



PATIENT MANUAL

PRIMA Visual Processor

Pixium Vision

74 rue du Faubourg St Antoine
75012 Paris
France

Exclusively for Clinical Investigation

CAUTION – Investigational device. Limited by
Federal (or United States) law to investigational use.

PN 26200

Copyright

©2019-2021 Pixium Vision. All rights reserved. Any copying reproduction or translation of all or part of the contents of this document without the express written permission of Pixium Vision is strictly forbidden by the provisions of the US federal law of March 11th, 1957.

Guarantees

Pixium Vision reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only.

Notation

Important passages in the following text are marked with italic text and an icon at the left. If it is a general note or information the icon is a blue circle with an “i”. If it is a warning message, a yellow triangle with an exclamation symbol is shown. If it is a prohibition, the icon is a red circle with a white cross.

Examples:



Note: Information considered important for the correct use



Caution: Could cause damage on the system or impact its performance



Warning: Potential safety hazards and serious adverse reactions
Could cause harm to person.

TABLE OF CONTENTS

1. Introduction	6
2. System Overview	6
3. Safety Information.....	8
3.1 Intended use	8
3.2 Intended user.....	8
3.3 Implant card.....	8
3.4 Precautions and warnings.....	8
3.4.1 General precautions and warnings.....	8
3.4.2 Unauthorized operations.....	9
3.4.3 MRI (Magnetic Resonance Imaging) safety information	9
3.4.4 Medical imaging with PRIMA implant	10
3.4.5 Other Medical therapies.....	10
3.4.6 Remote rehabilitation sessions	11
3.4.7 Electromagnetic Interference (EMI).....	11
3.5 Possible adverse events, side effects or complications related to the PRIMA System	12
4. System description.....	13
4.1 The pair of glasses.....	13
4.2 The Pocket Processor.....	14
4.3 System feedbacks.....	16
4.3.1 Switch-on of the Visual Processor.....	16
4.3.2 Power status	16
4.3.3 Nominal functioning	17
4.3.4 Switch-off of the Visual Processor.....	17
4.3.5 Charge.....	17
4.4 Remote Kit.....	22
5. Instructions for use.....	22
5.1 Installing your Visual Processor	22
5.2 Installing your Remote Kit items for remote rehabilitation.....	23
5.3 Powering your Visual Processor	24

5.4	Starting your Visual Processor	24
5.5	Zooming.....	24
5.6	Adjusting the brightness.....	25
5.7	Selecting the mode	25
5.8	Adjusting the audio volume	25
5.9	Acknowledging of a connection for rehabilitation.....	26
5.10	Switching your Visual Processor off	26
5.11	Charging your Visual Processor	26
5.12	Cleaning	26
5.13	Travelling with your Visual Processor.....	27
5.14	Storage, Handling and Transport	27
6.	Troubleshooting	28
6.1	Troubleshooting	28
6.2	System failure	31
7.	Service.....	32
7.1	Disposal.....	32
7.2	Contacting Pixium Vision	32
8.	Labelling symbols	33
9.	Technical Specifications.....	34
9.1	Essential Performance	34
9.2	Standards Compliance.....	34
9.3	Environmental.....	34
9.4	Physical	34
9.5	Electrical	34
9.6	Degree of Protection against Ingress of Water.....	35
9.7	Optical	35
9.8	Wireless communication	35
9.9	PRIMA Visual Processor expected service life: 2 years	35
9.10	PRIMA System lifetime: 36 months	35
10.	Glossary	36
11.	Document History	37

Appendix A: Electromagnetic Interference (EMI).....	38
Appendix B: RF Exposure Information	44

1. Introduction

PRIMA is a Bionic Vision Restoration System intended to partially replace the normal physiological functions of the eye's photoreceptor cells. PRIMA stimulates the remaining cells in the inner retina that transmit this signal to ganglion cells. Ganglion cells send the visual information to the brain via the optic nerve.

The PRIMA System is indicated for patients suffering from central vision loss due to advanced Atrophic Age-related Macular Degeneration (Geographic Atrophy) involving the fovea.

These instructions for use are designed to help patients, and those supporting the patient, understand how to use and care for the Visual Processor. It is important that you read and understand the warnings and precautions information provided in these instructions.

2. System Overview

Your PRIMA System includes following components:

- A **Retinal Implant Set** with a micro-size, battery-less and wireless retinal prosthesis ("**Retinal Implant**"),
- A **Visual Processor** (a.k.a. VP) comprising: a pair of glasses and a projection system (Projection Module with a camera and Pocket Processor), a power adaptor for charging and shoulder straps for easy carrying by the patient. A software embedded in the Visual Processor enables the signal to be optimized for each patient thereby aiding the rehabilitation process through which patients progressively learn to regain visual perception.

Additionally, the VP includes Wi-Fi¹ communication capability for remote rehabilitation sessions scheduled by the Bionic Vision Expert (BVE)².

The PRIMA System comprises the following components in addition to this manual:

Quantity	Product Name	Product Reference or Part Number
1	PRIMA Retinal Implant Set	I009
1	Implant Manual	PN 26178

¹ Wi-Fi is a trademark of the Wi-Fi Alliance.

² Only for Visual Processor equipped with a Projection System prod. ref. PS002. Remote rehabilitation is subject to the eligibility of the network capacities of your environment and that of your BVE.

Quantity	Product Name	Product Reference or Part Number
1	Implant Card	PN 26063
1	Projection System	PS001 ³ or PS002
1	Glasses	G001

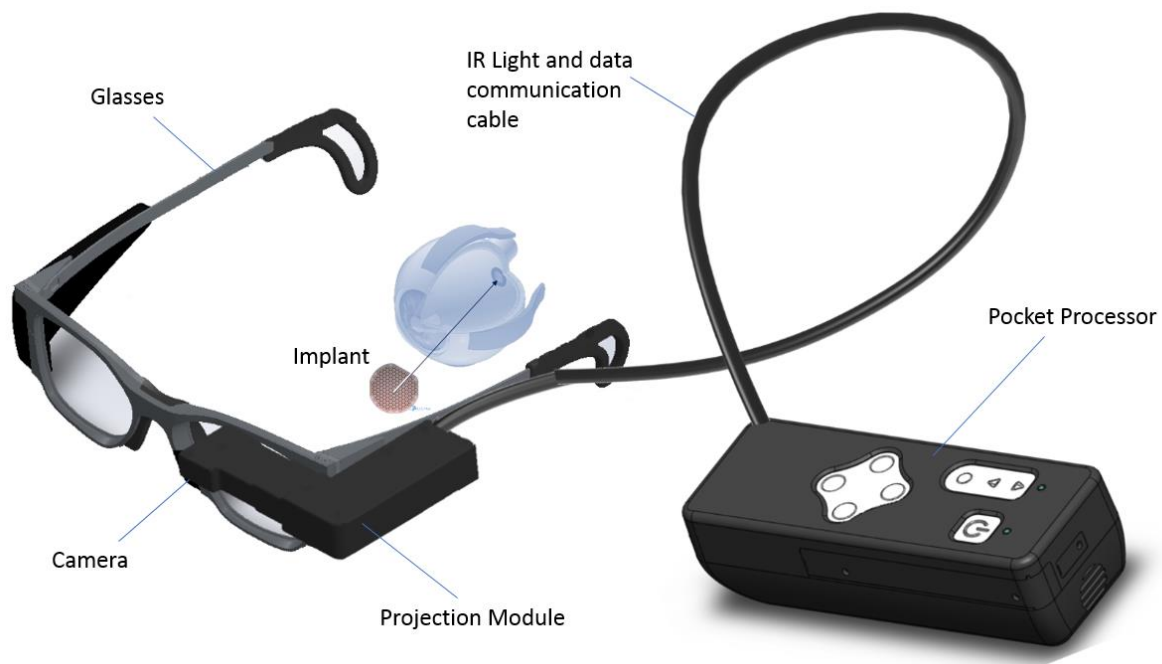


Figure 1: The PRIMA System

Depending on the eligibility of your System and your home environment, your BVE may suggest that you follow remote functional vision rehabilitation sessions. In this case, Remote Kit (prod. ref. RK001) will be also delivered to you (refer to section 4.4 for details).

