



WIRELESS CAMERA

USER MANUAL



Read this manual carefully before using the device. Pay close attention to the instructions given in the “Overview” chapter.

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SYNAPSYS SAS
2 Rue Marc Donadille –
Hôtel Technoptic
13013 MARSEILLE
FRANCE
Phone: (33)(0)491117575
Web: www.synapsys.fr

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1. OVERVIEW

1.1 DESCRIPTION

The wireless camera is used in video-nystagmoscopy/video-nystagmography masks for the study and analysis of eye and head movements. It is designed for use by otorhinolaryngologists, neurologists, ophthalmologists, and physiotherapists.

To use the equipment properly, we advise you to read the following information carefully.

The mask is made up of one goggle plus one or two wireless cameras.

The wireless camera is used either as

- with compatible video-nystagmoscopy Synapsys software;
- with compatible video-nystagmography Synapsys software.



1.2 SAFETY – CONDITION OF USE

1.2.1 Precautions

- To use this device properly, you must carefully read all this documentation, the instructions, and labels.

1.2.2 Warnings

- All peripherals (PC, printer, computer, etc) used with this device should conform to the IEC 60950-1 standard.
- The device should not be used in extreme humidity.
- The device should not be used in the presence of any explosive or flammable gas.
- Switch the device off before any cleaning is carried out.
- **CAUTION:** All modification of the equipment is expressly forbidden.
- To avoid accidents, the user should take care not to put the patient in contact with any equipment other than the ones provided by Synapsys and to ensure that all other electrical equipment, (monitors, power supply box, ...) are positioned beyond the patient's reach.

- **WARNING:** Remove the battery if the wireless camera is likely to remain unused for a period of time.

1.2.3 Contraindications

- To preserve optimum video image quality, the patient should not wear any corrective spectacles.
- The user must never be in contact simultaneously with the patient and with an electrical appliance.
- If the device or one of its components is damaged, do not use the system until it is repaired by a specialist trained by Synapsys.
- The device or one of its components may only be installed, updated, and repaired by a specialist trained by Synapsys.
- Only use the batteries designed for the wireless camera and buy your replacement batteries from the manufacturer. See Appendix 3: "Safety information & handling recommendations for the wireless camera charger & batteries".
- If water should be splashed on the wireless camera, the user must stop the examination, remove the battery from the camera unit and wipe it dry. The examination may only continue once the wireless camera is dry.
- Synapsys recommends cleaning or changing the parts in contact with the patient to use. (See Chap 3. MAINTENANCE).

1.2.4 FCC use restrictions and warnings

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

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.

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.

Responsible party's contact located in the United States

Inventis North America

Titusville

FL 32780, U.S.A.

Telephone: 1-844 683 6847

1.2.5 Radio equipment restriction on putting into service (RED 2014/53/EU)

The WiFi module of the Wireless camera works in the frequency bands 5150 – 5350 MHz and 5470 – 5725 MHz. The former requires an **indoor use only**. The restriction applies in the following Member States

	AT	BE	BG	CH	CY	CZ	DE
	DK	EE	EL	ES	FI	FR	HR
	HU	IE	IT	IS	LI	LT	LU
	LV	MT	NL	NO	PL	PT	RO
	SE	SI	SK	TR	UK(NI)		

1.2.6 Meaning of used symbols

SYMBOL	DESIGNATION
	Device serial number: • Characters 1-5: Synapsys product code • Characters 6-7: year of manufacture ("20" denotes 2020) • Characters 8-13: progressive serial number
	Catalog code
	Manufacturer name and contact information

	Do not mix with household rubbish
	Applied part type B
	Direct current
	Conformity with Council Directive 93/42/EEC concerning medical devices (as amended and expanded by Directive 2007/47/EC)
 (01)03760184931466 (21)SC1~21123456	UDI code
	The user shall read the instructions for use

1.3 SYSTEM COMPOSITION

Your system will include the following components:

- 1 Flex or Xpress goggles;
- 1 WNS camera unit;
- 1 Eye occlude;
- 2 batteries;
- 1 battery charger (with supply box and cable);
- 1 Wi-Fi access point;
- 1 USB cable for service purpose;
- 1 USB Wi-Fi interface.

The wireless camera can be customized in terms of the goggle mask, i.e. Flex or Xpress goggles.

1.3.1 About the components

Wireless camera device

The wireless camera device is a mask fitted with one infrared camera units. It is worn by the patient and ensures light-tightness for “closed field” testing. It is used for vestibular testing and rehabilitation. This mask has infrared

LEDs for illumination as well as LEDs visible to the patient as visual fixation targets.

