

Instruction for use

Electronic Terminal Device
for Upper Limb Prosthesis

Atri**EX**

Ver. 2.1
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Instructions for use

Please take the time to follow the instructions in this owner's guide carefully. It will help you set up and operate your system properly and enjoy its advanced features. Please save this guide for future reference.

Overview

Thank you for purchasing the Vispala® AtriEX Electronic Terminal Device for Upper Limb Prosthesis. AtriEX can perform challenging tasks with ease using EMG sensors.

Features

- Five finger movement.
- Robust metallic body.
- Rechargeable Lithium-ion battery provides hours of AtriEX performance.
- Protect electronic components against accidental splash.
- Easy to control.
- Low cost of maintenance and ownership.



Intended use

The Vispala® AtriEX Electronic Terminal Device is intended as a part of a prosthetic system that replaces the function of a missing upper limb. Fitment of the device should be mandatorily under the supervision of qualified CPOs (Certified Prosthetist and Orthotist) only.

Contraindications

Not known.

Unpacking

Check the carton for the Vispala® AtriEX Electronic Terminal Device, EMG Sensors, Charging cable, Battery pack, and USB cable. Be sure to save all of the packing materials. These provide the safest means for any necessary shipping or transporting.

If any part of the product appears to be damaged, do not attempt to use it. Contact Vispala's authorized representative immediately or call Vispala Technologies Customer Service. For contact information, refer to the contact list at the end of this guide.



Inside the box

1. AtriEX Electronic Terminal Device.
2. AtriEX friction wrist unit.
3. AtriEX Lithium-ion battery pack.
4. Realistic silicone prosthetic glove.
5. EMG Sensor 2 Nos.
6. AtriEX Charging Adaptor.
7. USB C-Type cable 1 No.

Setup

Connecting to AC power

Before using your Vispala® AtriEX Electronic Terminal Device the first time, connect it to AC (mains) power and charge the battery. You can connect the power supply cable to the charging cradle. Use the given USB cable and charger to charge the Terminal device.

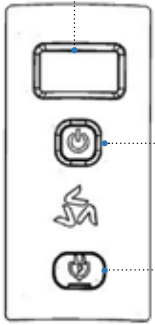
Caution: Avoid using the device while charging.

- Plug the power supply into a live AC (mains) outlet.
- The LED display shows the charging and Battery status.

Control buttons

The control buttons of your terminal device are located on the top of the AtriEX Terminal Device Battery Pack.

AtriEX Terminal Device

	1	Charging port	The USB port will allow you to charge the device using any standard 5V 2.5A mobile charger.
	2	Power On/Off	Push power switch to on/off the device.
	3	LED Display	The interactive display will help to understand battery level & charging indication of the TD.

Technical information

AtriEX Terminal Device

Weight	320 gms
Dimension (in mm)	141 X 66 X78
Battery Dimension (in mm)	65 X 36X18
Compatible glove	Silicone
Operating voltage	7.4V
Max. charging voltage	5.2V
Battery capacity	1000 mAH
Battery charge time	4-5 Hrs
Battery weight	70 gms
Maximum opening	90 mm
Wrist type	Friction; 350 D rotation
Waterproofing	Dust and Splash
Overall carry load	14Kgs
Operating temp	0-50°C
Pinch Force	40N

EMG SENSOR

Technical information

Mains Power Supply	50Hz - 60Hz
Power Supply	3.3V - 5V
Frequency Bandwidth	90-450Hz
Material	Silver

Maintenance and Care

Safety precautions when using your Vispala AtriEX Hand Prosthesis.

