PRODUCT SAFETY DATA SHEET

SECTION 1 — IDENTIFICATION

Product Name: Arclight Ophthalmoscope and Otoscope
Common Name: ARCLIGHT
Model: 1.4.5
Power Source: battery pack contains 1 Lithium-Ion, 3.7V, 90mAhr cell encased in a sealed ABS plastic enclosure.
Product Use: Class 1, non-measuring, non-sterile (low risk) Ophthalmoscope and Otoscope

Manufacturer: St Andrews Medical Innovations Limited

Billing address: Walter Bower House, Main Street, Guardbridge, St Andrews, KY16 0US

https://medicine.st-andrews.ac.uk/arclight/ Tel: +44 1334 466018

NOTE: The Arclight Ophthalmoscope and Otoscope is powered by 1 Lithium-Ion, 3.7V, 90mAhr cell encased in a sealed ABS plastic enclosure as defined by 29 CFR 1910.1200 (OSHA Hazard Communication Standard). User exposure to battery ingredients is not anticipated or expected with normal prescribed use. The information contained in this SDS is supplied at the customer's request for information only.

SECTION 2 — HAZARDS IDENTIFICATION

The lithium-ion battery cells powering the product are electromechanical storage devices. Subjecting them to mishandling or abuse can result in fires, severe personal injury and death.
Do not short circuit, puncture, incinerate, crush, force discharge or expose to temperatures above the declared operating range of the product.
Under normal conditions of use, the electrode materials and liquid electrolyte they contain will not be exposed to the outside, provided the structural casing of the machine is not damaged by abuse, the battery integrity is maintained and the seals remain intact.

Acute Effects **EXPOSURE IS NOT EXPECTED FOR PRODUCT UNDER NORMAL CONDITIONS OF USE**

In the event of damage to the structural casing of the unit together with damage to battery integrity, exposure to organic electrolyte solution is possible. Exposure or skin contact with organic electrolyte solution may lead to acute irritation to skin, corneal damage of eyes if left untreated and irritation of mucous membranes of eyes and upper respiratory system, including lungs. See Section 4. First Aid Measures.

Chronic Effects **EXPOSURE IS NOT EXPECTED FOR PRODUCT UNDER NORMAL CONDITIONS OF USE**

In the event of damage to the structural casing of the unit together with damage to battery integrity, exposure to organic electrolyte solution is possible. Exposure or skin contact with organic electrolyte solution may lead to acute irritation to skin, corneal damage of eyes if left untreated and irritation of mucous membranes of eyes and upper respiratory system, including lungs. See Section 4. First Aid Measures.

For Lithium Ion Battery

INGREDIENTS Common names	CAS No.	% by weight
Aluminum foil	7429-90-5	0.1-1w/w
Biphenyl (BP)	92-52-4	0-0.2 w/w
Copper foil	7440-50-8	1-3 w/w
Linear and Cyclic Carbonic solvents	N/APP	5-17 w/w
Graphite Powder	7440-44-0	12-17 w/w
Lithium Carbonate	554-13-2	0-0.3 w/w
Lithium cobaltite (LiCoO2)	12190-79-3	1-5 w/w
Lithium hexaflurophosphate	21324-40-3	1-5 w/w

Classification of Occupational Dangerous Substances Contained in the battery as per Directive

Substance	Chemical Symbol	% Content	Melt Point	Indication of Danger	Special Risk	Safety Advise
Lithium Cobalite	LiCoO2	23~33	>500		R22 R43	S2 S22 S24 S26 S36 S37 S45
Carbon	C	12~17	>1000			
Organic Solvents	EC	3	EC: 38*C	Flammable	R21 R22	S2 S 24
	DMC		DMC: 4*c		R41	S26 S36
	DEC		DEC: -43*		R42 R43	S37 S45
	LiPF6		N/A	Irritant Corrosive	R14	S2 S8 S22 S24 S26 S36

1. Name of Special Risk:

R14/15 Reacts with water and yields flammable gases
R21 Harmful in contact with skin
R22 Harmful if swallowed
R35 Causes severe burns
R41 Risk of severe damage to the eye
R42/43 May cause sensitization by inhalation and skin contact
R43 May cause sensitization by skin contact

2. Safety Advice:

S2 Keep out of reach of children
S8 Keep away from moisture
S22 Do not breathe dust
S24 Avoid contact with skin
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
S36 Wear suitable protective clothing
S37 Wear suitable gloves
S45 In case of incident, seek medical attention

SECTION 4 — FIRST AID MEASURES

Inhalation: **EXPOSURE IS NOT EXPECTED UNDER NORMAL CONDITIONS OF USE**

However, if organic electrolyte is released due to abuse, overcharging or fire remove exposed person to fresh air. In severe cases obtain medical attention.

Skin contact: **EXPOSURE IS NOT EXPECTED UNDER NORMAL CONDITIONS OF USE**

However, if organic electrolyte contacts skin, wash skin thoroughly with water. Remove contaminant immediately. If irritation develops, seek medical attention as soon as possible.