With the integrated motion sensor (i.e., gyroscope and accelerometer), the wireless camera also provides information about the patient's head movements.

Battery pack

A battery inserted in the camera block provides power to the device making it a stand-alone system.

Wireless communication

To communicate with the camera units, you must have a WI-FI-capable (card or USB adaptor) computer.

1.4 MINIMUM COMPUTER REQUIREMENTS

To use the wireless camera, your computer must have at least one 5 GHz Wi-Fi network connection.

The other technical specifications and requirements for your computer system will depend on the software you wish to use. Please refer to the corresponding Synapsys software User Manual.

2.USE OF THE PRODUCT

To use your wireless camera:

- Start the access point;
- Start the camera unit;
- Connect the computer to the wireless camera network via Wi-Fi;
- Put the mask on the patient's head;
- Launch the chosen Synapsys software.

2.1 STARTING THE SYSTEM

Start the access point



- Connect the access point to mains using the provided power adapter;
- The access point is ready when the power and the 5G LED indicators flash.

Start the camera

- Start the camera once the access point is ready.

Start-up is automatic upon inserting the battery into the camera unit.

You will need to wait a few seconds for the wireless camera system to be ready for use.



The camera is ready when its front left LED pulses with color green and right LED is off.

The front LED indicators of the camera unit show its status as reported in the table below.

LEFT RED (NETWORK STATUS)		RIGHT LED (DEVICE STATUS)	
BEHAVIOUR	MEANING	BEHAVIOUR	MEANING
White pulsing	WiFi initialization in progress	Blue pulsing	Boot mode (for firmware update)
Yellow pulsing	WiFi connection to the AP in progress	White pulsing	Camera initialization in progress
Green pulsing	WiFi connection to the AP established	Off	Camera running
Red pulsing	Error	Yellow fast pulsing	Battery charge lower than 20%
		Cyan pulsing	Standby mode
		Yellow slow pulsing	Standby mode with battery charge lower than 20%
		Red pulsing	Error

2.2 NETWORK CONNECTION

- Connect your computer to the Wi-Fi network "SYN_Wireless_Camera_Access_Point";

- Enter the default password “01234567” to establish the Wi-Fi connection.

Particular situations:

If you are using multiple wireless camera systems (i.e., with several access points) in a perimeter of 100 meters, please connect your computer to the corresponding network.

Please contact our support service to set up your systems according to your situation and needs.

Note: The network connection used to communicate with your camera is a point-to-point private connection between your computer and the camera transmitter, it will not provide any connection between you and a third-party network or the public Internet.

2.3 PUT THE MASK ON THE PATIENT’S HEAD

To avoid any stress of traction and torsion when putting on the mask, it is recommended to proceed as follows:

- Attach the camera to the mask;
- Insert the battery to start the camera;
- Loosen the Velcro strap;
- Position the mask comfortably over the patient's eyes;
- Stand behind the patient, take the strap buckles and tighten the strap slightly to ensure a good fit of the mask.

Once the eye to be filmed has been chosen, the camera and occluder should be placed on the goggles with battery entry pointing upwards. If this is not the case, rotate the camera.



At the end of the test session, remove the wireless camera mask from the patient’s head before removing the battery from the camera.

2.4 USE WITH SYNAPSYS SOFTWARE

Once the connection with your wireless camera system is established, you will have access to the video signals, sensor measurements, and various functionalities within the chosen Synapsys software.

For the use of the wireless camera system with your software, please refer to the corresponding user manual.

2.5 USING BATTERY PACKS

Make sure your batteries are charged before use.

The charging state of the battery is indicated by the charger, and the charge level is indicated in the Synapsys software.

The charger indicates the state of charge of each battery inserted in it by an individual indicator light:

- Fixed light: the battery is fully charged.
- Flashing light: the battery is charging.



Please refer to Appendix 3 for the detailed use instruction and safety information of the charger.

Please refer to the user manual of the corresponding software to locate the display of the battery level.

3.MAINTENANCE

3.1 CAMERA

No maintenance is required for the camera unit. The camera lens can be repeatedly cleaned like a normal camera, i.e., with a soft cloth or a small special brush.

Warning: Do not clean the lens with liquids or aerosol.

3.2 HYGIENE FOAM

After each exam, it is necessary to check the cleanliness of the surface which was in contact with the patient. We strongly recommend that you have spare foams available to ensure optimal cleanliness. It is possible to clean the surface of the foams with disinfecting wipes for example.

Warning: Before cleaning, remove the camera unit from the mask.

