

深圳市安普康科技有限公司 APK Technology Co., Ltd.

APK-WI-02-P-16 REV:A.3 生效日期: 2021-09-13



电缆、适配器说明书

产品名称: 电缆, 适配器 型号、规格:见产品标签

生产商名称:深圳市安普康科技有限公司

生产商地址:深圳市宝安区航城街道鹤洲恒丰工业城B2栋601

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网站: www.apk-technology.com 邮箱: info@apk-technology.com

※ 正常工作条件:

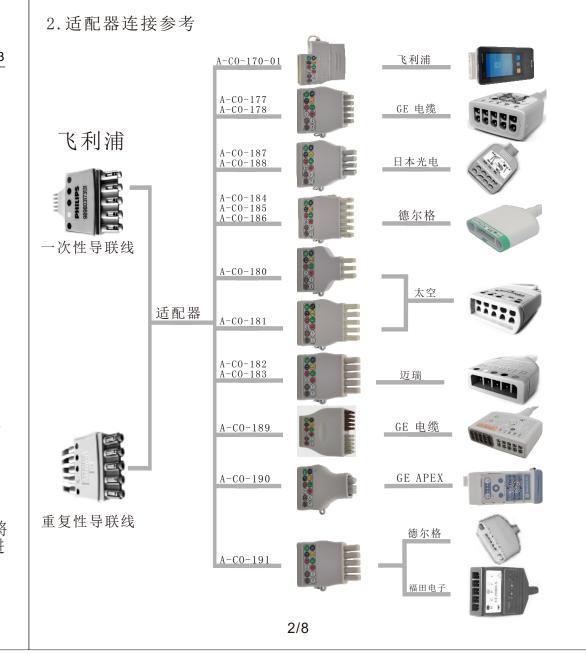
- 1.操作温度: +5℃~40℃
- 2. 相对湿度: 10%~95%(非冷凝)
- 3. 大气压力: 70kPa~106kPa

※ 使用方式:

- 1. 电缆:将电缆与监护仪相连,另一端与患者端的导联线、血氧探头、体温探头、 IBP探头端相连;
- 2. 适配器:将适配器与支线或探头相连,另一端与电缆或设备相连; 3. 敬请参照导联线、血氧探头、体温探头、监护仪等相关产品的操作手册使用。

※ 适用范围:

1. 电缆/适配器适于与心电、血氧、体温和有创压等监护设备配套使用,用于将放置于患者身上适当位置的电极、探头等连接至监护设备,供医护专业人员进行整体监护或诊断评估。请务必阅读并遵照相关监护仪附带的使用说明。



※ 注意事项:

- 1. 请将电缆/适配器放置妥当以免缠绕病人;
- 2. 对电缆/适配器进行擦拭时请拿稳电缆/适配器;
- 3. 请不要在接触药液、水或极度潮湿的环境中使用;
- 插头部分然后再将电缆/适配器与导联线/探头或仪器分离;
- 隔4小时检查电缆/适配器是否连接妥当;
- 6. 请保持插头干燥, 否则可能会影响正常的使用;
- 7. 请保持金属部分的清洁,否则可能会影响正常测试数据;
- 8. 拉伸线材或弯曲线材时不可用力≥50N, 否则将会导致线材破损或 撕裂;
- 9. 为确保电缆/适配器能够正常工作,可以通过相匹配的监护仪进行 ,如果发现开路、短路、波形不正确、无波形或无数据、数据 不准确,则表明电缆/适配器已损坏,则不能继续使用。发生任何 形式的损坏都应按照医院相关规定处理;
- 10.请遵照电缆、适配器手册说明使用。

- 1.清洁或消毒电缆/适配器时不要和监护仪相连:

- 2.用于新的病人之前要清洁或消毒; 3.定期对产品进行清洁或消毒; 4.用蘸有温和肥皂水的软布擦拭清洁,用酒精擦拭消毒,最后擦干, 确认无任何残留物。
- 5. 我们建议用75%医用酒精作为消毒电缆/适配器和病人接触的表面。

※ 警告:

- 1. 绝不能将电缆/适配器浸入任何液体;
- 2. 断开连接时,请直接拔下插头,不要拉拽电缆/适配器;
- 3. 确保支线/探头与心电电缆接头/适配器已正确完全插入并连接牢 固,与设备端连接的插头端也应当确保正确插入并连接牢固。

※ 产品运输和储存:

- 1.运输:防止运输过程中的剧烈冲击、振动及雨雪淋溅,运输要求按 订货合同规定;
- 2. 包装后的产品应储存在环境温度-20℃~+55℃, 相对湿度不大于 90%(非冷凝),无腐蚀性气体,通风良好的室内。

※ 图标释义

图示	说明	图示	说明
[]i	参考使用说明	Z.	不可随意丢弃
<u> </u>	警告,查阅随机文件	NON STERILE	非无菌包装
\subseteq	使用期限	R _{ONLY}	须在医师监督下购买及使用
LOT	批次代码		不含乳胶
REF	产品编号	S	不要沉浸
	制造商	Ø	不要高压
†	BF型号设备	IPX2	防水等级2
UDI	医疗器械唯一标识		生产日期

- **※产品有效期**:二年(生产日期见产品标签)
- ※ 说明书编制日期: 2021-09-13

如果您对上述信息有任何疑问, 请与安普康公司售后服务部或您当地的 安普康公司的代表机构联系。



APK Technology Co., Ltd.

