

Karie Duo R1 - Instructions for Use

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Document history

Version	Summary of changes	Link to document
v1.0_duo_eng_10/2024	First version.	
v2.0_duo_eng_02/2025	[summary of changes to be included when @Abhiraj Gour and @Steinar Løvli takes final review to ensure new workflow is reflected]	

Approval

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1. Introduction

Thank you for purchasing Karie Duo.

Karie Duo is a digital medication dispensing device. Karie Duo uses pre-packaged pouches filled with medications from a pharmacy, organized into multidose rolls marked with date and time. It dispenses medication according to a schedule imported from a pharmacy and alerts users with lights and sounds when it's time to take their medication.

Please read this instruction manual thoroughly before using Karie Duo. This instruction manual aligns with the European Electromagnetic Compatibility and Medical Device Regulation 2017/745. Prior to utilizing Karie Duo, it is crucial to carefully read the safety and user instructions outlined herein to prevent damage to the dispenser and potential harm to yourself and others. The guidance provided is applicable to the following dispenser with reference numbers under the Basic-UDI-DI: XXXX. Locate the serial number on the bottom of your Karie Duo dispenser for identification purposes.



With care, Karie Duo.

Karie Duo is CE certified as a Class I medical device pursuant to the Medical Devices Regulation (EU) 2017/745 (MDR) and 21 CFR 890.5050 Subpart F of US-FDA. The trade name of the product is Karie Duo, and the manufacturer of the product is AceAge (14190777 Canada Inc.).

Manufacturer/North America Contact	Org. no.	Address	Website address	Phone number	Email address
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These instructions have been meticulously crafted. If you identify any discrepancies with reality, kindly inform us for prompt resolution. We retain the right to modify these instructions as the product undergoes further development. The trademarks mentioned and depicted in this instruction manual are the property of their respective owners and are legally protected. Reproduction, translation or duplication in any form, even in abbreviated form, necessitates written approval from the manufacturer.

This manual is subject to revision management by the manufacturer, Document Number: XXXX (revised on MO/2024) © 2024 AceAge.

If you have any questions or require further details, please contact the manufacturer or the EU Authorized Representative directly, based on your geographical location, using the contact details provided above.

2. Intended purpose

Intended Use

Karie Duo is intended for automatic medication dispensing of pre-packed medication in the home and healthcare environment based on established pharmacy medication schedules.

Intended users

Karie Duo is intended to be used by individuals or care givers in both home and healthcare settings.

User interface

Karie Duo is an electric medication dispenser with a touch-screen, and light and sound notifications.

Karie Duo features a user interface that can integrate with other systems for caregiver use.

Please note that the availability of certain Karie Duo functions may differ based on location.

Indications for use

Karie Duo is indicated as an automatic medication dispenser that organizes, schedules and delivers medication to individuals that are in need of guidance and assistance.

Karie Duo is not intended to be used as a device for monitoring health status, medical diagnosis, or to make treatment decisions. Only qualified healthcare professionals can diagnose and treat medical conditions. The responsibility for prescribing medications lies with licensed healthcare providers who can evaluate the user's medical needs and make appropriate recommendations.

Karie Duo is not suitable for storing life-saving medications or those requiring specific temperature control.

Karie Duo should not be used without supervision by minors and persons with drug addiction.

3. General Precautions

Care providers assisting users with Karie Duo must undergo training conducted by the manufacturer or a local distributor, either through physical sessions or webinars. This training covers essential topics such as correctly loading the multidose rolls, ensuring timely medication loading, and other fundamental functions.