³ Note: Projection System prod. ref. PS001 does not provide remote rehabilitation capability.

3. Safety Information

3.1 Intended use

The intended use of the PRIMA system is the treatment of central vision loss due to advanced Atrophic Age-related Macular Degeneration (Geographic Atrophy) involving the fovea.

3.2 Intended user

The PRIMA System is designed to be used by patients in the framework of a clinical investigation at the healthcare centre during rehabilitation and at home during remote rehabilitation or daily usage.

Training will be provided on the use of the System. The training will help you familiarize with the PRIMA System and allow your healthcare professional to find the most appropriate parameters. It is important that you follow your healthcare professional's guidance. This will facilitate your use of the System at home, when you are operating it without supervision.

3.3 Implant card

You will receive an implant card after the implantation surgery (PN 26063). This card provides basic information about your implant and contact information of your physician.



The card will be very important in the event of a medical emergency and may be required in case you need to bypass a security system. Keep this card with you at all times.

3.4 Precautions and warnings

3.4.1 General precautions and warnings



Your Visual Processor emits invisible light radiation exposure. You should not allow other people to use your PRIMA System, do not let children use or play with your Visual Processor.



The PRIMA System is intended for daily use. It is important to note that the system is designed for use as a complementary aid, along with your other mobility aids (e.g. canes, dogs). You should not rely solely on your PRIMA System.



Keep your Visual Processor away from pets as they might damage the device.



Stop using the PRIMA System if you experience any discomfort. Should this occur, immediately remove the Glasses, turn off the system and contact your physician.



Do not use the system in the presence of a flammable agent (e.g. rubbing alcohol, etc.).



Do not use the PRIMA System in wetrooms or direct sunlight as this may damage your device.

3.4.2 Unauthorized operations



Do not connect any equipment with your PRIMA System other than those supplied by Pixium Vision. The use of unauthorized or unapproved cables, power adaptor or batteries may lead the PRIMA System to cause electrical shocks, malfunction or to interfere with other electronic equipment.



Do not modify the Visual Processor. Unauthorized alterations may compromise safety, and system performance.



You shall never open your Visual Processor, as its housing is a protection against unwanted electrical or optical exposure. Likewise, should your Visual Processor be damaged, switch it off immediately.



Your Visual Processor USB Port is only allowed to be accessed by trained healthcare personnel.



Your Visual Processor is using Wi-Fi technology. Although access to your system is secure, make sure that Wi-Fi communication is not prohibited before using it in a public place. Otherwise, shut down your Visual Processor.

3.4.3 MRI (Magnetic Resonance Imaging) safety information



Nonclinical testing has demonstrated that the PRIMA retinal implant is “MR Conditional” in accordance with the ASTM F2503-20 standard [3] definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Horizontal bore MRI system with a static magnetic field of 1.5 Tesla or 3 Tesla.
- Gradient magnetic fields lower or equal to 19T/m.
- $B_0 \cdot \Delta B_0 / \Delta t$ product lower or equal to 48T²/m.
- RMS value of the time varying gradient (encoding gradients) field below or equal to 42T/s.

- Encoding gradient maximal peak amplitude of 146.6 T/s.
- RF whole body transmit coil use only,
- Whole body averaged SAR (Specific Absorption Rate) limited to First level operating mode 4W/kg,
- RF electrical field maximal peak amplitude value below or equal to 3860 V/m at 64MHz or 128MHz,
- RF electrical maximal RMS amplitude value below or equal to 470 V/m at 64MHz or 128MHz.

During non-clinical testing, the PRIMA retinal implant produced after 15 minutes of continuous scanning a maximum temperature rise of the tested implants of 3.4 ± 0.9 °C at 1.5T and of 2.3 ± 0.9 °C at 3T, a minimum background temperature rise of 2.7 ± 0.9 °C at 1.5T and of 1.9 ± 0.9 °C at 3T, a maximum temperature rise difference between the test implant and the background of 0.7 ± 1.2 °C at 1.5T and of 0.4 ± 1.2 °C at 3T. Calorimetry assessed phantom WB - SAR (W/kg) was 4.11 ± 0.67 W/kg at 1.5T and 3.92 ± 0.73 W/kg at 3T.



Your Visual Processor is not compliant with Magnetic Resonance Imaging (MRI) scan. Do not wear your system when entering in MRI room.

Show the above-mentioned information to your radiologist for current MR Conditional labelling and instructions for this device in the MR environment.

3.4.4 Medical imaging with PRIMA implant



In case of medical imaging, the PRIMA implant may create limited imaging artefacts in the immediate surroundings of the implant. Therefore, it may be necessary to optimize imaging parameters for the presence of this implant when using MRI, CT scans or other imaging modalities. MR image quality may be compromised if the imaging area of interest is in the exact same area of the PRIMA retinal implant. In non-clinical testing, the image artifact caused by the device extends approximately 1mm from the PRIMA retinal implant when imaged by a 1.5T MRI system.

3.4.5 Other Medical therapies



The following therapies may cause malfunction or damage to the implant or harm to the patient and are therefore not recommended:

- Therapeutic ultrasound,
- Therapeutic X-Ray (e.g. proton beam therapy).

If any of the above are required by medical necessity, damage to the implant should be assessed after exposure to these treatments. Damage may appear over time.

3.4.6 Remote rehabilitation sessions

Your BVE may suggest that you follow remote functional vision rehabilitation sessions⁴. In this case, please follow the following precautionary measures.



An external connection request results in repeated vibrations of your VP, the blinking of the LED ® (refer to section 4.2) and an audio message asking you to accept the connection. Do not accept any connection to your system if you are not sure whether it is required by your BVE in a scheduled session.



Before starting a remote rehabilitation session, please make sure the battery of your system is fully charged or connect your VP to the mains power supply.

3.4.7 Electromagnetic Interference (EMI)



Electromagnetic interference is a field of energy emitted by electronic equipment that may be strong enough to interfere with the operation of your Visual Processor (See Appendix A).

In certain conditions, electromagnetic interference might lead to undesired switch off of the Visual Processor.

