

# stryker<sup>®</sup>

## Flyte<sup>®</sup> Charger

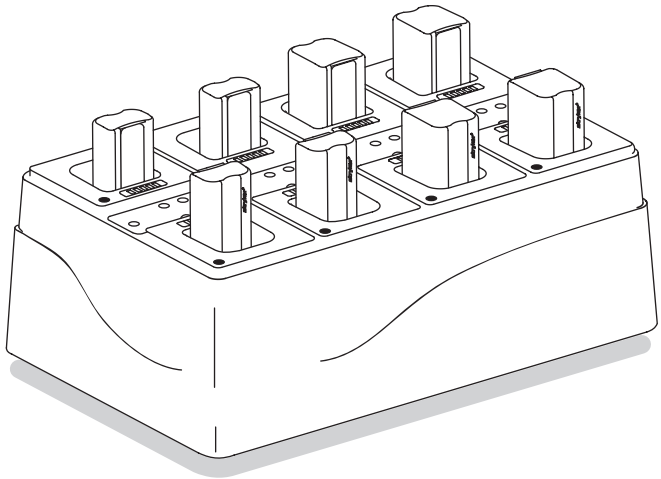
**REF** 0408-655-000

**REF** 0408-655-001

**REF** 0408-655-002

**Instructions For Use**

**R<sub>x</sub> ONLY**



ENGLISH (EN)

## Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, biomedical equipment technicians, and central supply/sterile processing technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

For additional information, including safety information, or in-service training, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

**NOTE:** The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

Trademarks not the property of Stryker Corporation are the property of their respective owners.

## Indications For Use

See the instructions for use supplied with the Stryker Flyte Helmet.

## Contraindications

See the instructions for use supplied with the Stryker Flyte Helmet.

## Intended Use

The Stryker Flyte Charger is intended to charge up to eight Stryker Flyte Power Packs simultaneously.

## For Use With



**WARNING:** ALWAYS use the Stryker Flyte Charger to charge Flyte Power Packs only, unless otherwise specified. Charging other power packs may cause the power pack to explode.

| DESCRIPTION                                | REF          |
|--|--------------|
| Flyte Lithium-Ion Extended Life Power Pack | 0408-660-000 |
| Flyte Lithium-Ion Power Pack               | 0408-650-000 |

## User/Patient Safety



### WARNINGS:

- Before using any component, or any component compatible with this equipment, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the components prior to use.
- Only trained and experienced healthcare professionals should use this equipment.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the *Inspection and Testing* section for inspection criteria.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the Flyte charger. Install and place the charger into service according to the EMC information in this manual. Portable and mobile radio frequency (RF) equipment can affect the function of the charger. See the *Specifications* section.
- DO NOT stack or place equipment adjacent to the product. If such a configuration is necessary, observe the configuration to ensure that electromagnetic interference does not degrade performance.
- DO NOT use the product in a magnetic resonance imaging (MRI) environment. Using the product in an MRI environment could affect the function of the system.

## Accessories

This section describes components that may be ordered to replace original equipment that is damaged, worn, or must be replaced. This section may also contain optional components used with the equipment.



### WARNINGS:

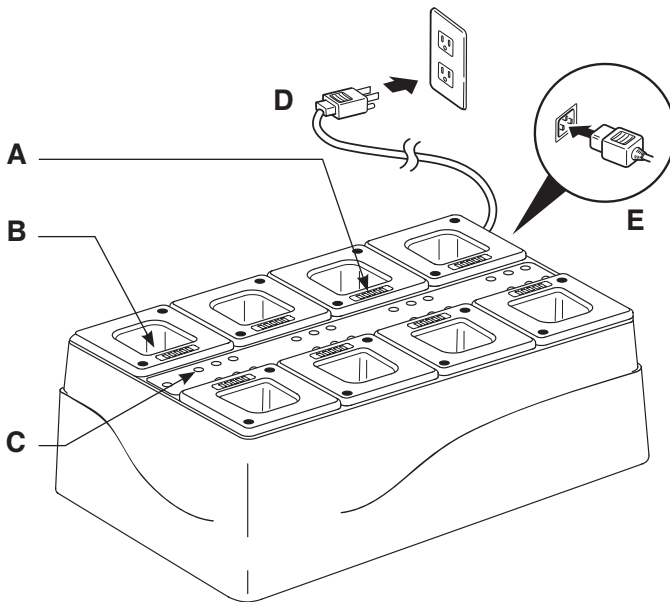
- Use only Stryker-approved components and accessories, unless otherwise specified. Failure to comply may result in fire, electric shock, or injury.
- Using other electronic components and accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- DO NOT modify any component or accessory, including the ground of the charger power cord.