Particular attention:

- Do not put the camera unit in contact with water;
- Do not expose the product to the sun for a long time;
- Do not put your fingers on the lens;
- Do not clean the mask with chemical products;
- Do not twist the mask.

4.TROUBLESHOOTING

In case of problems, please check:

- That your computer/device is turned on and connected to the correct Wi-Fi network.
- That there is no firewall or security program preventing data exchange over the Wi-Fi network.
- That your battery is charged.

Other common problems which may occur:

- The Synapsys wireless camera network does not appear:
reduce the distance to the transmitter and refresh the list of wireless networks on your computer. WNS is designed to operate over an obstacle-free distance of 10 m.
- No image:
 - Check that the batteries are charged.
 - Make sure the camera is powered correctly (i.e., battery well inserted) and that the infrared LEDs of your camera are not turned off (i.e., the scene is still illuminated when filming in darkness).
 - Verify there is no other computer connected to the same camera.

If the problem persists, please contact your dealer.

5.RESPONSIBILITIES

The manufacturer will be responsible for the results on the safety, reliability, and performance of the product only if it is used according to the instructions in this manual.

6.WARRANTY

This product is under warranty for two years, including the technical spare parts (excluding batteries) and labor cost under the condition that this product has been used in compliance with the notice. The consuming spare parts (i.e, hygiene foam and elastic bands) must be replaced regularly and are not under warranty.

The warranty is excluded in the following cases:

- Dismantlement or modification of the product without authorization of the manufacturer;
- Cleaning the mask with chemical products;
- Connection to a control system other than those distributed by Synapsys;
- Introduction of liquid or conductive particles into the camera unit.

7. TECHNICAL SPECIFICATIONS

Camera unit:

- Field of view: Horizontal: 100° Vertical: 55°
- Weight (without battery): 70 g

Image sensor:

- Cell type: CCD 1/3"
- Image resolution: 640(H)x480(V)
- Image framerate: 30 fps
- Consumption: 300 mA

Infrared light:

- Peak wavelength: 940 nm
- Maximum power received at eye: $P_{max} = 2 \text{ mW}$
- Light cone: 44 deg. per LED

Battery:

- Voltage: 3.7 V
- Capacity: 1200 mAh
- Battery life: Approximately 3 hrs
continuous operation at 25°C
for a new, fully-charged
battery
- Battery lifespan: > 500 cycles

Radio modules:

- Maximum emitted power: 15.1 dBm
- Operating frequency bands: 5150 – 5350 MHz
5470 – 5725 MHz

Applicable standards:

- IEC 60601-1 (General safety)
- IEC 60601-1-2 (EMC)
- IEC 62471
- ISO 10993-1
- FCC CFR 47 Part 15 Subpart B, C, E and Part 1 Subpart I (§1.1310)
- ETSI standards for the compliance to the RED Directive (2014/53/EU)

Classification:

- Electrical device Class II (Battery charger), Type B

Operating environment:

The device must be used in a room designed for medical examinations

- Temperature: 10°C to 35°C
- Humidity: 30% to 90%
- Pressure: 800 hPa to 1060 hPa

Storage and transport:

Please use the original packaging for transport and storage

- Storage temperature: -10°C to 55°C
- Humidity: 10% to 95%
- Pressure: 700 hPa to 1060 hPa

End-of-life equipment:

To respect the environment, we strongly recommend entrusting your velocimeter to an organization that can process devices containing electrical components.

Information about batteries:

Rechargeable batteries must not be disposed of with household waste. Please contact your local authority for information on where you can dispose of them.



APPENDIX 1: foam change procedure

The replacement of the foams can be easily done by following the instruction below. The care taken in this operation will ensure a good tightness of your VNS mask.

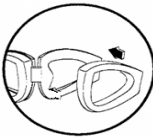
1. Removing the old foams

The glue used for the VNS foams is water-soluble. It is therefore sufficient to immerse the mask in lukewarm water for 15 minutes before removing the old foam.

WARNING: It is imperative to remove the camera unit from the mask before this operation!

2. Positioning new foams

Make sure that the mask is clean and dry, and locate the right and left eyepieces of the mask, as well as the corresponding foams. The foams will be glued in 2 steps: one side and the other.

Step	Picture	Description
1		Peel off half of the adhesive on the foam to facilitate its positioning on the mask
2		Apply in a first step on the external part
3		Remove the remaining adhesive and apply the foam along the contour by pressing on the front part of the foam

4		You should obtain a uniform result. Repeat the same steps for the second side Note: The foam must not protrude inside (see 3. Positioning check)
5		If the foam is misplaced, you could take it off and reposition it.

