Instructions for Use

RELUMINO

RELUMINO-S

Samsung Electronics Co., Ltd.

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1. General

1.1 About these instructions for use

These instructions for use provide the information necessary to operate the MODEL device**. PLEASE READ THESE INSTRUCTIONS FOR USE BEFORE OPERATING THE SYSTEM.** If any part of these instructions for use is not clear, please contact Customer Support for assistance.

1.2 Explanation of symbols

Safety notes

Safety notes in these instructions for use are introduced with a symbol and a signal word to describe the severity of the hazard.

Follow these safety notes and proceed with caution to avoid accidents, personal injury, damage to property, and to ensure patient safety.

Safety notes	Meaning
⚠ WARNING	This symbol and the word "WARNING" indicate a possible hazardous situation that, if not avoided, could cause death or serious injury. It could also indicate potential serious adverse reactions.
⚠ CAUTION	This symbol and the word "CAUTION" indicate a possible hazardous situation that, if not avoided, could result in minor or moderate injury to the user or patient or damage to the equipment of other property.

2. Introduction

2.1 Device information

Trademark	RELUMINO
Product name (Class)	Aid, Vision Image Intensification (Class 1)
Model	RELUMINO-S
Release Date	YYYY-MM-DD
Version	X.X.X
UDI	(01)08806094672527(10)X.X.X
Manufactured by	Samsung Electronics Co., Ltd.
Address	Room 10, C-Lab, Central Park, Samseong-ro 129 (Maetan-dong), Yeongtong-gu, Suwon-si, Gyeonggi-do, South Korea
This product is a medical device.	
Website	https://www.samsungRELUMINO.com
Contact	+82-2-6147-3480

2.2 Intended use

RELUMINO is a Software as a Medical Device (SaMD) App intended to be used as a vision aid to help Individuals with low vision by intensifying images that are captured by the camera of a Video See Through (VST) device.

2.3 Operation principle

RELUMINO is a mobile software App intended to assist visually impaired individuals with low vision. Install RELUMINO software on a smartphone and connect it to a Video See Through (VST) device. The VST's camera captures the input video, which is then processed through image processing techniques to transform it into an enhanced visual representation that improves the user's object recognition capability. The transformed image is displayed on the VST's screen. The software

offers features such as image zooming, brightness and contrast adjustments, color inversion, and edge enhancement, allowing users to perceive objects in a more accessible format. These transformations can be further magnified and displayed on the VST's screen for easier recognition.

2.4 Applied standards

(1) IEC 62304:2015
(2) ISO 15223-1:2021
(3) EN ISO 14971:2019

3. Safety

⚠ WARNING

- Do not use this product for any other purpose.

- Do not use RELUMINO App while engaged in activities such as walking, exercising, or any other outdoor activities. Using RELUMINO in situations that require attention, such as walking, cycling, or driving, can be extremely dangerous. Therefore, RELUMINO App should use only when in a stationary position.

- Do not use the VST device for infants, toddlers, or children under the age of 13, as it may potentially impact their visual development.

- Do not modify RELUMINO App without the manufacturer's Approval. The RELUMINO App should only be installed and updated by the manufacturer.

- To use RELUMINO properly, the user should have full mobility and a normal sense of balance. Please do not use RELUMINO in the following situations. Using RELUMINO under these conditions may worsen symptoms and lead to potential risks.

    - When feeling tired or in need of sleep.

    - Under the influence of alcohol or drugs.

    - Experiencing hangover, digestive disorders, stress, anxiety, cold, flu, headaches, migraines, or ear problems.

- For safe usage, please make sure to use the RELUMINO App while sitting or in a stationary position. The RELUMINO App enlarges the images captured by the camera built into the VST device, so the view seen while wearing it may be magnified compared to reality.

- When wearing the VST device, be cautious during vigorous movements as it may hinder the ability to see the surrounding environment, which could

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potentially cause harm to others nearby. Before using the VST device, carefully assess surroundings and remain attentive to the environment during its use to avoid injuries.

- To prevent tampering by external threats such as viruses, it is important to install antivirus software on the smartphone and keep it regularly updated. By doing so, a user can enhance the security of the device and protect the RELUMINO App from potential risks and malicious activities.

- If the RELUMINO App encounters any issues or threats from external factors such as viruses or other risks that may impact its functionality, please contact the manufacturer to receive relevant instructions and measures.

- Due to the magnification feature of RELUMINO, the distance between a user and surrounding objects may appear different from reality. Collisions or falls into walls, furniture, or other objects could result in serious injuries. Therefore, for safe usage, please take the time to carefully inspect the surroundings before using RELUMINO.

- While using RELUMINO or immediately after its use, please exercise extra caution to avoid colliding with other people, objects, stairs, balconies, railings, windows, furniture, firearms, ceiling fans, or any other fixed structures.

- When using RELUMINO to magnify objects, be aware that the user may not perceive people or pets approaching from the surroundings. The magnification effect may limit the field of view, potentially leading to a lack of awareness of nearby individuals or animals.

- Do not hand sharp or other hazardous objects while using RELUMINO.

⚠ CAUTION

- RELUMINO is intended for use in patients with low vision who have a best corrected visual acuity of at least 0.48 LogMAR and no more than 1.3 LogMAR in their better eye, and may not achieve its intended use in

patients who do not fall between 0.48 and 1.3 LogMAR.

