CareSens™ Air
Receiver

Table of contents

Before use

- This product only makes use of personal information which the user has agreed to allow to be collected.
- Contact the manufacturer or visit the website for details of this product.

References
- All standards and regulations mentioned are in effect as of the date this manual was issued.
- Some features described in this manual may not be available in some countries.
Please consult the local representative for region-specific information.
- The screenshots and illustrations in this manual are provided for explanatory purposes. They may differ from the actual appearance.

Document conventions

Notational conventions
This manual uses the following notational conventions to aid in understanding its content.

Notational conventions	Description
Boldface	Boldface is used to display elements of the graphic user interface, including menus and directories.
' '	Single quotation marks are used to indicate pages, portals, and screens from the graphical user interface.
'Cross-references'	'Cross references' are used to refer to different sections of this document.
Visual aids	Visual aids in the form of graphics, illustrations, or screen captures are used to help the reader understand the text.
Tables	Tables are used to present large amounts of data in an easy-to-read format.

Supplementary descriptions and explanations
You can refer to these for information about exceptions and limitations.

References
This marks helpful information for product use or safety information.

Precautions
This manual uses the following types of safety messages to alert the user of situations in which they need to take precautions when using the product:

⚠ Warning
This marks a potential danger that could result in serious injury or death if not avoided.

⚠ Caution
This marks a potential danger that could result in minor injury or property damage if not avoided.

Definitions of symbols
The following table lists graphical symbols for electrical equipment in medical practice set by the IEC (International Electrotechnical Commission). These symbols not only provide additional information on the product and product use, but also on safety.

Symbol	Description
MD	Medical device
⚠	Caution
📖	Please refer to the user manual
🚶	Type BF Applied Part
🗑	Guide for the disposal of electrical or electronic devices
🌡	Temperature limitation
💧	Humidity limitation
IP	Dustproof, waterproof grades
🏭	Manufacturer information
LOT	Batch/Lot number
~	Date of manufacture

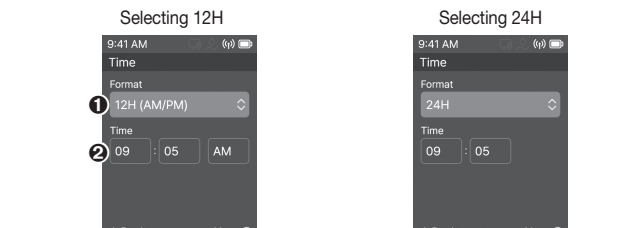## 01 Understanding the CareSens Air Receiver

Intended Use
The CareSens Air Continuous Glucose Monitoring (CGM) System is indicated for continuous monitoring of blood glucose levels via measurement of glucose in the interstitial fluid in patients with diabetes mellitus aged 18 years and older. CareSens Air CGM System enables blood glucose monitoring through either a smartphone app or a CareSens Air Receiver. The CareSens Air Receiver receives blood glucose readings from the sensor and displays them on the screen. CareSens Air Receiver helps to detect trends such as hyperglycemia and hypoglycemia by providing continuous blood glucose information, to manage changes in blood glucose levels through trend detection and pattern tracking, and to assist in diagnosis and treatment when consulting with medical staff. CareSens Air Receiver results should not be used to diagnose diabetes nor provide any medical decisions. CareSens Air Receiver is intended for use by patients at home and in healthcare facilities.

Significance of use
The CareSens Air Receiver can be used in the following cases when the user app cannot be used or to respond to a certain use scenario.
- When using a smart device that does not support the user app.
- When using in special cases, such as temporary use within a hospital or medical facility.
- When using in an environment where smart device use is difficult, such as during a national examination.
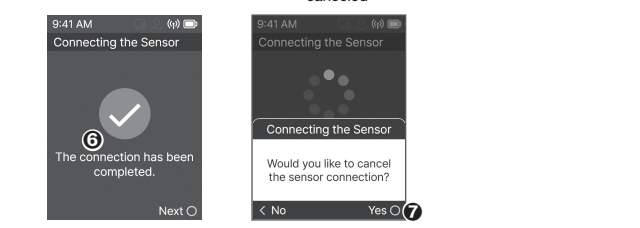
Product components

CareSens Air Receiver

Button configuration

Button	Description
○	Select, To next input value, Cancel power saving mode, Power On
‹	To previous input value (to previous menu), Start power saving mode
∧	Move menu (up), Change time displayed on graph, Cancel power saving mode
∨	Move menu (down), Change time displayed on graph, Cancel power saving mode

02 Using the CareSens Air Receiver

Turn on CareSens Air Receiver
Press the power button to turn on the CareSens Air Receiver.

Agree to Terms
Check the terms of the CareSense Air Receiver click **Agree**.

