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## **15 Steps to Getting Approval for IEC 60601-1**

Test procedure : IEC  
60601-1-2: 2014  
(Fourth Edition) Non-  
standard test method :  
N/A General disclaimer:  
The test plan  
presented in this report  
relate only to the

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object to be tested.

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60601-1. IEC 60601-1  
is the basis for the  
whole series of  
collateral and

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particular IEC standards. While 60601-1 is the basic general standard, particular standards branch off into specific devices, such as high frequency surgical, endoscopic equipment, and infant incubators.

## **TEST REPORT IEC 60601-1-11 MEDICAL ELECTRICAL EQUIPMENT ...**

en 60601-1-2: 2015 iec  
60601-1-2:2014 test

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report for led  
illuminator model  
number: p1347 report  
number: 11473017-  
e1v1 issue date: may  
15, 2017 prepared for  
techni-quip corporation  
530 boulder court suite  
103 pleasanton  
california 94566 usa  
prepared by ul  
verification services  
inc. 47173 benicia  
street fremont, ca  
94538, u.s.a.

**EMC Test Report**  
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**template - ultratech-**  
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IEC 60601-1-6 Usability Engineering - General comments. January 6, 2017. ... field trials and the like should have been done well before embarking on the formal IEC 62366 test. The formal test should only be performed when the design is sufficiently stable and the designers are confident of the result. The specifications for

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usability should be ...

**TEST REPORT EN  
60601-1: 2006**

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equipment ...**

See IEC 60601-1 Test  
Report Summary of  
testing: Tests

performed (name of  
test and test clause):  
4.2.1 Environmental  
condition test of  
transport and storage  
between uses 4.2.2  
Environmental  
operating condition

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test 10.1.2 a) Shock  
test 10.1.3 b) Vibration  
test The sample tested  
complies with the  
requirements of IEC  
60601-1-11:2010.

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Electrical Equipment  
Part ...**

List of test equipment  
must be kept on file  
and available for  
review. This Test  
Report Form is  
intended for the

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investigation of  
medical electrical  
systems. It can only be  
used together with IEC  
60601-1 Test Report.  
General product  
information: The  
Medikzap is a modern,  
electronic equipment  
generating a square  
wave current

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60601 -1 Medical  
electrical equipment  
Part ...**

Equipment Under Test

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(EUT) AC line voltage.  
The 2014 version of IEC 60601-1-2 requires only one nominal AC power line voltage and frequency for each test, with the exception of Voltage Dips and Interruptions (VDI) which calls for a minimum and maximum rated voltage.

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No.ETS-060065 TEST  
REPORT IEC 60601-1 /  
EN 60601 -1 Medical  
electrical equipment  
Part 1: General  
requirements for safety  
Report reference No.....  
: ETS-060065 Tested  
by (+ signature)..... :  
Arthur Sun Approved  
by (+ signature)..... :  
Una Tseng Date of  
issue.....

**TRF Details - IECEE**

MECA provides high-

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quality testing and documentation necessary to show compliance with medical and laboratory equipment standards, primarily related to the IEC 60601-1 and IEC 61010-1 series of standards.

## **TEST REPORT IEC 60601-1 Medical Electrical Equipment Part ...**

The Evaluation  
Package is a summary

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of the IEC

60601-1:2012

standard, other  
applicable

requirements,  
guidance information,  
and interpretations, to  
help evaluate medical  
electrical equipment to  
the requirements of  
the Standard. It is  
being provided FREE of  
charge, to help people  
understand and meet  
the requirements for  
medical devices.



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As from 1 January 1997  
all IEC publications are  
issued with a  
designation in the  
60000 series. For  
example, IEC 34-1 is  
now referred to as IEC  
60034-1. Consolidated  
editions The IEC is now  
publishing consolidated  
versions of its  
publications. For  
example, edition

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numbers 1.0, 1.1 and  
1.2 refer, respectively,  
to the base publication,  
the

**EN 60601-1-2: 2015  
IEC 60601-1-2:2014  
TEST REPORT FOR  
LED ...**

Page 22 of 46 Report  
No. TRS 10080067 EN  
60601+ Am. 1 & 2  
Clause Requirement +  
Test Result - Remark  
Verdict Audible  
warning provided  
where the loss of

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function caused by  
operation of a thermal  
cut-out presents a  
safety hazard No  
safety hazard caused  
by operation of a  
thermal cut-out.

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-1 Medical electrical**

...

Programmable  
Electronic Systems, IEC  
60601-1-4) Copy of  
Marking Plate - Refer to  
Enclosure titled

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Marking Plate for copy.  
Issue Date: Page 5 of  
28 Report Reference #  
E349607 -A26 -CB -1

**Medical EMC Testing  
- Details of IEC  
60601-1-2:2014 ...**

This Test Report Form  
applies to: IEC  
60601-1:2005,  
COR1:2006,  
COR2:2007,  
AMD1:2012 (or IEC  
60601-1:2012 reprint)  
Abstract. Medical  
electrical equipment

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Part 1: General requirements for basic safety and essential performance. Applies to IEC Standards. Reference Category; IEC 60601-1:2005: MED:

## **Get IEC Standard Distribution - IECCEE - IEC System of ...**

IEC 60601-1-2: 2007,  
EN 60601-1-2: 2007,  
IEC 60601-1-11: 2010  
Clause 12, EN  
60601-2-10: 2010

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Clause 12 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 test report GZME150500045101 relevant safety report IEC 60601-1.

## **Rapport IEC60601 1 - Medi-Flowery**

Tests performed (name

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of test and test clause):  
Testing location: All the  
requirements of IEC  
60601-1:2005 were  
evaluated in this report  
except the following  
clauses: 11.7

Biocompatibility of ME  
EQUIPMENT and ME  
SYSTEMS 17 \*

Electromagnetic  
compatibility of ME  
EQUIPMENT and ME  
SYSTEMS SHENZHEN  
HUATONGWEI  
INTERNATIONAL  
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**MECA-Medical  
Equipment  
Compliance | IEC  
60601-1 | Franklin ...**

This amendment shall be read in conjunction with Original Test Report and Test Certificate and with previous Amendment

1. Technical Considerations The product was investigated to the following additional standards: IEC



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60601-1, 2nd Edition:  
1988, UL 60601-1, 1st  
Edition, 2006-04-26  
(includes National  
Differences for USA),  
CAN/CSA-C22.2 No.

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Conformity Assessment  
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Equipment and  
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