To prevent the above, we recommend avoiding:

- Metal detectors or security screeners, like those used at the entrances/exits of department stores, libraries and other public establishments, and/or airport security screening devices. You should show your Implant Card to any personnel who may be able to assist you in bypassing these devices. If you must proceed through the screener, do not wear and carry the Visual Processor through the device and proceed with caution. Go through the centre of the screener as quickly as possible
- Power lines or power generators
- Electric steel furnaces and arc welders

⁴ Only for Visual Processor equipped with a Projection System prod. ref. PS002. Remote rehabilitation is subject to the eligibility of the network capacities of your environment and that of your BVE.

- Large magnetized stereo speakers
- Devices emitting strong magnetic fields
- Even equipment complying with CISPR⁵ emission requirement

If you come in proximity with these devices, you may experience discomfort. If this happens, turn the Visual Processor off. If the Visual Processor suddenly turns off by itself, first move away from the area. Next, press the Power Button on the Visual Processor: the functionality of the device should be restored.

The Visual Processor function may be interrupted near home appliances such as WIFI transmitters, walkie-talkies, high voltage sources or cables.

If interference occurs with the PRIMA Visual Processor, turn off the Visual Processor or move away from the device that could be responsible of the interference. Do not use the Visual Processor on aircrafts.

The potential effects of EMI from devices or procedures are summarized in Appendix A.

3.5 Possible adverse events, side effects or complications related to the PRIMA System

- Complications due to device explantation,
- Impairment of residual visual function,
- Damaged retina,
- Complications due to long term exposure to IR,
- Epileptic seizure,
- No increase of visual perception,
- Retinal or iris damage of a tier user (patient's family, etc.) or intended user due to exposure of infrared light of damaged external components,
- Severe or non-severe tissue necrosis,
- Ear pain or discomfort,
- Nose pain or discomfort,

⁵ Comité International Spécial des Perturbations Radioélectriques (CISPR; English: International Special Committee on Radio Interference)

- Headache due to training and/or clinical testing.

4. System description

4.1 The pair of glasses

The pair of glasses is equipped with the Projection Module connected to the Pocket Processor via a cable. The projection module captures an image of your surrounding environment and projects stimulation patterns on the retina to activate the Retinal Implant. The Projection Module is powered by the Pocket Processor.

The Projection Module also integrates a speaker which informs you on the status of the Visual Processor (audio feedbacks – refer to section 4.3 for more details).

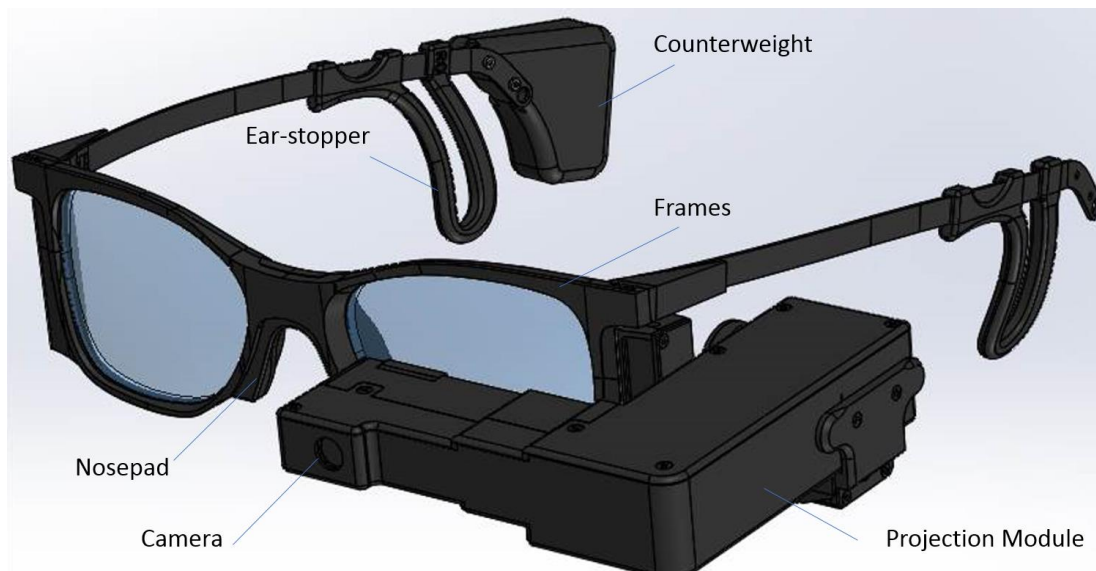


Figure 2: The pair of glasses equipped with the Projection Module

4.2 The Pocket Processor

The Pocket Processor is the processing unit of your PRIMA System controlling the different parameters and powering your PRIMA System via internal battery or directly on the mains.

The Pocket Processor User Interface is positioned on one face of your Pocket Processor. The Pocket Processor controls will allow you to turn the system on/off and change the brightness, zoom, visual processing mode and the volume of the Projection Module speaker. If you cannot initially locate the buttons, ask a sighted person to help you locate buttons thanks to their position and shape.

The Pocket Processor also integrates a vibrator and a buzzer which inform you about the status of the Pocket Processor (vibration and sound feedbacks – refer to section 0 for more details).

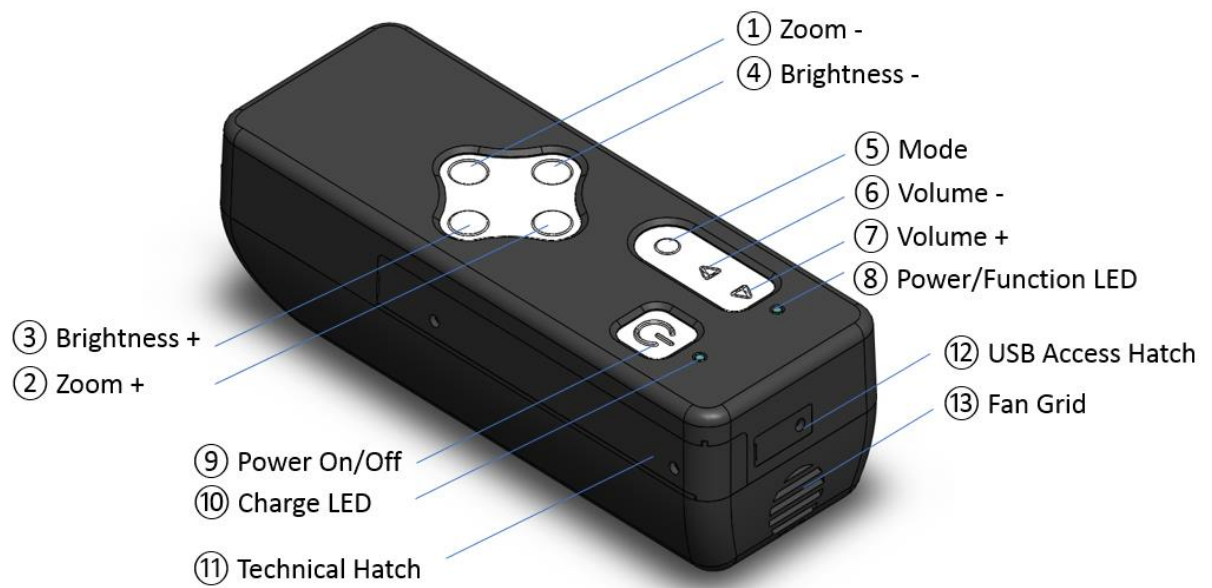


Figure 3: The Pocket Processor (all interfaces)