Index	Description
❶	Guide image
❷	Guide message
❸	Input window
❹	Back • When selected - Move to Information input stage
❺	OK • When selected - Move to How to use guide

Enter sensor information

Index	Description
❶	Guide image
❷	Guide message
❸	Input window
❹	Back • When selected - Move to Information input stage
❺	OK • When selected - Move to How to use guide

Time settings

Index	Description
❶	Selecting the Format
❷	Time settings

Unit settings

Index	Description
❶	Unit setting options

Connect to sensor

Product description

Safety information

Index	Description
❶	Content for Safety information
❷	Page

Re-enter the sensor information
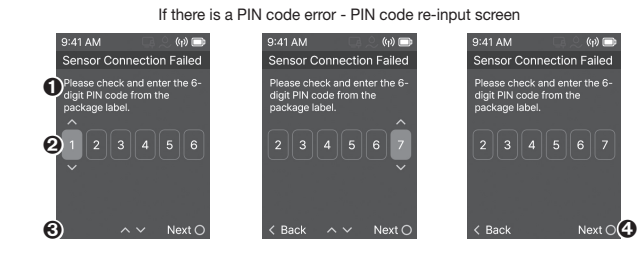
Index	Description
❶	An alert guide message for failed sensor connection
❷	Information input window • Show the previously entered PIN number.
❸	Cancel - Move to Home (no sensor connection)
❹	OK - Attempt connection
❺	OK • Reused, wrong PIN number -> PIN code input screen Communication problem -> Connection attempt screen

Connection complete

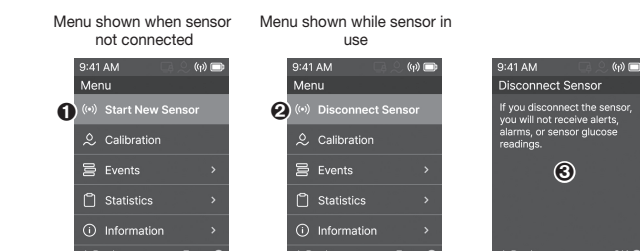| Index	Description
❶	Guide image
❷	Guide message
❸	Connecting status
❹	Remaining time
❺	Help key guide
❻	Connection complete
❼	When the connection is canceled • First connection: Move to "First alert settings" -> Set an alert and move to the no sensor connection status • Existing usage (2 types) : Move to Home (no sensor connection status) 1 . If started at Home -> Move to Home 2. If started at Menu -> Move to Home

03 Exploring menus

Understanding the Home screen
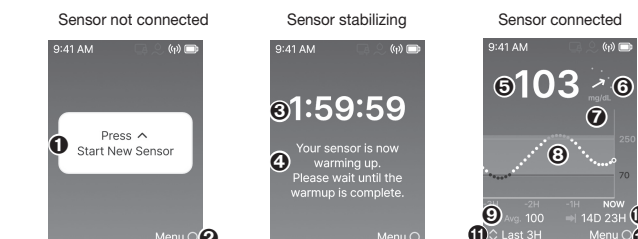
Index	Description
❶	New sensor connection guide
❷	O key guide • When selected - Move to Menu screen
❸	Time remaining until stabilization
❹	Stabilization guide message
❺	CGM value
❻	Changes in trend arrows
❼	Unit
❽	CGM chart • Specifications - See next page
❾	Average blood glucose value during the chart period displayed on the screen
❿	Time remaining until expiration of sensor
⓫	Up/down key guide • Chart scale adjustment when selected
⓬	O key guide • When selected - Move to Menu screen

Chart
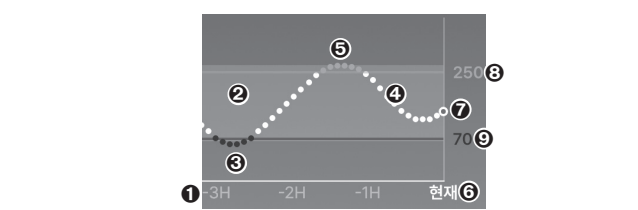
Index	Description
❶	Chart X-axis - Time unit (marking policy undecided)
❷	Range within the goal
❸	Low blood glucose record points - Red
❹	Normal blood glucose record points - White
❺	High blood glucose record points - Yellow
❻	Current status
❼	Current blood glucose value • Dark blue points • Normal blood glucose - White outline • Low blood glucose - Red outline • High blood glucose - Yellow outline
❽	High blood glucose alert standard line, standard value
❾	Low blood glucose alert standard line, standard value

Alert settings

Blood glucose alert settings

Index	Description
❶	Very low alert settings
❷	Low alert settings
❸	High alert settings
❹	Unit
❺	Check the settings