APK-WI-02-P-16 REV: A.3 Effective Date: 2021-09-13

Instructions for Use Cables & Adapters

Product Name: Cables, adapters Model/ Specification: See label

Manufacturer: APK Technology Co., Ltd.

Manufacturer (Customer Service): APK Technology Co., Ltd. Manufacturer Address: 6 Floor, Building B2, Industry of Hengfeng.

No. 739, Zhoushi Road, Hezhou, Hangcheng Street, Bao'an

District, Shenzhen, China Tel: +86-755-27325581

Website: www.apk-technology.com Email: info@apk-technology.com

X Environment Conditions

Operation temperature: $+5^{\circ}$ C $\sim 40^{\circ}$ C

Relative humidity(RH): $10\% \sim 95\%$ (No condensation)

Atmospheric pressure: 70kPa ∼ 106kPa

X Instructions for Use

- 1. Cable: Connect the cable to the monitor, and connect the other end to the patient end of the lead wire, SpO2 sensor, temperature probe, and IBP transducer:
- 2. Adapter: Connect the adapter to the lead wire or sensor, and connect the other end to the trunk cable or device;
- 3. Please refer to the operation manuals of related products such as lead wires, SpO2 sensors, temperature probes, and monitors for details.

X Intended Use

1. The cables/ adapters are intended to be used with ECG, EKG, SpO2 and IBP monitoring devices etc. by connecting electrodes or sensors on the patient to a trunk cable or directly to the monitoring device for overall monitoring and/ or diagnostic evaluation by a healthcare professional. Please read and follow all the instructions that come with the device.

2. Adapter reference A-CO-170-01 **PHILIPS** A-CO-177 A-CO-178 GE Multilink **PHILIPS** A-CO-187 A-CO-188 Nihon Kohden A-CO-184 A-CO-185 Draeger A-CO-186 Disposable leadwires A-CO-180 Spacelabs A-CO-181 **Adapters** A-CO-182 A-CO-183 Mindray A-CO-189 GE Multilink A-CO-190 Reusable leadwires Draeger A-CO-191 Fukuda -Densh

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X Cautions

- 1. Carefully place cable/ adapter to reduce the possibility of patient entanglement or strangulation.
- 2. Hold the cable/ adapter (not the sensing element) while wiping the product.
- 3. Don't immerse or contact with liquid/ water.
- 4. Please hold the connector part when unplug the cable/ adapter out from the lead wire/ sensor/ monitor.
- 5. Please check the cable/ adapter connection status at least every 4 hours.
- 6. Please keep the plug dry. Moisture in plug may cause failure.
- 7. Please keep the metal parts clean to avoid incorrect measurement.
- 8. Don't pull or circle the cable with pull force ≥50N, or the cable will be broken or mangled.
- 9. To ensure that the cable/ adapter is working properly, it can be tested with a matching monitor. Once the open circuit, short circuit, incorrect waveform, no waveform or no data, inaccurate data occurs, the cable/ adapter must have been broken and the user can't use it continuously. Any damage of the cable/ adapter shall be dealt with under relevant regulations of the hospital.
- 10. Please strictly follow the instructions for use of cables and adapters.

X Cleaning and Disinfection

- 1. Please unplug the cable/ adapter from the monitor before cleaning or disinfection.
- 2. Clean or disinfect the cable/ adapter before attaching to a new patient.
- 3. Clean or disinfecting the product periodically.
- 4. Wipe the cable/ adapter with a soft cloth saturated with mild soap and water to clean, wipe it with alcohol to disinfect, then wipe it dry and remove all residue.
- 5. We recommend using 75% medical alcohol as the disinfection solution to disinfect the cable/ adapter and patient contact surface.

X Warning

- 1. Never immerse cables/ adapters in any liquid.
- 2. When disconnecting, pull the plug itself, not the cable.
- 3. Be sure that the leadset/ sensor/ trunk cable/ device connector is properly and fully inserted into the adapter connector. All connections must be secure.

X Transportation and Storage

1. Transportation: In order to prevent severe vibration, rain and snow during transportation, transport requirements shall be in accordance with the order

contract.

2. Packaged products shall be stored in a well-ventilated and non-corrosive room environment with temperature -20 \sim +55 °C and relative humidity \leq 95%(No condensation).

X Icons Explanation

Icon	Definition	Icon	Definition
[]i	Instructions For Use	\$	Don't Throw It Away
\triangle	Warning	NON	Non-Sterile Packaging
LOT	Batch Code	R _{ONLY}	Must Be Purchased And Used Under Physician's Supervision
REF	Catalogue Number		Latex Free
***	Manufacturer	S	No Immersing
∱	BF Type		Do Not Autoclave
EC REP	European Authorized Representative	IPX2	Water Proof Level
MD	Medical Device	CE	CE Mark
	Manufacture Date	UDI	Unique Identification Of medical Devices
= 1	Quantity per pouch		

IFU Filed Date: 2021-09-13

If you have any questions, please contact APK's After-Sales Service Team or your local APK's representative.

EC REP

Ruiyi Healthcare GmbH Neuer Zollhof 3, 40221 Dusseldorf, Germany

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