3. Positioning check:

	The foam should not protrude more than 1mm inside: this could interfere with the video recording.
	The foam should not protrude more than 3 mm outwards.

APPENDIX 2: EMC Manufacturer Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
Wireless camera is intended for use in the electromagnetic environment specified below. The user of wireless camera should ensure it is used in such an environment		
Emission Test	Conformity	Electromagnetic environment guidance
RF Emission CISPR 11	Class A, Group 1	Wireless camera 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
Harmonic distortion IEC 61000-3-2	Not applicable	
Fluctuations in voltage/emission (flicker) IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity – Input a.c. power port		
Wireless camera works with a battery and is not connected by cable.		
Immunity test	Test level IEC 60601	Electromagnetic environment – Notes
Electrical fast transient/Burst IEC 61000-4-4	Input supply access: ± 2 kV, 100 kHz repetition frequency I/O access: ± 2 kV, 100 kHz repetition frequency	
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common-mode	
Conducted RF	$3 V_{RMS}$, 0.15 MHz – 80 MHz	

IEC 61000-4-6	6 V_{RMS}, in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: $U_T = 0\%$, 0,5 cycle (0, 45, 90, 135, 180, 225, 270 et 315°) $U_T = 0\%$; 1 cycle and $U_T = 70\%$; 25/30 cycles Single phase: at 0° Voltage interruptions: $U_T = 0\%$, 250/300 cycles	
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity – Enclosure port		
Wireless camera is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment		
Immunity test	Test level IEC 60601	Electromagnetic environment – Notes
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV +/- 4 kV +/- 8 kV +/- 15 kV air	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz + spot frequencies according to table 9 of the standard	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz + spot frequencies according to table 9 of the standard	
Power frequency (50/60 Hz magnetic field) IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	

RF RADIATION EXPOSURE STATEMENT

This device conforms with the General population/uncontrolled environment exposure limits defined in § 1.1310 that are applicable to portable devices.

APPENDIX 3: Safety information and handling recommendations charger and batteries



Reminder about batteries

Lithium batteries provide a high energy density which is often combined with a high-rate capability. Due to excellent performance properties, Lithium batteries contain a certain safety risk. If short-circuited, heat and sometimes sparks may be generated. Mistreatment outside of the recommended limits can cause gas generation, leakage, and fire.

Synapsys will take **no responsibility** for any accident when the cell is used under **other conditions than those described in this document**.

Average Charge Time	between 1 hour & 1h30 for a full and optimized charge
Lifespan	around 2 & 3 years according to the observance of recommendations
Warranty	6 months (identified as disposable)

General Recommendations

- At the first use, let discharge completely your batteries for sustainable recharging. For this, please use the batteries installed in your product until it stops.
- To avoid premature weakening, let you use them till the complete discharging. After, please charge them, and once recharged, please take off them from the charger.

Before leaving your office, please remind yourself to unplug the charger and to remove all batteries from the charger compartments.

Safety Rules

The cell shall be charged within the range of specified temperatures: **0 - +30°C** maximum. If the battery is charged or stored at a temperature out of the **specified** range, **leakage, heat generation, or other damages** may occur. Please **use only use the specified charger and batteries** as shown in the next pages.

Repeated charging and discharging at high and low temperatures may cause degradation of cell performance even within the specified temperature range.

Caution: The battery used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F), or incinerate.

Replace your batteries only with Synapsys batteries provided for your device.

Recharge your batteries only using the charger provided by Synapsys.

Never disassemble the cells. Disassembling cells may cause an internal short circuit in the cell, which could further **cause gassing, fire, or other issues**.

An electrolyte that leaks out from the cells is harmful to the human body. If the electrolyte comes into contact with the skin, eyes, or other parts of the body, the electrolyte shall **be flushed immediately with fresh water. Seek medical advice from a physician.**

Never short circuit the cells. It causes the generation of very high currents resulting in heating of the cells, which may cause electrolyte **leakage, gassing, or fire**.

