

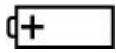









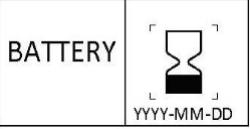


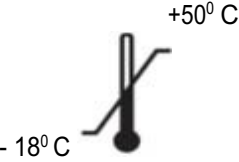


LUMOHS QUICK START: SAFETY SYMBOLS GLOSSARY

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Attention ISO 7000-0434A	Device use needs operator awareness or operator action to avoid undesirable consequences”
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Consult instructions for use ISO 7000-1641	Consult instructions for use
	IEC 60417: Graphical symbols for use on equipment 5-102	Battery orientation IEC 60417, No. 5002	Proper orientation of anode and cathode of battery within well
	IEC 60417: Graphical symbols for use on equipment 5-102	On power IEC 60417, No. 5007	‘On’ power symbol to denote switch position that turns the device on
	IEC 60417: Graphical symbols for use on equipment 5-102	Off power IEC 60417, No. 5008	‘Off’ power symbol to denote switch position that turns the device off

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	LOT symbol ISO 7000-2492	Version, month, and year of lot manufacture for device
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Non sterile ISO 7000-2609	Indicates device is not sterilized

	<p>ISO 15223 – 1: Medical devices – Symbols to be used with information supplied by the manufacturer Part 1 5-134</p>	<p>Medical Device ISO 15223-1, 5.7.7</p>	<p>Medical Device</p>
	<p>IEC 60417: Graphical symbols for use on equipment 5-102</p>	<p>Direct current symbol IEC 60417, No. 5031</p>	<p>Direct current</p>
	<p>IEC 60417: Graphical symbols for use on equipment 5-102</p>	<p>Battery symbol IEC 60417, No. 5001B</p>	<p>Battery operated</p>
<p>R_x only</p>	<p>21 CFR 801.109 (b)(1)</p>	<p>Prescriptive device symbol</p>	<p>Symbol meaning – Caution: Federal law restricts this device to sale by or on the order of a physician (or dentist)</p>
	<p>ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124</p>	<p>Fragile, handle with care ISO 7000-0621</p>	<p>Indicates a medical device that can be broken or damaged if not handled with care.</p>
	<p>IEC 60417: Graphical symbols for use on equipment 5-102</p>	<p>Type BF Applied Part IEC 60417, No. 5333</p>	<p>Indicates that the applied part provides a higher degree of protection against electrical shock than Type B. Not suitable for cardiac application.</p>

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Battery Expiration Symbol ISO 7000-2607	Indicates lumohs battery is not to be used after the date indicated under the hour glass.
IP ₂₂	IEC 60529	Ingress protection rating	Protected against solid foreign objects ≥ 12.5 mm. Protected against vertically falling water drops with enclosure tilted at 15 degrees.
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Keep packaging dry ISO 7000-0626	Keep packaging dry to protect medical device.
			Recycle symbol
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Transport or storage temperature range ISO 7000-0632	Indicates that the lower temperature range for storage/transport is -18° C and the upper is +50° C

SAFETY INFORMATION

- Protection Against Electric Shock (Section 6.2, IEC 60601-1) - The classification of the lumohs™ scalpel handle is as an INTERNALLY POWERED ME EQUIPMENT with Type BF Applied Part.
- Protection Against Harmful Ingress of Water and Particulate Matter (Section 6.3, IEC 60601-1) - The classification of the lumohs™ scalpel handle is IP₂₂.
- Mode of Operation (Section 6.6, IEC 60601-1) - The mode of operation of the lumohs™ scalpel handle is CONTINUOUS OPERATION.

WARNING: NO MODIFICATION OF THE DEVICE IS ALLOWED. THERE ARE NO SERVICEABLE PARTS OTHER THAN BATTERY REPLACEMENT.