

BLINK FRAMES

Indications for Use

Intended to hold prescription and non-prescription lenses and be worn by the individual it was prescribed to. May be indicated for the capture and storage of images of the eye and surrounding area in the general population. This product is designated as a prescription device.



Refer to instructions for use.

Please complete and retain for your records

The frames' serial number as well as the model/reference number are both located on the shipping box.

Serial number:

Model number:



Date of Manufacture: The first four digits in the serial number indicates the year of manufacture.



AT A GLANCE

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Important Safety Instructions:

1. Read these instructions.
2. Keep these instructions.
3. Heed all warnings.
4. Follow all instructions.
5. Do not use this device near water.
6. Clean only with a dry cloth.
7. Only use attachments/accessories specified by the manufacturer.
8. Unplug the device during lightning storms or when unused for long periods of time.
9. Refer all servicing to qualified personnel. Servicing may be required when the device has been damaged in any way, such as power-supply cord or plug is damaged, liquid has been spilled or objects have fallen into the device, the device has been exposed to rain or moisture, does not operate normally, or has been dropped.



WARNINGS/CAUTIONS

For Healthcare Professionals

Healthcare professionals must inform patients not to modify or discontinue their treatment plan without receiving instructions from the healthcare professional.

The responsible organization should identify, analyze, evaluate, and control any additional risks resulting from the device connected to IT networks, including other equipment.

Changes to the IT network could introduce new risks requiring additional analysis by the responsible organization. The changes include:

- changes in the IT network configuration
- connection of additional items to the IT network
- disconnecting items from the IT network
- update or upgrade of equipment connected to the IT network

NOTE: If a healthcare professional is unsure whether or not a patient may be eligible to use the device they should contact the manufacture for inquiry at support@blinkframes.com

For Patients and Healthcare Professionals

The frames are intended for personal use only. Use on others, animals, or objects is forbidden.

Patients should not modify or discontinue their treatment plan without receiving guidance from a healthcare professional.

Do not cover or obscure the cameras of the device during normal use and operation.

Although the device's own electromagnetic emissions are well below the levels permitted by the relevant standards, they may cause interference in other nearby devices, for example sensitive sensors.

If you need help in using Blink Frames, contact your healthcare professional.

Do not use eye patches which have been previously used or have damage to their packaging.

- Use caution while driving and follow applicable laws regarding use of a mobile phone.
- Focus on your safety and that of others if you use the frames while engaging in any activity requiring your attention, e.g., while riding a bicycle or walking in or near traffic, a construction site or railroad, etc.
- Do NOT use the frames if they emit any loud unusual noise. If this happens, turn the frames off and contact Globe Biomedical, Inc. customer service.
- Do NOT submerge or expose the frames for an extended period to water or wear them while participating in water sports, e.g., swimming, water skiing, surfing, etc.
- Remove frames immediately if you experience a warming sensation.



Contains small parts which may be a choking hazard. Not suitable for children under the age of 3.



This product contains magnetic material. Consult your physician on whether this might affect your implantable medical device.

- To reduce the risk of fire or electrical shock, do NOT expose this product to rain, liquids or moisture.
- Do NOT expose this product to dripping or splashing, and do not place objects filled with liquids, such as vases, on or near the product.
- Keep the product away from fire and heat sources. Do NOT place naked flame sources, such as lighted candles, on or near the product.
- Do NOT make unauthorized alterations to this product.
- Use this product only with an agency-approved power supply that meets local regulatory requirements (e.g., UL, CSA, VDE, CCC).
- Do not expose products containing batteries to excessive heat (e.g. from storage in direct sunlight, fire, etc.).
- Do NOT wear the frames while charging.
- After each use, wipe both sides of the lenses and all parts of the frame with the cloth provided or a dry cloth.

The frames are intended to be worn by the person to whom they are prescribed only. Use on others, animals, or objects is forbidden. The manufacturer is not liable for any damage arising from improper use.

Do not use the device in environments where temperatures are in excess of 110 °F or below 32 °F.

Do not charge the device in environments where the temperature is 110 °F/ 43 °C or higher.

Do not use with contact lenses.

When not in use, keep the Blink Frames on the provided charger or store in the provided bag to protect from direct sunlight.

Only lenses approved by Globe Biomedical, Inc. should be used with the this product.

Not for direct observation of the sun.

Not for protection against artificial light sources.

Not for use as eye protection against mechanical impact hazards.