4. Safety information

4.1 Safety instructions

- It is important to read and understand this instruction manual. Failure to follow the instructions noted may result in problems and void the product warranty.
- If Karie Duo is damaged, malfunctions, or comes in contact with liquid, please contact your Karie Duo Support Provider.
- This dispenser should only be used for the purposes outlined in this manual.
- Karie Duo requires Alternating Current power of 100-240V~, 50-60Hz, 1.0-0.5A . Be sure that Karie Duo is electrically rated to operate with the Alternating Current power available in your location.
- All system cables should be periodically inspected for signs of deterioration. If damaged, contact the manufacturer or your local Support Provider to fix or replace the cable(s).
- To prevent the risk of strangulation, ensure proper routing of the Power Connector connected to the dispenser. Utilize the provided wire tie to keep the cord as short as needed.
- Arrange the Power Connector in a manner that prevents tripping hazards or interference with chairs or other furniture.
- Do not place the dispenser on a heat source (e.g. a heater) or expose the dispenser to direct sunlight. The function of both the dispenser and the medication may deteriorate if they become too hot.
- Avoid inserting hands, fingers, or any other foreign objects into the dispenser while it is in operation.
- Do not drop the dispenser.
- Placement of the dispenser should not interfere with its proper ventilation.
- To minimize the risk of electrical shock, fire, or damage, keep Karie Duo away from water, liquids, and moisture. Avoid placing food or liquids near the device to prevent spills onto or into the device.
- Do not place your Karie Duo in a closed-in wall unit or on a bed, sofa, or rug.
- Connecting electrical equipment to a power strip or multiple socket outlet effectively leads to creating a Medical Electrical System and the result can be a reduced level of safety (refer to IEC 60601-1).
- Karie Duo uses LED lights as indicators.
- To terminate operation of the device, press and hold the Power Button on the back of the dispenser.

4.2 Cautions



The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

- **Risk of Electric Shock:** To prevent fire or electric shock, do not expose this device to rain or moisture. Do not open or remove the back of the device. There are no user-serviceable parts inside the device: refer to your Support Provider for repair.
- **Interference:** Medical electrical equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency (RF) electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or Near Radio-frequency sources, could result in performance and disruption. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning.
- **Handling Smoke, Power Adapter, and Dispenser Operation:** If you smell or notice smoke, disconnect the power adapter immediately. Contact your Support Provider before any future operation. Only use the power adapter provided with the dispenser; another type of adapter may damage the dispenser, cause fire or electric shock.
- **Restriction:** Keep out of reach of pets, pests, or children. Ignoring this cautionary advice may lead to injury or damage to the equipment may occur.

4.3 General Warnings



- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

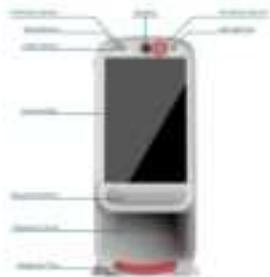
5. Package Contents

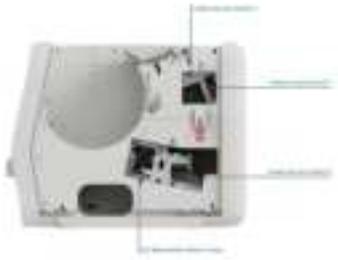
- Quick Start Guide
- Karie Duo Medication Dispenser
- Power Adapter
- Manual Override Tool (mounted at tool holder on bottom of the dispenser)

If anything is missing or damaged, please contact your Support Provider immediately (refer to Help & Support under Settings on the dispenser). We recommend that you keep the original packaging for transport or in the unlikely event that Karie Duo needs to be returned.

6. Karie Duo General Description

The illustrations below show Karie Duo and its main components. Please refer to these illustrations while reading the Instructions for Use if you need help locating specific parts.





7. Unpacking & Setup

7.1 Remove Karie Duo from packaging

- Take Karie Duo and the power adapter out of the box.
- Position Karie Duo upright on a level surface with the screen oriented towards the user.

Only use UPRIGHT

Karie Duo is designed to operate upright. Do not use Karie Duo on its side, upside down, or mounted to a wall.



7.2 Plug adapter into Karie Duo

Fit the power cord into the correct port on the back of Karie Duo.

7.3 Plug Karie Duo into an electrical outlet

Karie Duo will turn ON and connect through cellular automatically. If a "No Connection" screen appears, see Section 12 Troubleshooting.



7.4 Connect to Wi-Fi (optional)

Karie Duo will connect automatically to your local cellular network.

Connecting to Wi-Fi is recommended if you want a redundant data connection, and/or will use the device in an area with poor cellular connectivity. To set up Wi-Fi, follow these steps:

1. Tap the Settings icon
2. Tap Network
3. Tap Wi-Fi Settings
4. Select preferred network and enter the password

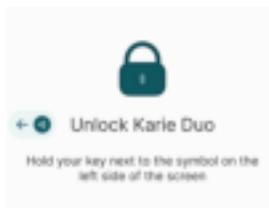
7.5 Opening the lid

To open the lid, the dispenser must be unlocked. Please follow the steps below. Note that the access to the dispenser will vary based on the settings designated for each user, distributor, or region.