Initial device settings

Date settings

Index	Description
❶	Selecting date style
❷	Date settings

How to use guide

Index	Description
❶	Guide image
❷	Guide message
❸	Page

Connect to sensor BT
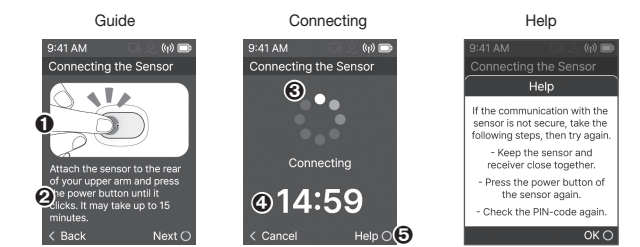
Rapidly change alert settings
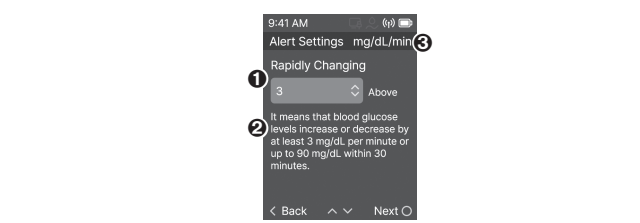
Index	Description
❶	Rapidly change alert settings
❷	Rapidly change description • Details vary depending on 2 mg/dL/min or 3 mg/dL/min selection.
❸	Unit

Alert type settings
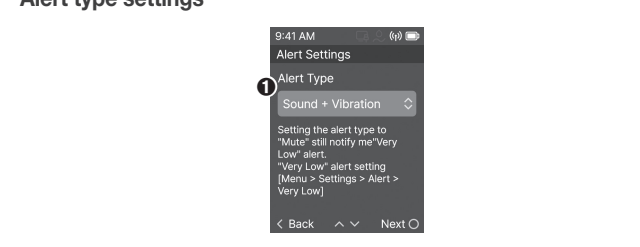
Index	Description
❶	Alert type settings

Menu
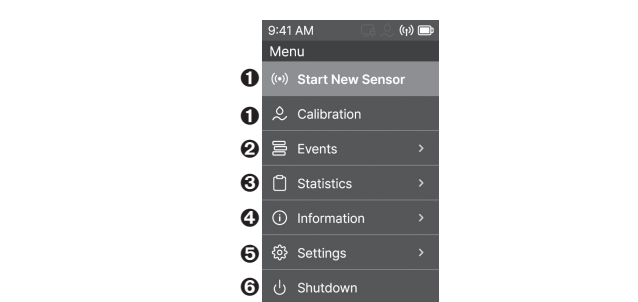
Index	Description
❶	Sensor start or end menu • If the sensor is not in use, show start sensor • When selected - Move to Sensor connection screen • If the sensor is in use, show end sensor • When selected - Move to Sensor disconnection screen (or pop-up)
❷	Calibration menu • When selected - Move to Calibration value input screen
❸	Event menu • When selected - Show Event drop-down menu
❹	Statistics menu • When selected - Show Statistics drop-down menu
❺	Information menu • When selected - Show Information drop-down menu
❻	Settings menu • When selected - Show Settings drop-down menu
❼	Shutdown menu • When selected - Show Shutdown confirmation pop-up

Initial calibration

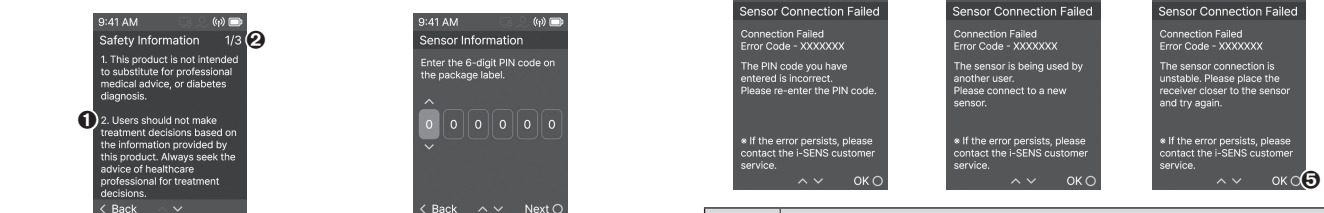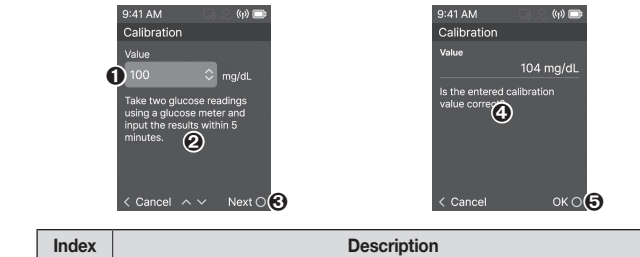| Index	Description
❶	Enter first calibration value • Present number 100 mg/dL. • Set so it appears as a blank space before input, and the number starts from 100 when number is selected
❷	Enter second calibration value
❸	Check input value
❹	Confirmation message after input is complete