Do not store or carry flammable liquids, gases, or explosive materials in the same compartment as your device, its parts, and/or accessories.

Do not charge or store your device in in areas with potentially explosive atmospheres.

Do NOT submerge or expose the frames for extended periods to water, or wear while participating in water sports, e.g., swimming, water skiing, surfing, etc.

Keep the Product's charging device away from liquids. It is not water resistant and exposure to liquids could damage the charging device or other property and lead to injury.

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 Blink Frames, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

May be unable to collect data when the device is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

DO NOT wear your Blink Frames during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

Contraindications

You should not use the Blink Frames if you:

- Blink Frames should not be prescribed to patients for whom the initial clinical setup fails to demonstrate valid eye imagery due to incompatibility between the sensing system of frames and the patient's facial geometry.

You may not be eligible for use of the Blink frames if:

- Your prescription lenses (sphere) are outside of the range of -5.00D to +5.00D in either eye.

The essential performance of Blink Frames is to capture images of the eye and the surrounding area, and to transfer the data into the Blink Frames software system.

If the essential performance of the frames is lost or degraded due to electromagnetic disturbances, the Blink Frames app will notify the user the next time the frames connect to Wi-Fi. See chapter “Electromagnetic declaration” for instructions on proper electromagnetic environment.





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 to an outlet on a circuit that is different from that which the receiver is connected.

Changes or modifications not expressly approved by Globe Biomedical, Inc. could void the user's authority to operate this equipment.

This device complies with part 15 of the FCC Rules and with ISCED Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interferences received, including interference that may cause undesired operation.

This device complies with FCC and ISCED Canada radiation exposure limits set forth for general population.

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



This symbol means the product must not be discarded as household waste, and should be delivered to an appropriate collection facility for recycling. Proper disposal and recycling helps protect natural resources, human health and the environment. For more information on disposal and recycling of this product, contact your local municipality, disposal service, or the shop where you bought this product.

The separate collection and recycling of your product or its battery at the time of disposal help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

The sales package and the probe boxes are carton and can be recycled.
Waste carton generally includes paper, carton, and cardboard packages.
Recycle according to local laws and regulations.

DO NOT attempt to remove the rechargeable lithium-ion battery from this product. Contact Globe Biomedical, Inc. for removal.



Please dispose of used batteries properly, following local regulations. Do not incinerate.

QTY: 1 EA



Manufactured For: Globe Biomedical, Inc. 5225 Canyon Crest Dr Riverside CA 92507



Do not use if package is damaged.



This product does not contain natural rubber latex.



This product is provided non-sterile.



+45C

Security Information

This product is capable of receiving security updates from Globe Biomedical, Inc. automatically when connected to Wi-Fi. In order to receive security updates, you must complete the product setup process in the Blink Frames app.

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Package: Mbed TLS 2.16.1

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The Blink Frames System Consists of the Following:

- Blink Frames
- Blink Frames' Launch Pad
- Blink Frames Clinicians Portal, a browser-based software service with which the healthcare professional can view patient data.
- Blink Frames App, a smartphone application from which a patient, healthcare professional, or guardian can review patient data.

With Blink Frames, clinicians and guardians who have received "shared" access will have the ability to review data related to an individual's ocular health. When the frames are worn by an individual, images of the eye and surrounding area are taken throughout the day and stored in the frames internal memory. Once the individual charges their frames, the data is securely offloaded to be reviewed.

Familiarize yourself thoroughly with the frames, software, and the operational procedures before use.

Information on Patch Wearing

Follow your healthcare professional's instructions on how to apply and if/when the patient should be wearing the provided patches. The eye patches are meant for one time use and should be discarded after being worn. When patching, use a new unused patch to cover the eye instructed by the healthcare professional. Use of other patches not produced/provided by Globe Biomedical, Inc. may negatively affect eye patch monitoring. For more information about the eye patches or how to order more patches please contact support@blinkframes.com

Support Materials

To learn to use the Blink Frames system, read this manual carefully. If you have problems using any part of the Blink Frames system, contact the organization from which you obtained the frames or Globe Biomedical, Inc. You can contact Globe Biomedical, Inc. at support@blinkframes.com

CONTENTS

Confirm that the following parts are included:



Blink Smart Frames



Launch Pad



Charging Cable



Head Strap



Cleaning Cloth



Storage Sleeve

NOTE: If any part of the product is damaged, do not use it.