The following Stryker-approved accessories are sold separately:

| DESCRIPTION                                | REF          |
|--|--------------|
| Flyte Lithium-Ion Extended Life Power Pack | 0408-660-000 |
| Flyte Charger Module                       | 0408-655-300 |
| T4 Charger Module                          | 0400-655-003 |
| T4 Power Pack                              | 0400-650-000 |
| (Power) Source Cord                        | 0277-702-019 |
| European (Power) Source Cord               | 0590-100-002 |

**NOTE:** For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

## Features












|          |  |
|----------|--|
| <b>A</b> | <b>Module Indicator Light Bars</b> - These light bars indicate the amount of energy remaining in the power pack. The more bars, the better the ability of the power pack to provide energy. An individual bar within the light bar array will flash as the power pack charges. |
| <b>B</b> | <b>Charger Modules</b> - Each module provides a pocket into which a Flyte power pack may be installed. Eight power packs may be charged simultaneously.  |
| <b>C</b> | <b>Indicator Lights</b> - These lights indicate the status of the power pack in the corresponding charger module: CHARGE, READY, and REPLACE. The amber REPLACE light also provides information about the corresponding module.  |
| <b>D</b> | <b>Power Source Cord</b> - To connect the charger to facility power, always use the appropriate power source cord. See the <i>Accessories</i> section.   |
| <b>E</b> | <b>Power Connection</b> - To connect or disconnect the charger to/from facility power, insert or remove the power cord connector to/from the power cord receptacle (appliance inlet).  |

## Definitions

### Symbols and Related Indicator Lights

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

| SYMBOL  | DEFINITION                          | INDICATOR LIGHT COLOR | STATUS   |
|---|-------------------------------------|-----------------------|--|
|    | CHARGE                              | Amber                 | The amber CHARGE light illuminates while the power pack is charging.   |
|    | READY                               | Green                 | The green READY light illuminates when the power pack is fully charged and ready to use.   |
|    | REPLACE                             | Amber                 | The amber REPLACE light illuminates if a module is empty, if a power pack has exceeded its operational life or if a power pack is damaged. Replace the power pack as required. |
|   |                                     | Amber Flashing        | The amber REPLACE light flashes if the corresponding charger module is not functioning properly. - See the <i>Troubleshooting</i> section.                                     |
| <b>Power</b>  | POWER                               | Green                 | The green POWER light illuminates to indicate the charger is connected to the facility power and is energized.   |
|    | General Warning Sign                | --                    | --   |
|    | Refer to Instruction Manual/Booklet | --                    | --   |
|    | Consult Instructions for Use        | --                    | --   |
|  | Alternating Current (AC)            | --                    | --   |
|  | Direct Current (DC)                 | --                    | --   |
|  | Protective Earth (ground)           | --                    | --   |

### Module Indicator Light Bars

| LIGHT BARS     | POWER PACK ENERGY |
|----------------|-------------------|
| 1 Amber light  | 0-39%             |
| 2 Amber lights | 40-59%            |
| 3 Amber lights | 60-79%            |
| 4 Green lights | 80-99%            |
| 5 Green lights | 100%              |

## Instructions



### WARNINGS:

- ALWAYS perform the recommended inspection and testing as indicated in the *Inspection and Testing* section.
- This equipment is suitable to use in a professional healthcare facility environment.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- ALWAYS operate the equipment at the specified nominal voltage. See the *Specifications* section.
- To avoid the risk of electric shock, ALWAYS connect this equipment to a hospital-grade, facility power receptacle with protective earth.
- ALWAYS position the equipment so that the power cord may be easily disconnected as required.
- ALWAYS place the power cord away from personnel traffic areas to eliminate a trip hazard and cord damage.
- DO NOT touch the power pack receptacle terminals of the charger module with a metal object.

## To Set Up the Charger

1. Position the charger so that the power cord may be easily connected and disconnected as required.
2. Install the plug of the power cord into the power cord receptacle on the charger.
3. Install the other end of the power cord into a hospital-grade facility power receptacle with protective earth.

