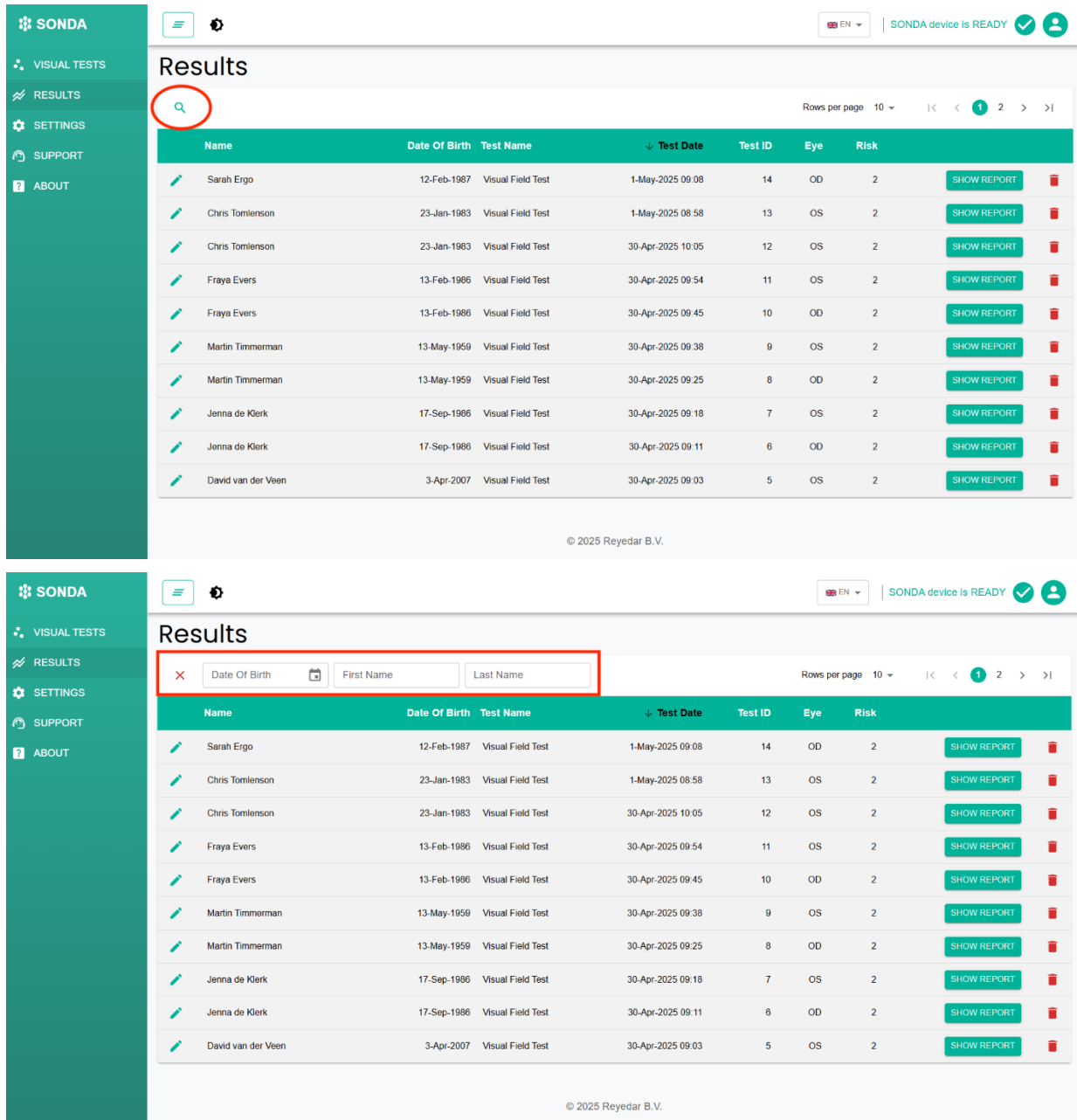


Figure 12: Accessing test results - show report button

However, the appearance and functionality of this button depend on the report generation status. If the report generation is still in progress, the button will be represented as a loading bar, indicating that the

report is being generated. On the other hand, if the analysis has failed and the report was not generated, the button will display "Analysis Failed" or "Preprocessing Failed". This can happen if a test was not executed as advised (e.g., the patient was at the wrong distance from the screen or looking elsewhere) or due to a system error.

To search for previous tests, click the icon in the top left corner. This opens search fields that allow filtering by Date of Birth, First Name, and/or Surname (see Figure 13).



SONDA

RESULTS

Results

Rows per page 10 | 1 2 > |

Name	Date Of Birth	Test Name	Test Date	Test ID	Eye	Risk	
Sarah Ergo	12-Feb-1987	Visual Field Test	1-May-2025 09:08	14	OD	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	1-May-2025 08:58	13	OS	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	30-Apr-2025 10:05	12	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:54	11	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:45	10	OD	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:38	9	OS	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:25	8	OD	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:18	7	OS	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:11	6	OD	2	SHOW REPORT
David van der Veen	3-Apr-2007	Visual Field Test	30-Apr-2025 09:03	5	OS	2	SHOW REPORT

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SONDA

RESULTS

Results

Rows per page 10 | 1 2 > |

Name	Date Of Birth	Test Name	Test Date	Test ID	Eye	Risk	
Sarah Ergo	12-Feb-1987	Visual Field Test	1-May-2025 09:08	14	OD	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	1-May-2025 08:58	13	OS	2	SHOW REPORT
Chris Tomlenson	23-Jan-1983	Visual Field Test	30-Apr-2025 10:05	12	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:54	11	OS	2	SHOW REPORT
Fraya Evers	13-Feb-1986	Visual Field Test	30-Apr-2025 09:45	10	OD	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:38	9	OS	2	SHOW REPORT
Martin Timmerman	13-May-1959	Visual Field Test	30-Apr-2025 09:25	8	OD	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:18	7	OS	2	SHOW REPORT
Jenna de Klerk	17-Sep-1986	Visual Field Test	30-Apr-2025 09:11	6	OD	2	SHOW REPORT
David van der Veen	3-Apr-2007	Visual Field Test	30-Apr-2025 09:03	5	OS	2	SHOW REPORT

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Figure 13 - Search functionality