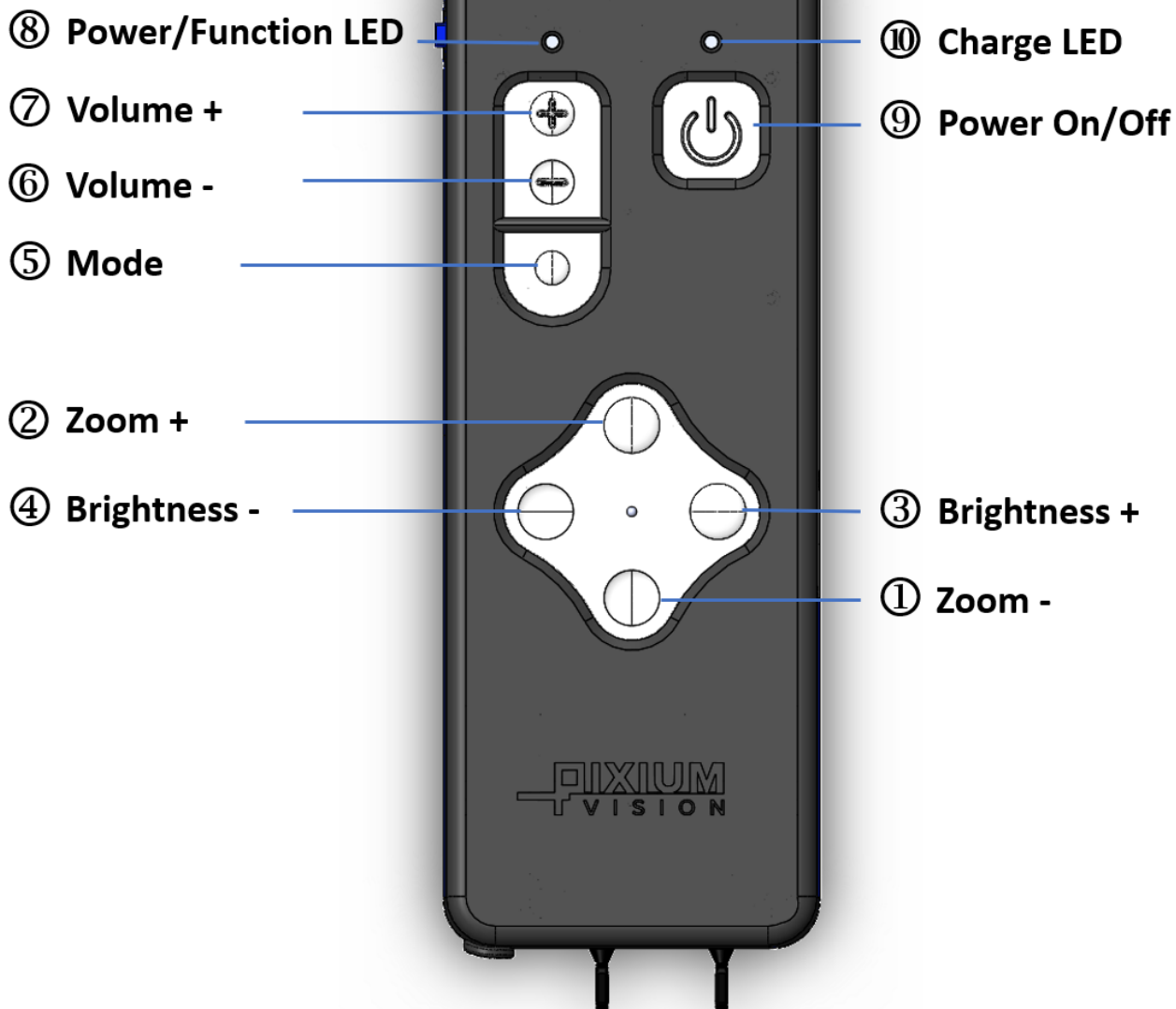


Figure 4: The Pocket Processor User Interface

4.3 System feedbacks

Your Pocket Processor uses a combination of vibration, sounds, indicator lights and audio sequences to inform you of its status. The feedbacks are summarized in Table 1 and Table 2 below.

There are two indicator lights on your Pocket Processor user interface:

- The Power/Function LED ⑧,
- The Charge LED ⑩.

4.3.1 Switch-on of the Visual Processor

When pressing the Power On/Off button ⑨ to switch on the Visual Processor, the Power/Function LED ⑧ will turn to green and vibrates⁶.

4.3.2 Power status

About ten seconds after pressing the Power On/Off button ⑨, the system will inform you about the autonomy of the Visual Processor.

If the Visual Processor is operating on its battery (supply adapter not plugged to the Pocket Processor), a combination of short sounds or vibrations will inform you on the status of the battery charge:

1. Three short sounds: battery charge is above 80%,
2. Two short sounds: battery charge is between 50% and 80%,
3. One short sound: battery charge is between 20% and 50%,
4. One short vibration emitted every minute: battery charge is low, between 20% and 5%,
5. Six alternating high-low tone short sounds, and automatic shutdown of the system: battery is completely depleted, and the Visual Processor automatically shuts down.

An audio sequence is played also by the speaker integrated in the Projection Module, which provides you the feedback.

⁶ If your Visual Processor is equipped with a Projection System prod. ref. PS002, it emits two (2) short sounds.

If the Visual Processor is plugged to its power adaptor, it will be powered by the mains rather than by its internal battery. In this case the Charge LED ⑩ turns to orange color.

4.3.3 Nominal functioning

When the system is fully operational the Power/Function LED ⑧ turns to blue after a few seconds.

4.3.4 Switch-off of the Visual Processor

The Visual Processor is switched off in the following cases:

- By pressing the Power On/Off button ⑨. In this case, two short sounds are emitted,
- If the autonomy of the system is too low when operating on its battery (i.e. approximatively 5%). Refer to sub-section 4.3.2,
- Because of a technical error. In this case, ten short sounds alternating high-low tone are emitted and the Visual Processor vibrates before switching off automatically.

In all cases, the Power/Function LED ⑧ will turn to green and blinks for a few seconds.

In all cases except for a technical error, an audio sequence telling that the system is switching off is played by the speaker of the Projection Module.

4.3.5 Charge

When switched off and plugged to the main through its power adapter, the Visual Processor is charging its internal battery. In this case the Charge LED ⑩ turns to red color and blinks. It turns to green color when the battery is full.

Table 1 - System Feedbacks when operating on battery

Use condition	Power/Function LED	Charge LED	Vibration	Buzzer sound	Audio sequence
System Switch-on	Green	OFF	YES	If your Visual Processor is equipped with a Projection System prod. ref. PS002, two (2) short sounds alternating low-high tone at system switch-on. In all case, depending on Battery status when the system is initialized: • Above 80%: Three short sounds • Between 50 and 80%: Two short sounds • Between 20 and 50%: One short sound • Between 20% and 5%: see below	YES
Nominal Functioning	Blue ⁷	OFF	NO	None	NO
Functioning with artificial patterns	Blue ⁷	OFF	NO	One (1) to two (2) short sounds of low tone are emitted every second.	NO
Rehabilitation connection request	Fast Blinking Blue	OFF	YES ⁸	None	YES

⁷ Blinking if your Visual Processor directly or remotely connected to the rehabilitation system of your BVE.

