Draft SI 60601 part 2.4 **טיוטה לתקן ישראלי ת"י 60601 חלק 2.4**

October 2018 אוקטובר 2018

ICS CODE: 11.040.10

ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מַפְעמים (דפיברילטורים) לבביים

Medical electrical equipment: Particular requirements for the basic safety and essential performance of cardiac defibrillators

תקן זה ייכנס לתוקף ב-

מכון התקנים הישראלי
The Standards Institution of Israel

רח' חיים לבנון 42, תל-אביב 69977, טל' 03-6465154, פקס' 03-6412762, www.sii.org.il

תקן זה הוכן ואושר על ידי הוועדה הטכנית 5801 – ציוד חשמלי לשימוש רפואי, בהרכב זה:

איגוד לשכות המסחר בישראל	-	יואב אסולין, זהבית זריהן
המועצה הישראלית לצרכנות	-	מיכאל שיזף
התאחדות התעשיינים בישראל	-	משה סמואל
מינוי אישי	-	ולנטין ויינטראוב, יוסי פרי פז
מכון התקנים הישראלי – אגף התעשייה	-	אבי אוחיון
משרד הבריאות	-	אלכסנדר וילנסקי (יו"ר)
משרד הכלכלה והתעשייה	-	שלומי אביסרור
רשות ההסתדרות לצרכנות	-	נתן אלדור

עמית אסא-ווקסלר ריכזה את עבודת הכנת התקן.

הודעה על מידת התאמת התקן הישראלי לתקנים או למסמכים זרים

תקן ישראלי זה, למעט השינויים והתוספות הלאומיים המצוינים בו, זהה לתקן של הנציבות הבין-לאומית לאלקטרוטכניקה

IEC 60601-2-4 - Edition 3.0: 2010-12

Amendment 1: 2018-02

הודעה על רוויזיה

תקן ישראלי זה בא במקום התקן הישראלי ת"י 60601 חלק 2.4 ממאי 2012

מילות מפתח:

ציוד רפואי, בטיחות חשמל, שולחנות ניתוח, סימון, הוראות שימוש, יציבות, הגנה מפני הלם חשמלי.

Descriptors:

medical equipment, electrical safety, operating tables, marking, instructions for use, stability, protection against electric shocks.

עדכניות התקן

התקנים הישראליים עומדים לבדיקה מזמן לזמן, ולפחות אחת לחמש שנים, כדי להתאימם להתפתחות המדע והטכנולוגיה.
המשתמשים בתקנים יוודאו שבידיהם המהדורה המעודכנת של התקן על גיליונות התיקון שלו.
מסמך המתפרסם ברשומות כגיליון תיקון, יכול להיות גיליון תיקון נפרד או תיקון המשולב בתקן.

תוקף התקן

תקן ישראלי על עדכוניו נכנס לתוקף החל ממועד פרסומו ברשומות.
יש לבדוק אם המסמך רשמי או אם חלקים ממנו רשמיים. תקן רשמי או גיליון תיקון רשמי (במלואם או בחלקם) נכנסים לתוקף 60 יום מפרסום ההודעה ברשומות, אלא אם בהודעה נקבע מועד מאוחר יותר לכניסה לתוקף.

סימון בתו תקן

כל המייצר מוצר, המתאים לדרישות התקנים הישראליים החלים עליו, רשאי, לפי היתר ממכון התקנים הישראלי, לסמנו בתו תקן:

מכון התקנים הישראלי

זכויות יוצרים

הקדמה לתקן הישראלי

תקן ישראלי זה הוא התקן של הנציבות הבין-לאומית לאלקטרוטכניקה IEC 60601-2-4 (מהדורה 3.0), לרבות AMENDMENT 1 שלו מפברואר 2018, שאושר כתקן ישראלי בשינויים ובתוספות לאומיים.

התקן כולל, בסדר המפורט להלן, רכיבים אלה:

- תרגום סעיפי חלות התקן ומטרתו בשינויים ובתוספות לאומיים (בעברית)
- פירוט השינויים והתוספות הלאומיים לסעיפי התקן הבין-לאומי (בעברית)
- תרגום חלקו העברי של התקן (באנגלית)
- התקן הבין-לאומי (כלשונו)

הערות לאומיות לתקן הישראלי מובאות כהערות שוליים וממוספרות באותיות האלף-בית.