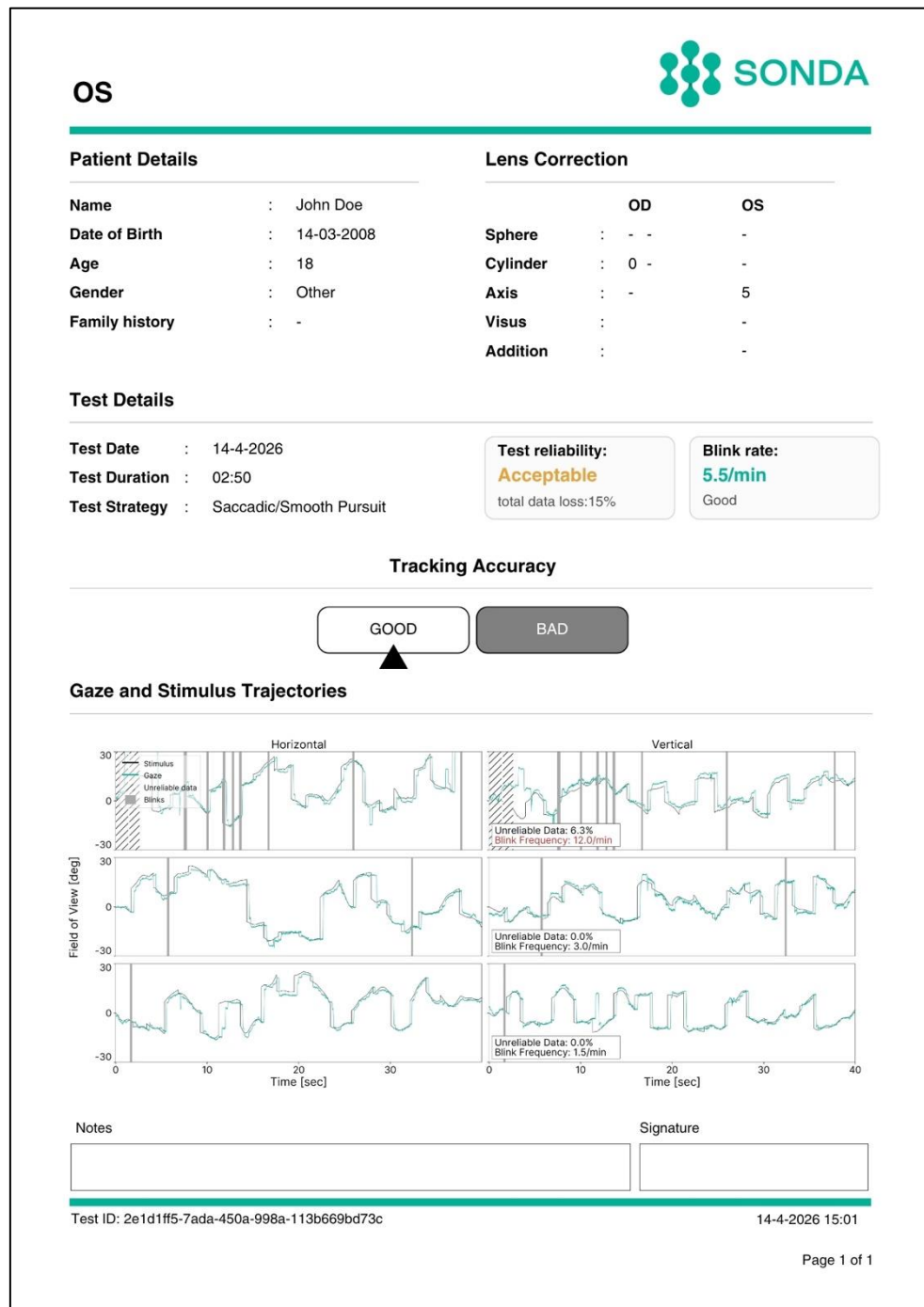
6.7 Report

Reports can be accessed from the results page by clicking on the button “SHOW REPORT”. The report appears as a PDF document, which can be easily downloaded and contains all the information that was input during the preparation of the visual test.

Test reports should be transferred to a secure, encrypted record-keeping system that is regularly backed up, in accordance with applicable legal or professional retention requirements. The device’s internal storage is intended only for temporary use; its contents may be erased by hardware failure and should not be relied upon for long-term retention.

6.7.1 SONDA Hub Report

An example of the page of SONDA Hub report is shown in Figure 14: The page of a sample test report generated by SONDA Hub. On this page, the user can visualize the oculomotor behavior of the patient



accompanied by quality metrics. The **Test reliability** indicates

how
test.

Figure 14: The page of a sample test report generated by SONDA Hub

much data was lost during the
Below 10% data loss is

considered optimal, between 10% and 50% is considered acceptable, above 50% the test is not reliable. The **Blink rate** indicates how often the person closed their eyes during the test. During a blink no data is collected, therefore an excessive blink rate affects the data loss. Lastly, the **Tracking accuracy** represent how well the patient follows the stimulus. This is purely a qualitative indication and no diagnostic conclusion can be derived.

The middle section features plots of the three saccadic pursuits for both horizontal and vertical directions. These plots show the gaze and the stimulus trajectory and mark any blinks and unreliable data points.

6.7.2 SONDA (SaMD) Report

If SONDA SaMD diagnostic module is present, it supersedes the report of SONDA Hub. An example of the first page of a diagnostic report is shown in Figure 15. On this page, the SONDA risk indication score is presented as a three-color bar accompanied by an arrow. When the arrow points to **white**, it signifies that the patient's visual function assessed during the test is within a normative range. When the arrow points to **gray**, it indicates abnormal visual function compared to the general population; a referral for a

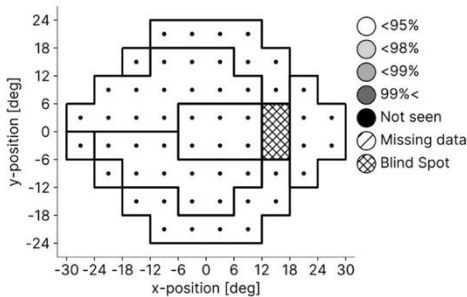


OD 24-2 Central Visual Field

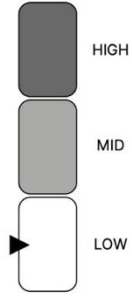
		OS	OD
Name	: Aiden	Sphere	: -
Date of Birth	: 15-11-2002	Cylinder	: -
Age	: 21	Axis	: -
Gender	: Male	Visual Acuity	: -

Stimulus Type	: Gaussian Blob	Test Date	: 21-8-2024
Stimulus Size	: 0.22 deg	Test Duration	: 02:50
Stimulus Luminance	: 132 asb	Test Strategy	: Saccadic/Smooth Pursuit
Background Luminance	: 94 asb		

Visual Field



Risk Indication



Notes

Signature

Test ID: 883e1a96-047e-407b-b08d-2152f58b7846
23-8-2024 12:54

Page 1 of 2

Figure 15: The first page of a sample test report generated by SONDA (SaMD)

specialized evaluation is recommended, also taking into consideration the outcome of other screening tests (e.g., tonometry). If the arrow points to **dark gray**, it indicates significantly abnormal visual function compared to the general population. In this case, a referral for a specialized evaluation is recommended. An abnormal visual function assessed by SONDA SaMD has been established as being associated with the presence of glaucomatous visual loss. SONDA SaMD is an aid to diagnostic decision making. The final diagnosis must take into consideration other standard diagnostic tests (e.g. fundus examination, OCT) and be confirmed by a qualified ophthalmologist.

The visual field locations analyzed during the test are presented on the first page and grouped into 6 zones to form a structural-functional map that relates sectors in the visual field to the underlying retinal nerve fiber layers according to the Garway-Heath model (Garway-Heath et al. 2000, Ophthalmology).