**NOTE:** During power initiation, all the indicator lights will illuminate briefly. The power indicator will stay illuminated. See the *Symbols and Related Indicator Lights* section for details.

## To Charge the Flyte Power Packs



### WARNINGS:

- ALWAYS make sure the power packs are dry BEFORE charging.
- DO NOT charge a power pack that gives off an odor, generates heat, becomes discolored, or leaks.
- DO NOT touch the charger's voltage output terminals and the patient simultaneously. Failure to comply may result in electric shock.

**CAUTION:** Make sure the correct charger module is installed for the appropriate power pack. Flyte charger modules used to charge Flyte power packs may be replaced with T4 charger modules to accommodate T4 power packs. See the *Accessories* section.

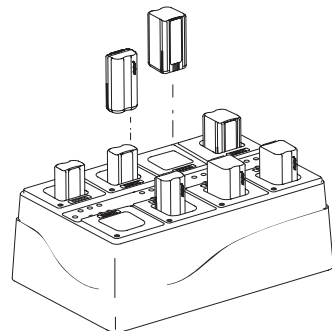
### NOTES:

- Charging time for the Flyte Extended Life Power Packs is approximately eight hours. Actual charging time depends on the remaining energy in the power pack before charging.
- If the power packs will be stored for an extended period, it is recommended that they remain in the charger to stay fully charged.

1. Insert a clean, dry power pack into a Flyte charger module. Make sure the power pack is properly seated in the module.

**NOTE:** The amber CHARGE indicator light will illuminate during charging and remain illuminated. The green READY indicator light will illuminate when the power pack is fully charged. See the *Symbols and Related Indicator Lights* section for details.

2. Once charged, keep the power packs in the charger so the power packs remain fully charged and ready for use.



## To Shut Down the Charger

**CAUTION:** To reduce the risk of damage to the power cord, ALWAYS grasp and pull the (mains) connector and plug when disconnecting the power cord from the charger and facility power.

1. Remove power cord plug from the hospital-grade facility power receptacle.
2. Remove the power cord (mains) connector from the power cord receptacle (appliance inlet) on the charger.

**NOTE:** If the charger is disconnected from facility power, remove the power packs from the modules to prevent discharge.

## Inspection and Testing



### WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect this equipment.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met.
- DO NOT disassemble or service this equipment, unless otherwise specified. Failure to comply may result in electric shock or fire.

### NOTES:

- For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.
- Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.

| INTERVAL   | INSPECTION CRITERIA  | ACTION  |
|------------|--|---|
| Before use | Check equipment for damage, wear, or missing components.   | If damage is apparent, replace the equipment. |
|            | Check power cord for cuts or bent pins.  |   |
|            | Check power cord receptacle or charger module for bent pins or bent contacts.  |   |
|            | Check charger housing and power pack housing for cracks. A cracked power pack housing has the potential to leak electrolytes and cause chemical burns. |   |

**NOTE:** If any component must be discarded, see the *Disposal/Recycle* section.

## Cleaning



### WARNINGS:

- Before cleaning the charger, ALWAYS disconnect the charger from facility power to reduce the risk of electric shock.
- Before cleaning the power pack, ALWAYS remove the power pack from the helmet power pack holster or charger module.
- DO NOT immerse any component in liquid, including the power pack.
- DO NOT sterilize any component, including the power pack.
- DO NOT use disinfectants with a pH level higher than 7.5 on the power pack. See the Safety Data Sheet of the disinfectant to verify the pH range. Failure to comply may cause the power pack housing material to crack and leak.

## Cleaning (continued)

### CAUTIONS:

- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT allow liquids or moisture into any electrical connections, including the power cord receptacle.
- DO NOT allow water to collect in the charger modules or on top of the charger.
- ALWAYS dry the power pack before installation into the charger. Failure to comply may result in damage to the power pack and charger.

### To Clean the Charger and Modules

1. Disconnect the charger power cord from the power cord receptacle and facility power.
2. Wipe the surfaces of the charger and modules with a soft cloth dampened with a non-abrasive, hospital disinfectant and immediately dry.
3. See the *Storage and Handling* section.

### To Clean the Power Pack

1. Remove the power pack from the helmet power pack holster.
2. Wipe the surfaces of the power pack with a soft cloth dampened with a non-abrasive, hospital disinfectant.
3. Dry the power pack with a lint-free towel or medical-grade compressed air.
4. See the *Storage and Handling* section.