תקן זה הוא חלק מסדרת תקנים החלים על בטיחות ציוד חשמלי לשימוש רפואי.
חלקי הסדרה הם אלה[א]:

ת"י 60601 חלק 1	-	ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים
ת"י 1011 חלק 1.1	-	ציוד חשמלי לשימוש רפואי: דרישות בטיחות כלליות - תקן נלווה: דרישות בטיחות למערכות חשמליות רפואיות
ת"י 60601 חלק 1.2	-	ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים - תקן נלווה: הפרעות אלקטרומגנטיות – דרישות ובדיקות
ת"י 60601 חלק 1.6	-	ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נלווה: שְמִישׁוּת
ת"י 60601 חלק 1.8	-	ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נלווה: דרישות כלליות, בדיקות והנחיות עבור מערכות אזעקה בציוד רפואי-חשמלי ובמערכות רפואיות-חשמליות
ת"י 60601 חלק 1.11	-	ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים – תקן נלווה: דרישות לציוד רפואי-חשמלי ולמערכות רפואיות-חשמליות המשמשים בסביבה רפואית ביתית
ת"י 1011 חלק 2.1	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מאיצי אלקטרונים בתחום מ-1MeV ועד 50MeV
ת"י 60601 חלק 2.2	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לניתוח הפועל בתדר גבוה ואבזרים לניתוח הפועלים בתדר גבוה
ת"י 60601 חלק 2.3	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד ריפוי בגלים קצרים
ת"י 60601 חלק 2.4	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מַפְעִמים (דפיברילטורים) לבביים

[א] חלקי הסדרה הממוספרים ת"י 1011 ימוספרו מחדש, והסדרה כולה תמוספר ת"י 60601 או ת"י 80601, בהתאם לסדרות התקנים הבין-לאומיים IEC 60601 או IEC 80601, וזאת במסגרת רוויזיה הנערכת לסדרה.

ת"י 60601 חלק 2.5 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לטיפול פיזיותרפי בגלים על-קוליים

ת"י 80601 חלק 2.12 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מכונות הנשמה לטיפול נמרץ

ת"י 80601 חלק 2.13 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של תחנת עבודה להרדמה

ת"י 60601 חלק 2.16 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד להמודיאליזה, להמודיאפילטרציה ולהמופילטרציה

ת"י 60601 חלק 2.18 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד אנדוסקופי

ת"י 60601 חלק 2.19 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של אינקובטורים (חממיות) לתינוקות

ת"י 60601 חלק 2.21 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מכשירי חימום קורנים לתינוקות

ת"י 60601 חלק 2.22 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לייזר ליישומים כירורגיים, קוסמטיים, רפויים ואבחוניים

ת"י 60601 חלק 2.24 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של משאבות עירוי ובקרים

ת"י 60601 חלק 2.27 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד ניטור של רִשְׁמַת לֵב חשמלית

ת"י 60601 חלק 2.33 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד תהודה מגנטית לאבחון רפואי

ת"י 60601 חלק 2.34 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד חודרני לניטור לחץ דם

ת"י 60601 חלק 2.37 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות ולביצועים החיוניים של ציוד עַל-שְׁמְעִי (ultrasonic) לאבחון ולניטור רפואי

ת"י 60601 חלק 2.39 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לדיאליזה פריטוניאלית

ת"י 60601 חלק 2.41 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של גופי תאורה לניתוח ושל גופי תאורה לאבחון

ת"י 60601 חלק 2.44 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד קרני רנטגן לטומוגרפיה ממוחשבת

ת"י 60601 חלק 2.45 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד קרני רנטגן לממוגרפיה ושל התקנים סטראוטקטיים לממוגרפיה

ת"י 60601 חלק 2.46 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של שולחנות ניתוח

ת"י 60601 חלק 2.49 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד מרובה-פעולות לניטור מטופלים

ת"י 60601 חלק 2.50 - ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד ריפוי באור לתינוקות

ת"י 60601 חלק 2.52	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של מיטות רפואיות
ת"י 60601 חלק 2.57	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד עם מקור אור שאינו לייזר המיועד לריפוי, לאבחון, לניטור ולשימוש קוסמטי/אסתטי
ת"י 80601 חלק 2.60	-	ציוד חשמלי לשימוש רפואי: דרישות מיוחדות לבטיחות בסיסית ולביצועים חיוניים של ציוד לרפואת שיניים
ת"י 1011 חלק 6	-	בטיחות ציוד חשמלי לשימוש רפואי: ציוד לטיפול בגלי-מיקרו

מהדורה זו של התקן הישראלי באה במקום המהדורה ממאי 2012, שאימצה את התקן הבין-לאומי IEC 60601-2-4 מדצמבר 2010 בשינויים ובתוספות לאומיים.
ההבדלים שבין מהדורת התקן הישראלי ממאי 2012 לבין מהדורה זו נובעים מגיליון התיקון (Amendment 1) לתקן הבין-לאומי מפברואר 2018.
לשם השוואה מדוקדקת בין המהדורות יש לעיין בנוסח המלא שלהן.