- Extended use of the VST device can potentially have negative effects on hand-eye coordination, balance, and multitasking abilities. Therefore, if children or adolescents aged 13 and above are using the VST device, parents or guardians should carefully observe whether they exhibit any of these symptoms. It is essential to limit the usage time and ensure they take breaks while using the device. Furthermore, please refer to the specific precautions provided by the manufacturer of the VST device for any additional details.

- Please use caution when moving immediately after use, as there is a possibility of tripping or falling.

- Please take a 10–15-minute break at least every 30 minutes. If a user uses the App for more than 30 minutes, he/she will receive a notification message on the App screen, and the App will automatically shut down. As fatigue levels vary among users, determine the most suitable rest time and frequency by taking longer and more frequent breaks if he/she experiences discomfort.

- If a user experiences any of the following symptoms: seizures, loss of cognition, eye fatigue, eye or muscle twitching, involuntary movements, vision impairment, blurriness, diplopia (double vision), or any other visual anomalies, dizziness, loss of directional sense, balance impairment, eye-hand coordination issues, excessive sweating, increased salivation, nausea, lightheadedness, headache, or any other symptoms resembling motion sickness, please stop using the device and take a rest.

- Some users may experience severe dizziness due to the flickering of the display light. This symptom is more likely to occur in children and adolescents under the age of 20. Users who have experienced severe dizziness or related symptoms should consult with a doctor before using the VST device.

- Symptoms similar to those experienced commonly after disembarking from a ship, which may persist for several hours after use and even appear more

pronounced, can occur. Post-use symptoms may include excessive drowsiness, nausea, and other symptoms mentioned earlier.

- Until all symptoms have completely subsided, refrain from engaging in activities such as driving, operating machinery, or any visually or physically demanding actions that could result in severe consequences (i.e., activities that could lead to death, injury, or property damage due to symptoms). Additionally, avoid activities that require a sense of balance or hand-eye coordination (such as sports or cycling). Ensuring full recovery is crucial before participating in such activities to ensure safety and prevent potential accidents or harm.

- Do not use the VST device for several hours until all symptoms have completely disappeared. If severe symptoms occur or if the symptoms persist, consult with a doctor for advice and further evaluation.

- Please ensure that the VST device is correctly adjusted to fit the user before use. Using the device without proper adjustment may result in an abnormal display on the screen. To ensure a clear and effective visual experience, it is important to wear the VST device in the correct and comfortable position for the individual user.

- Prolonged use of RELUMINO through the VST device may lead to muscle, joint, or skin injuries caused by repetitive stress. If any part of the body feels fatigued, painful, or experiences symptoms such as tingling, numbness, burning, or stiffness during RELUMINO usage, discontinue use and take a few hours of rest before using it again. If users continue to experience any of the mentioned symptoms or other discomforts while using RELUMINO, immediately stop using the device and consult with a doctor.

- Before using the RELUMINO App, make sure to thoroughly read and understand the user manual.

- Before using RELUMINO, please check the recommended hardware and software requirements for the smartphone. Failure to meet the recommended hardware and software specifications may increase the risk

of discomfort and other issues.

- The VST device is intended to be used by both visually impaired individuals and non-disabled individuals. Please refer to the user manual of the VST device for warnings and precautions related to its usage.

- If a user has a significant difference in visual acuity between both eyes, it is recommended to wear corrective lenses for vision correction before using the VST device.

- Gradually get accustomed to using RELUMINO to avoid any discomfort. Begin with a few minutes of usage initially and gradually increase the duration as a user become more familiar with the device.

- Do not use RELUMINO if any part of the VST device is faulty or damaged.

- Avoid looking directly at lasers or external light sources while using RELUMINO.

- If the smartphone battery is fully discharged while using RELUMINO, the screen may turn off. Make sure to fully charge the battery before usage.

- Pregnant women, nursing mothers, women of childbearing age, and elderly individuals should use RELUMINO under the guidance of a caregiver.

  - Users with specific medical conditions such as pregnancy, old age, mental disorders, or heart diseases should consult a doctor before using the VST device.

4. Installation of RELUMINO App

4.1 Preparation

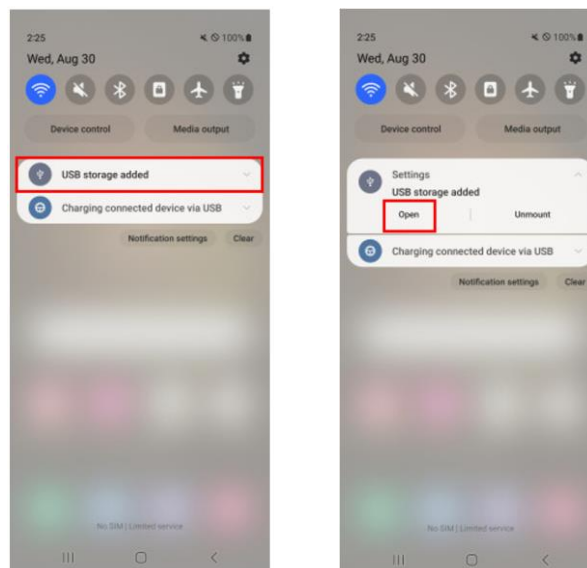(1) Prepare a USB for installing RELUMINO App.