Zones are colored depending on the quality of the information received (not seen, missing), the tested location (blind spot), and the median saccadic reaction time within the zone as compared with a normative database of healthy controls:

If a zone appears **white** on the map, the median saccadic reaction time of the patient is below the 95th percentile of the median saccadic reaction time in the normative database for that zone, indicating that the saccadic reaction time is normal.

If a zone appears **light gray**, the median saccadic reaction time of the patient is between the 95th percentile and the 98th percentile.

If a zone appears **gray**, the median saccadic reaction time of the patient is between the 98th percentile and the 99th percentile.

If a zone appears **dark gray**, the median saccadic reaction time of the patient exceeds the 99th percentile.

If a zone appears **black**, more than 75% of the stimulus saccadic shifts in that zone have been missed.

If a zone appears **diagonally hatched**, more than 75% of the data in that zone is missing, principally due to either misalignment between the participant and the screen, head movement, or the patient failing to track the stimulus.

The blind spot is represented on the map as a **crosshatched zone**.

The second page of the report provides a more detailed analysis and helps assess the reliability of the test. Refer to Figure 16 for an example.

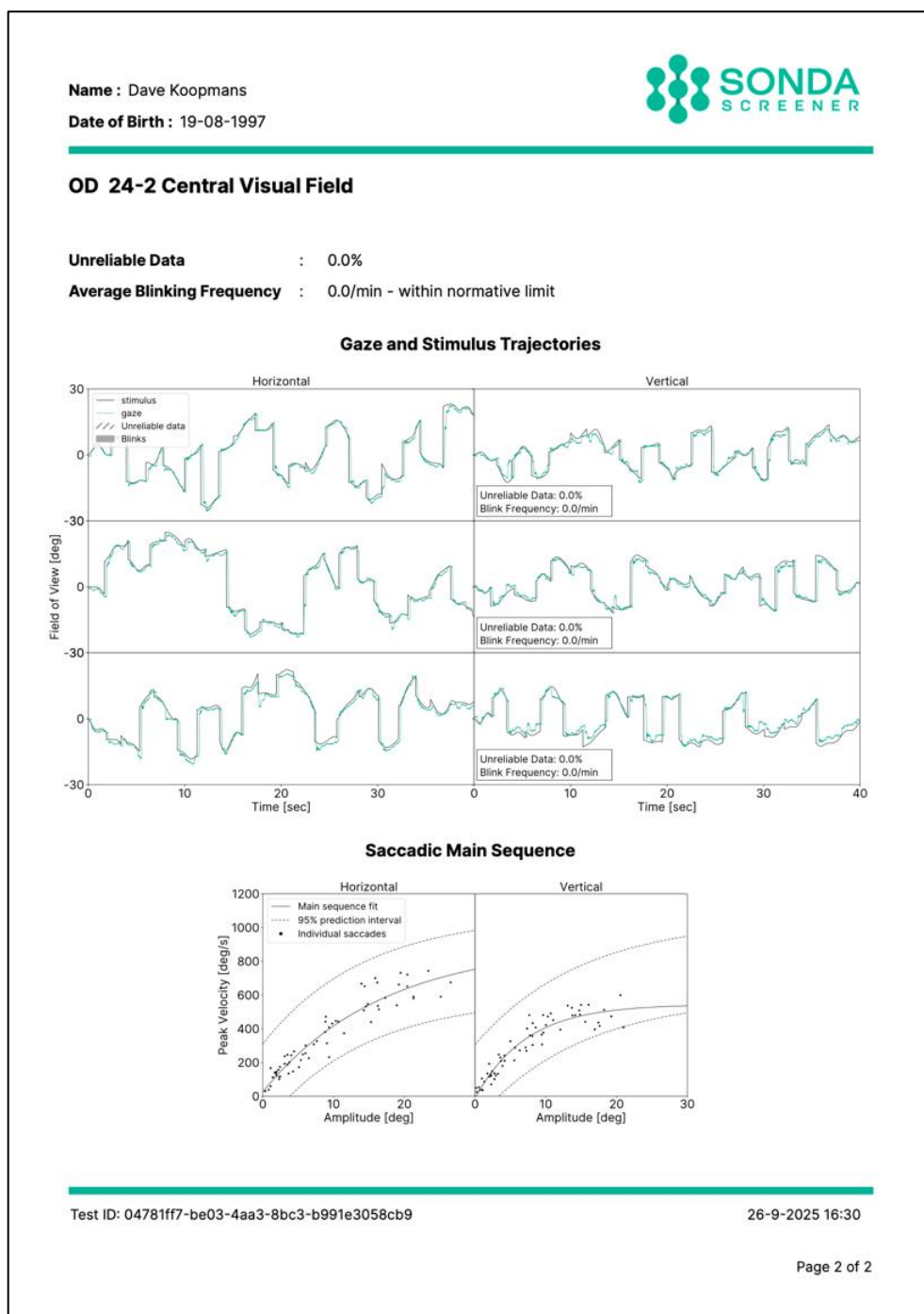


Figure 16: Second page of SONDA (SaMD) report.

At the top of the page, the percentage of unreliable data is displayed. If this percentage is too high, a warning message will appear (see Figure 17 and Figure 18), indicating that the test results may not be reliable. Additionally, the average blinking frequency is shown; a warning will be displayed if the blinking frequency is abnormally high compared to a normative dataset. This may indicate eye complications and difficulty for the patient in carrying out the test (see Figure 19).

The middle section features plots of the three saccadic pursuits for both horizontal and vertical directions. These plots show the gaze and the stimulus trajectory and mark any blinks and unreliable data points.

At the bottom left of the page, the patient's saccadic main sequence is presented. The saccadic main sequence is a relationship between the saccadic amplitude and the saccadic peak velocity. A warning message will be displayed if the saccadic main sequence deviates from normal patterns. This indicates eye movement complications that are likely **not** related to visual field defects (see Figure 19).

If the alignment between the patient and the screen is not optimal during the test, a warning is shown indicating that the visual field maps may not be accurate (see Figure 18).

Unreliable Data	: 99.8% - Risk Indication and Visual Field Map may be inaccurate
Average Blinking Frequency	: 19.4/min - outside normative limit (> 15/min)

Figure 17: Warnings appearing at the top of the second page of the report if Unreliable Data and Average Blinking Frequency are too high.

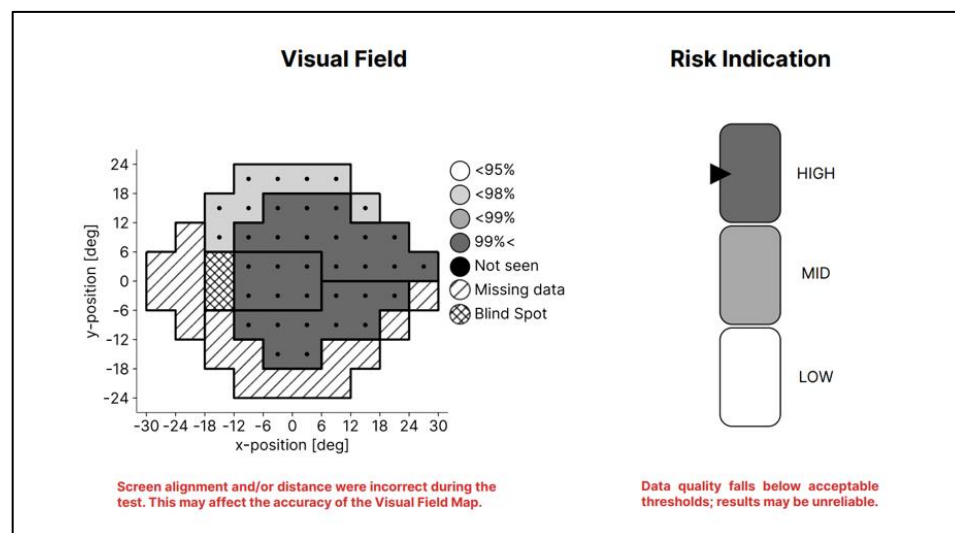


Figure 18: Warnings appearing if unreliable data is too high and screen alignment is not optimal.