## Storage and Handling

**CAUTION:** ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

## Disposal/Recycle



**WARNING:** ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.



To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, this device should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling. [charger]



Years of environmentally-friendly use, per China RoHS standard. [charger]



To comply with European Community Batteries Directive 2006/66/EC, this device has been designed for safe removal of the batteries at the end-of-life by a waste treatment facility. Infected units should be decontaminated before they are sent for recycling. If it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under Directive 2006/66/EC and Member State regulations.



Years of environmentally-friendly use, per China RoHS standard. [power pack]



## Troubleshooting



**WARNING:** DO NOT disassemble or service this equipment, unless otherwise specified.



**NOTE:** For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

| PROBLEM   | CAUSE   | ACTION   |
|---|---|--|
| The indicator lights do not illuminate.   | No power is applied to the charger.                           | Make sure the power cord connections between the charger and facility power are secure.                                    |
|   | The charger is damaged.                                       | Return the charger to Stryker.   |
| The amber REPLACE indicator light flashes.  | The charger module is not properly connected.                 | Make sure the charger module connection is secure.   |
|   | The charger module is damaged.                                | Replace the charger module. See the <i>Accessories</i> section. See the instructions for use supplied with charger module. |
|   | The power pack is damaged.                                    | Replace the power pack. See the <i>For Use With</i> section.   |
| The amber REPLACE indicator light flashes while the module indicator light bars are illuminated.              | Intermittent facility power has been supplied to the charger. | Remove and reinstall the power pack(s). If this condition persists, contact Stryker.                                       |
| The amber CHARGE indicator or the module light indicators do not illuminate when the power pack is installed. | The power pack is damaged.                                    | Replace the power pack. See the <i>For Use With</i> section.   |
|   | The charger module is damaged.                                | Replace the charger module. See the <i>Accessories</i> section.  |
| The charger module is loose.  | The charger module screws are not secure.                     | Tighten the charger module screws.   |
| The power pack becomes unusually hot during use or while charging.  | The power pack is damaged.                                    | Replace the power pack. See the <i>For Use With</i> section.   |
|   | The charger is not functioning properly.                      | Return the charger to Stryker.   |
| Sporadic electrical interference is experienced.  | Electrical noise is present.                                  | Turn off all electrical equipment not in use.  |
|   |   | Relocate electrical equipment; increase spatial distance.  |
|   |   | Plug electrical equipment into different electrical outlets.   |

**NOTE:** If any component must be discarded, see the *Disposal/Recycle* section.

## Specifications

**NOTE:** The Canadian Standards Association (CSA) certification mark only applies to the following charger models: REF 0408-655-000 (120 VAC) and REF 0408-655-001 (230 VAC).

|  |  |
|--|--|
| <b>Model:</b>                                | <b>REF 0408-655-000 Flyte Charger</b>  |
| <b>Electrical:</b>                           |  |
| <b>Input:</b>                                | 120 V $\sim$ , 50-60 Hz, 1.7 A   |
| <b>Terminal Nominal Voltage:</b>             | Open Circuit 20 V $\text{---}$   |
| <b>Power Cord:</b>                           | 2 m long, fitted with NEMA 5-15 hospital grade plug (USA)  |
| <b>Model:</b>                                | <b>REF 0408-655-001 Flyte Charger</b>  |
| <b>Electrical:</b>                           |  |
| <b>Input:</b>                                | 230 V $\sim$ , 50-60 Hz, 0.9 A   |
| <b>Terminal Nominal Voltage:</b>             | Open Circuit 20 V $\text{---}$   |
| <b>Power Cord:</b>                           | 2.5 m long, fitted with CEE 7/7 Schuko plug (Europe)   |
| <b>European Conformity:</b>                  |                   |
| <b>Model:</b>                                | <b>REF 0408-655-002 Flyte Charger</b>  |
| <b>Electrical:</b>                           |  |
| <b>Input:</b>                                | 100 V $\sim$ , 50-60Hz, 1.9 A  |
| <b>Terminal Nominal Voltage:</b>             | Open Circuit 20 V $\text{---}$   |
| <b>Power Cord:</b>                           | 2 m long, fitted with NEMA 5-15 hospital grade plug (Japan)  |
| <b>Ground Type:</b>                          |  Protective Earth |
| <b>Means of Isolation from Supply Mains:</b> | Disconnect the power cord connector from the power cord receptacle (appliance inlet).              |
| <b>Dimensions:</b>                           | 146 mm [5.75 inch] height<br>248 mm [9.75 inch] width<br>381 mm [15.0 inch] length                 |
| <b>Mass:</b>                                 | 5.5 kg [12.1 lb]   |
| <b>Ingress Protection (IP):</b>              | IPX0   |
| <b>Equipment Classification:</b>             | Class I Medical Electrical (ME) Equipment  |
| <b>Mode of Operation:</b>                    | Continuous   |

