



Underwriters Laboratories (UL LLC) Safety Report

Model: 3745, 3745P, 3745B, 3745BP, 3845, 3845P, 3845B and 3845BP, and "1-cell Li-Ion charger", "1c Li-Ion charger", "1-cell LI charger" or "1c LI charger". See enclosed nomenclature breakdown for further details.

Device Description: Battery chargers (Power Supply)

Applicant: MASCOT ELECTRONICS AS
MOSSEVEIEN 109
N-1601 FREDRIKSTAD NORWAY

Manufacturer: Same as Applicant

Manufacturing Facility(ies): MASCOT ELECTRONICS AS
MOSSEVEIEN 109, PO BOX 177
FREDRIKSTAD N-1601 NORWAY

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Mascot Power Supplies (Ningbo) Co., Ltd
No.128 Jinchuan Road, Zhenhai
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Report No.: E356182-D1006-1/A0/C0-ULCB

Report (Re)Issue Date: 2018-07-26

Base Standard(s): ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1 :2005 +A1 :2012

Additional Standards: EN 60601-1:2006/A1:2013/A12:2014, IEC 60601-1-6:2010 (Third Edition) + A1:2013, EN 60601-1-6:2010/A1:2015, IEC 60601-1-11:2015 (Second Edition), EN 60601-1-11:2015

Report Types: This report consists of the following report types:
[Yes] US Certification (UL Recognition)
[Yes] CAN Certification (cUL Recognition)
[Yes] CB Report & Certificate
[No] IEC/EN Informative Report

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

Table of Contents

CB - IEC REPORT:	1
Test Report.....	1
TABLE: List of critical components.....	153
National Differences.....	164
APPENDIX A: Enclosures (Page Section: A)	1
Collateral/Particular Standard Enclosures	1
Collateral Standard - (01) Home healthcare environment Report No. E356182-D1006-1-11	2
Collateral Standard - (02) Usability Report No. E356182-D1006-1-6	38
Other Enclosures	61
Diagrams - (01) Mascot transformer # 173748_specification	62
Diagrams - (02) Mascot transformer # 173775_preliminary specification	69
Licenses - (01) Great Leoflon Ind. - TIW for MED - VDE licence no.136581 (130C, 600Vpeak for MOPP, 1410Vpeak for MOOP)	70
Manuals - (01) Mascot User Manual_Li-Ion_(doc 5170)_2018-04	77
Marking Label - (01) 1.0 Mascot 3745 & 3745P_Screen print proposal for UL 07.05.18	97
Marking Label - (02) 1.1 Mascot 3845 & 3845P_Screen print proposal for UL 07.05.18	99
Marking Label - (03) 1.2 Mascot 3745B & 3745BP_Carton label proposal UL 07.05.18	101
Marking Label - (04) 1.3 Mascot 3845B & 3845BP_Carton label proposal UL 07.05.18	102
Marking Label - (05) 1.4 Mascot PASSED-sticker Baltic (16x8mm Silver).....	103
Marking Label - (06) 1.5 Mascot 3745_Versions Nomenclature Differences_20180508	104
Marking Label - (07) 1.6 Mascot Packaging label Env Cond _transport & storage between uses-(doc5037-rev20140617)	105
Photographs - (01) 1.0 Overall view of type 3745 with external batteries	106
Photographs - (02) 1.1 Overall view, bottom side, of type 3745 without external batteries	107
Photographs - (03) 1.2 Overall view, top side, of type 3745 without external batteries thout external batteries	108
Photographs - (04) 1.3 Overall internal view, top side, of type 3745	109
Photographs - (05) 1.4 Overall internal view, bottom side, of type 3745	110
Photographs - (06) 1.5 PWB top side view of Type 3745	111
Photographs - (07) 1.6 PWB bottom side view of Type 3745	112
Photographs - (08) 1.7 Overall view of Type 3845.....	113
Photographs - (09) 1.8 PWB top side view of Type 3845	114
Photographs - (10) 1.9 PWB bottom side view of Type 3845	115
UL CERTIFICATION DOCUMENTATION:	1
APPENDIX B: UL Certification Documentation (Page Section: B)	1
Test Record.....	2
APPENDIX C: Follow-Up Service Documentation (Page Section: C)	1
Follow-Up Service Procedure.....	2
UL Authorization Page	3
UL Appendix:.....	6
GENERIC INSPECTION INSTRUCTIONS	6
INSTRUCTIONS AND DUTIES FOR UL REPRESENTATIVE	7
INSTRUCTIONS FOR FOLLOW-UP TESTS AT UL	13
RESPONSIBILITIES AND REQUIREMENTS FOR MANUFACTURER	14
GENERAL TERMINOLOGY	18
GENERAL PRODUCT CONSTRUCTION REQUIREMENTS	19
UL CERTIFICATION MARK	28
Description	29
Markings and instructions	32
Special Instructions to UL Representative	32
Production-Line Testing Requirements	32
TABLE: List of Critical Components	34
TEST RESULTS:	1
APPENDIX D: Test Datasheets Enclosures (Page Section: D)	1
CERTIFICATE OF COMPLIANCE	1

Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:

(x) = Report (Re)Issue No.

(y) = Amendment No.

(z) = Correction No.

YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*




Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By



Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.	E356182-D1006-1/A0/C0-ULCB
Date of issue	2018-07-26
Total number of pages	170
CB Testing Laboratory	UL International Demko A/S
Address	Borupvang 5A, 2750 Ballerup, Denmark
Applicant's name	MASCOT ELECTRONICS AS
Address	MOSSEVEIEN 109 N-1601 FREDRIKSTAD NORWAY
Test specification:	
Standard	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	CB Scheme
Non-standard test method.....	N/A
Test Report Form No.....	IEC60601_1K
Test Report Form Originator	UL(US)
Master TRF	2015-11
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General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description:	Battery chargers (Power Supply)	
Trade Mark:	Trademark image(s):	
		
Manufacturer:	Same as Applicant	
Model/Type reference:	3745, 3745P, 3745B, 3745BP, 3845, 3845P, 3845B and 3845BP, and "1-cell Li-Ion charger", "1c Li-Ion charger", "1-cell LI charger" or "1c LI charger". See enclosed nomenclature breakdown for further details.	
Ratings:	Input ratings: 100-240Vac, 50-60Hz, max. 0.25A or 0.25A. Output ratings: 4.2 VDC, 1.5 A or 4.2 VDC, 1.5A/0.85A/0.45A.	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:		
Testing location/ address:	UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Michael Jespersen / Project Handler	
Approved by (name, function, signature):	Sven Friis / Reviewer	
<input type="checkbox"/> Testing procedure: CTF Stage 1:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		
<input type="checkbox"/> Testing procedure: CTF Stage 2		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
<input type="checkbox"/> Testing procedure: CTF Stage 3:		
<input type="checkbox"/> Testing procedure: CTF Stage 4:		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
Supervised by (name, function, signature):		

List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing

Tests performed (name of test and test clause):

Testing location:

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012

(or IEC 60601-1: 2012 reprint).

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	Portable
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	Battery chargers
Mode of Operation:	Continuous
Supply Connection:	Appliance Coupler
Accessories and detachable parts included:	N/A
Other Options Include:	None
Testing	
Date of receipt of test item(s)	2018-01-09, 2018-01-11, 2018-02-05
Dates tests performed	2018-02-02 to 2018-05-15
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP
General remarks:	
"(See Attachment #)" refers to additional information appended to the report.	
"(See appended table)" refers to a table appended to the report.	
The tests results presented in this report relate only to the object tested.	
This report shall not be reproduced except in full without the written approval of the testing laboratory.	
List of test equipment must be kept on file and available for review.	
Additional test data and/or information provided in the attachments to this report.	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	Yes
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies): MASCOT ELECTRONICS AS
 MOSSEVEIEN 109, PO BOX 177
 FREDRIKSTAD N-1601 NORWAY

MASCOT BALTIC OU
 TAEVAKIVI TN 15
 TALLINN 13619 EE ESTONIA

Mascot Power Supplies (Ningbo) Co., Ltd
 No.128 Jinchuan Road, Zhenhai
 Ningbo 315221 China

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.
 Refer to the Report Modifications for any modifications made to this report.