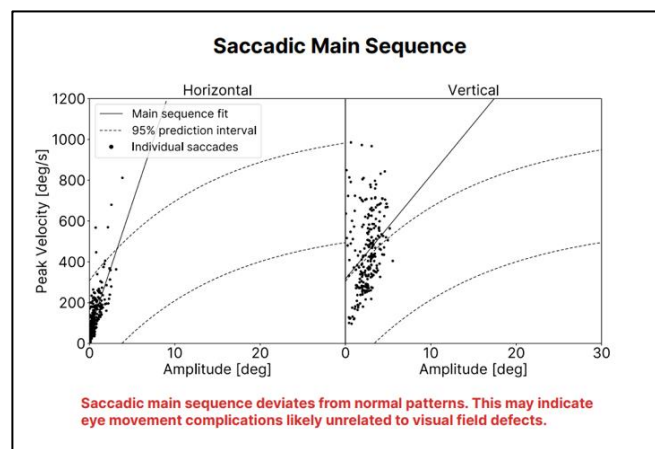


Figure 19: Warnings appearing at the bottom of the second page of the report if the Saccadic Main Sequence is atypical.

6.8 Settings page

Users can access useful information about the SONDA Hub device on the Settings page, shown in Figure 20.

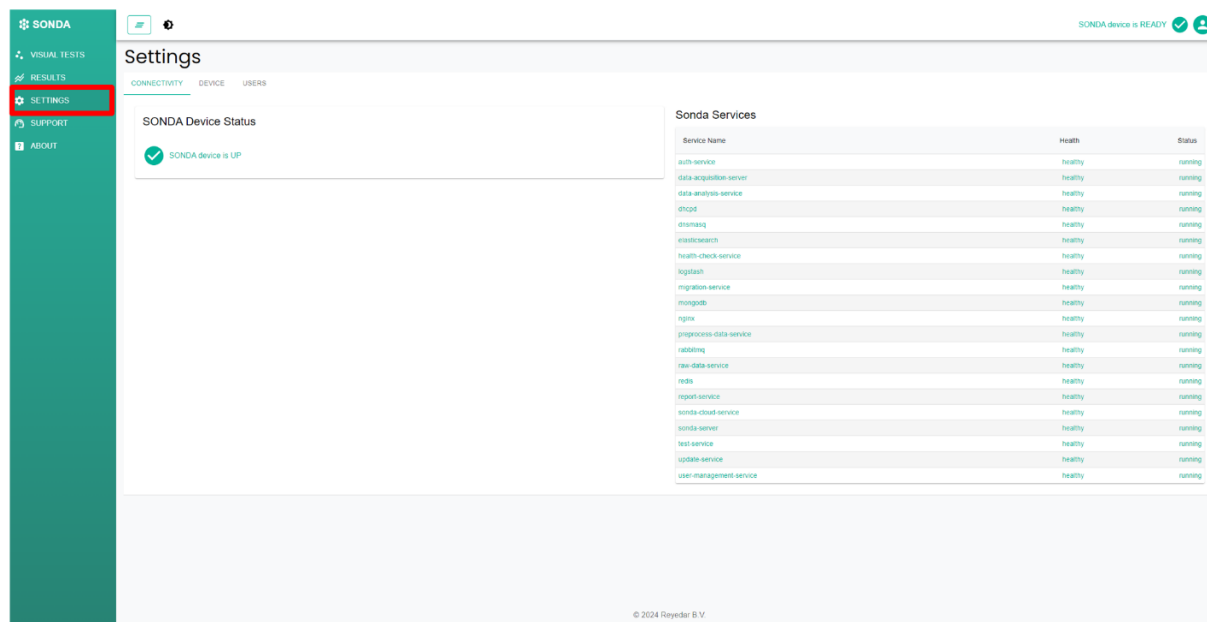


Figure 20: SONDA Hub settings page.

In the Connectivity tab, a list of services is displayed on the right side, where services appearing in green indicate proper functionality. However, services displayed in red indicate a malfunction, suggesting a device restart may be necessary. The Device tab contains technical details and is used only by Reyedat.

6.8.1 Adding a new User

In the "User" tab of the Settings page, SONDA Hub users can add additional users to the device. These newly added users will be able to log in and utilize the SONDA Hub device. When creating a new user, the user type can be selected as either a *user* or a *superuser*. The distinction between the two lies in their permissions: *users* are unable to create new users or delete previous visual field test entries on the Results page. On the other hand, *superusers* have the authority to perform these actions.

It is the responsibility of the superusers to train the newly added user. A superuser acknowledges that they are allowed to train new users only after completing a minimum of 20 visual tests.

Once a new user is added, a prompt with new user details will appear, as shown in Figure 21. Input the details of the new user and click on the 'ADD' button in order to proceed to the next step.