4.2 Installation

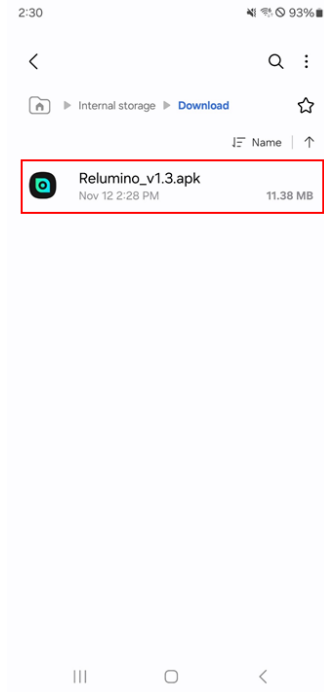(1) Connect the USB to the smartphone where RELUMINO App will be installed.

(2) Tap on the Samsung USB drive notification.
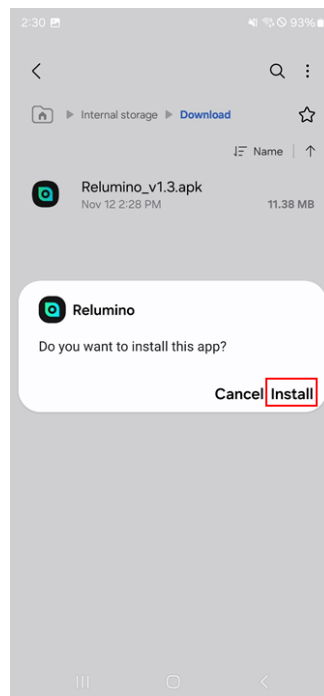
(3) Select RELUMINO_vX.X.apk.

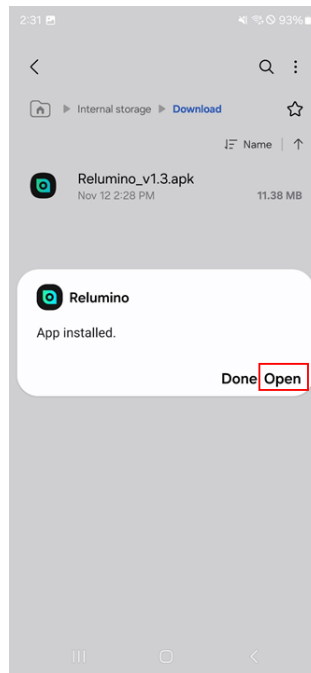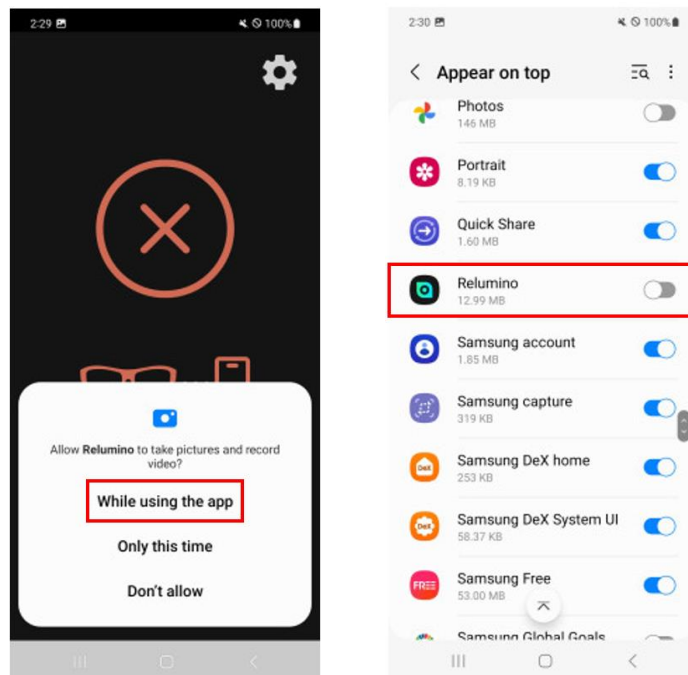<It is an example of an application installation file>

(4) Press the "Install" button.

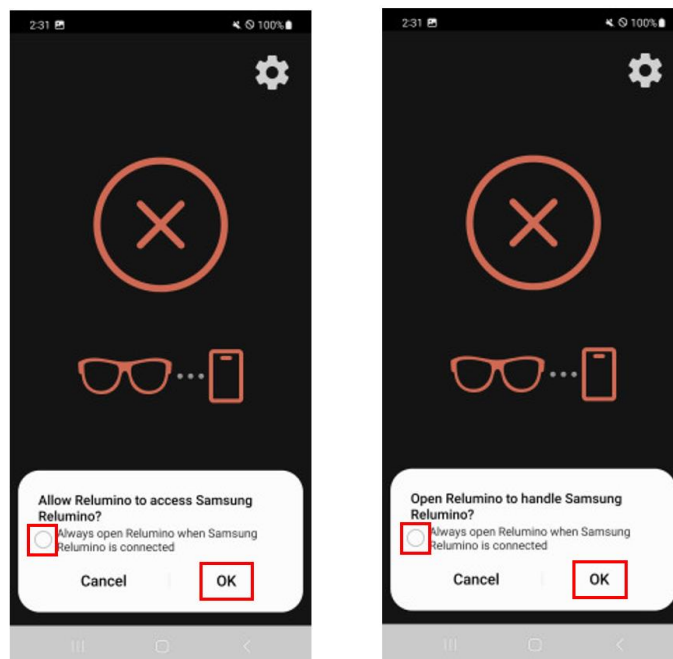(5) After the installation is complete, press "Open" to launch the App.