Sensor start/end

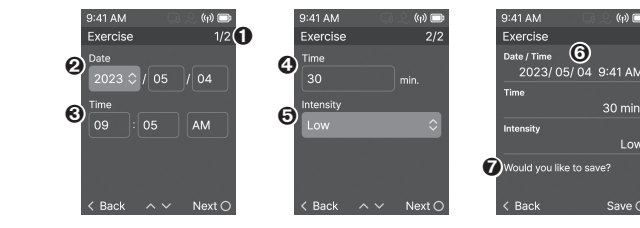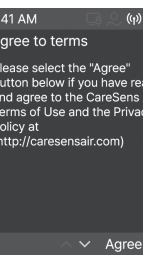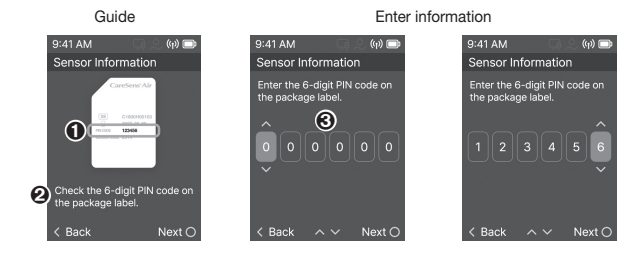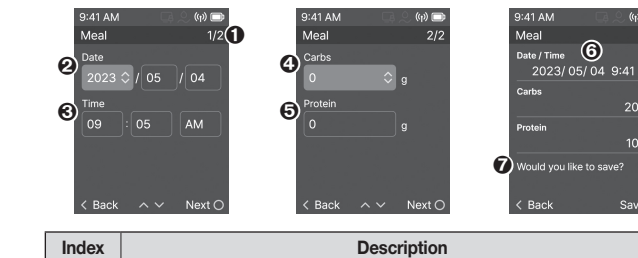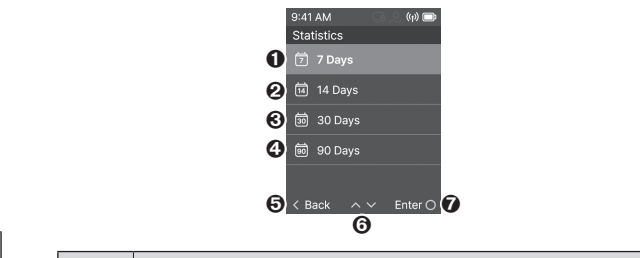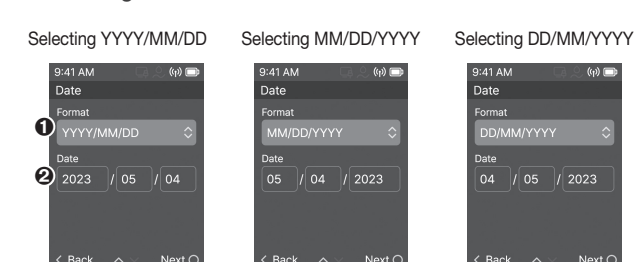| Index	Description
❶	New sensor connection menu • When selected - Move to PO-04-03 sensor information input screen
❷	Disconnect sensor in use menu • When selected - Move to Disconnect sensor screen
❸	Sensor disconnection guide message
❹	O key guide • When selected - Show Disconnection confirmation pop-up
❺	O key guide • When selected - Run Sensor disconnected

Calibration

Index	Description
❶	Calibration value input field • Default - Current CGMS value
❷	Calibration value input guide message
❸	O key guide • When selected - Move to Input confirmation screen
❹	Check calibration value screen
❺	O key guide • When selected - Calibration value saved

Event

Index	Description
❶	Enter blood glucose event • When selected - Move to Blood glucose event input screen
❷	Enter ketone event • When selected - Move to Ketone event input screen
❸	Enter insulin event • When selected - Move to Insulin event input screen
❹	Enter meal event • When selected - Move to Meal event input screen
❺	Enter oral medication event • When selected - Move to Oral medication event input screen
❻	Enter exercise event • When selected - Move to Exercise event input screen
❼	Event log • When selected - Move to Event log screen
❽	Back key guide
❾	Up/down key guide
❿	O key guide

Enter blood glucose

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Enter blood glucose value
❺	Check entered information
❻	Confirmation message after input is complete

Enter ketone

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Enter ketone value 0.0 • Present value 0.0
❺	O key guide

Enter insulin

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Select insulin type
❺	Enter insulin administration amount • Present value 0.0 • Previous value entered shown
❻	Check entered information
❼	Confirmation message after input is complete

Enter meal

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Enter amount of carbs consumed • Unit 5 g
❺	Enter amount of protein consumed • Unit 5 g
❻	Check entered information
❼	Confirmation message after input is complete

Enter oral medication

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Check entered information
❺	Confirmation message after input is complete

Enter exercise

Index	Description
❶	Event input page
❷	Enter date
❸	Enter time
❹	Enter exercise time
❺	Enter exercise intensity
❻	Check entered information
❼	Confirmation message after input is complete

Log book

Index	Description
❶	Date classification table
❷	Event log (Optional)
❸	Event log • Event type, value, time entered
❹	Information entered
❺	Edit option
❻	Delete option
❼	Delete confirmation message

Statistics

Index	Description
❶	Statistics of last 7 days • When selected - Move to Statistics of last 7 days screen
❷	Statistics of last 14 days • When selected - Move to Statistics of last 14 days screen
❸	Statistics of last 30 days • When selected - Move to Statistics of last 30 days screen
❹	Statistics of last 90 days • When selected - Move to Statistics of last 90 days screen
❺	Back key guide
❻	Up/down key guide
❼	O key guide