⁸ Repeated vibrations

Use condition	Power/Function LED	Charge LED	Vibration	Buzzer sound	Audio sequence
Rehabilitation connection established	Slow Blinking Blue	OFF	NO	None	YES
Re-habilitation connection closed	Blue	OFF	NO	None	YES
Battery below 20%	Blue ⁹	OFF	YES ¹⁰	None	YES
Switch-off (on power button press)	Blinking in green	OFF	YES	Two (2) short sounds alternating high-low tone	YES
Automatic Switch-off (battery is too low)	Blinking in green	OFF	YES	Six (6) short sounds alternating high-low tone	YES
Automatic Switch-off (Technical error occurs)	Blinking in green	OFF	YES	Ten (10) short sounds alternating high-low tone	YES ¹¹

⁹ Blinking if your Visual Processor directly or remotely connected to the rehabilitation system of your BVE.

¹⁰ Vibrates every minute until reaching 5% of charge before automatic switch-off.

¹¹ Except on technical errors due to software

Table 2 - System Feedbacks when operating on mains

Use condition	Power/Function LED	Charge LED	Vibration	Sound	Audio sequence
System Switch-on	Green	Orange	YES	If your Visual Processor is equipped with a Projection System prod. ref. PS002, two (2) short sounds alternating low-high tone at system switch-on. In all case, depending on battery status when the system is initialized: • Above 80%: Three short sounds • Between 50 and 80%: Two short sounds • Below 50%: One short sound	YES
Nominal Functioning	Blue ¹²	Orange	NO	None	NO
Functioning with artificial patterns	Blue ¹²	Orange	NO	One (1) to two (2) short sound of low tone are emitted every second.	NO
Re-habilitation connection request	Fast Blinking Blue	Orange	YES ¹³	None	YES

¹² Blinking if your Visual Processor directly or remotely connected to the rehabilitation system of your BVE.

¹³ Repeated vibrations

Use condition	Power/Function LED	Charge LED	Vibration	Sound	Audio sequence
Re-habilitation connection established	Slow Blinking Blue	Orange	NO	None	YES
Re-habilitation connection closed	Blue	Orange	NO	None	YES
Switch-off (on power button press)	Blinking in green	Orange	YES	Two short sounds alternating high-low tone	YES
Automatic Switch-off (Technical error occurs)	Blinking in green	Orange	YES	Ten short sounds alternating high-low tone	YES ¹⁴
Battery Charge	OFF	Charging: Blinking in red Full charge: Green	NO	None	NO

¹⁴ Except on technical errors due to software

4.4 Remote Kit

When eligible to remote visual function rehabilitation in connection with your Bionic Vision Expert (BVE)¹⁵, your Visual Processor has been delivered with Remote Kit to connect your Visual Processor to the internet network. This kit contains:

- A router device for internet access, that creates a Wi-Fi network accessible by your Visual Processor and the display device (see below), allowing its connection with the hospital,
- A display (tablet) device, which can be controlled remotely by your BVE in order to communicate with you and display images during the rehabilitation session,
- A support for your display device.

Both display and router devices are pre-configured to connect to the hospital thus you just need to plug and switch them on prior to a remote session scheduled by your BVE (refer to section 5.2).



Figure 5: Remote Kit items

5. Instructions for use

5.1 Installing your Visual Processor

- A. Place the Pocket Processor Shoulder strap on your shoulder.
- B. Place the Glasses on your head as you would do for a pair of glasses.
- C. If the Glasses are sliding or feel uncomfortable ask your healthcare provider to adjust the nose pad or ear-stoppers.



Do not handle the Glasses by the Projection Module (refer to Figure 2 in section 4.1).



You should wait at least 30 minutes before using your Visual Processor if it was recently stored below -25 °C or above 45 °C in order to let your device warm up or cool down.

¹⁵ Only for Visual Processor equipped with a Projection System prod. ref. PS002. Remote rehabilitation is subject to the eligibility of the network capacities of your environment and that of your BVE



Do not use the device if the lens of the implanted eye is broken, as this could potentially lead to retina damage harm or injury.



You should have your vision checked on a regular basis, i.e. if you need new glasses. In case of major change (more than 2D), this could potentially lead to retina damage harm or injury when using your PRIMA System. Please contact your Health Care Professional to check if the lenses of your PRIMA 2 Bionic Vision System need to be changed.



Wearing the Visual Processor in cold or hot temperatures: The Pocket Processor may heat up after a prolonged use at ambient temperature above 35°C (95°F). In case of discomfort due to the increased temperature of the Visual Processor during prolonged use, turn off the system for at least half-an-hour to let it cool down before re-using the system.



The Visual Processor will automatically switch off if it becomes too hot. For proper operation, avoid wearing your Pocket Processor under your clothes.

5.2 Installing your Remote Kit items for remote rehabilitation

When eligible to visual rehabilitation from home in connection with your Bionic Vision Expert (BVE)¹⁶, your Visual Processor has been delivered with Remote Kit pre-configured to connect your Visual Processor to the hospital through the internet network (refer to section 4.4).



Remote Kit items are installed following steps below.

Before a remote rehabilitation session scheduled by your BVE:

- A. Install your router in a room conducive to reception of the 4G network, in direct line of sight and not far from the place where you will conduct remote rehabilitation sessions with your BVE, as far as possible from metal plates and electronic devices (and especially the microwave) for best efficacy of Wi-Fi communication.
- B. Plug it to the mains and switch it on as described by the manual delivered with the device.



The indicators will turn on when the router has successfully connected to a network. If the MODE indicator is red, it indicates there is no network connection. Please refer to the FAQs in the manual delivered with the router or ask support to your BVE.

¹⁶ Only for Visual Processor equipped with a Projection System prod. ref. PS002. Remote rehabilitation is subject to the eligibility of the network capacities of your environment and that of your BVE

- C. Install the display on its support, placed on a stable surface (ideally in the same room as the router for best efficacy of Wi-Fi communication). Plug it to the mains and switch it on. Refer to the manual delivered with the device for more information or ask support to your BVE.
- D. Sit in front of the table and positioned the display on its support at approximately eye level at 40 cm distance of your face so that the BVE can see you.

5.3 Powering your Visual Processor

Your Visual Processor can be powered either by its internal battery or by mains when the power adapter delivered with the system is connected to the Pocket Processor.

5.4 Starting your Visual Processor

- E. Press the Power On/Off button ⑨ for a few seconds until the Power/Function LED ⑧ turns on and your Visual Processor vibrates (approximately 1 second). It emits one to three short sounds after 15 seconds, depending on the battery status (refer to section 4.3.2).
- F. You should experience the visual perception about 15 seconds after your Visual Processor is switched on.
- G. When the battery is depleted, the system will automatically switch off. Recharge your system directly on the mains using the power adaptor delivered with your Visual Processor. Actual battery life may vary based on settings, usage patterns and environmental conditions. On average, the battery of the Visual Processor will provide energy to the system for five (5) hours.

5.5 Zooming

- A. To zoom in, press the Zoom + ② button,
- B. To zoom out, press the Zoom - ① button.