חלות התקן הישראלי ומטרתו (תרגום סעיפים 201.1.1 [חלות] ו-201.1.2 [מטרה] של התקן הבין-לאומי, בשינויים ובתוספות לאומיים)

הערה:
השינויים והתוספות הלאומיים בסעיף זה מובאים בגופן שונה.

סעיף 1 של התקן הכללי[1] חל, למעט המפורט להלן:

201.1.1. חלות התקן

החלפה:

תקן זה חל על הבטיחות הבסיסית והביצועים החיוניים של מַפְעִמים (דפיברילטורים) לבביים, המכונים להלן "ציוד רפואי-חשמלי" (ME EQUIPMENT).

אם סעיף או סעיף-משנה מיועד באופן ספציפי להיות ישים לציוד רפואי-חשמלי (ME EQUIPMENT) בלבד, או למערכות רפואיות-חשמליות (ME SYSTEMS) בלבד, כותרת הסעיף או סעיף-המשנה ותוכנו יציינו זאת. אם אין זה המקרה, הסעיף או סעיף-המשנה חל הן על ציוד רפואי-חשמלי והן על מערכות רפואיות-חשמליות, לפי העניין.

לגורמי סיכון (HAZARDS) הטבועים בתפקודם הפיזיולוגי המיועד של ציוד רפואי-חשמלי או של מערכות רפואיות-חשמליות, הנידונים במסגרת חלותו של תקן זה, אין דרישות ספציפיות בתקן זה, למעט בסעיפים 7.2.1.3 ו-8.4.1 של התקן הכללי.

הערה: ראו גם סעיף 4.2 של התקן הכללי.

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[1] התקן הכללי הוא: התקן הישראלי ת"י 60601 חלק 1 - ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים.
התקן זהה בשינויים ובתוספות לתקן הבין-לאומי IEC 60601-1:2005+AMD1:2012 Edition 3.1 (2012-08-20)

תקן מיוחד זה אינו חל על מַפְעמים הניתנים להשתלה, מַפְעמים בעלי שלט רחוק, או מוניטורים (משגוחים) לבביים עצמאיים נפרדים (שחל עליהם התקן[2] IEC 60601-2-27:2011 [2] [ב]). תקן זה אינו חל על מוניטורים (משגוחים) לבביים העושים שימוש באלקטרודות נפרדות לניטור רְשְמַת לֵב חשמלית (ECG), אלא אם הם משמשים בסיס יחיד לזיהוי הקצב של מַפְעֵם (דפיברילטור) חיצוני אוטומטי (AED) או לאיתור קצב לב בהיפוך חשמלי מסונכרן.

אלקטרודות מַפעם (דפיברילטור) המתוארות בסעיף 201.108 יכולות גם הן לשמש לניטור רְשמת לב חשמלית (ECG); אולם משום ששטח האלקטרודה גדול יותר, הדרישות של IEC 60601-2-27 אינן ישימות עבור אלקטרודות מַפעם.

הטכנולוגיה של צורת גל (waveform) להַפְעָמָה (דפיברילציה) מתפתחת במהירות. מחקרים שפורסמו מצביעים על כך שהאפקטיביות של צורת הגל אינה אחידה. הבחירה בצורת גל מסוימת, לרבות מבנה הגל (waveshape), האנרגייה המועברת בו, יעילותו ובטיחותו, היא בפירוש מחוץ לחלות תקן זה.

עם זאת, עקב החשיבות הקריטית של צורת הגל הטיפולית, הוסיפו לתקן הערות הנוגעות לשיקולים המנחים בבחירת צורת הגל.

201.1.2. מטרה

החלפה:

מטרת תקן מיוחד זה היא לקבוע דרישות מיוחדות לבטיחות הבסיסית ולביצועים החיוניים של מַפְעמים לבביים כמוגדר בסעיף 201.3.202.

פירוט השינויים והתוספות הלאומיים לסעיפי התקן הבין-לאומי

201.2. Normative references

במקום אחד התקנים הבין-לאומיים המאוזכרים בתקן והמפורטים בסעיף זה חל תקן ישראלי, כמפורט להלן:

התקן הבין-לאומי המאוזכר	התקן הישראלי החל במקומו	הערות
IEC 60601-1: 2005	ת"י 60601 חלק 1 – ציוד חשמלי לשימוש רפואי: דרישות כלליות לבטיחות בסיסית ולביצועים חיוניים	התקן הישראלי, למעט השינויים והתוספות הלאומיים המצוינים בו, זהה לתקן של הנציבות הבין-לאומית לאלקטרוטכניקה IEC 60601-1 - Third edition: 2005-12

[2] מספרים בסוגריים מרובעים מתייחסים לביבליוגרפיה.

