CONDOR INSTRUMENTS

ACTLUMUS - USER MANUAL

Model: AL0101

ActStudio v2.2.2

Condor Instruments Ltda

01/11/2024

Index

Introduction

Before using the device, please read the entire manual.

Indications for use

ActLumus is an ultra-compact and lightweight monitor of activity, temperature and ambient pulse light that can be used to analyse circadian rhythms, automatically collect and store data for sleep parameters, and evaluate activity in any instance where quantifiable analysis of physical motion is desired. The device is intended to monitor limb or body movements during daily life and sleep.

Contraindications

There are no contraindications to the use of the device.

Adverse effects

Patients should tell their doctor and discontinue use immediately in case they experience itching or irritation in the skin contact area of the device.

Maintenance

Sterilization is not required for any part of the product.

PRECAUTIONS

Inspections and repairs should only be carried out by an authorised agent. Under no circumstances should you attempt to open, or personally repair or maintain the device.

This product must be inspected by an authorized Condor service centre five years after the date of manufacture. Prior to this, the device is intended to provide safe and reliable operation provided that its use and maintenance complies with the instructions provided by Condor. Details regarding the applicable Condor warranty are provided with the device from your original purchase. Obviously, like all electrical devices, you should be careful and request inspection of the device at a Condor authorized service centre if you detect anomalies in it.

General Warnings and Precautions

Notices

A warning for the possibility of bodily injury.

- Before using the device, read the manual in its entirety.
- The device and accessories should only be used for the purpose for which they are intended.
- Use only original and Condor approved accessories and parts.

Additional equipment connected to electrical medical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations must meet the requirements for electrical medical systems (see IEC 60601-1-1 or clause 16 of the 3rd ed. of IEC 60601-1, respectively). Anyone who connects additional equipment to electrical medical equipment configures a medical system and is therefore responsible for the system meeting the requirements for electrical medical systems. Attention is drawn to the fact that local legislation has precedence over the above-mentioned requirements. If in doubt, consult your local representative or technical assistance department.

WARNING: The use of this adjacent equipment or other equipment should be avoided, as it may result in improper operation, if this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally

WARNING: The use of accessories, transducers and cables other than those specified or supplied by the MANUFACTURER of this equipment could result in high electromagnetic emissions or reduced electromagnetic immunity from this equipment and result in improper operation

WARNING: Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the (EQUIPMENT IN OR IN SYSTEM), including cables specified by the MANUFACTURER, otherwise performance degradation of this equipment may occur

Notifications

- Condor Instruments and ActLumus are trademarks and therefore subject to applicable copyright laws and regulations.
- This product is manufactured by:
  Condor Instruments Ltda - EPP
  Av Lineu Prestes, 2242
  IPEN - CIETEC
  Prédio D-4; Sala 10
  Butantã
  São Paulo - SP
  CEP 05508-000
  Brazil

Note

The EMISSION characteristics of this equipment make it suitable for use in industrial areas and hospitals (ABNT NBR IECICISPR 11 class A), if used in a residential environment (for which ABNT N8R IEC/CISPR 11 class B is normally required), this equipment may not offer adequate protection for radio frequency communication services, The user may need to take mitigation measures, such as relocating or reorienting the equipment,