The zoom controls are stepped, that is, one press on the Zoom + ② button will automatically adjust the image to the next highest zoom level. In the same way as one press on the Zoom - ① button will adjust the image to the next lowest zoom level.

5.6 Adjusting the brightness

- A. To increase brightness, press Brightness + ③ button,
- B. To decrease brightness, press Brightness - ④ button.

The brightness controls are stepped, that is, one press on the Brightness + ③ button will automatically adjust the image to the next higher brightness level. In the same way as one press on the Brightness - ④ button will adjust the image to the next lower brightness level.

5.7 Selecting the mode

Modes are stimulation settings for specific use cases, adapted to your needs. If configured by your HealthCare provider for training purposes, one or more modes can also allow selection of specific Artificial sequences. Artificial sequences are images generated by the Pocket Processor. They do not come from the external environment. When an Artificial sequence is being projected you are notified by a series of bips. To change the stimulation mode or the training sequence, use the Mode ⑤ button:

- A. By a short press for forward selection,
- B. If your Visual Processor is equipped with a Projection System prod. ref. PS002, by a long press for backward selection. Note that in the case of a backward selection of the mode, the Visual processor is vibrating for distinction with forward selection.

5.8 Adjusting the audio volume

- A. To increase the Projection Module speaker volume, press Volume + ⑦ button.

If your Visual Processor is equipped with a Projection System prod. ref. PS002, a short press of less than one second will increase the volume by one step. A long press will increase the volume of one step every 750 ms (if your Visual Processor is not in condition of rehabilitation connection request - refer to section 5.9).

- B. To decrease the Projection Module's speaker volume, press Volume - ⑥ button. If your Visual Processor is equipped with a Projection System prod. ref. PS002, a short press of less than one second will decrease the volume by one step. A long press will decrease the volume of one step every 750 ms (if your Visual Processor is not in condition of rehabilitation connection request - refer to section 5.9).

An audio message is played by your Visual Processor at each audio adjustment step.

5.9 Acknowledging of a connection for rehabilitation¹⁷

Before starting a session to re-educate your visual function at the hospital or remotely, you must authorize the connection of your Visual Processor with your BVE's rehabilitation system. A connection request results in repeated vibrations of your VP, the blinking of the LED ⑧ and an audio message asking you to accept the connection.

- A. To accept the connection, press the Volume + ⑦ button for more than 1 second. At the end of the rehabilitation session, your Visual Processor will be automatically disconnected from the hospital system when your BVE closes the rehabilitation session.



Pay attention to not press the Power On/Off ⑨ instead of the Volume + ⑦ button, otherwise you will have to switch your Visual Processor again and ask your BVE to initiate a new remote connection.

- B. To refuse the connection, wait for more than 30 seconds without pression on Volume + ⑦ button, or switch off your system,

5.10 Switching your Visual Processor off

Press the Power On/Off button ⑨ for a few seconds until the Power/Function LED ⑧ blinks in green. After about 10 seconds, your Visual Processor is switched totally off.

5.11 Charging your Visual Processor

Plug your system to the mains with the power adaptor provided with your Visual Processor.



Pay attention to close the charger hatch after charging your device.



Note: Your system can remain connected to the mains after full charge (power/function LED blinking in green), without time recommendation. However, it is advisable to unplug it after charge in order to reduce your electricity consumption.

5.12 Cleaning

Clean the Projection Module's camera frequently with a dry cloth intended for standard eyeglasses, in order to keep a good quality of image as lint and dust might accumulate.

- A. Switch your Visual Processor off

¹⁷ Only if your Visual Processor is equipped with a Projection System prod. ref. PS002.

B. Wipe your Visual Processor with a soft dry cloth

5.13 Travelling with your Visual Processor

A. Switch your Visual Processor off

B. Wipe the Visual Processor with a soft dry cloth.

C. Place the Visual Processor in your travelling case, taking care that the cable is not twisted,

D. When you are traveling by plane, place your system in carry-on luggage.

5.14 Storage, Handling and Transport



To store your Visual Processor for an extended period, store it in its transport bag with the battery half charged. Recharge the battery every 3 months to ensure battery life.



Handle the PRIMA System and accessories with care and use the transport bag provided by Pixium Vision when you need to travel. Keep the system dry. Do not expose your Visual Processor to excessively cold or hot conditions. Do not leave your device in your car or outdoors.



Store your device in an environment which does not exceed -25°C to +45°C (-13 °F to 113 °F). Do not wear your Pocket Processor under your clothes. Should your Visual Processor become damaged, speak with your physician, who will arrange a replacement Visual Processor. For information on operation and storage temperatures for the Visual Processor, see Section 9.3.

6. Troubleshooting

6.1 Troubleshooting

The table below lists some of the problems you may experience and possible solutions:

Problem	Probable Reason	What to do
Nothing happens when you press the power button.	The Visual Processor battery is depleted.	The battery of your system may be depleted. Plug the power adapter delivered with your system to the Pocket Processor for functioning on mains (Visual Processor switched on) or battery charging (Visual Processor switched off).
No stimulation occurs after feeling a vibration and at least one short sound.	Your Visual Processor is not fully operational.	Wait about 10 seconds after switching on for your system to be fully operational. However, if the problem still occurs, please contact your healthcare professional to verify the stimulation configuration of your system.
The image you perceive is divided into two parts with top and bottom exchanged.	Your Visual Processor is not fully operational.	Push the Zoom in button of the Pocket Processor, then the Zoom out button. If the problem still occurs, please contact your healthcare professional to verify the stimulation configuration of your system.
The Pocket Processor's zoom button does not work	Zoom action has not been fully performed.	Retry the operation. If it is still ineffective, switch off the VP then switch it on again.
Visual Processor emits ten short sounds alternating high-low tone and switches off.	Your Visual Processor detected an error or it is too hot.	If the system is hot, let it cool down for 30 min. You can restart your Visual Processor, however if the problem occurs more than three times in a day, please

Problem	Probable Reason	What to do
		contact your healthcare professional or Pixium Vision.
Visual Processor emits six short sounds alternating high-low tone and turn off.	Your battery is depleted.	Plug the power adapter delivered with your system to the Pocket Processor for battery charging (Visual Processor switched off).
Power/Function LED is on but staying green even after waiting 1 min 30.	Warm-up phase of the visual processor could not finish because of a technical error.	Please contact your healthcare professional or Pixium Vision.
Your Visual Processor is cracked or damaged.	Your Visual Processor was dropped or mishandled.	If your Visual Processor does not operate properly after being dropped or mishandled, switch it off and contact your healthcare professional or Pixium Vision.
Your Visual Processor is too warm or too cold.	Your Visual Processor was used outside of its operating temperature range.	Switch off your Visual Processor and remove your Visual Processor. Wait 30 minutes before using it again.
The autonomy of your Visual Processor is decreasing	The battery may be defective, or the battery lifetime is exhausted.	Contact your healthcare professional or Pixium Vision for replacement.
Your Visual Processor is not operating when plugged on mains (Charge LED not lightening in orange)	The power supply may be not well connected to the Pocket Processor.	Verify that the Power supply component is correctly plugged to your Pocket Processor. When the Pocket Processor is switched on and the power supply is correctly plugged in, the charge LED will be lightning in orange.
Your Visual Processor is not charging when plugged on mains (Charge LED not blinking in red, nor lightning in green)	The power supply may be not well connected to the Pocket Processor	Verify that the Power supply component is correctly plugged to your Pocket Processor. When the Pocket Processor is switched off and the power supply is correctly plugged in, the charge LED will

