Instruction for use for **Aether Battery System AET-BAT-BS1**

For Qualified Personnel / Users

Version 4.0 / 2025.03.20

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Introductory information

Intended use

The Aether Battery System [AET-BAT-BS1] is intended to provide electrical power to the prosthesis and its components.

Indication for use

The Aether Battery System is intended for use with an upper-limb prosthesis.

Condition of use

This product was developed for everyday use to provide power for prosthetic hand devices.
This product is intended for use on one patient only.

Contraindication

The Aether battery system cannot be used with devices other than those approved by Aether Biomedical.

Indications

- Amputation level below-elbow, above-elbow and shoulder disarticulation.
- For unilateral or bilateral amputation.
- Dysmelia of the forearm or upper arm.
- The patient must be able to understand usage and safety messages and put them into practice.

Patient Population

Aether Battery System is recommended for:

- Adults only
- All genders
- Age 18-65 while starting to use the prosthesis - older people already using a bionic limb are in the target group

- People with circulation or respiratory problems after consulting their physician

Aether Battery System is not recommended for:

- Children under age 18
- People with serious mental disorders and blind person.

- Please avoid use in situations with heavy loads, vibrations or impacts.
- Battery System is developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill, mountain biking) or extreme sports (free climbing, paragliding, etc.).
- Furthermore, the Battery System should not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.

Qualification

This product maybe fitted by qualified personnel only.
This document provides information for the prosthetist that will be installing Aether Battery System.

Manufacturer:
Aether Biomedical Sp. z o.o.
ul. Mostowa 11, 61-854 Poznań
POLAND

This symbol is used throughout the guide to indicate important cautionary information.
Text following this symbol should be read carefully.

Device description

Aether Battery System is an equipment consisting of a battery pack (7.4V) and a battery charger. The purpose of this system is to provide electric power to the prosthetic hand. The system is designed to have the charging port embedded in the prosthetic socket. The charging port has a USB-C connector and can be used with the provided AC/DC power wall adapter.

The battery pack is equipped with an electronic circuit that precisely measures the capacity and communicates with the charger that displays the battery level using 4 embedded LED's. The battery pack circuit also provides additional safety for the battery cells by controlling their current, voltage and temperature and keeping it within the safe operation range.

Package contents

Aether Battery System AET-BAT-BS1 consists:

1. **AET-BAT** battery pack
2. **AET-CHR** battery charging port which should be mounted into prosthetic socket
3. **AET-CON -** Connector board - connecting the battery pack and charging port, and providing output to the terminal device through a 2-Pin kidney-style output connector.
4. **AET-USBC USB** cable, 1m long, with USB A and USB C connectors
5. **AC/DC** power supply with AC power adapter for the country of use:
   a. **AET-PWR-USB-EU** for Europe
   b. **AET-PWR-USB-US** for the United States
6. **AET-GLU** Sil-Poxy adhesive used for assembly of the charger to the prosthetic socket
7. **AET-GLN** Sil-Poxy disposable nozzles to ensure precise application of the glue
8. **AET-DUM** Dummies with and without the lip to help in process of socket fabrication
9. **AET-COV** covers for charging port
10. **AET-CUT** Cutting guides with adhesive to help with process of socket fabrications
11. **AET-DRL** 5mm drill to help with the process of socket fabrication
12. Instruction for Use : **U03DC-0100**


11
6
Sil-Poxy™
7
8
3
2
9
1
5a/5b
4
10
Cutting Guide
Cutting Guide
Cutting Guide

Technical specification

Temperature (use and storage)	0° C to +50° C (32° F to 120° F)
Humidity range (use and storage)	0% to 90%
Pressure (use and storage)	700 hPa to 1060 hPa
Dimensions	• **AET-BAT** - two cells (22X65mm), connected with a 110mm cable • **AET-CHR** - 45X20mm • **AET-CON** - 20X30mm
Voltage output	7.4V DC nominal, 8.4V DC at fully charged
Current output	Up to 10A (Maximum) / 5A (Continuous)
Nominal capacity	2600mAh (+0%, -5%)
Charging current / time	Up to 1.2 A / Up to 4 h
Input voltage / frequency range for AC/DC power supply	90 ~ 264 VAC / 47 ~ 63Hz
Output voltage / current on the USB connector of the AC/DC power supply	5.0 V DC / 2.4 A
Service life	Up to 2 years or 500 charging / discharging cycles
Weight	**AET-BAT** - 102g **AET-CHR** - 11g **AET-CON** - 4g

Installation

Mechanical installation

Before making the electrical connections of the various components, **AET-CHR** should be mounted into the prosthetic socket. This should be done by using the dummy to create a suitable opening. Battery pack **AET-BAT** should be fixed to the inner surface of the socket e.g. by using adhesives. Battery pack should not have direct contact with the user's skin or be mechanically stressed.