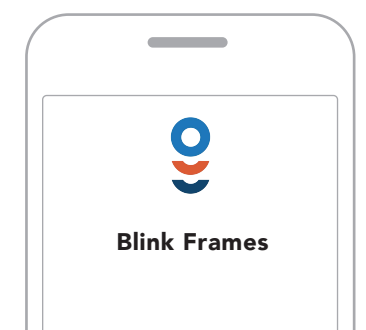
For customer service, visit: blinkframes.com/support

The Blink Frames app lets you set up and control the frames from any smartphone running Android 10.0 and iOS 14 and above.

Using the app, you can setup and share data from a device to an authorized account, review data, review device details, and obtain new features.

DOWNLOAD THE BLINK FRAMES APP

1. On your mobile device, download the Blink Frames app.



2. Follow the app instructions to setup your account.

ADDING YOUR FRAMES TO YOUR ACCOUNT

1. Make sure that your frames are charging on the provided Launch Pad.
2. In the Blink Frames app, tap the "add device" icon to add your frames.
3. Select your frames when they appear on the app to initiate frame setup.

NOTE: If the app cannot find the frames, see "Blink Frames app cannot find frames" on page 33.

The frames are rated IPX3 water resistant. They are designed to be sweat and weather resistant against drops of water but are not meant to be submerged under water or exposed to excessive moisture.



NOTE: IPX3 is not a permanent condition, and resistance might decrease as a result of normal wear.

CAUTIONS:



- Do NOT use this device in a bathtub, shower or water-filled reservoir.



- Do NOT swim or participate water sports with the frames.
- Do NOT submerge the frames in bodies of liquid.

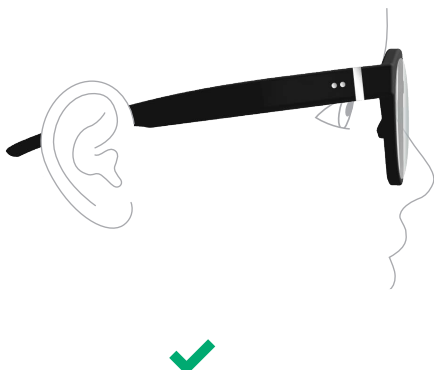
CHECK YOUR FIT

Move your head up and down to check if the frames stay in place.

NOTES:

- If the frames don't feel comfortable and secure, see "Try the head strap" on page 20.

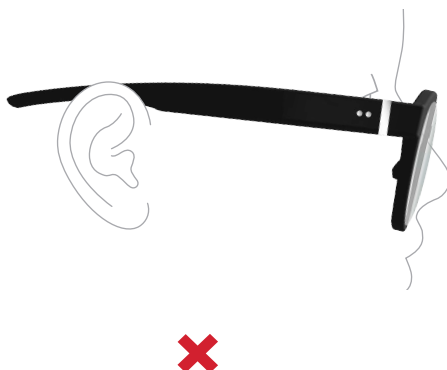
PROPER FIT



When the frames fit:

- The nose pads comfortably rest on the sides of your nose.
- The lenses comfortably rest over your eyes and don't move when you smile.

IMPROPER FIT



When the frames don't fit:

- The lenses might sit too low or too high on your face.
- The lenses might slide forward or too far from your face.

TRY THE HEAD STRAP

In the box you can find a head strap.

PLACING THE HEAD STRAP

1. Using the provided cleaning cloth, firmly push one end of the head strap along the back end of the temple frame. Repeat on the other side.



2. Check your fit (see page 19).

INITIAL CHARGE

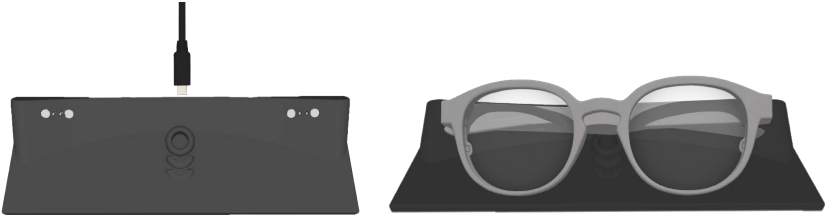
Remove the contents of the box.

Connect the supplied USB-C cable to an approved wall charger.

Connect the other end of the USB-C cable to the Launch Pad.