**Product Safety  
Certification:**



CSA International

**Canadian Standards Association (CSA)**

CAN/CSA-C22.2 No. 60601-1:08, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*

CAN/CSA-C22.2 No. 601.1-M90, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

**American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)**

ANSI/AAMI ES60601-1:2005, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; Consolidated Reprint (2009); Amendment 2 (2010)

**Underwriters Laboratories (UL)**

UL 60601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition*; Revisions through and including April 26, 2006

**International Electrotechnical Commission (IEC)**

IEC 60601-1:2005, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; Corrigendum 1 (2006); Corrigendum 2 (2007)

IEC 60601-1:1988, *Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition*; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995)

**European Committee for Electrotechnical Standardization (CENELEC)**

EN 60601-1:2006, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011)

**Environmental  
Conditions:**

**Operation**

**Storage and Transportation**

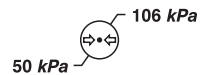
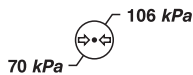
**Temperature  
Limitation:**




**Humidity Limitation:**



**Atmospheric  
Pressure Limitation:**




## Specifications (continued)

| Guidance and manufacturer's declaration - electromagnetic emissions   |            |   |
|---|------------|---|
| The Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) is intended for use in the electromagnetic environment specified below. The customer or the user of the Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) should assure that it is used in such an environment. |            |   |
| Emissions test  | Compliance | Electromagnetic environment - guidance  |
| RF emissions<br>CISPR 11  | Group 1    | The Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.   |
| RF emissions<br>CISPR 11  | Class B    | The Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:   |
| Harmonic emissions<br>IEC 61000-3-2   | Class A    |   |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3   | Complies   |  <p><b>WARNING:</b> This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. Mitigation measures may be necessary, such as reorienting or relocating the Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) or shielding the location.</p> |



| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>   |   |  |  |
|---|---|--|--|
| The Flyte Charger (REF 0408-655-000 and 0408-655-002) is intended for use in the electromagnetic environment specified below. The customer or the user of the Flyte Charger (REF 0408-655-000 and 0408-655-002) should assure that it is used in such an environment. |   |  |  |
| <b>Immunity test</b>  | <b>IEC 60601 test level</b>   | <b>Compliance level</b>  | <b>Electromagnetic environment - guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | $\pm 6$ kV contact<br>$\pm 8$ kV air  | $\pm 2, 4, 6$ kV contact<br>$\pm 2, 4, 8$ kV air   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.  |
| Electrical fast transient/burst<br>IEC 61000-4-4  | $\pm 2$ kV for power supply lines<br>$\pm 1$ kV for input/output lines  | $\pm 2$ kV for power supply lines<br>$\pm 1$ kV for input/output lines   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | $\pm 1$ kV differential mode<br>$\pm 2$ kV common mode  | $\pm 0.5, 1$ kV differential mode<br>$\pm 0.5, 1 \& 2$ kV common mode  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8  | 3 A/m   | 3 A/m at 50 Hz<br>CRT 1A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11  | $< 5\% U_T$<br>( $> 95\%$ dip in $U_T$ )<br>for 0.5 cycle<br>$40\% U_T$<br>( $60\%$ dip in $U_T$ )<br>for 5 cycles<br>$70\% U_T$<br>( $30\%$ dip in $U_T$ )<br>for 25 cycles<br>$< 5\% U_T$<br>( $> 95\%$ dip in $U_T$ )<br>for 5 seconds | 95% Reduction (10 ms)<br><br>60% Reduction (100 ms)<br><br>30% Reduction (500 ms)<br><br>95% Reduction (5 sec) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flyte Charger (REF 0408-655-000 and 0408-655-002) requires continued operation during power mains interruptions, it is recommended that the Flyte Charger (REF 0408-655-000 and 0408-655-002) be powered from an uninterruptible power supply or a battery. |
| NOTE: $U_T$ is the alternating current mains voltage prior to application of the test level.  |   |  |  |