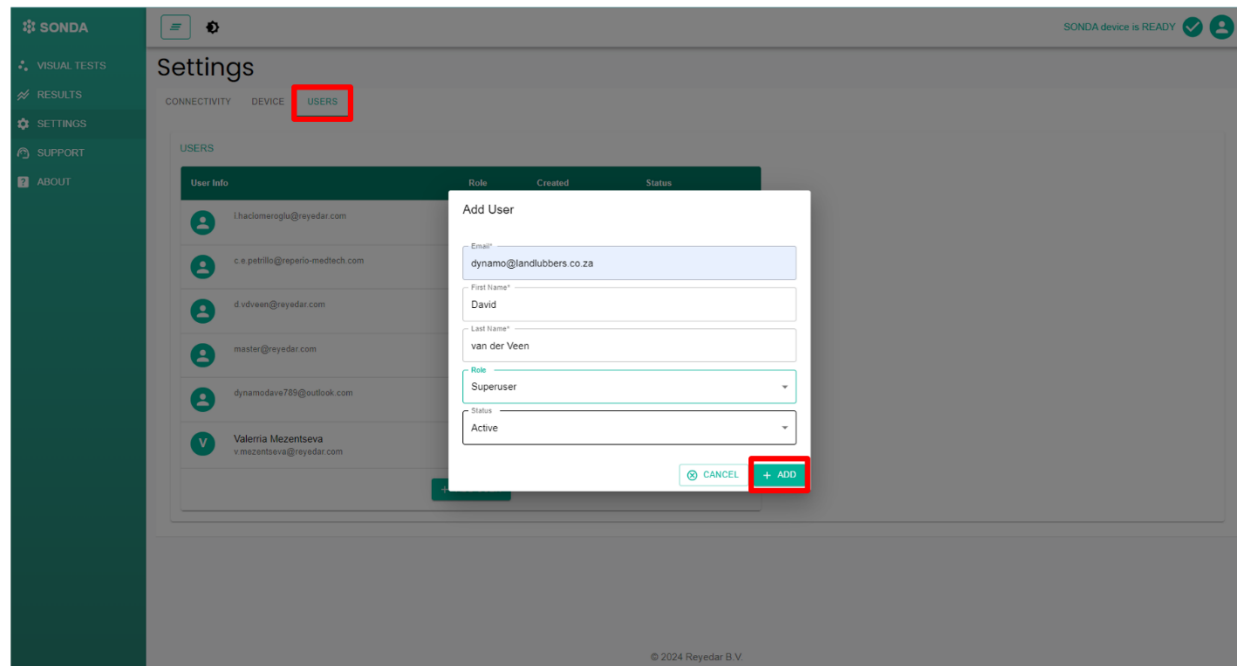


Figure 21: Adding details of a new user.

A new prompt will appear after clicking 'ADD', as shown in Figure 22. By clicking the SEND EMAIL button on the prompt, your standard email application will open with a pre-generated email with the new user details ready to be sent. If this should not work, please send the details as visualized on the prompt to support@reyedar.com.

Then, the newly added user will receive an email within the next 2 business days with a temporary password to login to SONDA Hub.

To edit user information and privileges, click the pencil icon located to the right of each user entry. If you wish to delete a user, select *Deleted* from the Status menu. If you wish to temporarily deactivate a user, set its status to *Inactive*. This menu is shown in Figure 23.

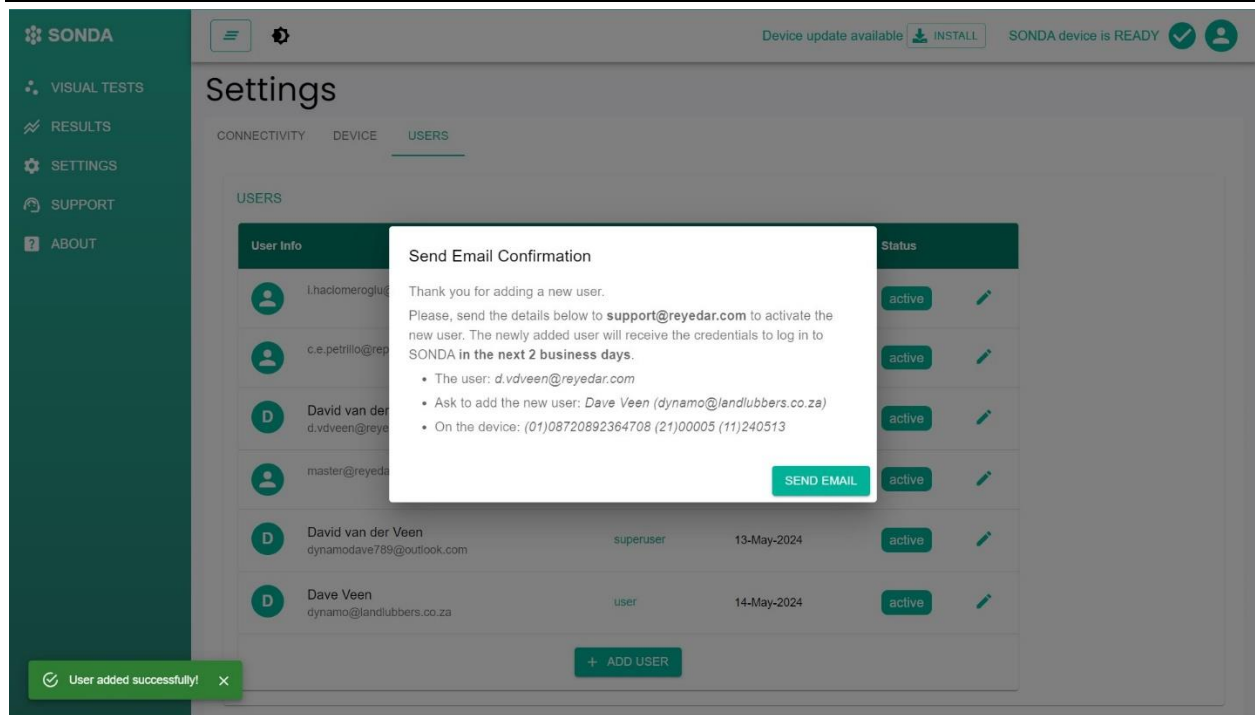


Figure 22: Communicating newly added users to Reyedar.

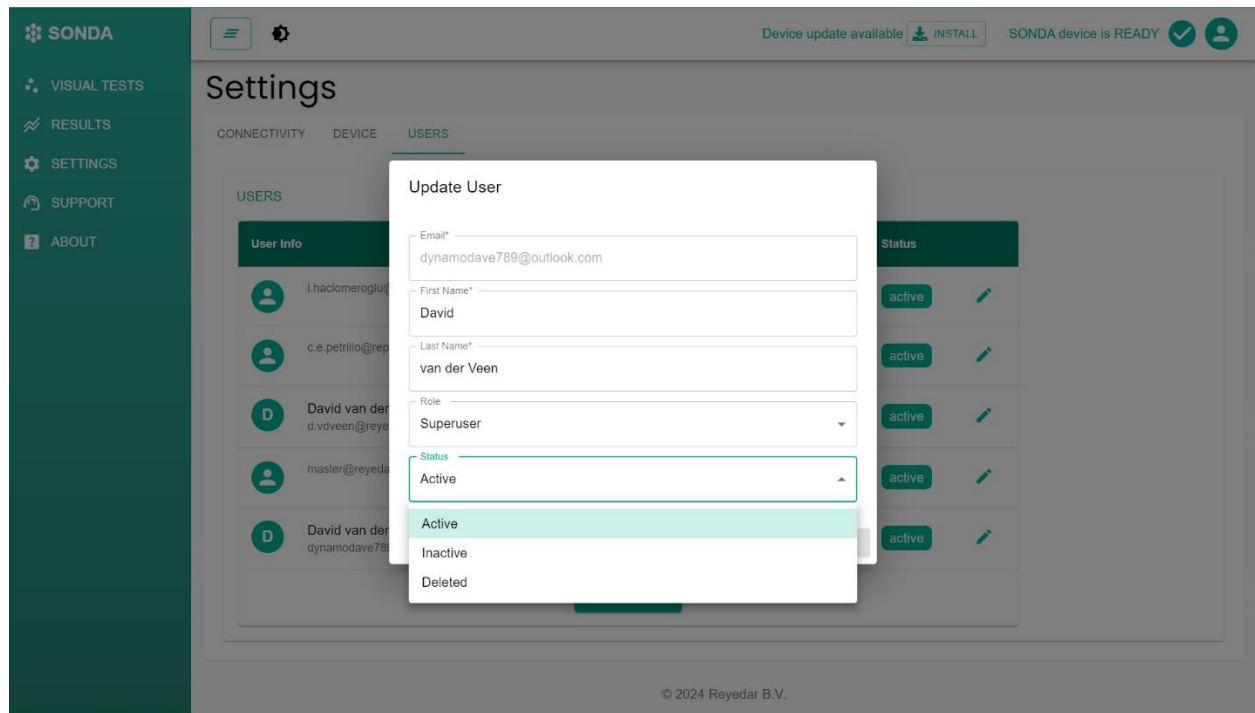


Figure 23: Updating the status of a user.