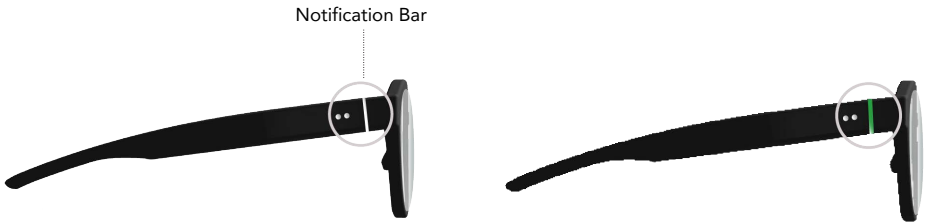
Set the frames on the Launch Pad.

NOTE: readjust the frames until the notification bar glows white.



POWER ON

The frames will automatically power on after connecting to the launch pad and the notification bar will turn white.



The notification bar is located on both temples.

NOTE: The frames ship with a partial charge and may need to charge before initial use.

POWER OFF

There are two ways to power off Blink Frames.

Close-to-Off



The notification bar flashes red.

Flip-to-Off

Flip the frames upside down for 2 seconds.



The notification bar flashes red.

NOTES:

- To power the frames back on, return them to an open, upright position. Notification bar will flash green to indicate normal operation.

CHARGE THE FRAMES

1. Connect the small end of the USB cable to the USB-C port.



2. Connect the other end to a USB-A wall charger (not provided).
CAUTION: Use this product only with an agency-approved power supply that meets local regulatory requirements (e.g., UL, CSA, VDE, CCC).
3. Place frames on launch pad. When charging, the notification bar will change color (see page 24).



NOTES: Don't wear the frames while charging.

CHECK THE BATTERY LEVEL

- Check the home screen in the Blink Frames app.
- While charging, the notification bar will indicate charge level (see page 24).

The notification bar reflects the *bluetooth*, battery charge, and error status of the frames.

Notification Bar



BLUETOOTH CONNECTION STATUS

Shows the *Bluetooth* connection status of mobile

LIGHT ACTIVITY	SYSTEM STATE
Slowly flashes blue	Ready to connect
Quickly flashes blue	Connecting
Solid blue	Connected

BATTERY STATUS

Shows the frames battery charge

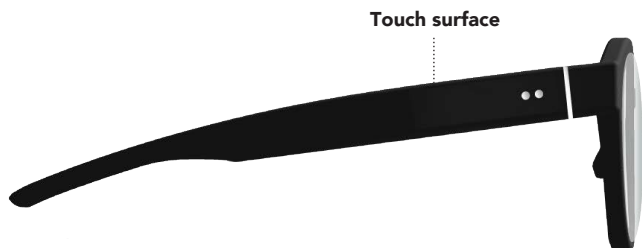
LIGHT ACTIVITY	SYSTEM STATE
Slowly flashes red	Battery is 0-20% while charging
Slowly flashes orange	Battery is 21-80% while charging
Slowly flashes green	Fully charged
Solid red	Uploading images 0-20% charged
Solid orange	Uploading images 21-80% charged
Solid green	Uploading images 81-100% charged

ERROR STATUS

Shows the error status.

LIGHT ACTIVITY	SYSTEM STATE
Slowly flashes yellow	Error - contact Blink customer service

TAP AND GESTURES



1. Tap and gesture controls can be changed in the app when connected to your frames over bluetooth.
2. By default, all tap and gesture settings are dissabled.

CONTROL	FUNCTIONALITY
Bluetooth On/Off	Enables bluetooth connectivity for 10 seconds.
Image Capture	Enables/disables image capture

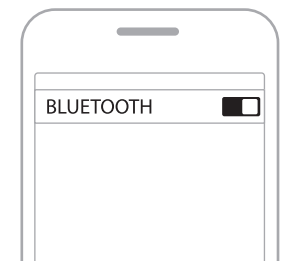
NOTES:

- When Image Capture is enabled the notification bar flashes green.
- When Image Capture is disabled, the notification bar flashes red.

CONNECTING TO YOUR FRAMES ON YOUR MOBILE DEVICE

1. On your mobile device enable bluetooth.

NOTE: The bluetooth feature is usually found in the Settings menu.



2. Open your Blink Frames app and navigate to the Summary page.

3. Place your frames on the Launch Pad charger.

NOTE: You can connect to your frames over bluetooth within the first 30 seconds of charging your frames to the Launch Pad.



NOTE: During this time the notification bar will flash blue.