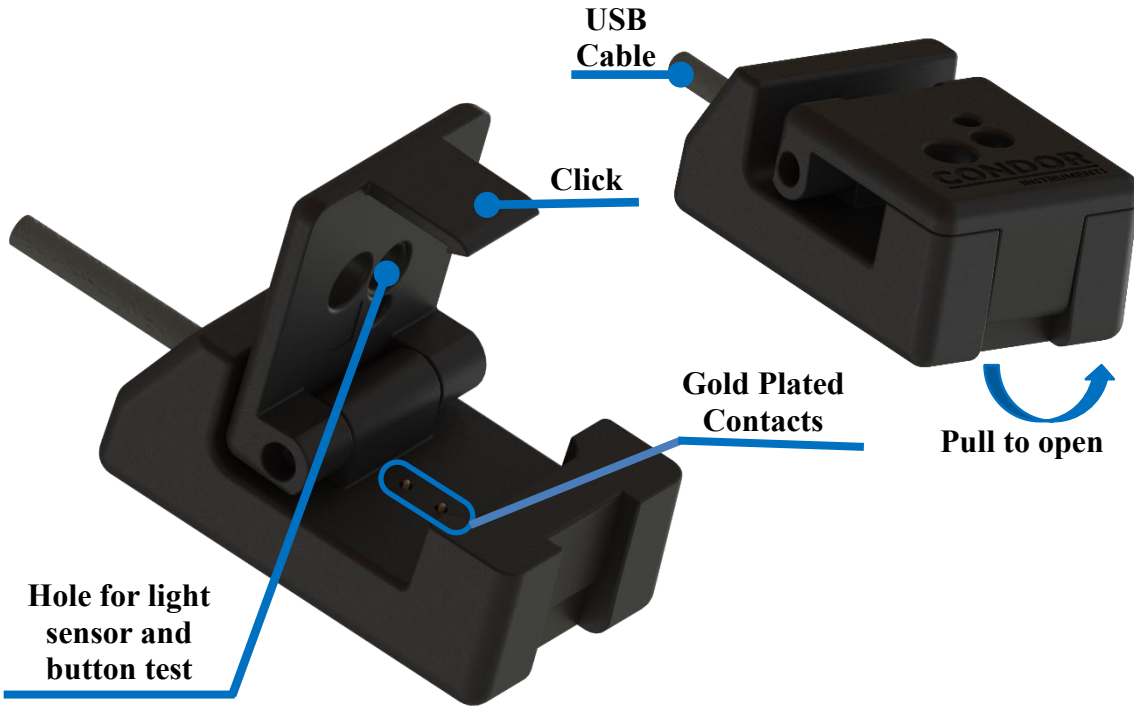
Training and qualification

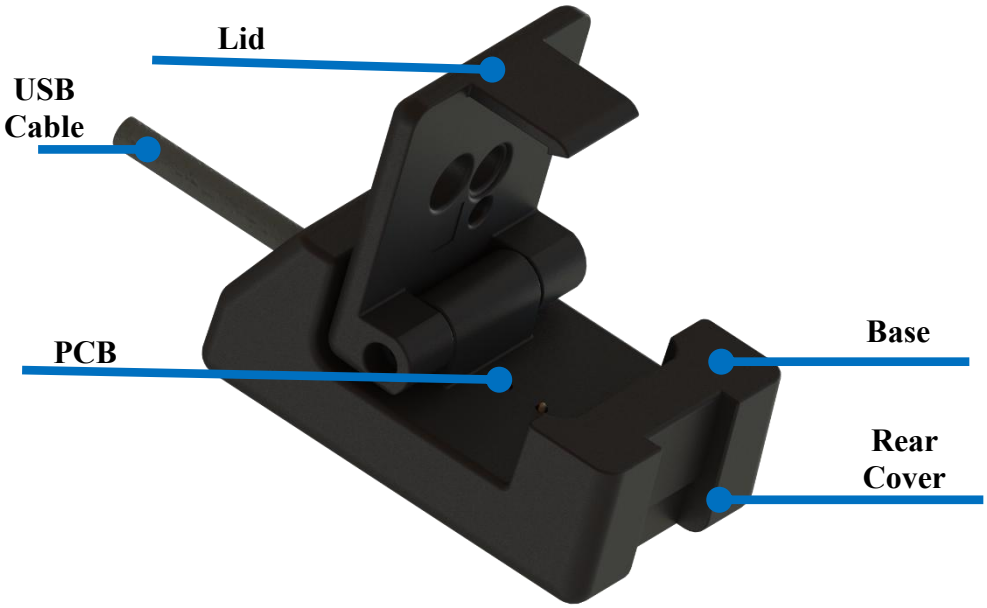
Any operator must have read the manual and have the necessary computer skills to configure the devices

Analyses should only be carried out by persons qualified to do so

ActDock Lumus (ADL0101)

Description and Functionality





The ActDock Lumus (a USB/Bluetooth adapter) consists of five parts, Lid, Base, Rear Cover, PCB and USB cable. This accessory is intended to adapt the USB pins in ActLumus to a normal USB connector as well as enable the Bluetooth connection of the ActLumus to the computer.