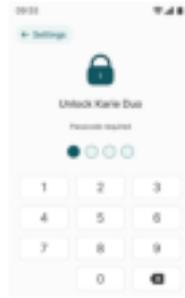
- **No security:**
 - Go to Settings and select Unlock Dispenser.
 - The display on the dispenser will signal when the lock has been released.
- **PIN only:**
 - Go to Settings and select Unlock Dispenser.
 - The screen will prompt you to enter your PIN. If you do not know the PIN code, please contact your Support Provider.
 - Upon successfully entering the PIN, the display will signal when the lock has been released and the dispenser is unlocked.
- **RFID:** Unlocking the dispenser using an RFID key requires pairing the key to the dispenser. Please contact your Support Provider if you need help doing this.

To unlock the dispenser using an RFID key:

- Place the RFID tag against the RFID reader logo on the side of the dispenser. OR
- Go to the Settings and select Unlock Dispenser. A Message will direct user to present the RFID to side of dispenser. Place the RFID tag against the RFID reader logo on the side of the dispenser.



- Based on your set-up, the dispenser might also require you to enter a PIN. Upon successfully entering the PIN, the display on the will signal when the lock has been released and the dispenser is unlocked.
- The lid is spring-loaded. Once unlocked, it will pop up slightly.
- Grab the bottom edge of the lid and rotate it open fully.
- If more accessibility to the internal storage is desirable, you may open the Side Panel by pulling the top edge away from the dispenser.



Manual Override Tool: In rare circumstances, the electronic lock may not work (e.g. due to power outage). To mitigate this issue, a Manual Override Tool is included for accessing the dispenser. This tool is stored at the bottom of the dispenser. To unlock the device with the Manual Override Tool:

1. Locate the Manual Override Tool at the bottom of the device.
2. Pull straight down on the Manual Override Tool to remove it from its holder.
3. Line up the long end of the Manual Override Tool with the Manual Override Keyhole. Ensure the key pattern is in the correct orientation.
4. Insert the long end of the Manual Override Tool into the Manual Override Keyhole.
5. Gently push the Manual Override Tool all the way until it reaches the end of its travel. The lid should pop open slightly.

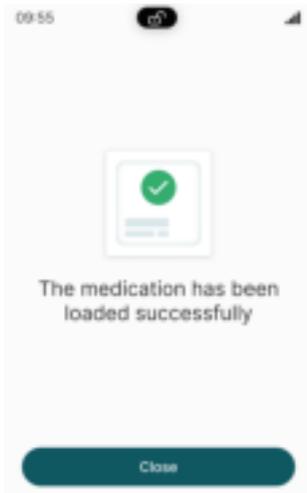
7.6 Insert medication roll

i Interactive tutorials are available on Karie Duo.

To access the tutorials, follow these steps on the device: Settings → Unlock dispenser → Tutorials → Load new medication



- Open the lid (and Side Panel if desired) as described above.
- Ensure that the storage compartment is clean and free from any dirt or debris.
- Examine the medication roll to verify that all information is correct and that it is rolled up in the correct chronological order (the first dose to be taken should be the first one entered into the dispenser).
- Choose a vacant intake, as indicated by blue indicator light. Lift the Intake Flap in order to load the Front Intake, or leave it down to load the Rear Intake.
- Please remember to remove the header pouch from the strip before loading the strip into the intakes. This ensures proper functioning and prevents potential errors during the loading process.
- Insert the medication roll into the storage compartment with the text facing upward and the leading edge positioned toward the intake.
- Insert the leading edge of the medication roll into the intake.
- The intake mechanism will automatically feed the medication roll. If the information on the medication roll does not match the medication schedule or if the roll is unreadable, the dispenser may reject it.
- Once the loading sequence is complete, ensure that the medication roll is still upright.
- Lower the Intake Flap (if required), close the Side Panel, and then close the lid.
- A message will appear on the screen confirming that the medication has been successfully loaded.