(6) Set permissions and App display preferences.

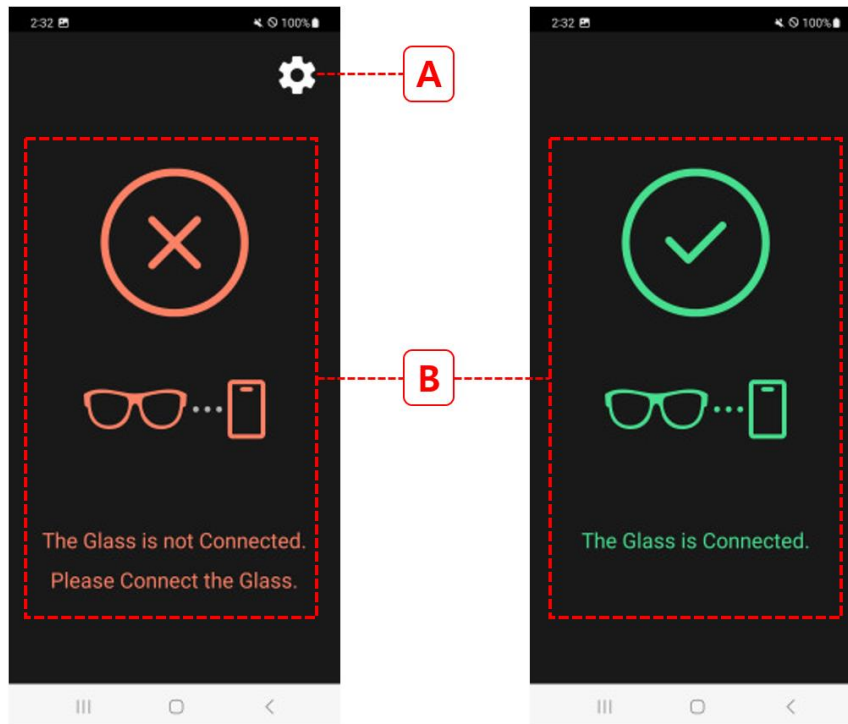(7) Confirm that App is running correctly.
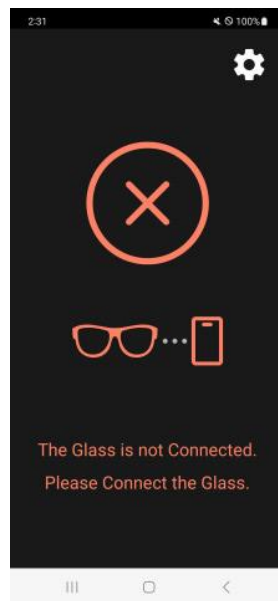
(8) If the permission request popup appears as shown below, check the content and press "OK" to proceed.

5. RELUMINO App Display

5.1 Display layout

No.	Item	Description
A	Setting button	Device Labeling Information
B	Connect status display area	The "Connection Status Display Area" shows the status of the connection between the smartphone and the VST device.