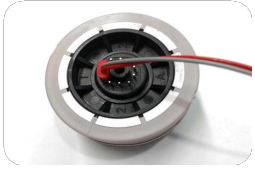
Electrical installation

Warning!

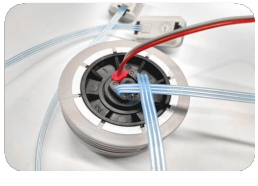
Connectors only attach one way, so please do not try to force them.

1. Connect AET-CHR charging port and AET-BAT battery pack to AET-CON board via the 7-pin and 4-pin connectors respectively.

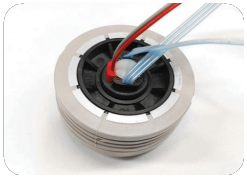
2. Connect AET-CON using output 2-pin kidney style connector to the coaxial plug, to the spot marked. Make sure it is properly aligned



3.Attach the electrodes to the coaxial plug into the connectors marked



4. Secure the connectors on the coaxial plug using the screw supplied with the EQD socket.



Warning! Please make sure that all wires are connected to the correct connectors and that they are properly oriented.

Operation

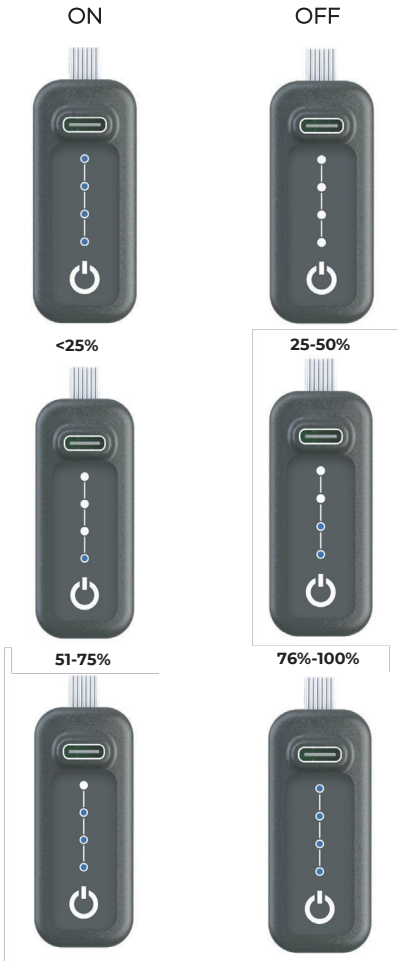
Battery charging port AET - CHR has one button and four LEDs (pic. 7). Pressing the button will turn on the LEDs to show the current charge level of the battery pack AET-BAT (pic.8).

To turn on the battery system, press and hold the button for 1.5s. The 4 LEDs will illuminate, signifying the turning on process. To turn off the battery system, press and hold the button for 1.5s. The 4 LEDs will illuminate, signifying the turning off process.

To check if the system is turned on or off, press the button. If the LEDs blink 3 times, the system is turned off. If the LEDs glow constantly for 3s, the system is turned on.

If the battery pack AET-BAT charge level is critically low, the last LED will blink quickly 6 times after pressing the button when the system is turned off. When the system is turned on, the last LED will blink constantly, regardless of button presses.

“Constantly on” mode can be toggled on/off by pressing the button 10 times during the charging process. In this mode, the LEDs will glow constantly, showing the current battery pack AET-BAT charge level when the system is turned on. LEDs behavior when the system is turned off does not change.



Charging

To charge the battery pack **AET-BAT**, use the charging port **AET-CHR**, charger AC/DC adapter **AET-PWR-USB-xx** and the USB cable **AET-USBC** provided by the manufacturer. Charging should take place while the prosthesis and the prosthetic socket are disconnected from the patient.

1. Plug the supplied wall mount power adapter AET-PWR-USB-xx into electric outlet
2. Connect the AET-CHR charging device to AET-PWR-USB-xx using provided USB cable
3. The charging process will start automatically. Blue LEDs will illuminate indicating charging process.
4. When charging process is finished, all LEDs will blink twice and turn off. If you press the button, all LEDs will blink, indicating the batteries are fully charged. You can disconnect the cable from the Aether Battery Pack

The charger should be equipped with an adapter that corresponds to the electrical outlet standard used in the country of destination.

In exceptional situations, you can use portable power banks for charging that are not connected to the electrical outlet while charging the Aether Battery System.
While charging, the Aether Battery System does not supply power to the prosthesis.