7.7 Dispense Tray

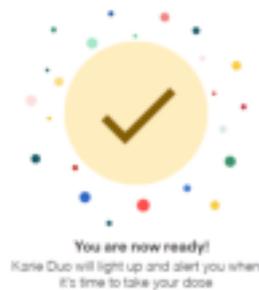
i Interactive tutorials are available on Karie Duo.

To access the tutorials, follow these steps on the device: Settings → Unlock dispenser → Tutorials → Pull out dispense tray

For the ease of collection of dispensed medication pouch, pull out the dispense tray located below the dispense button.

7.8 You are now ready!

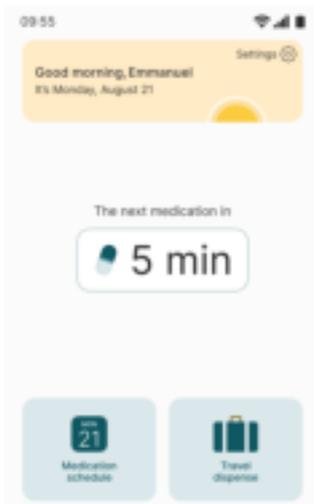
Karie Duo will light up and alert you when it's time to take your dose.



8. Key functionality

8.1 Home screen

The home screen always tells the user when the next dose or reminder is due.



8.2 Dispensing of doses

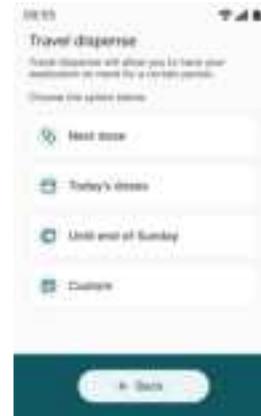
- The Dispense Button will light up when the next dose time window is available.
- When Karie Duo is ready to dispense medication, the Dispense Button light pulses on and off and the alert sounds.
- Press the Dispense Button to deliver medication pouch(es).
- Wait for your medication pouch(es) to drop onto the dose tray before taking the medication. Each pouch is pre-cut for easy opening.

8.3 Medication schedule

Karie Duo's Medication Schedule function enables you to track your medication schedule.

Look back and ahead at your doses for the duration of the medication pouches that is currently inserted into Karie Duo.

8.4 Travel dispense



If the user needs to dispense doses prior to the planned dispense time, the user can use Travel Dispensing.

To perform a travel dispense, follow the steps below:

- Before dispensing the travel dose, close the pouch tray and ensure the ejection chute is clear from any obstruction.
- From the Home Screen, press "Travel dispense".
- Select the number of days you need and Karie Duo will deliver those pouches as a complete strip (without the easy-open pre-cut).
- The dispenser automatically calculates the amount of pouches for that time period and ejects a continuous strand of medication pouches.

Travel dispensing may only be available for certain users and care providers. Contact your Support Provider for more information.

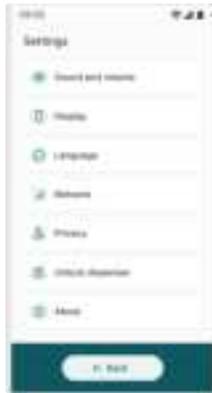
CAUTION: Do not pull on the medication strip when the dispenser is dispensing a travel dose. Excessive force may compromise the medications.



9. Karie Duo's Settings

Access Karie Duo's Settings by pressing the cog-shaped icon in the upper right corner of the Home screen.

In Settings, you will find the following controls (some options might be unavailable based on your care provider's settings):

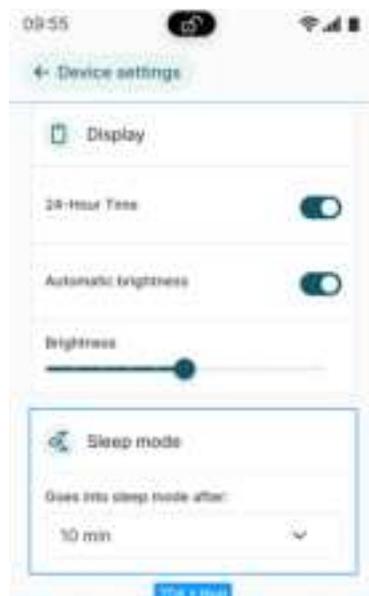


9.1 Sound and Volume

The Sound and Volume screen allows adjustments such as melody, enable voice alert, and volume.