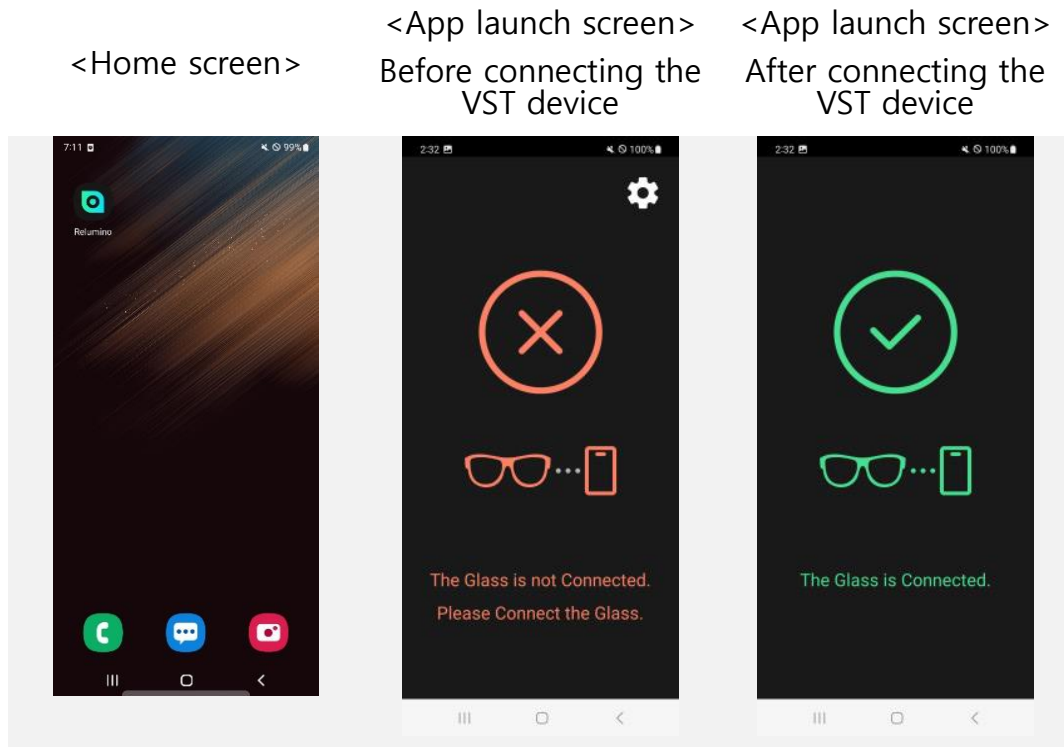## 6. Setting up the RELUMINO App

6.1 Preparation before use

(1) Carefully read the App user manual.

(2) Carefully read the VST device user manual.

6.2 Running the App

(1) Tap the RELUMINO icon on the smartphone's home screen to launch the App.

※ If the App has been granted auto-run permission, the RELUMINO App will automatically start when he/she connects the VST device to the smartphone.

(2) Connect the VST device to the smartphone's charging port and check the RELUMINO App screen for the text "Glasses connected."
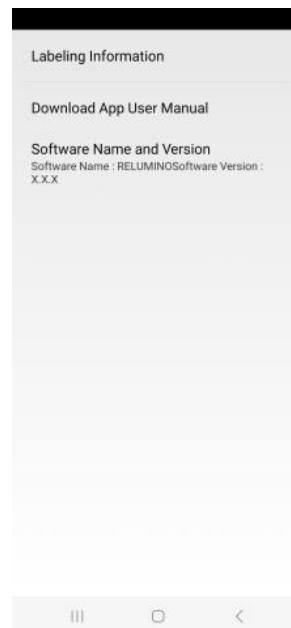
<table>
<tr><td></td><td><App launch screen>
Before connecting the
VST device</td><td><App launch screen>
After connecting the
VST device</td></tr>
<tr><td><Home screen></td><td></td><td></td></tr>
</table>

6.3 App Screen Functions

6.3.1 Settings

(1) In the settings screen, a user can enter the App settings by tapping the "(A) button" in the top left corner.
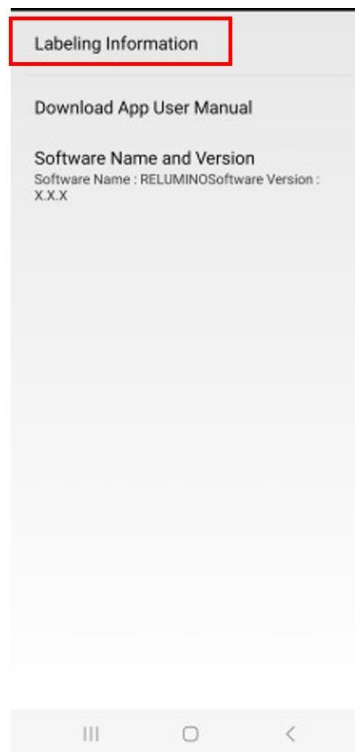
(2) When a user enters the App settings, the following menu will appear.
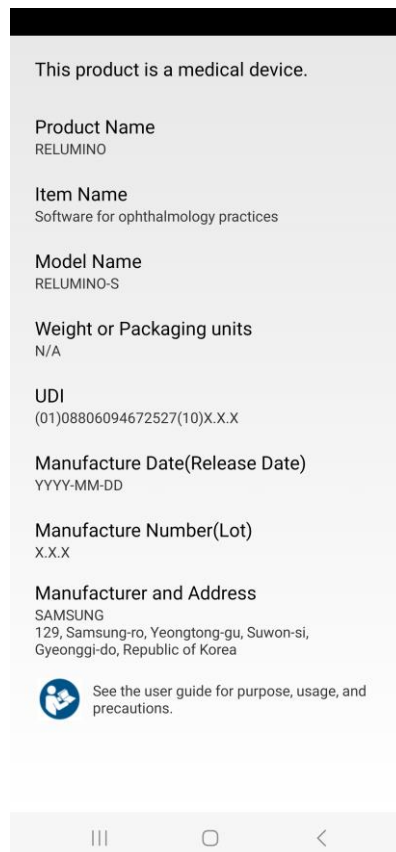