Maintenance

Perform a visual inspection of each battery and all wiring every few months. Make sure no connectors or wires are broken.

Cleaning

Outer surface of the battery charging port can be cleaned with a dry soft cloth.
Don't use water directly on the surface or any other chemical cleaning substances.

Storage

Batteries should be stored at the temperature and humidity specified in the technical specification.
Every 6 months, in case of unused batteries, they should be recharged due to the self-discharge effect.

Safety and warnings

- If an AC/DC adapter or cable is broken please contact the manufacturer or distributor.
- If the Battery Pack starts to generate heat, gasses, appears abnormal during charging or discharging, changes color, please remove the prosthesis (previously disconnect hand and/ or charging cable) and Battery Pack (contact qualified person for battery removal) and store the battery in a safe place inside a container that is fireproof and contact Aether Biomedical via info@aetherbiomedical.com.
- The AET-BAT batteries should not be bent. Excessive bending can damage the batteries.
- Portable RF transmitters should be used no closer than 30 cm (12 inches) to any part of the device. Doing so could result in the degradation of the device's performance.
- Please avoid water that can flow into the USB-C socket on the AET-CHR battery charging port or any other part of the Battery System v1 components.
- Avoid mechanical stress or bending cables that can break parts of the Aether Battery System components. Applying continued force to the battery cells can cause unwanted chemical effects and damage the batteries.
- Do not expose the Aether Battery System components to fire or to temperatures outside of the given parameters (below 0°C/ 32°F, above 50°C/ 120°F). This can reduce service life or damage the battery pack.
- Do not remove the batteries during usage.
- Do not submerge AET-BAT-BS1 in any fluid.
- Before usage ensure the AET-BAT-BS1 is dry.
- If any malfunction occurs during use or battery life expires, replace with a new AET-BAT.
- Do not try to repair cables, battery cells, connectors or any other components of the Aether Battery System.
- In case of any other malfunction please contact the manufacturer info@aetherbiomedical.com or distributor.

Symbols

CE Mark

This mark indicates the product conforms with the essential requirements and provisions of MDR 2017/745 .

Refer to operating instructions

This mark indicates the user should read the operating instructions before use.

Manufacturer (adjacent to company name)

This mark indicates the manufacturer.

Manufacturer (adjacent to company website)

AETHER BIOMEDICAL This indicates www.aetherbiomedical.com

Protect from water

This symbol indicates the product should be protected from water.

Electronic Equipment: Dispose of Properly (WEEE Compliance)

Aether Battery System should not be thrown away with common household waste.

Serial Number

SN Indicates the model number of the product.

Unique Device Identification

UDI Indicates a carrier that contains unique device identifier information.

Temperature Range

This symbol indicates the products temperature range.

Date of Manufacture

Indicates the date the medical device was manufactured.

Country of manufacture

To identify the country of manufacture of products.

Type BF applied part

To identify a type BF applied part complying with IEC 60601-1.

Quantity

Indicates the quantity.

Atmospheric Pressure Limitation

Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Humidity Limitation

Indicates the range of humidity to which the medical device can be safely exposed.

Single patient multiple use

Indicates a medical device that may be used multiple times (multiple procedures) on a single.

Caution: Federal law restricts this device to sale by or on the order of a prosthetist.

UK Responsible Person (UKRP) and Importer

Indicates identification of UKRP and Importer on UK market..

Regulatory information

Aether Battery System has been tested for compliance with the following standards and regulations:

IEC 60601-1
IEC 60601-1-2:2015
UN38.3
IEC 62133-2:2017

They cover topics related to the EMI, RF, ESD as well as battery safety.

EU DECLARATION OF CONFORMITY

with the **Medical Device Regulation**
we,
Aether Biomedical Sp. z0.0
Mostowa 11, Poznan Poland 61-854
SRN (Single Registration Number): PL-MF-000005368
Under the sole responsibility of the manufacturer, declare that the following products are in conformity with the European Medical Device Regulation (EU) 2017/745 amended by Regulation (EU) 2020/561 in effect as of 26th May 2021.
Aether Biomedical Medical Product Family:
Aether Battery System
Technical file/Product group No: 0804_TF
MDR Annex II and III
MDR Classification: I
MDR Rule: 13
Intended purpose:
The Aether Battery System [AET-BAT-BS1] is intended to provide electrical power to the prosthesis and its components.

Reporting

Any serious incident that has occurred in relation to the device should be reported to Aether Biomedical Sp z o.o. complaints@aetherbiomedical.com and the competent regulatory authority of the country in which user is resident.

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