6.9 Support page

The Support page, shown in Figure 24, offers various options to contact Reyedar for assistance when support is required. When you need to report an incident, please keep record of as many details as possible, and follow reporting obligations as described in Section 1.3 of this document. Instructions and all the necessary documentation will be provided to you by Reyedar as soon as the request for support is received.



Warning: For any incident that results or has the potential to result in harm to the patient or the user in any way, please discontinue use of the device immediately.

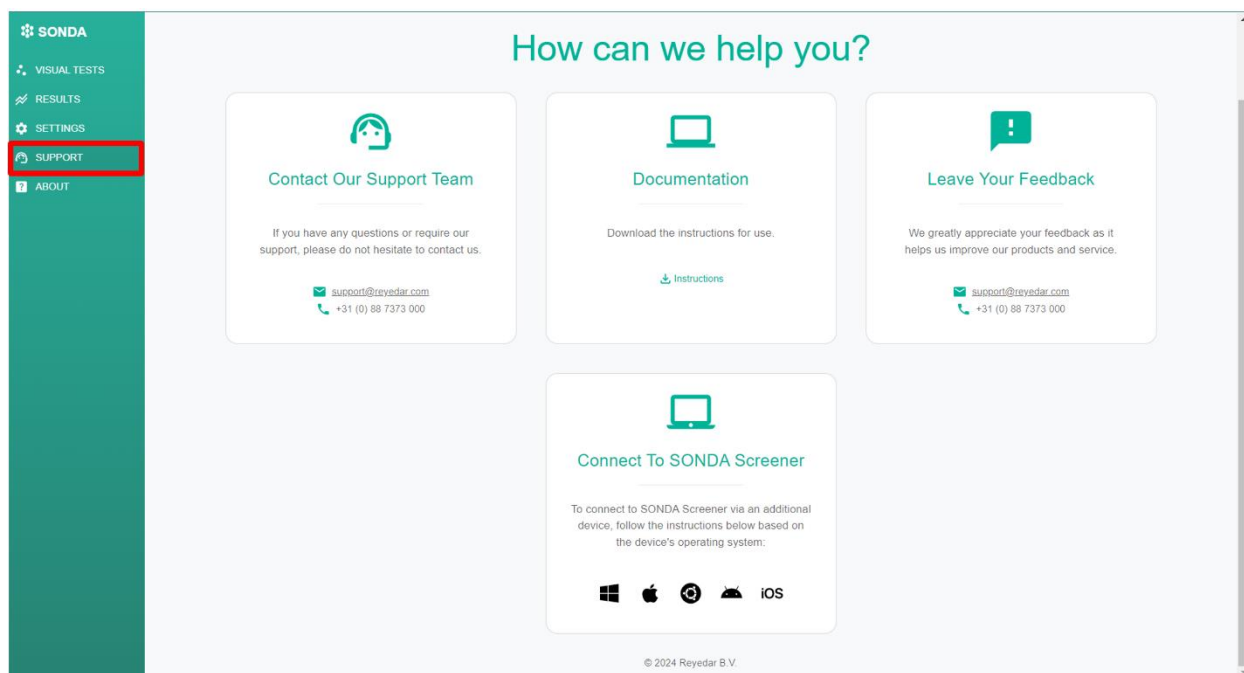


Figure 24: SONDA Hub 'Support' page.

6.9.1 Setup connection to SONDA Hub with a new computer

Depending on your network configuration, you may directly connect a new computer to SONDA Hub, or you may need to follow additional steps (if you are in doubt about your network setup, please contact us).

To set up a new computer for accessing SONDA Hub, click on the appropriate icon in the 'Connect to SONDA Hub' window, depending on the new computer's operating system. A prompt will appear with detailed instructions to setup the connection.

6.10 About page

The About page provides access to the product label of SONDA Hub and, if available, the SaMD diagnostic module. For SONDA Hub this will be the same regulated medical device label that is permanently affixed to the case of the device, while for the SaMD it is only going to be displayed digitally. Information on the current software versions of the device, both regarding the frontend and backend are also included in the About page, shown in Figure 25.

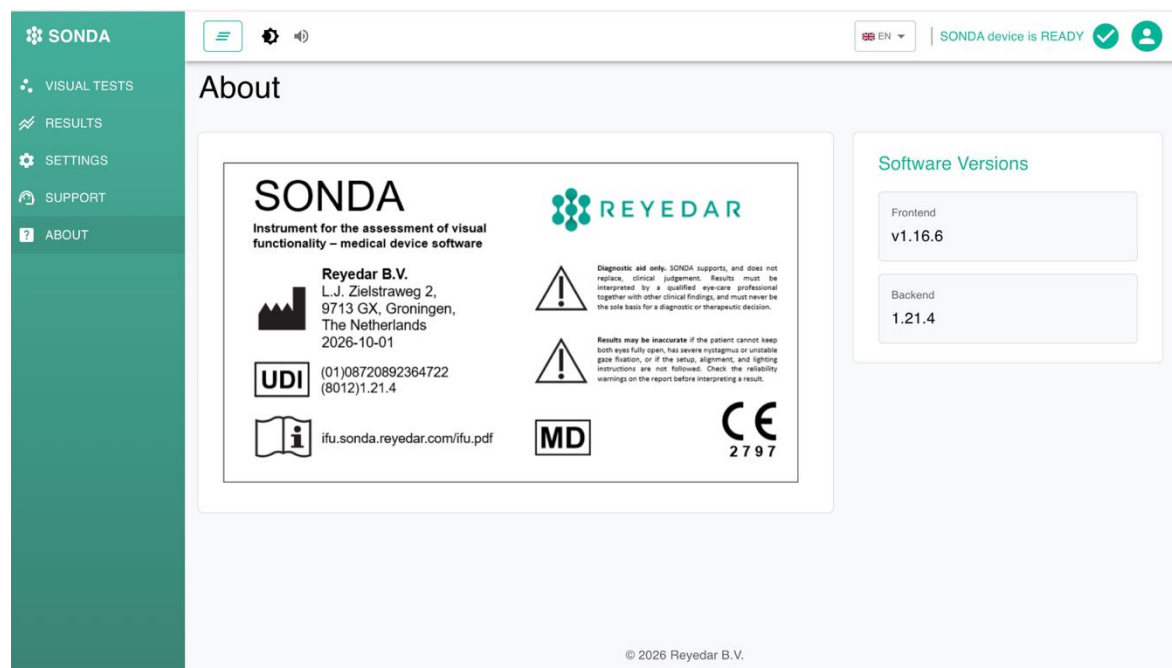


Figure 25: 'About' page, showing labels for SONDA (SaMD)

7.0 System updates

Software updates for the SONDA Hub and the SONDA SaMD diagnostic module are deployed and managed independently. There are two types of system updates available: *mandatory* and *optional*.