7 Days Statistics

Index	Description
❶	Statistics period on page title
❷	Page
❸	Average blood glucose during selected period
❹	SD during selected period
❺	CV during selected period
❻	TIR

14 Days Statistics
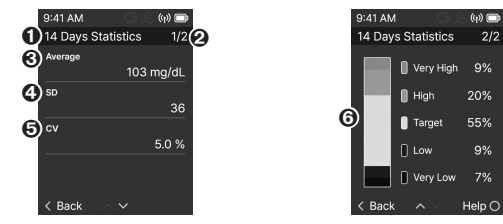
Index	Description
1	Statistics period on page title
2	Page
3	Average blood glucose during selected period
4	SD during selected period
5	CV during selected period
6	TIR

Receiver
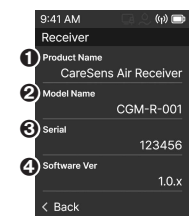
Index	Description
1	Model Name
2	Model information
3	Serial
4	Software Ver

Connecting the sensor
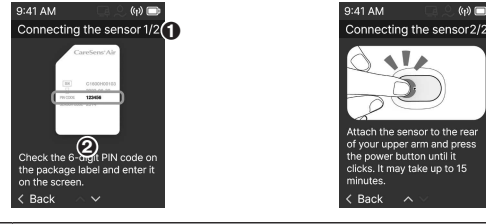
Index	Description
1	Page
2	Content for how to Connecting the sensor

Disconnecting/Removing
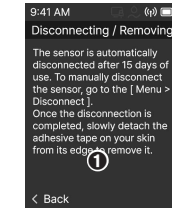
Index	Description
1	Content for how to Disconnecting/Removing

LANGUAGE
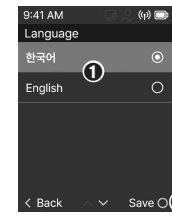
Index	Description
1	Language settings item
2	O key guide • When selected - Change Receiver language to selected language
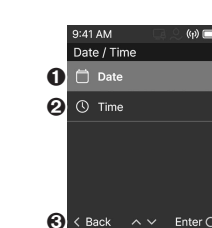
Alert

Index	Description
1	Very low alert settings • When selected - Move to Very low alert settings screen
2	Low alert settings • When selected - Move to Low alert settings screen
3	High alert settings • When selected - Move to High alert settings screen
4	Rapidly change alert settings • When selected - Move to Rapidly change alert settings screen
5	System alert settings • When selected - Move to System alert settings screen
6	Mute • When selected - Move to Mute screen
7	Reset alert settings • When selected - Move to Reset alert settings screen
8	Back key guide
9	Up/down key guide

System
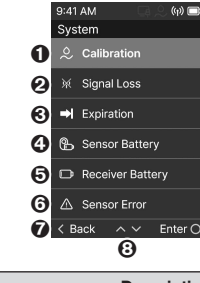
Index	Description
1	Calibration alert settings When selected - Move to Calibration alert settings screen
2	Signal loss alert settings • When selected - Move to Signal loss alert settings screen
3	Expiration alert settings • When selected - Move to Expiration alert settings screen
4	Sensor battery alert settings • When selected - Move to Sensor battery alert settings screen
5	Receiver battery alert settings • When selected - Move to Receiver battery alert settings screen
6	Sensor error alert settings • When selected - Move to Sensor error alert settings screen
7	Back key guide
8	Up/down key guide
9	O key guide

Sensor error alert settings
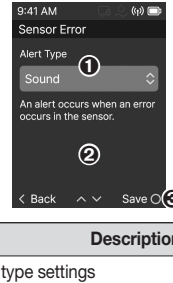
Index	Description
1	Sensor error alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Sensor error alert information
3	O key guide • When selected - Save selected alert type

Mute settings
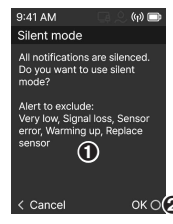
Index	Description
1	Mute settings information
2	O key guide • When selected - Run Mute settings

Receiver low battery - End
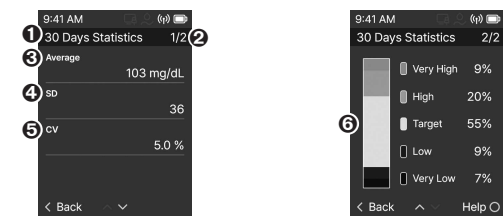
The receiver shutdown because the battery is low.

Boot loader

Software update screen — Software Update - Do not remove the cable until the update is complete.

Error screen in the case of cable separation during update — Software Update Error - Proceed with the software updating process again.

Error screen in the case of failed booting due to main application error — System Error - Software update is required.