Maintenance and Cleaning

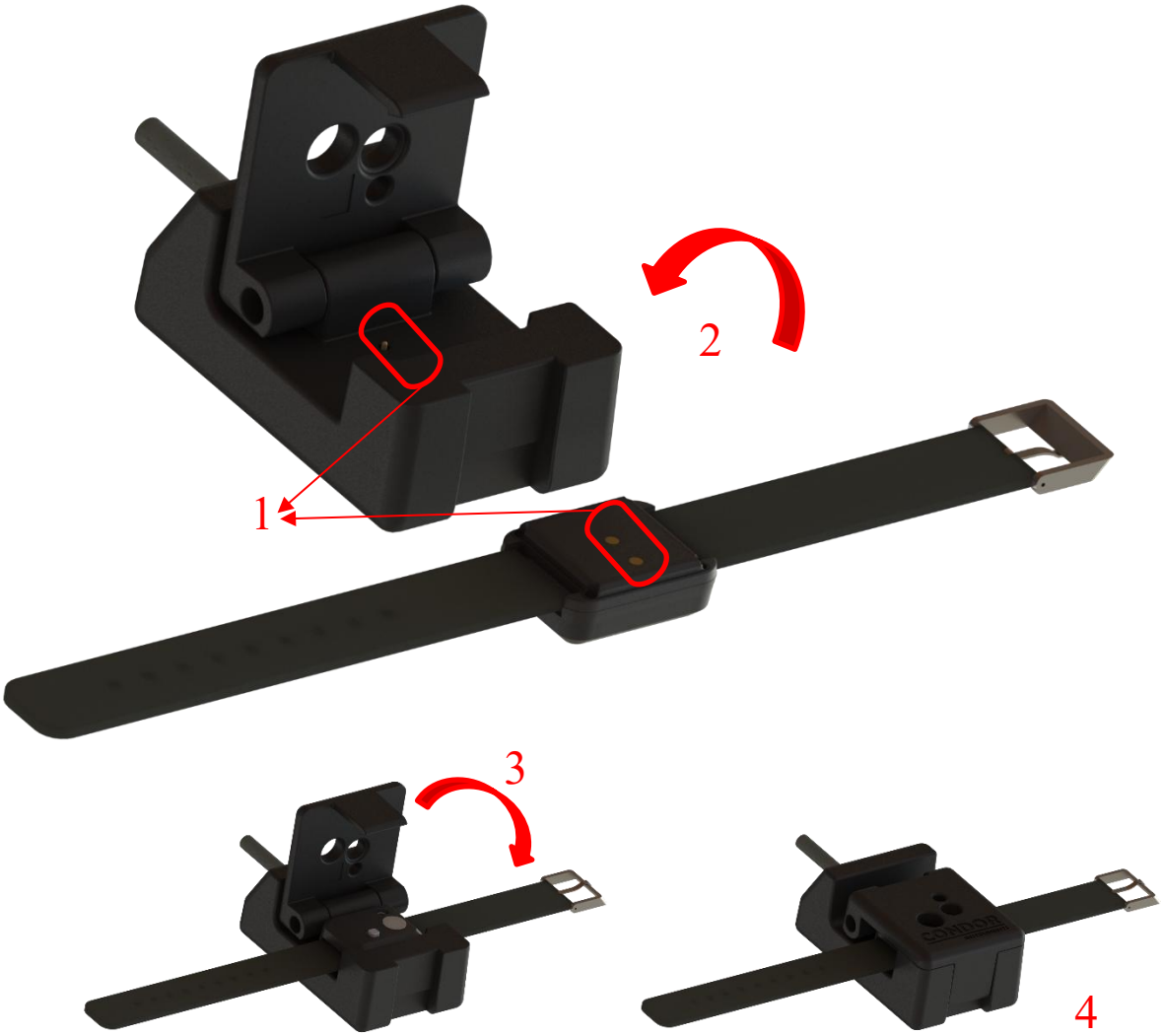
- Clean with damp cloth and mild soap.

Notes:

- Avoid contact with gasoline, benzene, thinner or acetone and, in case of contact with one of these substances, clean with damp cloth and neutral soap as soon as possible.
- Do not use abrasive or highly alkaline products (e.g., saponaceous or ammonia-based cleaning products).
- Do not use Isopropanol or Butyl cellulose on any of the dock surfaces.

Av Lineu Prestes, 2242 – IPEN – CIETEC – Prédio D-4 – Sala 10 – Butantã – São Paulo – SP – CEP 05508-0000 – Brazil

Using ActDock Lumus



1. Ensure that the gold pins of both the dock and the device are aligned as shown in the figure.

2. Rotate ActLumus to fit it into the dock.

3. Close the dock and press until the click locks.

ActLumus (AL0101)

Description and Functionality

ActLumus is a Device whose function is to use activity data, skin temperature and exposure to light. It is intended to be used in one of the limbs to hurt the sleep parameters needed to assess sleep quality and sleep disorders. Require one of the ActDock Lumus accessories to extract the data.

Maintenance and Cleaning

- Wash only with warm water and mild soap.
- Always wash the device when it has contact with salt water.
- Whenever ActLumus is to be stored for a while, put it to “Power Down” mode.
- Do not leave ActLumus for long periods with the battery fully discharged. This can lead to a reduction in the device’s service life.
- **If the device is stored for long periods of time, make sure you fully charge it at least every three (03) months**.

Notes:

- Avoid contact with gasoline, benzene, thinner, or acetone. If the device comes into contact with any of these substances, clean it immediately with a damp cloth and neutral soap.
- Do not use abrasive or highly alkaline cleaning products (e.g., soaps or ammonia-based cleaners).
- Avoid using Isopropanol or Butyl cellulose on any surface of the ActLumus.
- **Do not use ActLumus while swimming or diving**.

Software ActStudio

ActStudio software is used to extract, export, and analyse ActLumus data. It has 3 main menus as explained below. Please note that this manual was written based on the version of ActStudio found on the cover of this manual and some features described here may not be available in earlier versions

Installation

This software does not require any installation. It can run from thumb drives or any other form of external drive or from the computer itself.

Windows

To run the program just unzip it in the preference folder and run the EXE file.

macOS

Since our software isn't available on the Apple Store, you may encounter an error message when trying to open ActStudio: **"cannot be opened because the developer cannot be identified."** Here's how to bypass this and open the software on your Mac:

1. **Locate the software in Finder**: You should find it in your **Downloads** folder.
2. **Control-click the software**: Hold the **Control** key, click the app icon, and select **"Open"** from the menu. A similar security message will appear, but this time, there should be an option to **"Open"** at the bottom of the dialog box. Click **"Open"** to confirm.