9.2 Display



- 24-Hour Time
 - When 24-Hour Time is disabled, Karie Duo uses a 12-hr clock.
 - When 24-Hour Time is enabled, Karie Duo uses a 24-hr clock.
 - Enable Automatic Brightness
 - When enabled, Automatic Brightness will automatically adjust to room lighting conditions.
 - Brightness
 - Adjust Brightness manually using the slider.

9.3 Sleep Mode



- Sleep Mode is disabled by default. When Sleep Mode is checked, the screen will darken with the next dose time shown in white text.
 - While in Sleep Mode, Karie Duo will wake when the next dose time is due, if the screen is touched or the Delivery Button is pressed.
 - Karie Duo will automatically enter Sleep Mode if unplugged or there is a power outage. Karie Duo will continue to operate as intended until the battery charge is exhausted. The battery icon will flash red when the battery capacity reaches a critical level.
 - Karie Duo will enter Sleep Mode when there has been no activity for the selected time option.

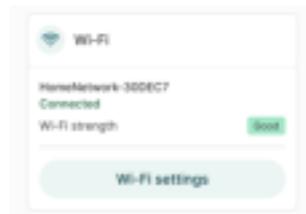
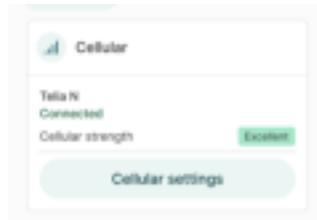
9.4 Language

Select preferred language for display and voice.



9.5 Network

- Click on Cellular Settings to change/select provider
- Click on Wi-Fi settings to change/select an available wi-fi network.
 - Under Available Networks screen: Click on preferred network and enter password, then click on Connect.
 - Consult your Internet Service Provider or care providers for assistance.



9.6 Privacy

- This option enables the user to enable/disable the dispenser's access to the camera and microphone.

9.7 Unlock dispenser

- This option enables the user to unlock the lid to access and refill medication. To unlock, the user might be required to enter a PIN and/or present an RFID tag. Please refer to Section 7.5 Opening the Lid for details.
- Unlocking the dispenser also gives the user access to advanced settings. Please contact your Support Provider if you need help understanding how to use these settings.

CAUTION: In unlocked mode, the user's access to medication can be changed (e.g. whether the user has access to travel dispense and/or missed doses).



9.8 About

- For more information about your Karie Duo dispenser, refer to the 'About' section in the settings.

About dispenser	
Serial number	EN 74D JYR DT7
Model name	Karie Duo
Model number	MOMT3Q

MAC address	88:98:4a:2e:52:99
-------------	-------------------

App	1.00
Firmware	3.5.2
OS	A.15
Launcher	1.8.2
Installer	2.5.2

10. Dispensing and related behavior

i Interactive tutorials are available on Karie Duo.

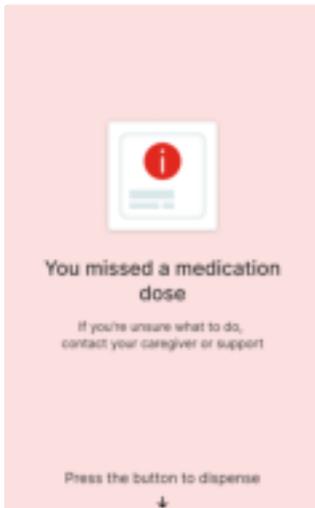
To access the tutorials, follow these steps on the device: Settings → Unlock dispenser → Tutorials → Dispensing of medication

10.1 Dose Ready



Karie Duo will light up and alert you when it's time to take your dose. Press the Dispense Button and wait for your medication pouch(es) to drop onto the tray. Each pouch is pre-cut for easy opening.

10.2 Missed Dose



Any dose that is not delivered/taken within its scheduled dispensed dose time window is considered "Missed." The dose time window is defaulted to within 1 hour of the scheduled dose time and may be changed by the user or caregiver in unlocked mode.

If the user is allowed to dispense a missed dose, they can press the button to dispense it. If the user is *not* allowed to dispense a missed dose, a caregiver must be contacted to dispense the dose or the dose will be moved to the Missed Dose Compartment.