- ⚠ Contact your clinician or Vispala customer service team if something is wrong with your prosthetic hand.
- ⚠ Do not try to repair or modify the hand yourself.
- ⚠ Dismantling of your AtriEX beyond removal of defined user replaceable components by anyone not authorised by Vispala Technologies will invalidate the warranty of your device.
- ⚠ Do not expose the hand to hazards that would injure a natural hand, for example:
 - Heavy impact
 - Rapid vibration
 - Explosions
 - Corrosive chemicals
 - Dangerous machinery
 - Make sure the hand is turned off before you attach or remove it from the socket

- ⚠ Do not use your Vispala AtriEX Hand Prosthesis in a way that could cause a safety hazard.
- ⚠ Do not use your Vispala AtriEX Hand Prosthesis for holding anything that could cause harm if dropped, such as a heavy or fragile object or container holding a hazardous substance.
- ⚠ Do not rely solely on your Vispala AtriEX Hand Prosthesis to support your weight, or as the primary means to prevent a fall.
- ⚠ Do not use your Vispala AtriEX Hand Prosthesis where a flammable liquid or gas is present.
- ⚠ Avoid mud, oils, and other kinds of dirt that could stain or discolour the hand. If you need to use the hand in these environments, you should wear company-provided gloves or wash the hand as soon as possible afterward.
- ⚠ Use your Vispala AtriEX Hand Prosthesis carefully to avoid injuring people or damaging objects.
- ⚠ The use of a prosthetic arm can cause body strain, discomfort, or irritate the residual limb. Talk to your clinician if your Vispala AtriEX Hand Prosthesis is causing pain or discomfort.
- ⚠ Keep your Vispala AtriEX Hand Prosthesis away from naked flames or anything hot enough to burn human skin.
- ⚠ Keep your Vispala AtriEX Hand Prosthesis clear of any live electrical wiring.
- ⚠ Take care when using your Vispala AtriEX Hand Prosthesis to avoid pinching skin, injuring people, or damaging objects.
- ⚠ If your hand is broken or shows visible signs of damage, please contact your Clinician for repair options.

⚠ Before use, check for any visible electrode damage, particularly the Silver contacts.

⚠ The electrode should be placed against undamaged skin, avoiding scarred or unhealed areas.

⚠ Do not disassemble the electrode

⚠ Do not immerse the electrode in water

⚠ Do not expose the electrode to a naked flame or excessive heat.

⚠ The Silver contacts can be easily damaged and must be handled with care. The Silver contacts must not be placed face down.

Battery care

If treated correctly, the AtriEX Battery will offer excellent performance.

Treating the battery well means:

- Avoid complete discharge of batteries.
- Charge the battery before storing it for long periods.

Battery warnings

⚠ Do not expose the battery to naked flames or temperatures above 50 C.

⚠ Do not bend, pierce, or damage the case of the battery.

⚠ Do not change or short circuit the battery wires. If your battery is leaking or you notice fluid on your socket contact your clinician immediately for repair and cleaning.

⚠ Stop using your hand immediately if you notice that the battery is swollen or unusually hot.

⚠ Contact your clinician for a replacement battery

Limited warranty

The warranty for the AtriEX, excluding the battery and silicone cover is two years. The warranty for the battery and silicone cover is for 6 months and 3 months respectively. Warranty covers design and manufacturing issues only.

Where a claim is made under warranty by your provider on your behalf, this claim must be supported by appropriate documentation. You may be asked by your provider to take photographs of any failed products if applicable, please do not send faulty batteries back to Vispala.

The warranty will be void on all system components if any components have been subject to abuse, modification, neglect, deliberate or accidental damage, loads beyond those for which the product was designed, or repair or maintenance by an uncertified person.

The design and manufacture of Vispala equipment and components are subject to a policy of continuous reappraisal. The company, therefore, reserves the right to introduce changes and withdraw products without notice.

The service life of the AtriEX is five years. Outside of this, your prosthetist should contact their local Vispala representative for possibilities regarding service and repair.

Warranty Registration

Register this device's warranty using the QR code shown below. Failure to register will affect your limited warranty rights.



Contact us

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India

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Quality Assurance

Vispala operate a Indian Medical Device Compliance Authority approved quality management system and fully complies with the requirements of ISO 13485:2016.

This certifies that Vispala meet the appropriate international quality standards for the design, manufacture and supply of prosthetic products.

Test Certification

The device and its associated components listed within this document have been tested and certified to the following standard and requirements:

IEC 60601-1:2005, AMD:2012
IEC 60601-1-2:2014