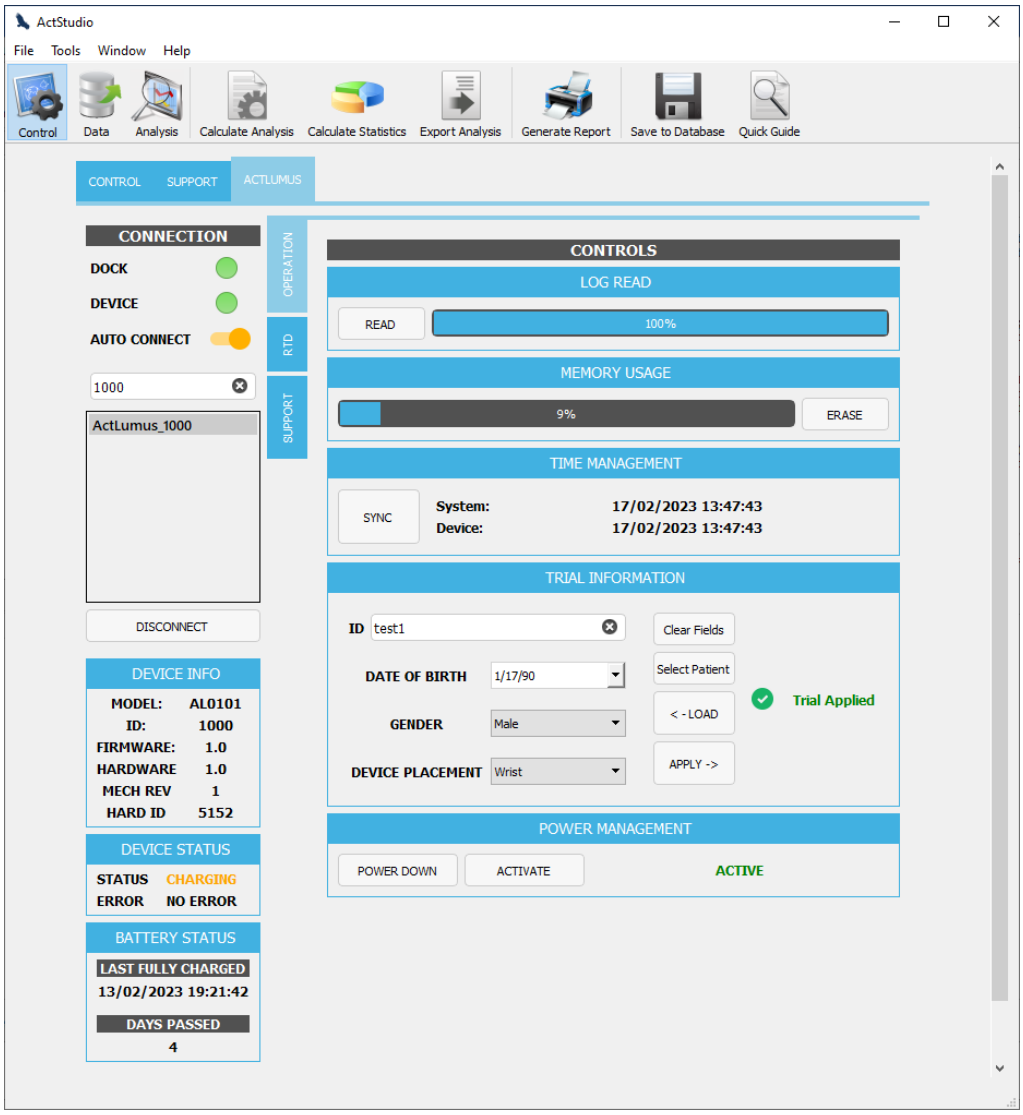
If this doesn't work, you can adjust your security settings:

1. Open **System Preferences** by clicking the Apple menu in the top-left corner, then select **System Preferences > Security & Privacy**.
2. In the **General** tab, click the padlock icon at the bottom left and enter your password to unlock the settings.
3. You should see a message about the app under **"Allow apps downloaded from"**. Click **"Open Anyway"** next to it.

This process is standard for software downloaded outside the Apple Store.

Av Lineu Prestes, 2242 – IPEN – CIETEC – Prédio D-4 – Sala 10 – Butantã – São Paulo – SP – CEP 05508-0000 – Brazil