Problem	Probable Reason	What to do
		blink in red or be lightning in green.
Your Visual Processor is unable to connect remotely to the BVE system for rehabilitation purpose.	Your Visual Processor may be too far from the Remote Kit router device provided by your BVE.	Get closer to the router. Avoid obstacles between your Visual Processor and the router.
	The Remote Kit router device provided by your BVE may be switched off or does not correctly communicate with the 4G network.	Verify that your router is switched on and installed in a place conducive to reception of the 4G network.
	The Remote Kit router device provided by your BVE may be placed in near proximity of metal plates or other electronic devices.	Install your router in direct line of sight and not far from the place where you will conduct remote rehabilitation sessions with your BVE, as far as possible from metal plates and electronic devices (and especially the microwave).
	Nearby or hidden devices emitting magnetic fields can interfere with your Visual Processor, even if the other equipment complies with applicable emission requirements.	Move away from or turn off equipment that could generate electromagnetic interference or strong magnetic fields (e.g. induction hob, micro-wave oven, wireless speakers).
The BVE can connect to your Visual Processor but cannot reach your Remote Kit display to drive the remote rehabilitation session.	Your Remote Kit display device provided by your BVE may be switched off.	Verify that your display is switched on.

Problem	Probable Reason	What to do
	Your Remote Kit display device may be too far from the Remote Kit router device provided by your BVE.	Get your display closer to the router. Avoid obstacles between your display and the router.
	Nearby or hidden devices emitting magnetic fields can interfere with your Remote Kit display, even if the other equipment complies with applicable emission requirements.	Move your display away from or turn off equipment that could generate electromagnetic interference or strong magnetic fields (e.g. induction hob, microwave oven, wireless speakers).

6.2 System failure



The PRIMA System might fail due to random component failure or loss of battery functionality. If the device stops functioning when charged, switch off the Visual Processor and contact your healthcare professional so the system can be evaluated.



One possible failure mode of the implant is that it could stop responding to signals from the Visual Processor and thus stop stimulating. If it fails in this manner, you should not experience any harmful effects, but a System failure should be reported to Pixium Vision by your health care professional.

7. Service

7.1 Disposal



Dispose of this device in accordance with local regulations. Do not dispose of the Visual Processor in normal garbage, it is recommended to return all parts to Pixium Vision.

7.2 Contacting Pixium Vision



In case anything unexpected occurs with the device or if any assistance is required to use or maintain the device please contact your healthcare professional who will contact Pixium Vision if required. Any maintenance performed on the device shall meet the requirements of IEC 60601-1 Ed 3.1.

Contact address:

Pixium Vision

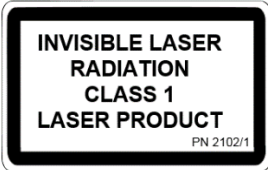
74 Rue du Faubourg Saint-Antoine

75012 Paris

France

Website: <https://www.pixium-vision.com/contact-us/>

8. Labelling symbols

	Name and address of the manufacturer		Product should be stored at the temperature range indicated
	Serial number		Product should be stored at the humidity range indicated
	Product reference		Product should be stored at the atmospheric pressure range indicated
	Date of manufacture		Do not use the product if the package has been damaged or opened
	Read the instruction for use		Keep the product in a dry place, away from water and rain.
	Fragile	 IP22	This product complies with international electrical safety rating IP22 with regard to ingress of dust, other foreign objects, and water as required by 60601-1-11
	Invisible Laser Radiation Class 1 Laser Product		Instruction that disused devices must not be disposed with household garbage
Rx Only	Can only be purchased and used solely under a health care provider's written authorization		Warning: Potential safety hazards and serious adverse reactions, could cause harm to person
	Non-ionizing electromagnetic radiation		Note: Information considered important for the correct use
	Caution: Could cause damage on the system or impact its performance		Power supply meeting the safety requirements specified for Class II equipment according to IEC 61140

9. Technical Specifications

9.1 Essential Performance

The essential performance of the PRIMA System is the emission of IR irradiance at 880nm +/- 10nm within the defined safety range.

9.2 Standards Compliance

This device is designed to conform to the following standards:

EN 60601-1:2006+A1:2013, Edition 3.1 – Medical electrical equipment. General Requirements for basic Safety of and essential performance,

IEC 60825-1:2014 Safety of laser products. Equipment classification and requirements.

9.3 Environmental

Operating Temperature: 0° to 35° C (41° to 95° F)

Storage Temperature: -25° to 45° C (-13° to 113° F)

Relative Humidity (operating & storage): 15 to 93% (non-condensing)

Atmospheric Pressure: 70 to 106 kPa

The PRIMA System is designed to work optimally in normal office lighting conditions. Its camera has been tested for performance in ambient light conditions between 50 and 15000 lux.

9.4 Physical

Glasses and Projection Module dimensions: 213 x 188.5 x 43 mm (8.4" L x 7.4" W x 1.7" H), weight 164 g (0.36 lbs)

Visual Processor cable: 1200 mm (47.2" L)

Pocket Processor dimensions: 212 x 78 x 60 mm (8.3" L x 3.1" W x 2.4" H), weight 690 g (1.52 lbs) with battery

AC/DC Power Adapter dimensions: 132 x 58 x 30.5 (5.2" L x 2.28" W x 1.2" H), weight 345 g (0.76 lbs)

9.5 Electrical

Visual Processor Nominal Operating Voltage: 14.4V VDC

AC/DC Power Adapter:

- Input Voltage/Current Range: 100 VAC (1.62 A) to 240 VAC (0.72 A)
- Input Frequency: 47 to 63 Hz
- Safety: IEC60601-1 Edition3.1, ES60601-1:2005(R2012), CSAC22.2 NO.60601-1:14

Battery capacity and voltage range: 3.35 Ah / 12 to 16.4 VDC

Battery number of charges: 500 Cycles

Degree of Protection Against Electric Shock: Type BF Applied Part

9.6 Degree of Protection against Ingress of Water

Visual Processor: IP22

Mode of Operation: Continuous

9.7 Optical

Maximum peak output power: 71mW ($\pm 5\%$)

Nominal output wavelength: 880 nm

Laser output radiation: Invisible Laser Radiation Class 1 Laser Product

9.8 Wireless communication

Technology used: Wi-Fi 802.11 b/g/n (2.4 GHz), balanced dual band antenna.