10.3 Missed Dose Compartment full

i Interactive tutorials are available on Karie Duo.

To access the tutorials, follow these steps on the device: Settings → Unlock dispenser → Tutorials → Empty missed dose compartment

If the user misses several doses, the missed compartment will become full. The compartment must be emptied by a user or caregiver who has access to unlock the device.

To empty the Missed Dose Compartment:

- Unlock and open the lid.
- Open the Side Panel.
- The Missed Dose Compartment is the rounded square opening directly under the Medication Roll Compartment.
- Remove the pouches from the Missed Dose Compartment.
- Close the Side Panel and close the lid.

CAUTION: Avoid contacting the sensors inside of the Missed Dose Compartment.



11. Display symbol directory and color codes

11.1 Display Symbols

The following symbols are used on the dispenser screen to inform the user about the dispenser's state.

Symbol	Description
	Locked
	Unlocked
	Connection Error / No Connection
	Wait
	Battery Indicator (Charging, full, half, low)
	Battery critically low (below 20%)
	Medication reminder
	Medication
	Medication
	Action/task completed
	Information
	Warning
	Error

11.2 Intake Indicator Colors

When installing a new roll, the user can see what intake is available by looking at the color coded light Intake Indicators (LEDs). For users with limited color vision, please refer to the information on the screen instead.

- **White:** Intake available; insert roll. The indicator will flash when the roll is inserted.
- **Green:** Roll successfully installed.
- **Yellow:** An error has occurred with the roll. Please refer to the dispenser's screen for more information. When the roll is ejected, the roll intake indicator will start flashing.



white



green



yellow

12. Troubleshooting

12.1 No network

If "No network" is shown on the home screen, Karie Duo is not connected to the Wi-Fi network or cellular network. See Section 9.5 Network for instructions on how to connect.

12.2 Pouch is jammed

i Interactive tutorials are available on Karie Duo.

To access the tutorials, follow these steps on the device: Settings → Unlock dispenser → Tutorials → Handling a pouch jam

If a pouch is jammed, the user will get the following error message on the screen: "There is a problem dispensing your medication." To resolve the issue, follow the steps below:

1. Read and record the error message displayed on the screen.
2. Unlock the device and open the loading lid.
3. Flip down the Side Panel.
4. Rotate the Manual Release Knob clockwise to the release position.
5. Manually pull the medication strip(s) out from the intake.
6. Once medication strip is fully removed from the intake, identify if there are any missing pouches or opened pouches with missing medication. If all medication is accounted for proceed to step 12, otherwise proceed to the next step.
7. Use the provided Manual Override Tool to detach the Upper (A) Maintenance Panel and Lower (B) Maintenance Panel. Unplug and shut down Karie Duo.
8. Inspect the cutting mechanism area, internal feeding path, and both intakes.
 - a. If the knife remains in the center of the feeding path, inspect the cutting mechanism for any jamming. If necessary, turn the Cut Mechanism Reset Screw manually with the provided Manual Override Tool.
9. Clear any visibly remaining medication and/or medication strip.
10. Replace the Upper (A) Maintenance Panel and Lower (B) Maintenance Panel.
11. Rotate the Manual Release Knob counter-clockwise to the regular position.
12. Flip up the Side Panel.
13. Read the message on screen to confirm that the issue is resolved. The roll can now be re-inserted.

12.3 Too many pouches were dispensed

1. Check the top of each pouch for the date and time of your dose.
2. Take your medication from those pouches with the appropriate date and time.
3. Save any remaining unused pouches until the next dose time indicated on each pouch.
4. If the problem persists, call the Support Provider.

12.4 Pouch is cut in half

To remove the compromised medication roll using dispenser power:

1. Unlock and open the lid as described in Section 7.5 Opening the Lid.
2. Press the eject button on the touchscreen.
3. Depending on the reminder length of the roll, the dispenser may eject from either the intakes or Dispense Chute. If you see that the next leading pouch is jammed, see the steps in Section 12.2 Pouch is Jammed.
4. Double-check the information printed on the compromised medication pouch.
5. Only take the medication if it is the correct dose. Call Support Provider if otherwise.
6. Tear off the remaining half of the pouch that was cut open.
7. Reinsert the roll.
8. If the problem persists, call the Support Provider.