Control Menu

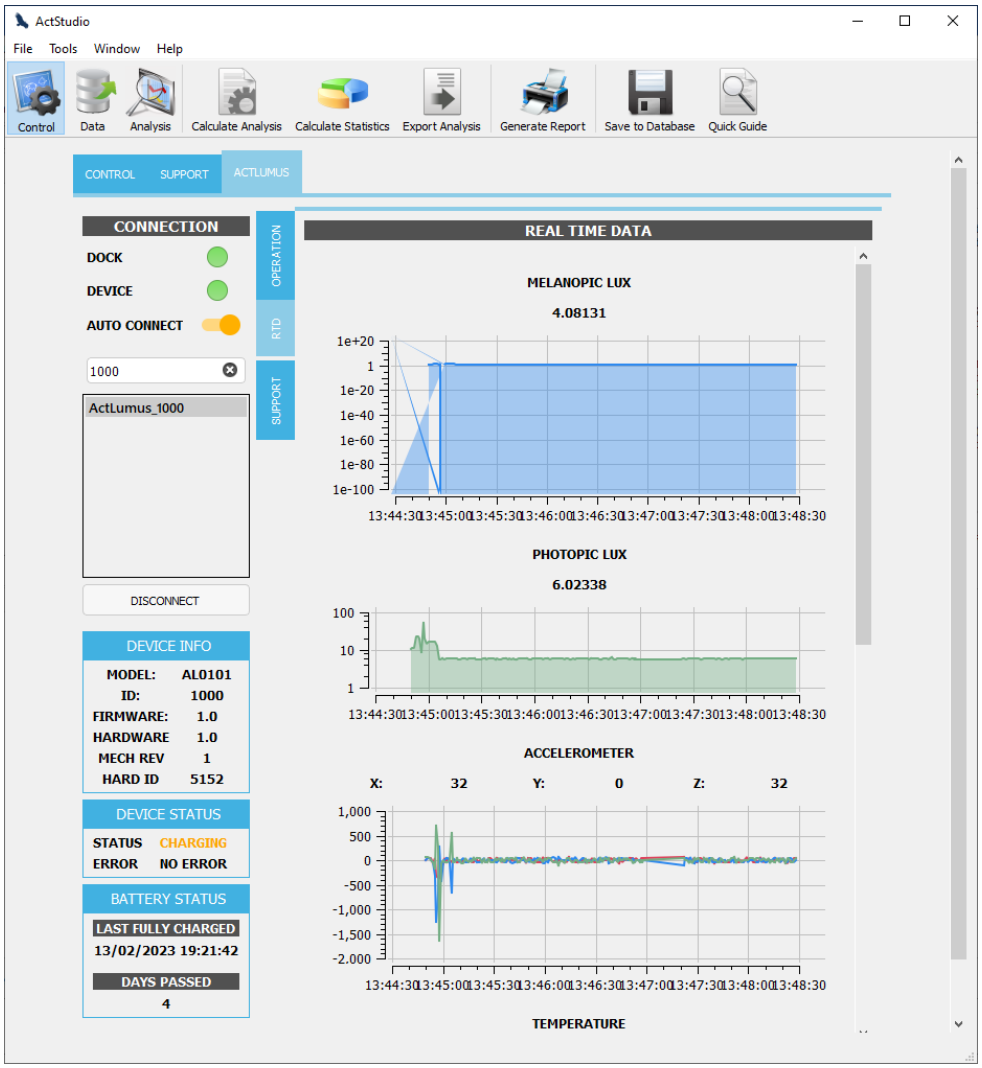


CONNECTION	
DOCK	Represents dock connection state
DEVICE	Represents device connection
AUTO CONNECT	Enables the software to connect to some device automatically. If the user enters a number on the editable line bellow, the software will connect only to the device that has the ID entered.
DEVICE LIST	List just below the editable line that lists the available devices to connect to. By double-clicking on a list item, the software will attempt to connect to the chosen device.
DISCONNECT	Button to disconnect from a connected device.
DEVICE INFO	Connected device information: MODEL: Model ID: Device ID FIRMWARE: Firmware Version

	HARDWARE: Hardware Version MECH REV: Mechanical Review HARD ID: Device Hardware ID
DEVICE STATUS	Connected device status: STATUS: Battery Status ERROR: Device Error
BATTERY STATUS	Connected device battery status: LAST FULLY CHARGED: date of the last full charge DAYS PASSED: days since the last full charge