6.3.2 Labelling information

(1) When a user presses the "Labeling Information" in the App settings, the user can view the medical device labeling information.
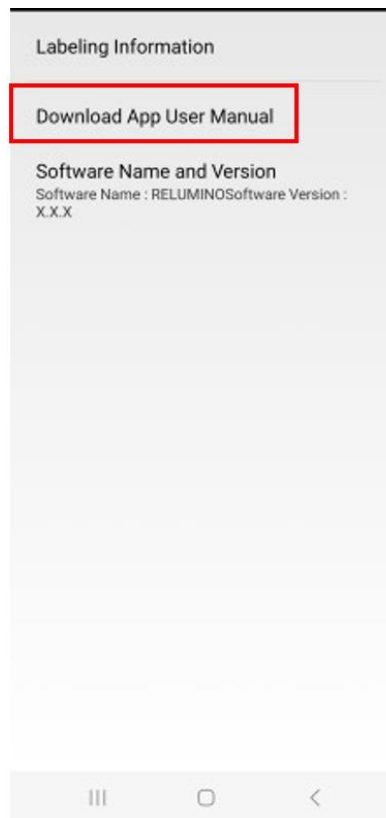
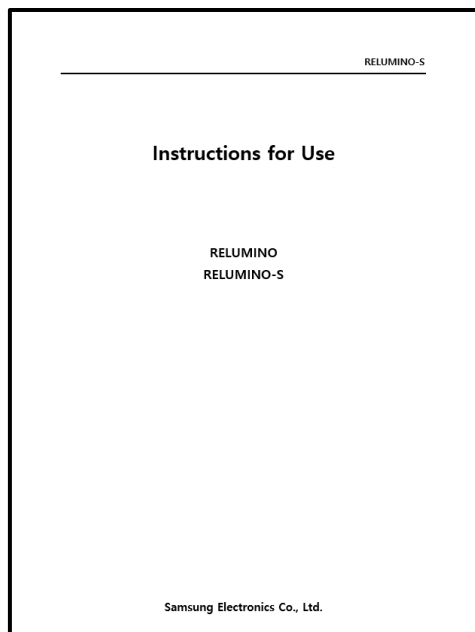(2) When the user enters the "Labeling Information," the following content will be displayed.

6.3.3 App User Manual

(1) When the user clicks on the "Download App User Manual" button in the App settings, the user will be redirected to an internet page where the user can access the App's user manual.


(2) The user can view the User Manual on the internet page.

7. Using RELUMINO App

7.1 Connect VST device

(1) Execute the App on the smartphone.

(2) Connect the VST device to the smartphone. Please refer to the IFU of the specific VST device for instructions on how to establish the connection.

(3) Once the VST device is successfully connected, the RELUMINO App will display the message "Glasses are connected" and the VST device's display will show the screen as follows:
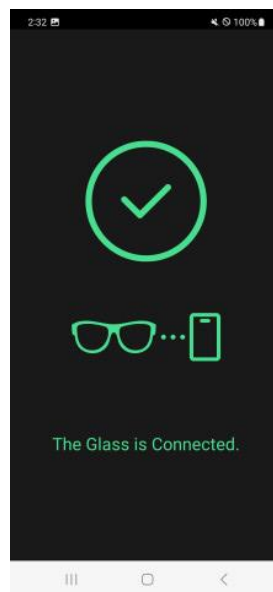

7.2 How to use RELUMINO App

7.2.1 Zoom In and Out 1

(1) To zoom in on an object viewed through the VST device, place two fingers on the RELUMINO App screen on the smartphone and spread them diagonally apart.

(2) To zoom out on an object viewed through the VST device, place two fingers on the RELUMINO App screen on the smartphone and pinch them diagonally together.

Zoom In   Zoom out

7.2.2 Zoom in and out 2

(1) To zoom in on an object viewed through the VST device, place one finger on the RELUMINO App screen on the smartphone and swipe upwards.

(2) To zoom out on an object viewed through the VST device, place one finger on the RELUMINO App screen on the smartphone and swipe downwards.

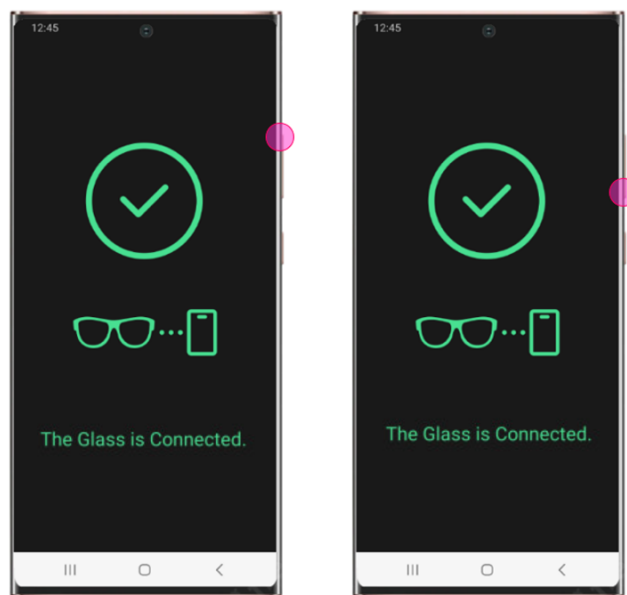(3) For fine adjustment in zoom, slowly move your finger up or down while touching the screen.
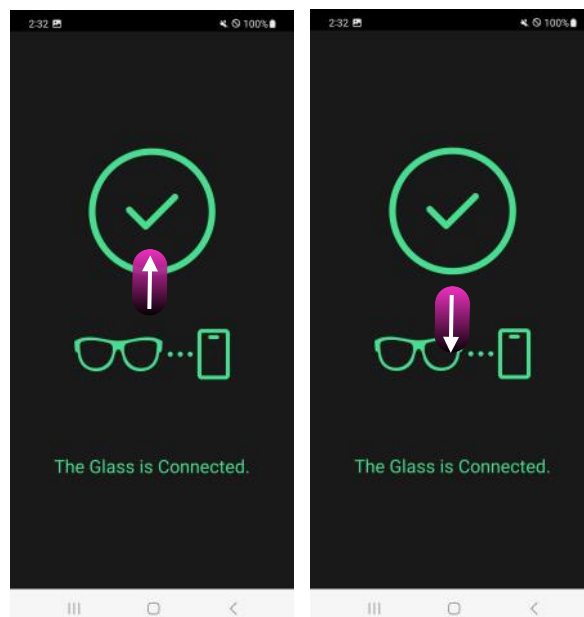
Zoom in Zoom out