12.5 Karie Duo is stalled and/or screen is frozen

If the dispenser freezes or you are directed to restart, follow these steps:

1. Ensure Karie Duo is plugged in.
2. To initiate a shutdown, press and hold the power button for five (5) seconds, ensuring a controlled and safe power-off process for the device.
3. When the device is turned off, press the power button again to turn on the dispenser. This may take a few minutes until you see the Home screen.
4. If stall or frozen screen persists, call Support Provider.

12.6 The roll does not belong to me

1. Each dispenser is designated for a single user. If the dispenser identifies a discrepancy between the medication strip details and the assigned user, it will automatically reject the medication strip. Ensure the loading lid is completely open, and the strip cutter is in the vertical position during the rejection sequence.
2. Call Support Provider for direction.

12.7 There is a power outage

1. In the event of a power outage, Karie Duo will continue to function via battery backup and will also automatically enter Sleep Mode to conserve power.
2. If an outage is expected to be long-lasting, consider delivering future doses by using the Travel Dose function.

12.8 Karie Duo has no power or is off

1. If Karie Duo is plugged in but the screen is completely dark, check that the power cord is fully inserted into the dispenser.

2. Ensure the power cord is plugged into a working electrical outlet.
3. Press the POWER button in the back to turn on Karie Duo.
4. If Karie Duo fails to restart, contact Support Provider.

12.9 Other error message

If you see any other error message or screen not explained in this section, please contact your Support Provider.

13. Cleaning instructions

Clean and disinfect the dispenser as needed. The following components can undergo cleaning and disinfection: the exterior, the Dispense Tray, the Medication Roll Compartment, and the lid. Carefully disinfect the display to prevent it from becoming dull due to frequent exposure to disinfectants. Follow these steps:

1. Open the dispenser and remove the medication roll.
2. Turn off the dispenser.
3. Unplug the adapter from the socket and detach it from the dispenser.
4. Use a slightly damp soft cloth to carefully wipe the mentioned parts of the dispenser.
5. Dry the dispenser components with a clean towel.
6. Use soft disinfectant like 70% Isopropyl alcohol wipes suitable for medical device cleaning. Only disinfect the mentioned parts of the dispenser.

14. Disposal

When disposing off your Karie Duo device, please follow the applicable local medical and electronic equipment disposal regulations and acts, including the Waste Electrical and Electronic Equipment Directive (WEEE Directive) if applicable. Do not dispose of Karie Duo as general waste.

15. Technical Specifications

15.1 Name and Model

Karie Duo

Model: AA-DUO-1.0

15.2 Features

- Karie Duo is designed with a minimum service life of five years or 10,000 dispense cycle with average use
- Dimensions:
 - Length: 395 mm or 15.55 in
 - Height: 310 mm or 12.20 in
 - Width: 130 mm or 5.11 in
- Weight:
- Display: 7 inches, resolution 1280 x 800
- Emergency battery: Provides up to 24 hours of emergency power
- RFID lock

15.3 Communication

Karie Duo is equipped with a module which can connect to the mobile network. Karie Duo is completely autonomous: No provisions need to be made on installation.

15.4 Power

- Model: AD1002-1905200D6
- Adapter power input: 100-240 V AC 1.5 A
- Frequency: 50 - 60 Hz
- Adaptor power output: 19 V DC 5.2 A

15.5 Transport

Please note the transport symbols on the box such as 'Temperature range', 'Keep away from rain', 'Handle with care' and 'This side up'.

- Transport temperature: -10°C (14°F) to 45°C (113°F)
- Transport relative humidity: TBC

15.6 Operating environment requirements

- Operating temperature 5°C (41°F) to 40°C (104°F)
- Storage temperature: -10°C (-4°F) to 45°C (113°F),
- Relative humidity: TBC 30%-75%
- Avoid use in presence of harmful vapors

- Maximum operating altitude 3,000m (9,842.5ft)
- Do not place on or near a heat source or in the sun
- Dust and damp proof according to IP21

15.7 Battery Information

- Avoid battery handling. Karie Duo has a removable, rechargeable battery.
- Do not attempt to replace the battery; this could result in damage to the battery and potential overheating. The battery must be only removed when it is at the end of life.
- To remove the battery:
 - Place Karie Duo on its side
 - Remove bottom 4 Foot Pads
 - Unfasten the four Base Stand Screws
 - Pull out the Base Stand
 - Carefully pull out battery from the compartment and disconnect Power Connector



16. Regulatory Information

16.1 EU Medical device certification

Karie Duo is certified as a class I medical device pursuant to the Medical Devices Regulation (EU) 2017/745 (MDR).