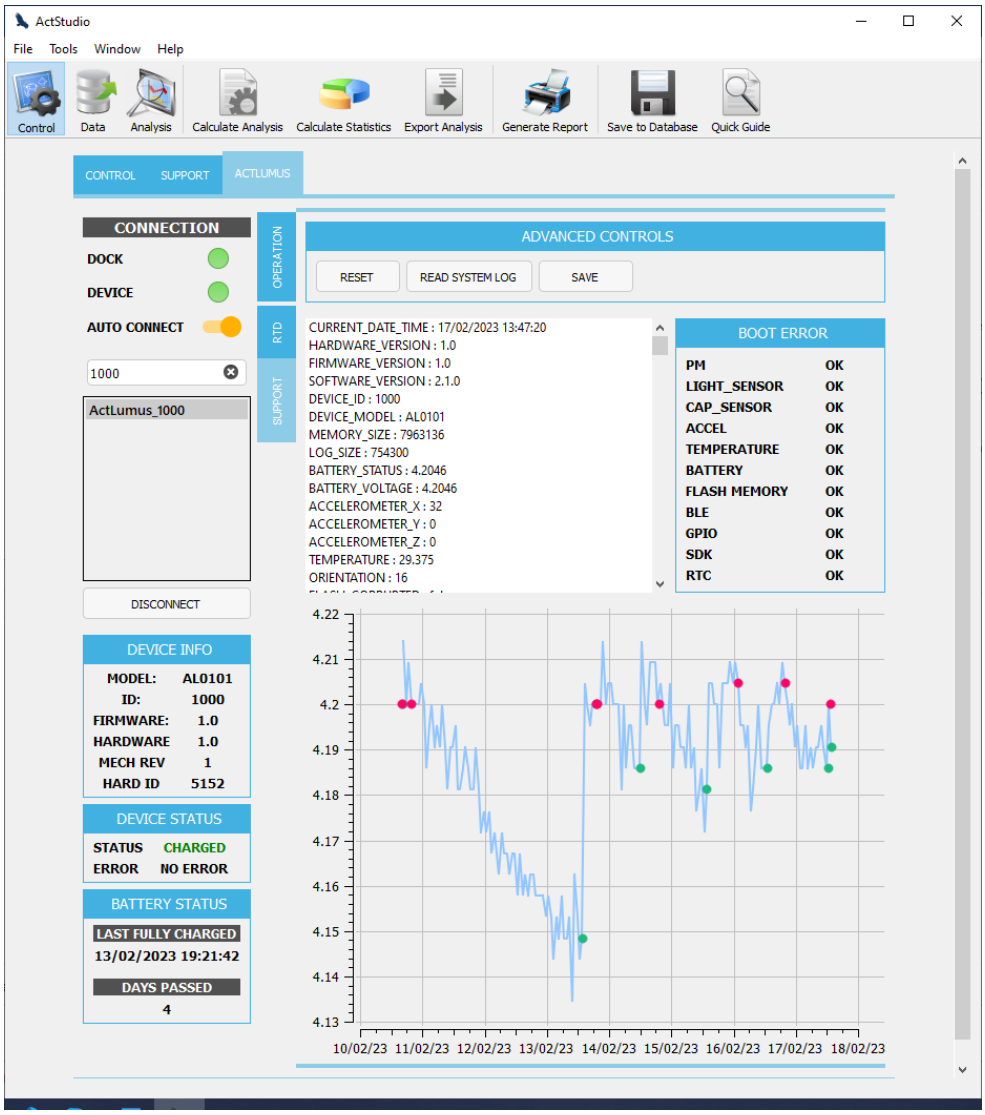
CONTROLS	
READ	Button to read the data stored on the connected device.
MEMORY USAGE	Percentage of the memory used from the connected device.
ERASE	Erases internal memory from the connected device.
SYNC	Synchronizes the device time with the system time.
TRIAL INFORMATION	ID: patient's identification DATE OF BIRTH: patient's date of birth GENDER: patient's gender DEVICE PLACEMENT: Where the device is placed on the patient.
Clear Fields	Clear the Trial information fields.
Select Patient	Select a patient from the database to fill the Trial Information fields.
LOAD	Loads the information from the connected device to fill the Trial Information fields.
APPLY	Apply the current Trial Information fields to the device.
POWER DOWN	The connected device will enter low-power mode when it is disconnected and removed from the dock
ACTIVATE	Activates the connected device.

Real Time Data Tab



REAL TIME SENSORS	
Real-time data from those collected by the sensors of the connected device.	
MELANOPIC LUX	Melanopic Lux Measurement
PHOTOPIC LUX	Photopic Lux Measurement
ACCELEROMETER	Accelerometer measurement
TEMPERATURE	Temperature sensor measurement
BATTERY VOLTAGE	Measurement of the voltage of the device's internal battery
CAPACITIVE SENSOR	Measurement of capacitive sensor

Support Tab



SUPPORT	
RESET	Reinitializes connected device.
READ SYSTEM LOG	Boots reading the system logs of the connected device.
SAVE	Saves the system log to a text file.
BOOT ERROR	Reports if there were any errors at the time of device startup on any of the system components.
SYSTEM LOG	Text box below the READ SYSTEM LOG button. Contains system logs read from device memory
BATTERY	Graph with battery voltage stored in logs.

Specifications

General Specifications	
Weight Without Bracelet	12g
Weight With Bracelet	31g
Dimensions	33,5 mm x 26,5 mm x 13mm
Environmental conditions	• Operating conditions: 0°C to 50°C (32 °F to 122 °F) • Storage Temperature: -20 °C to 50 °C (-4 °F to 122 °F) • Operating Pressure, Storage and Transportation: 480 to 780mmHg • Operating Humidity, Storage and Transportation: 10 to 90%
Memory	8MB
Sampling Time	1 month (60s sampling interval)
Battery Time	1 month (60s sampling interval)
Battery type	Rechargeable Li-ion
Tightness	IP67
Sampling Interval	60s
Sensors	Accelerometer Skin temperature Spectral Light + Photon + Melanopic Off-Wrist
Communication	Bluetooth
Activity logging modes	PIM, TAT e ZCM
Electromagnetic compatibility	The product meets all applicable electromagnetic compatibility (EMC) requirements in accordance with IEC60601-1-2 for home, commercial, and light industry environments. For more details see "Manufacturer's Guide and Statement — Immunity and Electromagnetic Emissions."
Power voltage	3,7V c.c.