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30 Days Statistics

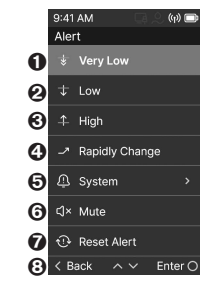| Index	Description
1	Statistics period on page title
2	Page
3	Average blood glucose during selected period
4	SD during selected period
5	CV during selected period
6	TIR

Connected sensor
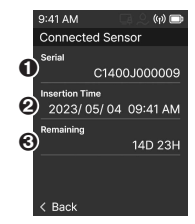
Index	Description
1	Sensor serial number information
2	Sensor starting date and time
3	Remaining time on sensor • If there is no connected sensor: - shown

About CareSens Air

CareSens Air continuously monitors glucose concentration in interstitial fluid and provides information on glucose trends and how quickly glucose levels are changing.

Calibration

Index	Description
1	Content for how to Calibration
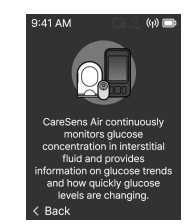
Data upload

Index	Description
1	Content for how to Data upload

Date settings

Index	Description
1	Selecting date style
2	Date settings
3	O key guide • Show as Save on last item settings • When selected - Save as selected date

Very low alert settings

Index	Description
1	Very low alert standard value settings
2	Alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute/Off • Default - Sound
3	O key guide • Show as Save on last item settings • When selected - Save selected alert value, alert type

Calibration alert settings

Index	Description
1	Calibration alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Calibration alert information
3	O key guide • When selected - Save selected alert type

Signal loss alert settings

Index	Description
1	Signal loss alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Signal loss alert information

Reset alert settings

Index	Description
1	Reset alert settings information
2	O key guide • When selected - Run Reset alert settings

Chart Y-axis settings

Index	Description
1	Chart Y-axis settings options
2	O key guide • When selected - Save selected Y axis value

Radio regulation compliance (FCCID: OELCGM-R-001)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Part15.21 statement:

Changes or modifications not expressly approved by the manufacturer (or party responsible) for compliance could void the user's authority to operate the equipment.

RF exposure statement:

This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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90 Days Statistics

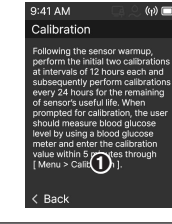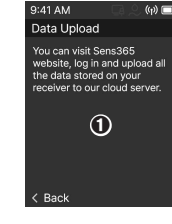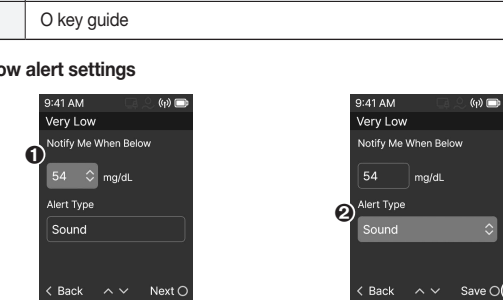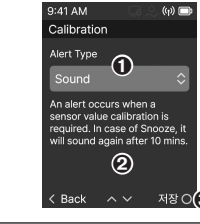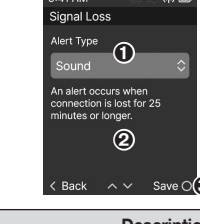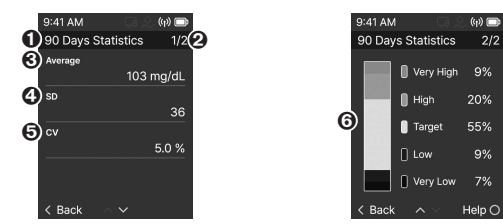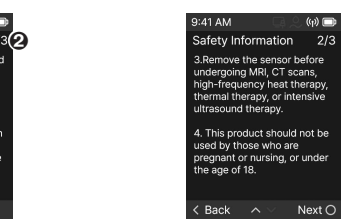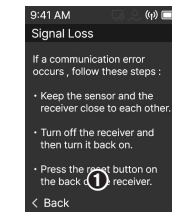| Index	Description
1	Statistics period on page title
2	Page
3	Average blood glucose during selected period
4	SD during selected period
5	CV during selected period
6	TIR

Safety information

Index	Description
1	Page
2	Content for Safety information

How to use
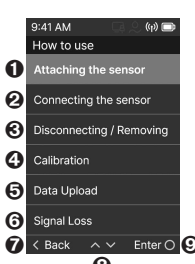
Index	Description
1	Attaching the sensor • When selected - Move to Attaching the sensor guide screen
2	Connecting the sensor • When selected - Move to Connecting the sensor guide screen
3	Disconnecting/Removing • When selected - Move to Disconnecting/Removing guide screen

Index	Description
1	Calibration • When selected - Move to Calibration guide screen
2	Data upload • When selected - Move to Data upload guide screen
3	What to do when the signal is lost • When selected - Move to Signal loss guide screen
4	Back key guide
5	Up/down key guide
6	O key guide

What to do in the case of a signal loss

Index	Description
1	Content for how to manage the Signal loss

Legal notice
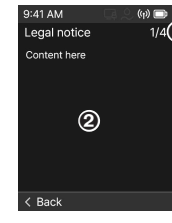
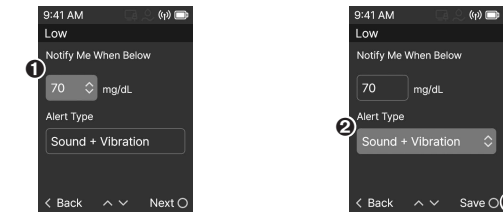| Index	Description
1	Page
2	Content for Legal notice