Eye contact: **EXPOSURE IS NOT EXPECTED UNDER NORMAL CONDITIONS OF USE**

However, if organic electrolyte enters eyes, thoroughly flush eyes with lukewarm water for 15 minutes and obtain medical attention immediately,

Ingestion: **EXPOSURE IS NOT EXPECTED UNDER NORMAL CONDITIONS OF USE**

However, if internal battery components are ingested, rinse mouth out thoroughly and give plenty of water. Call Emergency Services 24 hours a day for procedure for treating ingestion of chemicals. Do not induce vomiting. Seek immediate medical attention.

SECTION 5 — FIRE FIGHTING MEASURES

Extinguisher Media Dry chemical, foam, CO_2 extinguishers or, generous amounts of water.

Use a positive pressure self-contained breathing apparatus if batteries are involved in a fire. Full protective clothing is necessary. During water application, caution is advised as burning pieces of flammable particles may be ejected from the fire.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

Damage to Batteries: Damaged batteries that are NOT burning should be placed in a plastic bag or plastic lined metal container. Chemical resistant glove must be worn to handle all battery components. Dispose of in accordance with local regulations.

SECTION 7 — HANDLING AND STORAGE

1: Use only approved battery charger and do not charge a known damaged machine.
2: Do not disassemble machine, battery compartment, battery or bypass any safety devise.

SECTION 7 — HANDLING AND STORAGE (continued)

3: **Product should be stored in a cool dry area away from excessive heat, combustible chemicals or materials. Excessive heat can reduce the battery service life.**

4: **Never store the machine in temperatures above 60° C or below – 32° C**

SECTION 8 — EXPOSURE / PERSONAL PROTECTION

Respiratory Protection: NONE REQUIRED under normal operating conditions; see also Section 5 – Fire Fighting Measures.

Skin Protection: NONE REQUIRED under normal operating conditions; see also Section 4 – First Aid Measures.

Eye Protection: NONE REQUIRED under normal operating conditions; see also Section 4 – First Aid Measures.

SECTION 9 — PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	N/A	**Boiling Point:**	>500°C Lithium Cobalite (LiCoO2)
Vapor Pressure:	N/A	**Vapor Pressure:**	>90°C
Specific Gravity:	N/A	**Specific Gravity:**	N/A
Solubility in Water:	N/A	**Solubility in Water:**	Yes

SECTION 10 — STABILITY & REACTIVITY

Reactivity in Water: N/A

Flash Point: N/A

Stability: Stable; see also Section 7 – Handling and Storage.

SECTION 11 — TOXICOLOGICAL INFORMATION

NOTE: Under normal conditions this product does not present a health hazard. The following information is provided for organic electrolyte and the mixed metal oxide exposure that may occur due to crushing or breaking the machine or exposure to extreme conditions such as fire.

Threshold Limit Value: Exposure limit of LiCoO2 = 0.1mg/m3 (OSHA)

Signs and Symptoms: None. (In fire or rupture of internally protected battery situations, refer to Sections 4,5 & 8.)

SECTION 12 — ECOLOGICAL INFORMATION

NOTE: The chemicals noted in Section 2 are sealed inside the batteries and again sealed inside the water tight motor housing. Under normal use, the chemicals will not be released. It does not pose a physical or health risk to the users, see Section 13 for disposal.

Hazardous Decomposition Products: When properly used and disposed, the product does not cause a hazard to the environment.

SECTION 13 — DISPOSAL

NOTE: The product contains Lithium-ion batteries. The product should be disposed of in accordance with local, municipal regulations for products containing batteries.

1. The batteries should be fully discharged prior to disposal. In the event the batteries are removed and the physical condition is not compromised, each terminal of the battery should be insulated and the battery be wrapped in plastic prior to disposal.
2. The user should NEVER attempt to incinerate the batteries.
3. Land Filling: Contact your state and local municipality for regulatory guidelines.

SECTION 14 —TRANSPORT INFORMATION

This report applies to by air and by land:

- Each battery pack contains 1 Lithium-Ion, 3.7V 90mAhr cell encased in a sealed ABS plastic enclosure.

The Li-ion battery contained in the Arclight Device is tested according to the requirements of the UN manual of tests and Criteria, Part III, subsection 38.3;
Li-ion battery is protected so as to prevent short circuits. This includes protection against contact with conductive materials within the same packaging that could lead to short circuit;

Air Freight
DGR Classification: UN3481, Lithium Ion Batteries Contained in Equipment, Class 9, PI 967, Section II. An airway bill is required for shipment; the following words must be included on the AWB:
“Nature and Quantity of Goods” box: “Lithium ion batteries in compliance with Section II of PI 967”