The device is compliant with the applicable sections of the following regulations and standards:

- Medical Devices Regulation (EU) 2017/745 (MDR)
- ISO 13485:2016 for medical device quality management
- ISO 14971:2019 for medical device risk management
- ISO 27001:2017 for information security management
- ISO 15233-1:2016 for medical device symbols
- IEC 62304:2006 + Amd 1:2015 for medical device software development lifecycle

16.2 FCC Compliance statement

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.

16.3 FCC & IC Radiation Exposure Statement

This equipment complies with FCC and Canada radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20cm between the radiator and your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The device for operation in the band 5150-5350 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems

16.4 RF Power Parameter for RED

Module/Antenna	Frequency	Max Output Power/H-field
2.4G WIFI	2412MHz to 2472MHz	16.22 dBm
5G WIFI	5180MHz to 5825MHz	18.81 dBm
BT Classic	2402MHz to 2480MHz	2.16dBm
BT LE	2402MHz to 2480MHz	1.95dBm
GSM	880.2MHz to 914.8MHz, 925.2MHz to 959.8MHz	35dBm
DSC	1710MHz to 1784.8MHz, 1805.2MHz to 1879.8MHz	32dBm
WCDMA	Band I: 1922.4MHz- 1977.6MHz, 2112.4MHz- 2167.6MHz Band VIII: 882.4MHz- 912.6MHz, 927.4MHz- 957.6MHz	25dBm
LTE	Band 1:1920-1980, 2110- 2170MHz Band 3:1710-1785, 1805- 1880MHz Band 7:2500-2570, 2620- 2690MHz Band 8:880-915, 925-960MHz Band 20:832-862, 791- 821MHz Band 28:703-736,758- 791MHz Band 38: 2570-2620MHz Band 40: 2300-2400MHz	25dBm
NFC	13.56MHz	10.09dBuA/m@3m

16.4 Safety and Standards Conformity

Karie Duo is medical electrical equipment and is in compliance with the following standards:

- **IEC 60601-1** - Edition 3.2 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE with EU, USA, and CAN National Differences
- **IEC 60601-1-2** - Edition 4.1 2020-09 CONSOLIDATED VERSION - EU, USA, and CAN National Differences
- **IEC 60601-1-11:2015/AMD1:2020** Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

16.5 Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

17. Patent Information

[Patents - AceAge](#)

18. Customer Support

If you require assistance, please reach out to your local Support Provider. The contact details for your local Support Provider may be found on the Help & Support page under Settings on the Karie Duo device. Our team is ready to help you with any inquiries or issues you may have.

19. Symbol Glossary

Description	Symbol
Read Instructions carefully	
General Warning	
Caution sign	
Operator's manual; operating instructions online at Customer Support	
Mark aligning with downward triangle mark present on the Manual Release Knob indicating dispenser is in an operable condition	
Mark aligning with downward triangle mark present on the Manual Release Knob indicating dispenser is in an inoperable condition	
Spiral arrow indicating the orientation of the medication roll for loading	
Catalogue Number	
Manufacturer	
Medical Device	
Serial Number	
Unique Device Identifier	
Stand-by Power Indicator	
RFID Reader	
Electromagnetic radiation from the device is below the limits specified by the Federal	

Communications Commission	
CE marking is the medical device manufacturer's claim that a product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations and is a legal requirement to place a device on the market in the European Union.	
UK Conformity Assessment	
Class II Equipment	
Ingress Protection Code	
Keep Dry Indicates the device should be protected from rain or other damp conditions.	
Certification Body mark. Product has been tested for electrical safety and certified for use in EU, Canada and the USA	
Temperature Range	
Do not discard in the garbage/rubbish bin. Waste of Electronic and Electrical Equipment. Discard to collection facility for recovery and recycling.	
This side up	
Handle with care	
Authorized Representative Indicates the authorized representative in the European community.	