Time settings
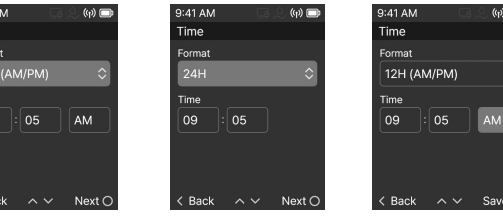
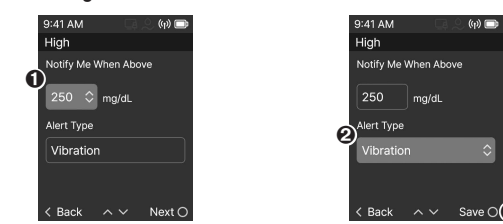| Index	Description
1	Selecting the Format
2	Time settings
3	O key guide • Show as Save on last item settings • When selected - Save as selected time

Screen

Index	Description
1	Screen brightness level
2	O key guide • When selected - Save as selected screen brightness

Low alert settings

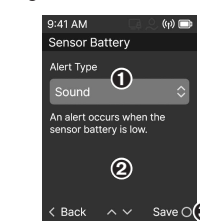| Index	Description
1	Low alert standard value settings
2	Alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute/Off • Default - Sound
3	O key guide • Show as Save on last item settings • When selected - Save selected alert value, alert type

High alert settings

Index	Description
1	High alert standard value settings
2	Alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute/Off • Default - Sound

Expiration alert settings
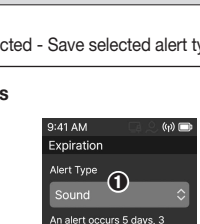
Index	Description
1	Expiration alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Expiration alert information
3	O key guide • When selected - Save selected alert type

Sensor battery alert settings

Index	Description
1	Battery alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Battery alert information
3	O key guide • When selected - Save selected alert type

Shutdown

Index	Description
1	Shutdown information
2	O key guide • When selected - Show Shutdown confirmation pop-up
3	O key guide • When selected - Run Shutdown

Shutdown — Turn off the receiver. If the sensor is connected, only the most recent 12 hours of data will be saved, and previous data will be deleted. Do you wish to turn off the receiver?

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04 Product specifications

Information

Index	Description
1	Receiver information • When selected - Move to Receiver information screen
2	Connected sensor information • When selected - Move to Connected sensor information screen
3	About CareSens Air • When selected - Move to About CareSens Air screen
4	Safety Information • When selected - Move to Safety information screen
5	How to use • When selected - Move to How to use screen
6	Legal notice • When selected - Move to Legal notice screen
7	Back key guide
8	Up/down key guide
9	O key guide

Attaching the Sensor

Index	Description
1	Page
2	Content for how to Attaching the sensor

Configuration
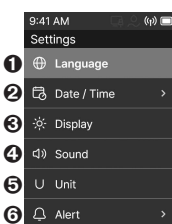
Index	Description
1	Language settings • When selected - Move to Language settings screen
2	Date/Time settings • When selected - Show Date/Time drop-down menu
3	Display settings • When selected - Move to Display settings screen
4	Sound settings • When selected - Move to Sound settings screen
5	Unit settings • When selected - Move to Unit settings screen
6	Alert settings menu • When selected - Show Alert settings drop-down menu
7	Chart Y-axis settings • When selected - Move to Chart Y-axis settings screen
8	Back key guide
9	Up/down key guide
10	O key guide

Sound
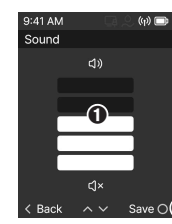
Index	Description
1	Volume level
2	O key guide • When selected - Save as selected volume

Unit

Index	Description
1	Select blood glucose unit
2	O key guide • When selected - Save as selected unit