Product Description

The product covered by this Report is a component in patient care equipment intended for use in health care facilities. Since the battery charger is intended for charging lithium battery for use with patient carts, patient hoists and other hospital equipment, it is regarded as accessory for medical electrical equipment. The product is mounted with a Class II appliance inlet for a detachable power supply cord.

Model Differences

All types are similar except for different output ratings and some internal components in secondary circuit. Type designation including a "P" provides 2 MOPP with two Y1 capacitors in series bridging the insulation barrier. Type designation without a "P" provides 2 MOOP with two Y2 capacitors in series bridging the insulation barrier.

Additional Information

N/A

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012,
 CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1 :2005 +A1 :2012

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards:

EN 60601-1:2006/A1:2013/A12:2014, IEC 60601-1-6:2010 (Third Edition) + A1:2013, EN

60601-1-6:2010/A1:2015, IEC 60601-1-11:2015 (Second Edition), EN 60601-1-11:2015

- The following additional investigations were conducted:
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product:
- The company trademark may be applied to the exterior of product, product literature or product packaging

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

The battery chargers shall be installed in compliance with the enclosure, mounting, spacing and segregation requirements of the end-use product.

The output cord was provided with appliance coupler with +/- marking to indicate polarity intended for connection to the mating plug in the end-use product. The output connections are not suitable for field wiring connection. The acceptability of the mating connection relative to secureness, insulating material, leakage current and temperature shall be considered in the end-used product.

The battery chargers were intended for charging batteries to be used for medical electrical equipment such as carts, patient hoists and other hospital equipment. The batteries were not evaluated in this investigation. Additional requirements on the battery charger with the battery used shall be investigated in the end-used product.

The Temperature Test was conducted with simulated load at maximum ambient temperature (T_{mra}) of 40°C. Temperature Test shall be considered when installed in the end-use product.

Leakage Current Tests shall be considered on the end-use product, see CL. 8.7.

The housing containing the batteries was not investigated. When installed in the end-used product, consideration shall be taken to providing ventilated housing to minimize the risk of gas accumulation and ignition during charging or discharging as required by CL. 15.4.3.1.

When installed in the end-use product, the battery compartment shall be designed to prevent the risk of accidental short-circuiting the battery where such short circuits could result in a HAZARDOUS SITUATIONS, see CL. 15.4.3.1.

The type of battery and the mode of insertion shall be marked in end-use product. If a HAZARDOUS SITUATIONS could arise when installed in the end-use product, it shall be fitted with a means of preventing incorrect polarity of connection. See CLs. 7.3.3 and 15.4.3.2.

Special skills, training, and knowledge required of the intended operator or the responsible organization and any restrictions on locations or environments in which the product can be used shall be considered in end-use manual, see CL. 7.9.1.

The end-use manual shall be considered written at a level consistent with the education, training, and any special needs of the person(s) for whom they are intended, see CL. 7.9.1.

Necessary information provided for operator to bring equipment into operation including initial control, settings, and connection to or positioning of patient prior to use of equipment, its parts, or accessories shall

be considered in end-use manual, see CL. 7.9.2.8.

The intended for use in patient environment and the type of applied parts shall be considered in end-use product.

Permissible environmental conditions for transport and storage marked on outside of packaging shall be considered in the end-use product.

If power supply cord is not provided with the product, it shall be considered in the end-use product.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By