Accelerometer	
Axes	3
Resolution	12 bits
Sampling Rate	25Hz

Temperature Sensors	
Precision	+/-0.5°C (20°C to 40°C)/ 1°C For other values
Operating Range	**0°C – 70°C**

Light Sensor	
Spectrum	**Photopic, Melanopic and Spectral**
Observations	**It takes the intensity of each of the 10 channels and makes a combination to get melanopic, photopic and total light.**
Operating interval	**1 – 100.000 Lux**
Precision	**10% to 1,000 Lux (typical)**

Notes:

- *The manufacturer reserves the right to change these specifications without prior notice*

Applicable Standards

Pattern	Description
IEC60601-1:2006	Electrical medical equipment - Part 1: General requirements for basic safety and essential performance.
IEC60601-1-2:2014	Electrical medical equipment - Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests.
IEC60601-1-11:2010	Electrical medical equipment – Part 1-11: Collateral standard: Requirements for electrical medical equipment and electrical medical health systems used at home.

Manufacturer's guide and statement — Immunity and electromagnetic emissions

Medical electrical equipment requires special precautions regarding the Electromagnetic Compatibility (CEM) and needs to be installed and put into operation according to the information regarding the EMC contained in this document.

Guide and Manufacturer's Declaration - Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. It is advisable that the purchaser or user of the device ensures that it is used in such an environment.

Emissions test	Adhesion	Electromagnetic environment - guide
RF emissions (Radio frequency) CISPR11	Group 1	The device only uses radio frequency energy for its inner workings. For this reason, RF emissions are very low and are unlikely to cause interference to electronic equipment in their vicinity.
RF emissions (Radio frequency) CISPR11	Class B	The device is suitable for use in all locations, including homes and locations connected directly to the low-voltage public network that provides power to
Harmonic emissions IEC 61000-3-2	Does not apply	Domestic purposes.
Fluctuations in voltage/ Emissions with jitter IEC 61000-3-3	Accordingly	

Guide and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. It is advisable that the purchaser or user of the device ensures that it is used in such an environment.

Immunity test	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment - guide
Electrostatic Discharge (DES) IEC 61000-4-2	± 8 kV Per contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Via or	± 8 kV Per contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Via or	The floors should be made of wood, concrete or ceramic. If the floors are covered by synthetic material, the relative humidity should be at least 30%.
Fast/salvac electrical transients IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Does not apply	The device is charged via computer and is not directly subject to the power supply network
Outbreaks IEC 61000-4-5	± 1 kV line(s) the line(s) ± 2 kV line(s) solo	Does not apply	The device is charged via computer and is not directly subject to the power supply network
Voltage outages, short interruptions and voltage variations in the input lines of the power supply IEC 61000-4-11	<5% Ut (>95% drop in Ut) during 0.5 cycle 40% Ut (60% drop in Ut) for 5 cycles 70% Ut (30% drop in Ut) for 25 cycles <5% Ut (>95% drop in Ut) during 5	Does not apply	The device is charged via computer and is not directly subject to the power supply network
Magnetic field generated by the frequency of the electrical network (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields in the frequency of the power supply network should have levels characteristic of a typical location in a typical hospital or commercial environment.

NOTE 1: Ut is the voltage of alternating current before applying the t level

Guide and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. It is advisable that the purchaser or user of the device ensures that it is used in such an environment.

Immunity test	**Test level IEC 60601-1-2**	**Compliance level**	**Electromagnetic environment - guide**
			Mobile or portable RF communication equipment should not be used at smaller distances from any part of the device, including cables, than the recommended separation distance calculated by the equation applicable to the transmitter frequency. **Recommended separation distance**
RF driven IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1.17 √P
Irradiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	d = 0,35 √P 80 MHz to 800 MHz d = 0,70 √P 800 MHz to 2.5 GHz Where *P* is the maximum declared level of transmitter output power in Watts (W) according to the transmitter manufacturer *and d is* the recommended separation distance in meters (m). The field intensity from fixed RF transmitters, determined by an electromagnetic survey of field [a], is less than the compliance level for each frequency range Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the highest frequency range is applicable.
NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

a - The field intensity of fixed transmitters, such as base stations for radio phones (cellular /wireless), terrestrial mobile radios, amateur radio, broadcasting broadcasts (AM and FM) and television, cannot, in theory, be accurately predicted. To evaluate the electromagnetic environment caused by fixed RF transmitters, an electromagnetic inspection of the site should be carried out. If the field strength value at the location where the device is being used exceeds the applicable RF compliance level mentioned above, the device should be checked for proper operation. If unusual performance is observed, additional measures may be required, such as changing the position or installation location of the device.

[b] - In the frequency range between 150 kHz and 80 MHz, the field intensity should be less than 10 V/m.