Rapidly change alert settings

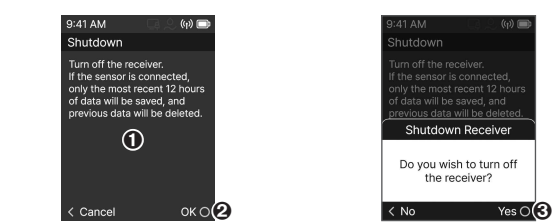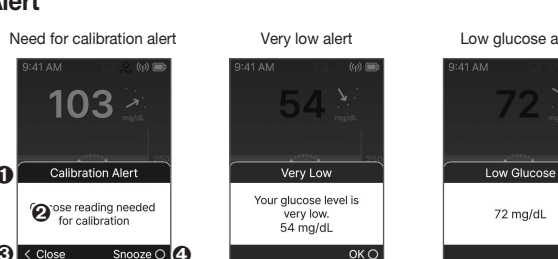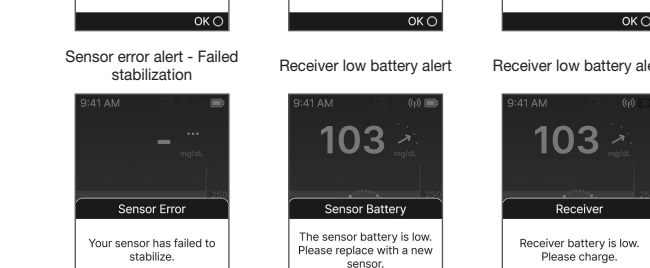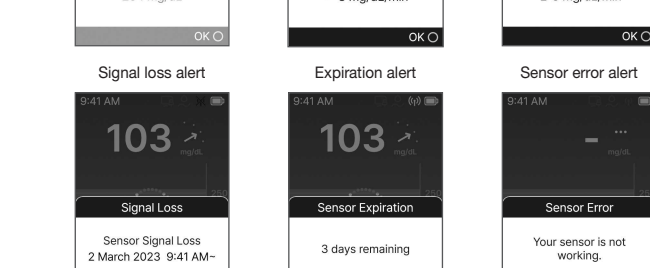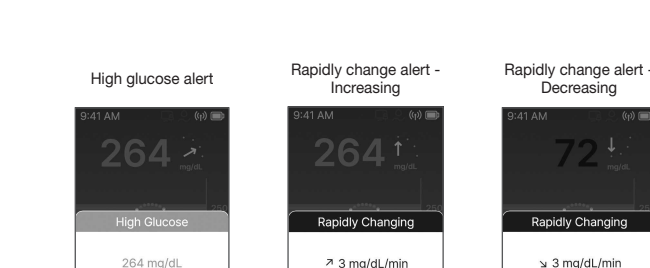| Index	Description
1	Rapidly change alert standard value settings
2	Alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute/Off • Default - Sound
3	O key guide • Show as Save on last item settings • When selected - Save selected alert value, alert type

Receiver battery alert settings

Index	Description
1	Receiver battery alert type settings • Options - Sound/Vibration/Sound + Vibration/Mute • Default - Sound
2	Receiver battery alert information
3	O key guide • When selected - Save selected alert type

Product specifications

Device specifications

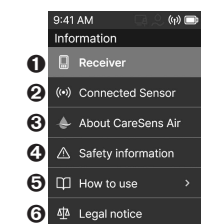| ITEM	Specifications
Operation conditions	Temperature: +0 – +40 °C (32 – 104 °F) (TBD) / Relative humidity: 10-90%
Storage and transport conditions	Temperature: +0 – +40 °C (32 – 104 °F) / Relative humidity: 10 - 90%
Dust proof/moisture proof	IP22
Alert	• Alert style: sound, vibration, mute alert • Very low, Low glucose, High glucose, Rapidly change, Calibration, Signal loss, Expiration, Sensor error, Sensor battery low, Receiver battery low
Receiving intervals	5 minutes
Storage capacity	180 days (TBD)
User controls	• 4 user control buttons − 1 select/power button − 1 go back button − 2 up/down buttons − 1 reset pinhole
Power	3.7 V
MCU	STM32L4P5ZGT6
Battery lifespan	Fully charged in 5 hours, usable for 7 days
Power consumption	• Power saving mode: ≤ 2 mA • Operation mode (maximum): ≤ 200 mA (TBD)

ITEM		Specifications
Communication	Wire	USB type-C cable
	Wireless	Bluetooth 5.2
Modulation		GFSK
Transmission distance		6 m
Size		• Height (H): 50 mm • Width (W): 96 mm • Thickness (D): 13.8 mm
Weight		69.7 g (TBD)
LCD		2.4" Color LCD
Color		Black

Other indicators
- Medical device
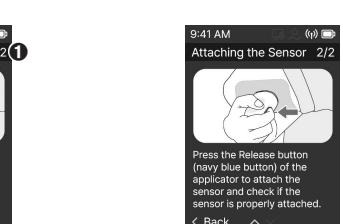- Product name: CareSens Air Receiver
- Model name: CGM-R-001

Alert

Need for calibration alert — Calibration Alert - Use reading needed for calibration.

Very low alert — Very Low - Your glucose level is very low. 54 mg/dL

Low glucose alert — Low Glucose - 72 mg/dL

High glucose alert — High Glucose - 264 mg/dL

Rapidly change alert - Increasing — Rapidly Changing - ↗ 3 mg/dL/min

Rapidly change alert - Decreasing — Rapidly Changing - ↘ 3 mg/dL/min

Signal loss alert — Sensor Signal Loss - 2 March 2023

Expiration alert — Sensor Expiration - 3 days remaining

Sensor error alert — Sensor Error - Your sensor is not working.

Sensor error alert - Failed stabilization — Sensor Error - Your sensor has failed to stabilize.

Receiver low battery alert — Sensor Battery - The sensor battery is low. Please replace with a new sensor.

Receiver low battery alert — Receiver - Receiver battery is low. Please charge.

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