The packaging shall be adequate to avoid mechanical damage during transport, handling and stacking. The materials and pack design shall be chosen so as to prevent the development of unintentional electrical conduction, corrosion of the terminals and ingress of moisture.
The package must be handled with care and that a flammability hazard exists if the package is damaged; Each package must be labeled with a Li-ion battery handling label or in addition to the **Class 9 hazard label**. With regard to transport, the following regulations are cited and considered:
- The International Civil Aviation Organization (ICAO) Technical Instructions.
- **The International Air Transport Association (IATA) Dangerous Goods Regulations**. UN number of Li-ion battery: **UN3481**;

SECTION 14 —TRANSPORT INFORMATION (continued)

UN Proper shipping name/Description (technical name): **Lithium ion batteries contained in equipment** or Lithium ion batteries packed with equipment;
- **An airway bill** is required for shipment; the following words must be included on the AWB:
"Nature and Quantity of Goods" box: "Lithium ion batteries in compliance with Section II of PI 967
UN Classification (Transport Hazard class): Non Dangerous; Marine pollutant (Y/N): Y;
- AIR SHIPMENT LABEL REQUIREMENT

- GROUND TRANSPORT (USA)
- Each battery pack contains 1 Lithium-Ion, 3.7V 90mAhr cell encased in a sealed ABS plastic enclosure.
The Li-ion battery contained in the Arclight Device is tested according to the requirements of the UN manual of tests and Criteria, Part III, subsection 38.3;
Li-ion battery is protected so as to prevent short circuits. This includes protection against contact with conductive materials within the same packaging that could lead to short circuit;

- Placarding (Class 9) is not required. [2]. Consult local regulations when transporting inside or outside USA.

- BULK shipments - Shipping Papers - must be declared on all ground shipping papers as "HM" or 'Hazardous Materials' per U.S. regulations and must be available in the driver side pocket of the vehicle to the authorities during transit. Consult the regulations for the mandated retention time.

[1] See 49 CFR 383.93 (b) (4): 49 CFR 383.5, definitions: Hazardous Materials; CFR 172.504 table 2 "class 9"
[2] See 49 CFR 172.504 (f) additional placarding exceptions.

For lithium-ion batteries by sea, provided that packaging is strong and prevent the products from short-circuit.
UN number of Li-ion battery: UN3480 or **UN3481**; UN Proper shipping name/Description (technical name):
Lithium ion batteries or Lithium ion batteries contained in equipment or Lithium ion batteries packed with equipment; UN Classification (Transport hazard class): Non dangerous;
Marine pollutant (Y/N): Y;
Special Provision: International maritime dangerous goods code (IMDG) **188,** 230, 310, 348, 957;
- The US Hazardous Materials Regulation (HMR) pursuant to a final rule issued by RSPA
- The Office of Hazardous Materials Safety within the US Department of Transportations' (DOT) Research and Special Programs Administration (RSPA)
All Li-ion battery with the necessary testing requirements under the UN38.3 Manual of Tests and Criteria as referenced in the following transportation regulations.

SECTION 14 —TRANSPORT INFORMATION (continued)

1. UN recommendations on the Transport of Dangerous Goods Model Regulations.
2. U.S Department of Transportation of Dangerous Goods Model Regulations.
3. International Civil Aviation Organization (ICAO) Technical Instructions
4. International Maritime Dangerous Goods (IMDG) code

Li-ion battery(cylindrical) are exempted from these regulations since they meet all UN testing requirements and contain no more than 8 grams of equivalent lithium content (see 49 CFR 173.185 of the US HMR, IATA Dangerous Goods Regulations and Special Provision 188 of the IMDG Code and UN model Regulations.

SECTION 15 — REGULATORY INFORMATION

The transport of rechargeable Lithium-ion batteries is regulated by various bodies (IATA, IMO, ADR, US-DOT) that follow the United Nations "Recommendations on the Transport of Dangerous Goods, Model Regulations, specifically applicable to the product:
ICAO Technical Instructions for Safety Transport of Dangerous Gods by Air.
IMO IMDG
IATA Dangerous Goods Regulations (DGR)
US Department of Transportation DOT (49 CFR 100-185), (USA)

OSHA hazard communication standard (29 CFR 1910.1200)
_____**Hazardous** **x____Non-hazardous**

SAFETY: The battery pack has been designed and manufactured under a quality management program as prescribed under the regulations, equipped with ah means to prevent accidental activation and short circuits, incorporates a safety venting devise, and does not allow reverse current flow.

SECTION 16 — OTHER INFORMATION

Compliance: Batteries; In accordance with Heavy Metals Content in Batteries and Accumulators. Directive 2013/56/EU, and its amendment directives.

Test Items(s)	Limit	Unit	MDL	002
Lead (Pb)	-	%(w/w)	0.0010	ND
Cadmium (Cd)	0.002	%(w/w)	0.0001	ND
Mercury (Hg)	0.0005	%(w/w)	0.0001	ND

DISCLAIMER

As of the date of this document, the foregoing information is believed to be accurate and is provided in good faith. However, no warranty or representation of law or fact, with respect to such information, is intended or given.