## Specifications (continued)

| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>   |   |   |  |
|---|---|---|--|
| <p>The Flyte Charger (REF 0408-655-001) is intended for use in the electromagnetic environment specified below. The customer or the user of the Flyte Charger (REF 0408-655-001) should assure that it is used in such an environment.</p> <p><b>NOTE:</b> The values provided in the table below have changed due to 60601-1-2 4th Edition requirements.</p> |   |   |  |
| <b>Immunity test</b>  | <b>IEC 60601 test level</b>   | <b>Compliance level</b>   | <b>Electromagnetic environment - guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | $\pm 8$ kV contact<br>$\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air   | $\pm 8$ kV contact<br>$\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.  |
| Electrical fast transient/burst<br>IEC 61000-4-4  | $\pm 2$ kV at 100 kHz repetition frequency for power supply lines<br>$\pm 1$ kV at 100 kHz repetition frequency for input/output lines  | $\pm 2$ kV at 100 kHz repetition frequency for power supply lines<br>$\pm 1$ kV at 100 kHz repetition frequency for input/output lines  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | $\pm 0.5$ kV, $\pm 1$ kV line(s) to line(s)<br>$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to earth  | $\pm 0.5$ kV, $\pm 1$ kV line(s) to line(s)<br>$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV line(s) to earth  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11  | $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle<br>$40\% U_T$ (60% dip in $U_T$ ) for 5 cycles<br>$0\% U_T$ (100% dip in $U_T$ ) for 0.5 cycle at $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ , and $315^\circ$<br>$0\% U_T$ ( $>100\%$ dip in $U_T$ ) for 1 cycle at $0^\circ$<br>$70\% U_T$ (30% dip in $U_T$ ) for 25 and 30 cycles at $0^\circ$<br>$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 seconds<br>$0\% U_T$ (100% dip in $U_T$ ) for 250/300 cycles | $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle<br>$40\% U_T$ (60% dip in $U_T$ ) for 5 cycles<br>$0\% U_T$ (100% dip in $U_T$ ) for 0.5 cycle at $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ , and $315^\circ$<br>$0\% U_T$ ( $>100\%$ dip in $U_T$ ) for 1 cycle at $0^\circ$<br>$70\% U_T$ (30% dip in $U_T$ ) for 25 and 30 cycles at $0^\circ$<br>$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 seconds<br>$0\% U_T$ (100% dip in $U_T$ ) for 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flyte Charger (REF 0408-655-001) requires continued operation during power mains interruptions, it is recommended that the Flyte Charger (REF 0408-655-001) be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8  | $3$ A/m, $30$ A/m at 50 and 60 Hz   | $3$ A/m, $30$ A/m at 50 and 60 Hz   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| <p>NOTE: <math>U_T</math> is the alternating current mains voltage prior to application of the test level.</p>  |   |   |  |

| Guidance and manufacturer's declaration - electromagnetic immunity   |                                |                                |  |
|--|--------------------------------|--------------------------------|--|
| The Flyte Charger (REF 0408-655-000 and 0408-655-002) is intended for use in the electromagnetic environment specified below. The customer or the user of the Flyte Charger (REF 0408-655-000 and 0408-655-002) should assure that it is used in such an environment.  |                                |                                |  |
| Immunity test  | IEC 60601 test level           | Compliance level               | Electromagnetic environment - guidance   |
| Conducted RF<br>IEC 61000-4-6  | 3 Vrms<br>150 kHz to<br>80 MHz | 3 Vrms<br>150 kHz to<br>80 MHz | <p>Portable and mobile RF equipment should be used no closer to any part of the Flyte Charger (REF 0408-655-000 and 0408-655-002), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.2\sqrt{P}$ <p><math>d=1.2\sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d=2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  <p>(Non-ionizing electromagnetic radiation)</p> |
| Radiated RF<br>IEC 61000-4-3   | 3 V/m<br>80 MHz to<br>2.5 GHz  | 3 V/m<br>80 MHz to<br>2.5 GHz  |  |
| NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.  |                                |                                |  |
| NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |                                |                                |  |
| <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Flyte Charger (REF 0408-655-000 and 0408-655-002) is used exceeds the applicable RF compliance level above, the Flyte Charger (REF 0408-655-000 and 0408-655-002) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Flyte Charger (REF 0408-655-000 and 0408-655-002). |                                |                                |  |
| <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.  |                                |                                |  |