4. In the Blink Frames app, tap the "Device" icon to add your frames.

5. Select your frames when they appear on the app.

NOTE: If this is your first time connecting to your frames, the app will walk you through the device setup process.

Once connected, the notification bar will glow solid blue.

These settings are only available when connected to your frame over bluetooth.

The below settings can be accessed by pressing the  icon on the device page

FRAME OPTIONS:

- **DISCONNECT:** Disconnect your mobile device from your frames.
- **AUTO-CONNECT:** Automatically connect to your frames when in the Device Menu.
- **DEVICE NAME:** Add a custom display name for your device.
- **WIFI:** Connect to an available wifi network. From here, enter your WiFi SSID and your network password under WiFi Password and select update.
- **DE-AUTHENTICATE FRAMES:** De-authenticating frames unlocks and removes the device from your account.
 - You will be asked to verify your sign-in credentials.

NOTE: If you wish to add the device back onto your account, follow the instructions on page 2. Once the frames are associated to your account you may consider updating the device name by following the steps outlined on page 2x.

- **WIPE SD CARD:** Will clear the captured and stored data on your frames

NOTE: Clearing the SD card permanently removes all stored image data collected on the device. This action can not be undone.

- **REBOOT FRAMES:** Will restart the hardware on the device.
 - For more information regarding why you may want to reboot your frames see page 37-38.

NOTE: Rebooting your frames will disconnet you from your device.

STORE THE FRAMES

The frames collapse for easy, convenient storage.

1. Fold the temples inward towards the lenses so the temples lay flat.
2. Place the frames in the provided pouch



NOTES:

- Make sure to charge the frames before using them after periods of prolonged storage.

MAINTAIN THE FRAMES

COMPONENT	CARE INSTRUCTIONS
Frames	<p>Prior to any maintenance, be sure to remove the frames. It is not recommend to wipe and clean any surfaces when the frames are adorned.</p> <p>After each use, wipe both sides of the lenses and all parts of the frame with the provided cleaning cloth or a dry cloth.</p> <p>In case of water exposure, dry the Product thoroughly and clear the charging areas of residue or other debris.</p> <p>CAUTIONS:</p> <ul style="list-style-type: none">• Do NOT use any sprays near the frames.• Do NOT use any solvents, chemicals, or cleaning solutions containing alcohol, ammonia, or abrasives.• Do NOT allow liquids to spill into any openings.
Launch Pad	Wipe the launch pad with a dry cloth.
Headstrap	Wipe the headstrap with a dry cloth.

REPLACEMENT PARTS AND ACCESSORIES

If your frames or accessories are damaged or broken please contact support@blinkframes.com for information regarding service.

LIMITED WARRANTY

The frames are covered by a limited warranty. Visit our website for details: blinkframes.com/warranty-information

To register your product, visit blinkframes.com/registration for instructions. Failure to register will not affect your limited warranty rights.

LIFETIME

The expected service life of the frames is 2 years. The maintenance procedures described in this manual are required during the expected service life.

Inspect the frames for mechanical and functional damage annually. Contact the manufacturer if you detect any damage or deterioration.

MODEL/REFERENCE NUMBER LOCATIONS

The device product number, serial number, associated FCC ID, region of assembly, device input voltage, and IPX rating are located on the left temple.

The model/dimensional markings are located on the inner right temple.



RETURN FOR SERVICE OR REPAIR

NOTE: Before contacting for service, write down the serial and model number of your frames and, if applicable, the service ID number displayed on the app.

Contact Globe Biomedical, Inc. for shipping instructions. Unless otherwise instructed by Globe Biomedical, Inc. there is no need to ship any accessories with the frames. Use a suitable cardboard or similar box with the appropriate packaging material to protect the frames during shipment. Return the frames using any shipping method that includes a proof of dispatch and delivery .

NOTE: For assistance in setting up, using, or maintaining the frames or to report unexpected operation or events, contact the manufacturer or manufacturer's representative.

RECYCLE



Do not dispose of the frames with household waste. Send it to an appropriate facility for recovery and recycling. The frames should be recycled as electronic waste.

The separate collection and recycling of your product or its battery at the time of disposal help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

The packaging can be recycled. Recycle according to local laws and regulations.

TRY THESE SOLUTIONS FIRST

If you experience problems with the frames:

- Connect the frames to power for 2 seconds and then disconnect (see page 23).
- Charge the battery (see page 23).
- Check the status lights (see page 24).
- Make sure your mobile device supports *bluetooth* connections.
- Make sure that your mobile device has the *bluetooth* connection set on.
- Download the Blink Frames app and run available software updates.
- Connect another mobile device (see page 26).