7.2.3 Brightness Adjustment

(1) To increase the brightness of the VST device screen, press the volume up button on the smartphone.

(2) To decrease the brightness of the VST device screen, press the volume down button on the smartphone.

Increase brightness Decrease brightness

7.2.4 Contrast

(1) Contrast is a feature that changes the color contrast on the VST device screen.

(2) To increase the color contrast on the VST device screen, place one finger on the RELUMINO App screen on the smartphone and simultaneously press the volume up button.

(3) To decrease the color contrast on the VST device screen, place one finger on the RELUMINO App screen on the smartphone and simultaneously press the volume down button.

(4) When adjusting the contrast, users can easily do so by holding the smartphone in the one hand and using a finger from their other hand.
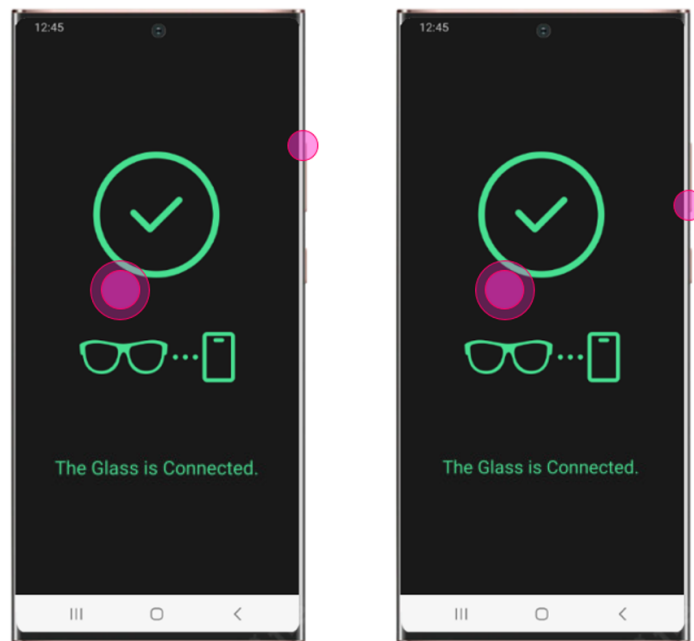
<div align="center">Increase contrast   Decrease contrast</div>
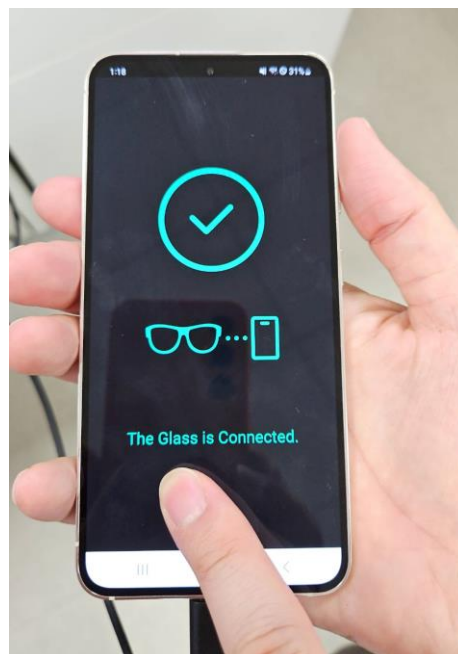
Recommended smartphone holding position for using the contrast feature

7.2.5 Edge Enhancement

(1) The edge enhancement is a feature that enhances the outlines of objects, allowing individuals with low vision to see blurry images more clearly. There are five types of edge enhancement available:

- Edge 1: Black edge

- Edge 2: Green edge

- Edge 3: White edge

- Edge 4: Black + White edge

(2) To activate the edge enhancement feature on the VST device screen, place two fingers on the RELUMINO App screen on the smartphone and simultaneously press the volume up button.

(3) At this point, a user can cycle through the desired edge enhancement colors by repeatedly pressing the volume up button. The sequence of colors is as follows:

- Edge 1 > Edge 2 > Edge 3 > Edge 4 > Turn off edge enhancement (cycle through these options).