## Specifications (continued)

| Guidance and manufacturer's declaration - electromagnetic immunity  |  |  |  |
|---|--|--|--|
| The Flyte Charger (REF 0408-655-001) is intended for use in the electromagnetic environment specified below. The customer or the user of the Flyte Charger (REF 0408-655-001) should assure that it is used in such an environment. |  |  |  |
| Immunity test   | IEC 60601 test level   | Compliance level   | Electromagnetic environment - guidance   |
| Conducted RF<br>IEC 61000-4-6   | 3 V 0.15 MHz – 80 MHz<br><br>6 V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz   | 3 V 0.15 MHz – 80 MHz<br><br>6 V in ISM bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz   | <p>IEC 60601-1-2 3rd Edition:<br/>Portable and mobile RF equipment should be used no closer to any part of the Flyte Charger (REF 0408-655-001), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance<br/> <math>d=1.2\sqrt{P}</math> 150 KHz to 80 MHz<br/> <math>d=1.2\sqrt{P}</math> 80 MHz to 800 MHz<br/> <math>d=2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>IEC 60601-1-2 4th Edition:</p> <p><b>WARNING:</b> Portable RF equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Flyte Charger (REF 0408-655-001), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> <p>(Non-ionizing electromagnetic radiation)</p> |
| Radiated RF<br>IEC 61000-4-3  | <sup>b</sup> 3 V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1 kHz<br>27 V/m<br>385 MHz, pulse modulation 18 Hz, Maximum power = 1.8 W<br>28 V/m<br>450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power = 2 W<br>9 V/m<br>710, 745, 780, 5240, 5500, 5785 MHz, pulse modulation 217 Hz, Maximum power = 0.2 W<br>28 V/m<br>810, 870, 930 MHz, pulse modulation 18 Hz, Maximum power = 2 W<br>28 V/m<br>1720, 1845, 1970, 2450 MHz, pulse modulation 217 Hz, Maximum power = 2 W | <sup>b</sup> 3 V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1 kHz<br>27 V/m<br>385 MHz, pulse modulation 18 Hz, Maximum power = 1.8 W<br>28 V/m<br>450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power = 2 W<br>9 V/m<br>710, 745, 780, 5240, 5500, 5785 MHz, pulse modulation 217 Hz, Maximum power = 0.2 W<br>28 V/m<br>810, 870, 930 MHz, pulse modulation 18 Hz, Maximum power = 2 W<br>28 V/m<br>1720, 1845, 1970, 2450 MHz, pulse modulation 217 Hz, Maximum power = 2 W |  |



NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

\*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Flyte Charger (REF 0408-655-001) is used exceeds the applicable RF compliance level above, the Flyte Charger (REF 0408-655-001) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Flyte Charger (REF 0408-655-001).

<sup>o</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**IEC 60601-1-2 3rd Edition:**

**Recommended separation distances between portable and mobile RF equipment and the Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002)**

The Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF equipment (transmitters) and the Flyte Charger (REF 0408-655-000, 0408-655-001, and 0408-655-002) as recommended below, according to the maximum output power of the equipment.

| Rated maximum output power of transmitter<br><br>W | Separation distance according to frequency of transmitter<br><br>m |                                      |                                       |
|--|--|--------------------------------------|---------------------------------------|
|  | 150 kHz to 80 MHz<br>$d=1.2\sqrt{P}$                               | 80 MHz to 800 MHz<br>$d=1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d=2.3\sqrt{P}$ |
| 0.01   | 0.12   | 0.12                                 | 0.23                                  |
| 0.1  | 0.38   | 0.38                                 | 0.73                                  |
| 1  | 1.2  | 1.2                                  | 2.3                                   |
| 10   | 3.8  | 3.8                                  | 7.3                                   |
| 100  | 12   | 12                                   | 23                                    |

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.





|                |              |
|----------------|--------------|
| ES/DE/FR/IT/NL | 0408-655-713 |
| JA/ZH/KO       | 0408-655-720 |
| SV/DA/FI/PT/NO | 0408-655-730 |
| PL/EL          | 0408-655-750 |



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