Guide and Manufacturer's Statement - RF Immunity

Test frequency [MHz]	Band [MHz]	Service	Modulation	Maximum power [W]	Distance [m]	Immunity test level (V/m)
385	380-390	TETRA 400	18Hz pulse modulation	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1kHz sine	2	0,3	28
710 745 7480	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Banda LTE 5	Pulse modulation 18 Hz	2	0,3	28
1720 1845 1970	1700 -1990	GSM 1800; CDMA 1900; GSM 1900; DECT; Banda LTE 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, Banda LTE 7	Pulse modulation 217 Hz	2	0,3	28
5240 **5500** **5785**	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which RF irradiation disturbances are controlled. The purchaser or user of the device can help prevent electromagnetic interference by keeping the minimum distance between mobile or portable RF communications equipment (transmitters) and the device, as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to transmitter frequency (m)		
Maximum rated transmitter output power (W)	150 kHz to 80 MHz d = 1,17 √P	80 MHz to 800 MHz d = 0,35 √P	800 MHz to 2.5 GHz d = 0,7 √P
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,7
10	3,70	1,11	2,21
100	11,70	3,50	7,0

For transmitters whose maximum output power is not indicated above, the *recommended separation distance d* in meters (m) can be determined using the equation applicable to the transmitter frequency, *where P* is the maximum output power of the transmitter in Watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance is applicable for the highest frequency range.
NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

Essential Performance

Within normal operation the ActLumus equipment must show the accelerometer, light sensor and temperature sensors every 1 (one) minute and should store the collected data within its non-volatile flash memory.

Failures related to Electromagnetic Disturbances

In case the device suffers a failure related to electromagnetic disturbances it is expected that the device will present loss of data associated with reset events.

Environmental information

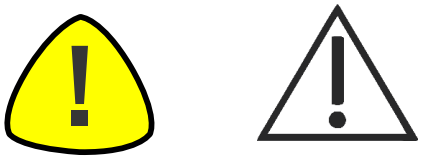
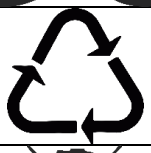
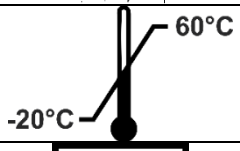
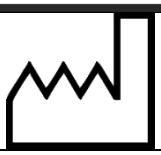
This device must be disposed of in accordance with the laws and regulations of the country in which the disposal takes place. For more information on product disposal, please contact your Condor representative or specialist distributor in your area or visit our website at www.condorinst.com.

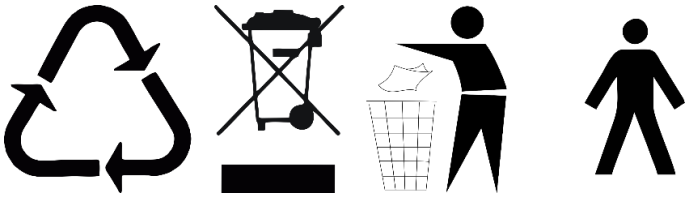
Maintenance Related to Electromagnetic Perturbations

The Device does not require any maintenance related to electromagnetic disturbances during its expected service life.

Av Lineu Prestes, 2242 – IPEN – CIETEC – Prédio D-4 – Sala 10 – Butantã – São Paulo – SP – CEP 05508-0000 – Brazil

Symbology

	General warning symbol
	Operating instructions
	Recyclable Material
	WEEE - Directive for disposal of electrical or electronic material
	Play in Proper Receptacle
	Temperature Limits
	Applied Part Type BF
	Manufacturing Lot
	Year of Manufacture



Manufactured by Condor Instruments Ltda EPP

Av Lineu Prestes, 2242 –

IPEN – CIETEC – Prédio D-4 – Sala 10

Butantã – São Paulo – SP – Brazil

EU-Declaration of Conformity

The product

Type Reference, Description:	ActLumus – Wrist Actimeter
Design layouts:	ActLumus
Model numbers:	AL0101
Manufacturer:	Condor Instruments Ltda. - EPP, Rua Prof. Tulio Ascarelli. 290, 05449-020 São Paulo - SP, Brazil

to which this declaration relates is in conformity with the directive 2014/30/EU relating to electromagnetic compatibility, the directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits. The requirements and the following standard(s) or normative document(s) are fulfilled:

IEC 60601-1-2:2014	Medical electrical requirement Part1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

The conformity assessment for the Bluetooth complies with the essential requirements and other relevant provisions of Radio Equipment Directive (RED) 2014/53/EU and with the Directive 2011/65/EU (EU RoHS 2) and its amendment Directive (EU) 2015/863 (EU RoHS 3).

EN 62368-1:2014+A11:2017	Audio/video, information and communication technology equipment - Part 1: Safety requirements.
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz).
EN 301 489-1 V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU.
EN 301 489-17 V3.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU.
EN 300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum.

Date of issue: São Paulo (Brazil) 01/01/2024

Valid Until: 01/01/2027

The sole responsibility to issue this declaration of conformity is taken by the manufacturer.

Authorised Signature:

Managing Director/ Chief Financial Officer