(4) When adjusting the edge enhancement mode, holding the smartphone with one hand and using two fingers from your other hand makes it easy to adjust.
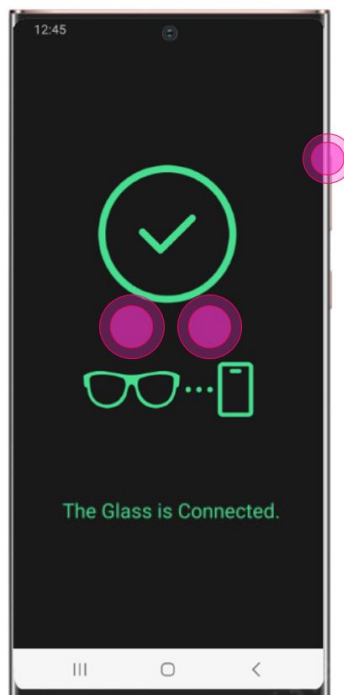
Edge enhancement

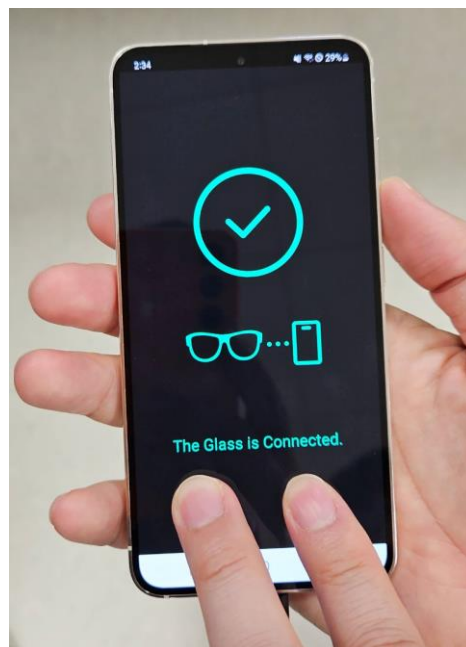Recommended smartphone holding position for using the edge enhancement feature

7.2.6 Color Inversion

(1) Color inversion is a feature that changes the colors of the background and text to make it easier for users with low vision to read. There are four color inversion options available:

- Color Inversion 1: Black background / White text

- Color Inversion 2: Black background / Yellow text

- Color Inversion 3: Black background / Green text

- Color Inversion 4: Blue background / Yellow text

(2) To invert the colors on the VST device screen, place two fingers on the RELUMINO App screen on the smartphone and simultaneously press the volume down button.

(3) At this point, a user can cycle through the desired color inversion modes by repeatedly pressing the volume down button. The sequence of color inversions is as follows:

- Color Inversion 1 > Color Inversion 2 > Color Inversion 3 > Color Inversion 4 > Turn off color inversion (cycle through these options).

(4) When adjusting the color inversion mode, holding the smartphone with one hand and using two fingers from your other hand makes it easy to adjust.

Color Inversion

Recommended smartphone holding position for using the color inversion feature

7.3 App Messages

7.3.1 App closure upon motion detection

(1) During VST device usage, if the user walks or moves, the VST device screen will display a message indicating "Step Detection."

(2) While this message is displayed, any further App interaction will automatically result in the App being closed.

7.3.2 App closure after prolonged use

(1) When wearing the VST device and using it for an extended period (30 minutes or more), a warning message "Running Time Over" will appear.

(2) While this message is displayed, any further App interaction will automatically result in the App being closed.

8. Troubleshooting

Issue	Causes	Recommended action(s)
The App terminates	The required permissions have not	To grant all permissions for the RELUMINO App, follow

Issue	Causes	Recommended action(s)
on the loading screen	been granted/allowed in the App	these steps: 1.Go to [Settings] on the smartphone. 2.Select App. 3.Find and select [RELUMINO] from the list of installed Apps. 4.Within the RELUMINO App settings, locate the [Permissions] section. 5.Grant all the permissions required by enabling each permission switch.
The App and VST device are not connecting properly.	Caused by poor connection with the VST device or other connectivity problems.	After separating the VST device from the smartphone, restart the App and try reconnecting them again.
During the usage of VST mode, the connection with the VST device is interrupted.	Caused by poor connection with the VST device or other connectivity issues	After separating the VST device from the smartphone, restart the App and try reconnecting them again.

9. Specifications

9.1 Software operating environment

Android smartphone	OS: Android 12 and above CPU: 2GHz and above RAM: 3G and above Display: Touch LCD Camera: 760p/30fps above

9.2 Software main features

Features	Description
Setting	Display of Medical Device Labeling Information and User Manual URLs

VST Device Connection Indicator	VST Device connection status indicator
	[Before connection]
	  - The VST device and smartphone are displayed with a red icon (Ⓧ)
	  - Message: "Glasses are not connected. Please connect the glasses"
	[After connection]
	  - The VST device and smartphone ae displayed with a green icon (✓).
	  - Message: "Glasses are connected"

Zoom in/out	The feature that allows a user to zoom in or out on the VST device's screen. "Pinch-to-zoom" or "vertical drag" on the App screen.
Brightness	Adjust the brightness of the VST device's screen.
Contrast	Adjust the color contrast on the VST device's screen.
Edge Enhancement	Edge enhancement Feature:

Features	Description
	- Edge 1: Black Edge - Edge 2: Green Edge - Edge 3: White Edge - Edge 4: Black + White Edge
Color inversion	The feature that changes the colors of the background and text while reading: - Color Inversion 1: Black background / White text - Color Inversion 2: Black background / Yellow text - Color Inversion 3: Black background / Green text - Color Inversion 4: Blue background / Yellow text