In the case of a *mandatory update*, upon logging in, a prompt offering to update the system will appear; other actions will not be possible. To proceed with the update, click on the "UPDATE NOW" button. During the update process, other actions within the system will be temporarily unavailable. An example of a mandatory update prompt is shown in Figure 26. Please follow the instructions on the screen, once the update is in progress.

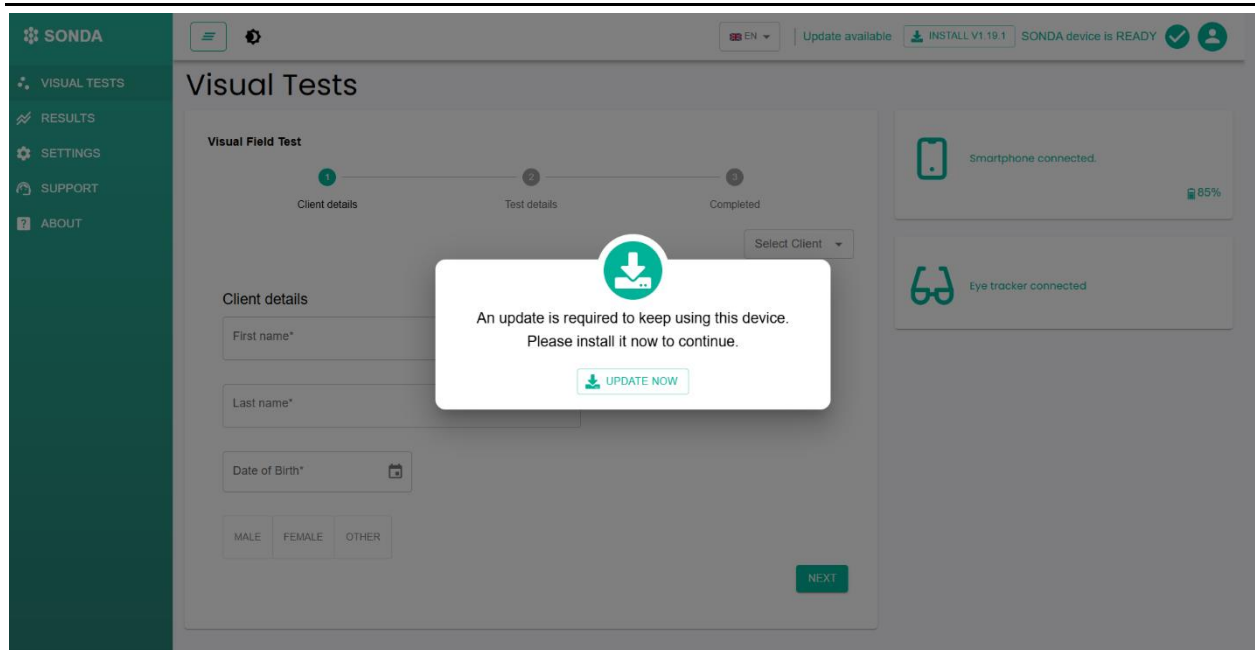


Figure 26: SONDA Hub mandatory update prompt.

When an *optional* update is available, a 'Device update available' message will appear at the top right side of any user interface page, with an 'INSTALL' button next to it, as shown in Figure 27.

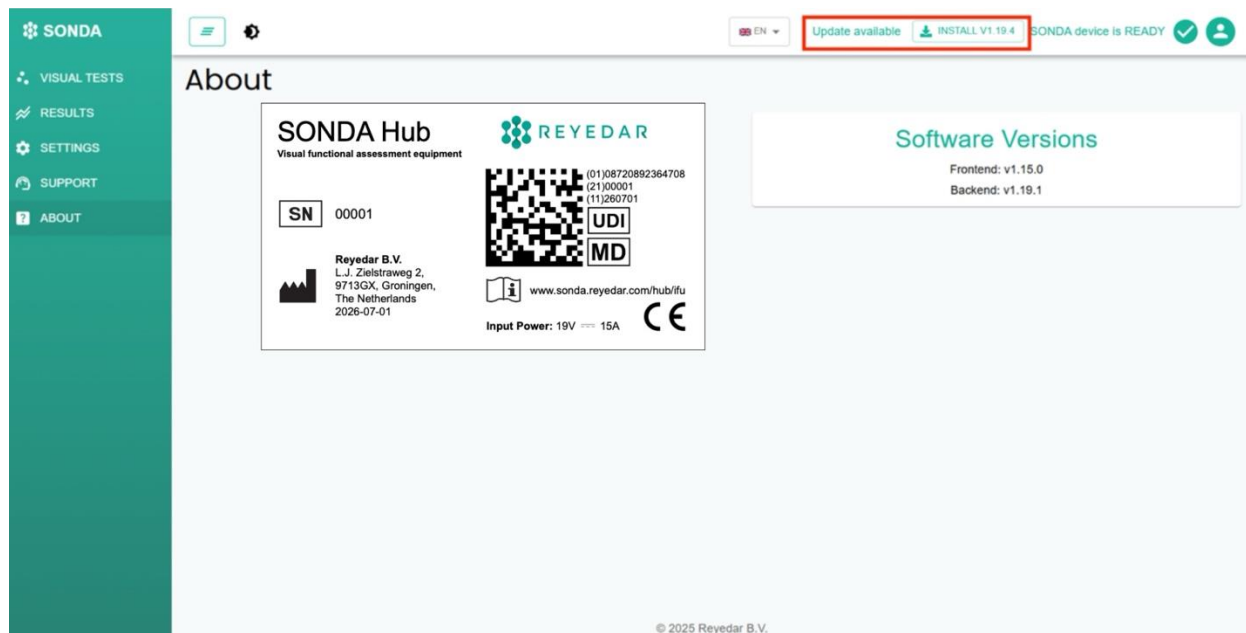


Figure 27: SONDA Hub optional update.

Please click on the button to initiate the update process. It is suggested to install optional updates as soon as possible.

An update can take about ten minutes to finalize. During the update, the user may be automatically logged out. It will be possible to log back in when the update is completed.

8.0 Maintenance and reporting

Users of SONDA Hub are not responsible for conducting preventive or regular maintenance on the device. Reyedar has established a comprehensive maintenance program to ensure the device operates efficiently and safely over its lifespan. Under no circumstances should users interfere with the hardware part of the device outside the scope that is outlined in this manual. Disregarding this warning may invalidate the test results and/or introduce additional risks to the user, including safety risks.

Warning:



Do not disassemble or modify the device in any way. Only Reyedar B.V. service personnel are allowed to assemble, disassemble, and move the device, once installed. Modifying the device in any way may invalidate the test results and/or result in personal injury or electric shock.

Should you encounter any issues or irregularities with the operation of the SONDA Hub device, you must not attempt to rectify these issues yourself. Instead, we urge you to contact Reyedar B.V. as soon as possible to report the problem with as much detail as possible. This includes any service requests or events that may be considered problematic to the device's performance. For more information on the nature of incidents, please refer to Section 1.3 of this document.