Frequencies: 2400 – 2483.5 MHz

Max RF power output: 17.4 dBm

9.9 PRIMA Visual Processor expected service life: 2 years

9.10 PRIMA System lifetime: 36 months

10. Glossary

Adverse effect	Undesired harmful effect
Adverse event	Untoward medical occurrence
BVE	Bionic Vision Expert
Electromagnetic interference (EMI)	Electromagnetic signals that interfere with a variety of electrical signals
Ear-stoppers	Adjustable parts of the Glasses that allow to stare glasses on the ears
External Components	External parts of the PRIMA System, comprising the Glasses, Projection System and its Power adapter
Glasses	Pair of glasses on which the Projection Module is attached
Implant Card	A wallet size card that lists the patient and physician names, and PRIMA information
Indicator lights	Light used to convey information on the Visual Processor status
LED	Light Emitting Diode (see also Indicator lights)
Mode	Stimulation setting for a specific use case, adapted to your needs, and set by your healthcare professional
Nose pad	Part of the Glasses that rests on the nose
Parameter	System numerical setting defining the conditions of the Visual Processor operation
Pocket Processor	Processing unit of the Visual Processor
Power adapter	Power supply for your Visual Processor devices. Plug into a wall outlet and convert AC to a single DC voltage.
Precaution	A precaution addresses a risk of damage to the device or system
Projection Module	Part of the Projection System that records your environment via a camera and sends the light power to your Retinal Implant for stimulation pulses delivery to the retina
Projection System	Parts of the PRIMA Visual Processor System, comprising the Projection module, attached to the Glasses, and the Pocket Processor.

Remote rehabilitation	Remote sessions of visual function rehabilitation training at home scheduled with your BVE.
Retina	Part of the eye responsible for the reception of light, the conversion of the image into electrical signals and the transmission of these signals to the brain.
Retinal Implant	Small implantable electrical pulse generator
Speaker	Speaker used to convey information on the Visual Processor status
Stimulation pulses	Electrical signal delivered by the Retinal Implant to the retina of the patient.
Vibrator	Vibrator used to convey information on the Visual Processor status
Visual Processor	External parts of the PRIMA System, comprising the Glasses, Projection System and its Power adapter
Warning	A warning addresses a risk of injury for the user or operator
Wi-Fi	Wireless communication protocol governed by IEEE 802.11 group standards. Wi-Fi is a trademark of the Wi-Fi Alliance.

11. Document History

Version	Date	Changes
dmr-prima-01-01-00001, revision 1	December 2021	Initial version
dmr-prima-01-01-00001, revision 2	January 2022	Caution added on pair of glasses holding in section 5.1. Figures and sections references fixed in document.

Appendix A: Electromagnetic Interference (EMI)

Electromagnetic Interference (EMI)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices when in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Pixium Vision applied the EN 60601-1-2 Ed4 standard for the development of the PRIMA System.



Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Pixium Vision, with the exception of cables sold by Pixium Vision as replacement parts for internal components, may result in increased emission or decreased immunity of the device and lead to an improper operation,
- The medical devices should not be used adjacent to or stocked near other equipment. If this occurs the medical device should be observed to verify normal operation in the configuration in which it will be used.

Refer to further guidance in the following pages and tables (Table 3, Table 4, Table 5 and Table 6) regarding the EMC environment in which the device should be used. Following the guidance will ensure that your device produces the best results.

Table 3: Cables Length

Cables and accessories	Maximal cables Length	Test type	Compliant to
Cables / Cordon, etc..	< 3 m	RF emission	CISPR 11, Classe B
		Harmonic emissions	IEC 61000-3-2
		Voltage fluctuations/flicker emissions	IEC 61000-3-3
		Electrostatic discharge (ESD)	IEC 61000-4-2
		Electromagnetic Field Radiated RF	IEC 61000-4-3
		Electrical fast transient/burst	IEC 61000-4-4
		Surge	IEC 61000-4-5
		Conducted RF	IEC 61000-4-6
		Power frequency (50/60 Hz) magnetic field	IEC 61000-4-8
		Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11

Recommended Separation Distance: The medical device is intended for use in an electromagnetic environment in which the disturbances due to RF radiation are controlled. The user or installer of the medical device can help to prevent electromagnetic interference by now a minimum distance, depending on the maximum power of the transmission equipment radio frequency.



Do not use RF handheld communications equipment (including peripherals such as antenna cables and external antennas) closer to 30 cm (12 inches) from any part of the Visual Processor, including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.



Caution: the user that changes or performs modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The medical device is intended for use in the electromagnetic environment described in the table below. The user and the installer must therefore ensure that the medical device is used in the environment described below.

Table 4: Guidance and Pixium Vision declaration - electromagnetic EMISSIONS - for Visual Processor

Guidance and manufacturer's declaration – electromagnetic emissions		
The Visual Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the Visual Processor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Visual Processor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Visual Processor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies ⁽¹⁾	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies ⁽¹⁾	
⁽¹⁾ NOTE Only applicable when the device is used with its respective Battery charger.		

Table 5: Guidance and Pixium Vision declaration – Magnetic & Electromagnetic IMMUNITY - for Visual Processor

Guidance and manufacturer's declaration – electromagnetic immunity			
The Visual Processor is intended to be used in the electromagnetic environment specified below. The customer or user of the Visual Processor should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Home healthcare environment and professional health care facility environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Home healthcare environment and professional health care facility environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Home healthcare environment and professional health care facility environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Home healthcare environment and professional health care facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles at 50Hz and for 30 cycles at 60Hz single-phase at 0°	0 % for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles at 50Hz and for 30 cycles at 60Hz single-phase at 0°	Home healthcare environment and professional health care facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _T : for 250 cycles at 50Hz and for 300 cycles at 60Hz	0 % U _T : for 250 cycles at 50Hz and for 300 cycles at 60Hz	Home healthcare environment and professional health care facility environment.
NOTE U _T is the a.c. mains voltage prior to application of the test level.			

Table 6: Guidance and Pixium Vision declaration - electromagnetic IMMUNITY - Radiofrequency for Visual Processor

Guidance and manufacturer's declaration – electromagnetic immunity			
The Visual Processor is intended to be used in the electromagnetic environment specified below. The customer or user of the Visual Processor should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electromagnetic Field Radiated RF IEC 61000-4-3	3 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz 10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	3 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz 10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	Home healthcare environment and professional health care facility environment.
Proximity fields issued by RF wireless communications devices IEC 61000-4-3	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Home healthcare environment and professional health care facility environment.
Conducted RF IEC 61000-4-6	3 V 150KHz at 80MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz, amateur radio band included. 80% MA at 1 KHz	3 V 150KHz at 80MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz, amateur radio band included. 80% MA at 1 KHz	Home healthcare environment and professional health care facility environment.

Appendix B: RF Exposure Information

(Only applicable to Projection System prod. ref. PS002)

The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power Wireless devices emit low levels of radio frequency energy (RF) in the microwave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been confirmed by additional research.

The exposure standards for wireless devices employ a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC/IC is 1.6W/kg. The SAR limit recommended by The Council of the European Union is 2.0W/kg.

Visual Processor equipped with a Projection System prod. ref. PS002 device has been tested and meets applicable limits for Radio Frequency (RF) exposure, in compliance with Council of the European Union and FCC radiation exposure limits set forth for an uncontrolled environment.

This device's maximum SAR values are listed in table below:

EU SAR_{10g} limit	FCC/IC SAR_{1g} limit	Highest reported Body SAR value	Highest reported Extremity SAR value
2.0 W/kg	1.6 W/kg	SAR _{10g} = 0.512 W/kg SAR _{1g} = 1.377 W/kg	SAR _{10g} = 0.512 W/kg SAR _{1g} = 0.591 W/kg

Caution: the user that changes or performs modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.