OTHER SOLUTIONS

If you could not resolve your issue, see the table below to identify symptoms and solutions to common problems. If you are unable to resolve your issue, contact Globe Biomedical, Inc. customer service.

Visit: blinkframes.com/support

PROBLEM	WHAT TO DO
Frames don't connect with mobile device	<p>On your device:</p> <ul style="list-style-type: none">• Turn the <i>bluetooth</i> feature off and then on. <p>Move your device closer to the frames and away from any interference or obstructions.</p> <p>Connect a different mobile device (see page 26).</p>
Blink Frames app doesn't work on device	<p>Make sure the Blink Frames app is compatible with your device.</p> <p>Uninstall the Blink Frames app on your device then reinstall the app (see page 17).</p>

PROBLEM	WHAT TO DO
Blink Frames app can't find frames	<p>Power on the frames (see page 21).</p> <p>If this is your first time connecting to the frames, verify that the notification bar is flashing white and follow the instruction on page 21.</p>
Intermittent Bluetooth connection	<p>In the Blink Frames app, run available software updates.</p> <p>Connect again (see page 26).</p> <p>Move the mobile device closer to the frames.</p>
Frames don't charge	<p>Ensure both ends of the charging cable are properly connected.</p> <p>If the frames have been exposed to high or low temperatures, let the frames return to room temperature and then try charging again.</p> <p>Try a different approved USB wall charger or wall socket.</p> <p>Try removing the frames from the Launch Pad and reconnecting them to the charging unit.</p>
Frames don't respond to touch control	<p>Make sure you are touching the correct touch surface (see page 25).</p> <p>Make sure your hands are dry.</p> <p>If wearing gloves, remove them before tapping the touch control surface.</p> <p>Make sure that tap is enabled via the Blink Frames App.</p>

Operation environment:

Temperature: 0 °C to +45 °C (32 °F to 113°F)

Relative humidity: 30 % to 90 %

Atmospheric pressure: 800 hPa to 1,060 hPa

Storage environment:

Temperature: -10 °C to +55 °C (14 °F to 131 °F)

Relative humidity: 10 % to 95 %

Atmospheric pressure: 700 hPa to 1,060 hPa

Transport environment:

Temperature: -10 °C to +55 °C (14 °F to 131 °F)

Relative humidity: 10 % to 95 %

Atmospheric pressure: 500 hPa to 1,060 hPa

The device and its materials are compliant with RoHS Directive 2011/65/EU.

The device and its parts are not made of natural rubber latex.

Mode of operation: continuous

The manufacturer and serial number is located on the original product packaging. The model and frame dimensional markings are located on the inside face of the left temple frame.

There are no electrical connections from the frames to the patient. All the parts of the frames are applied parts and the frames have BF-type electric shock protection.

Power Supply

5V input power supply, 3.7V rechargeable battery, lithium-ion. Battery life, charge cycles vary by use and settings.

System Requirements for Blink Frames Clinician's Portal

Internet connection

Minimum web browser versions: Edge (v 88), Chrome (v 58), Firefox (v 53) and Safari (5.1.7)

System Requirements for Blink Frames App





















Internet Connection





Android smart phone with USB OTG support, operating system v10 or newer or iPhone with operating system iOS 14 or newer.

IT Network Specifications

To transfer the data from the frames to a mobile device, the frames must be connected via bluetooth. The mobile device must be connected to the Internet. The frames can be used as a stand-alone without a bluetooth or Internet connection. The device is designed in such a way that network failures do not prevent the frames from working normally.

SYMBOLS AND DESCRIPTIONS

SYMBOL	DESCRIPTION
	Wi-Fi
	Choking hazard
	Catalogue number
	Customer support
	Date of manufacture
	Documentation
	Do not use if package is damaged
	Does not contain latex
	Downloads
	FCC certification
	Forum
	Green Dot trademark symbol
	Keep dry
	Magnetic interference
	Manufacturer
	Images
	Warnings/Cautions
	Waste of electrical and electronic equipment directive symbol
	Non-sterile
	Temperature limit

SYMBOL	DESCRIPTION
	Regulatory compliance mark
	Refer to instructions for use
	Security information
	Serial number
Rx Only (U.S.)	Federal law (U.S.) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