Your reports are an integral component of our post-market surveillance plan. By notifying us of any concerns or issues, you contribute to our ongoing effort of monitoring the safety, effectiveness, and reliability of the SONDA Hub device. This process allows us to implement necessary updates or corrections, ensuring the highest standards of patient care and safety.

For reporting any issues, service requests, or concerns regarding the SONDA Hub device, please contact support@reyedar.com, as described in Section 6.9.

8.1 Cleaning the eye-tracker



Warning: The eye tracker part of the device contains cameras and sensitive electronic components, **DO NOT** rinse or wet-clean.

The glasses' lenses must be cleaned with the provided microfiber cloth. The scene and eye camera lenses of the eye tracker can be carefully cleaned with the provided microfiber cloth if dust is visible.

The eye-tracker is cleaned with a disinfectant before shipping. Between each use with different patients, disinfecting of the eye tracker frames is recommended.

The recommended disinfectant is composed by 22.0 g Ethanol, 21.0 g 2-Propanol, 8.0 g 1-Propanol per 100 grams of solution. One such brand name is "Vibasept". Similar products should be available globally under different brand names.

When cleaning using wetted towelettes (wipes), be careful around the eye cameras, world camera, and USB connection. Liquid from disinfectant might damage sensitive electronics inside the frame.

After cleaning or disinfection, allow the eye-tracker to air-dry completely for a mandatory minimum of 15 minutes before use or reconnecting to power.

8.2 Cleaning the monitor and housing

The screen surface and outer housing of the stimulus display hub may be cleaned using a soft, lint-free cloth lightly dampened with water or a mild, non-abrasive cleaning solution. Do not spray liquids directly

onto the screen. Do not use solvents, alcohol-based products, or abrasive materials, as these may damage the screen coating. Ensure the device is switched off before cleaning. Allow all surfaces to dry completely before switching the device back on.

9.0 Disposal of the device

9.1 Disposal of the SONDA Hub

Reyedar B.V. takes responsibility for the safe disposal of the SONDA Hub device. Please contact us at support@reyedar.com for guidance on proper disposal procedures.

9.2 Decommissioning of the SONDA SaMD

When the SONDA SaMD is taken out of clinical use — whether due to end of subscription, replacement by a newer system, or facility closure — the steps below must be followed to ensure that patient data is handled safely and that the software is properly decommissioned.



Warning: Do not continue clinical use of an outdated version of SONDA SaMD. Using a version of the software that is no longer supported or has been superseded by a mandatory update may result in diagnostic output that has not been validated against the current normative database or model. The software will automatically prevent clinical use when a mandatory update is available and not installed. If your software has been formally retired, contact Reyedar B.V. immediately and cease all clinical use.

Step 1 — Back up and export patient data

Before initiating decommissioning, export any patient test results and reports that are required for clinical records or archiving. Reports can be downloaded in PDF format from the Results page by authorised users. Ensure that all relevant records have been exported and stored in your facility's patient record system in accordance with your local data retention policies.

Step 2 — Delete patient data from the SONDA Hub

Patient test results and associated data stored on the SONDA Hub must be deleted prior to decommissioning. Administrators and Super Users can delete individual records from the Results page. To request a full data purge from the local database and confirm removal from cloud storage, contact Reyedar B.V. at support@reyedar.com. Reyedar B.V. will confirm in writing when all patient-linked data has been removed from its systems

NOTE: Personal patient identifiers (name, date of birth) are stored locally on the SONDA Hub. Anonymised eye-tracking data may also be stored in cloud infrastructure managed by Reyedar B.V. Both must be addressed as part of decommissioning to comply with applicable data protection regulations (including GDPR where applicable).

Step 3 — Deactivate user accounts

All user accounts associated with the decommissioned device should be deactivated by an Administrator prior to shutdown. This prevents any residual access to the system or stored data. Contact Reyedar B.V. if assistance is required to remove user accounts from the identity management system.

Step 4 — Notify Reyedar B.V.

Contact Reyedar B.V. at support@reyedar.com to formally register the decommissioning of your SONDA SaMD installation. Reyedar B.V. will confirm the deactivation of your license, the removal of your device from cloud-connected services, and the completion of any outstanding data deletion.

10.0 Revision History

Revision	Summary of Changes
1.0	Initial release
2.0	Update prior to IMDD
3.0	Limited launch edition, added screenshots of latest updates, Figures, refined text
4.0	Corrected version placeholder in header
5.0	Updated test report (Figure 15), Section 6.9.1 Added automatic fill-in of tested patients in Section 6.4.
6.0	Corrected section 'revision history' Updated Figure 7 and added in the instruction recommendations for screen position and rotation in Section 6.4. Updated Figure 10 and added description of risk indication in Section 6.6. Added pictures of second page report Figure 16 and its description in Section 6.7. Added Figure 17 and Figure 19 to show warnings appearing on the report (new feature).
7.0	Added Figure 13 to illustrate search functionality and added description in 6.6. Updated Figure 7, Figure 8, Figure 9, Figure 10, Figure 19.
8.0	Remove reprocessing functionality description from 6.6. Added description of eye video streaming and new operator monitor in 6.4 and 6.5. Updated Figure 7, Figure 8, Figure 9, Figure 10, Figure 12, Figure 13, Figure 26, Figure 27.
9.0	Added backup recommendation in 6.7.
10.0	Updated report images Figure 15, Figure 16, Figure 17, Figure 18, Figure 19 and description in 6.7.
11.0	Added warning about not connecting USB peripherals to the device in Sec. 3.0. Expanded warning on eye occlusion and placement in Sec. 6.4. Updated Figure 7 and Figure 8. Added warning on date of birth in Sec 6.4. Updated intended light conditions in 2.8. Updated 2.6 with essential performance and safe state and new accuracy, sensitivity and specificity. Added Section 6.5.1. Added client PC specifications to 4.0. Changed operating temperature limits in 2.8 according to latest test results. Updated warnings and indications in section 3.1. Added network requirement in section 4.0. Introduced clearer split between SONDA Hub and the diagnostic module, updated all figure indices

12.0	Added option for provision of paper version of IFU in 1.1. Updated Figure 25. Added dedicated decommissioning instructions for SONDA SaMD in Section 9.2
13.0	Included link to Member State competente authorities in §1.3 Added §2.2.1 Clinical Benefit statement Aligned intended users (§2.3) and Intended patient target group (§2.4) to the rest of the TD Removed nystagmus from Contraindications (§2.5) and added statement on absence of undesirable side effects Added §2.6.3 Declared Limits of Accuracy Added §4.1 IT Security Requirements Added IFU version, SaMD version and CE marking with notified body number to the front page Added statement on requirements to access eIFU in §4.0 IT Requirements Added statement in §2.6.2 that the output of SaMD is the result of a version-locked machine learning model
14.0	Updated warnings in section 3.1, to align with design changes in the SONDA Hub device Updated section 8.1, adding mandatory drying period. Updated Login screenshot and About page screenshot.