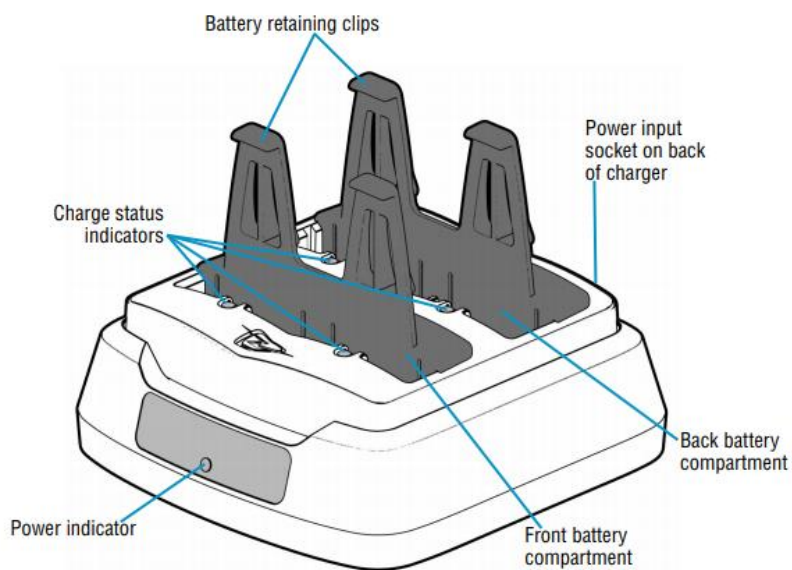
Never incinerate nor dispose of cells into the fire. The cells shall never be soaked with liquids such as water, seawater, drinks such as soft drinks, juices, coffee, or others.

Cells have a chance to be damaged during shipping by shocks, or other causes. If any abnormal features of the cells are found such as damage to a plastic envelope of the cell, deformation of the cell container, smell of electrolyte, an electrolyte leakage, or other abnormalities, the cells shall not **be used anymore**.

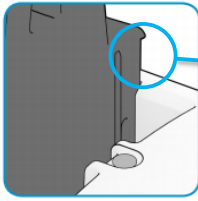
Cells with a smell of electrolyte or leakage shall be kept away from the fire to avoid **ignition**.

Dispose of used battery promptly according to current collection arrangements in your country. Keep away from children.

A3.1. THE CHARGER

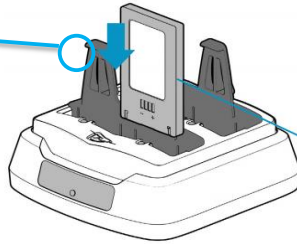


A3.2 INSERTION & REMOVAL OF THE BATTERY

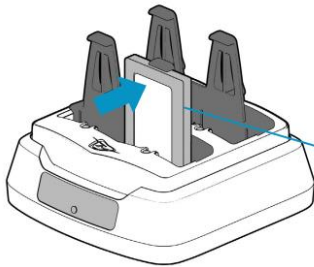


INSERTION

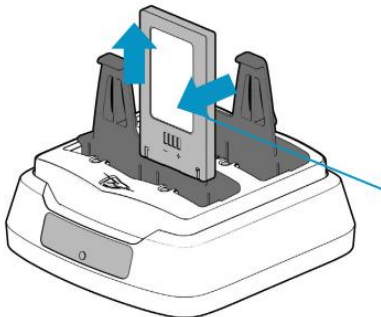
1. Insert into the first notch for EasyPack L



2. Slide battery in to compartment, gold contacts and label to the front.



3. Ensure battery hooks under battery retaining clip.



REMOVAL

1. To remove the battery, pull the top forwards towards the charge status indicator so that it is clear of the hook on the battery retaining clip. Lift the battery out of the charge compartment.
2. Pull the top of the battery forwards and lift the battery out of the compartment.

A3.4. MAINTENANCE & TROUBLESHOOTING

For trouble-free service observe the following precautions when using the Battery Charger:

- Do not store or use the 1136 Battery Charger in any location that is dusty, damp, or wet.
- Do not attempt to use any other power supply than the recommended ones.
- Do not attempt to charge other types of batteries.

Symptoms	Possible Cause	Action
The charger indicates a fault (fast flash)	The battery is too hot.	Leave the battery to cool down; the charger will automatically start to charge once the battery temperature falls.
		Move the charger to a cooler location.
	The battery is too cold.	Leave the battery to warm up; the charger will automatically start to charge once the battery temperature rises.
		Move the charger to a warmer location.
	The battery has a fault	Do not use the battery.
The charger indicates full charge (continuous indicator) after a short time	The battery is already charged.	Use the battery.
	The battery has a fault.	Do not use the battery.
The charge status indicator does not light when a battery is inserted	The charger is not powered.	Verify that the power supply is connected and powered. The blue power indicator on the front of the charger must be lit.

	The battery retaining clip is not in the correct location for the battery type.	Move the battery retaining clip to the correct location.
	The battery is not properly located.	Ensure the battery has been fully pushed into the compartment and is held by the hook on the battery retaining clip.
	The battery has a fault.	Do not use the battery.