[ב] התקן הישראלי ת"י 60601-2-27 ממרס 2012 מאמץ את התקן הבין-לאומי IEC 60601-2-27 Ed 3.0: 2011-03 בשינויים ובתוספות לאומיים.

IEC 60601-2-4

Edition 3.0 2018-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

Appareils électromédicaux – Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques

IEC 60601-2-4:2010-12/AMD1:2018-02(en-fr)

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AMENDMENT 1
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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
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INTERNATIONALE

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1549/FDIS	62D/1555/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

_____

201.1.1 * Scope

Replace the fourth existing paragraph by the following new paragraph:

This particular standard does not apply to implantable DEFIBRILLATORs, remote control DEFIBRILLATORS, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2][1]). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

201.2 Normative references

Replace, in the "Amendment" section, the existing reference IEC 60601-1-2, including its title, by the following new reference:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

_____

1 Numbers in square brackets refer to the bibliography.

Replace, in the "Addition" section, the existing reference "ISO 15223-1:2007" *by* "ISO 15223-1:2016"

Add, in the "Addition" section, the following new reference:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

201.3 Terms and definitions

Replace the first existing paragraph by the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 apply, except as follows:

201.3.202

Replace the existing Note 2 by the following new note:

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions (e.g. transcutaneous pacing).

201.3.203

Add, after the definition, the following new note:

NOTE The CHARGING CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.204

Replace the existing definition and note by the following new definition and note:

electrode intended to deliver an electrical pulse for the purpose of cardiac defibrillation and which may also be used to provide transcutaneous pacing and other monitoring functions

NOTE DEFIBRILLATOR ELECTRODES may be internal or external and disposable or reusable.

201.3.206

Add, after the definition, the following new note:

NOTE The DISCHARGE CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.209

Replace the existing note by the following new note:

NOTE The energy storage devices for defibrillation and pacing functions may be separate or combined.

Add, after 201.3.220, the following new term and definition:

201.3.221
PACER
EXTERNAL TRANSCUTANEOUS PACEMAKER
optional circuit within the DEFIBRILLATOR intended to stimulate the heart by a series of electrical pulses via electrodes applied to the PATIENT's skin

201.7.2.103 Disposable defibrillator electrodes

Replace, in item a) of the existing paragraph, the reference "ISO 15223-1:2007" *by* "ISO 15223-1:2016".

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Add, after 201.8.3, the following new subclause:

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Addition:

Where the MAXIMUM MAINS VOLTAGE has been assigned the value of 250 V, and the derivation of test voltage from the value of the MAXIMUM MAINS VOLTAGE includes a 110 % multiplier, that multiplier shall not apply.

201.8.7.1 General requirements

Replace the existing instruction by the following new instruction:

Replacement of b) dash 4 with:

201.8.8.3 * Dielectric strength

Replace, in the "Addition" section, the first existing paragraph by the following new paragraph:

For the DEFIBRILLATOR and PACER high-voltage circuits, between high-voltage parts of opposite polarity and high-voltage to low-voltage circuits, the following tests shall replace those of the general standard.

Delete, in the second paragraph in the "Addition" section, the words "during discharging".

Replace, in the fifth paragraph of Test 1, the term "DEFIBRILLATOR" *by "*DEFIBRILLATOR or PACER".

Replace, in the seventh paragraph of Test 1, the term "DEFIBRILLATORS" by "DEFIBRILLATORS or PACERS".

Add, after the last paragraph of the Subclause, the following new paragraph:

For the dielectric tests of the general standard, the WORKING VOLTAGE is determined without regard to the presence of defibrillation or pacing voltages.

201.8.9.1.5 * ME EQUIPMENT RATED for high altitudes

Replace the existing paragraph by the following new paragraph:

General standard subclause 8.9.1.5 does not apply to DEFIBRILLATORS rated for use at altitudes up to 5 000 m.

201.8.9.1.101 * DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

Delete, in the note, the words "but is under consideration for future application".

Replace the existing item b), excluding the compliance statement, by the following new paragraphs:

b) * Except for components where the adequacy of ratings can be demonstrated (e.g. by component manufacturers' ratings or by the dielectric strength tests of 201.8.8.3 of this standard) the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the DEFIBRILLATOR or PACER high-voltage circuits and other parts, and between different parts of the high-voltage circuits, shall be at least 3 mm/kV.

This requirement shall also apply to the isolating means between the high-voltage circuit of the DEFIBRILLATOR or PACER and other PATIENT circuits.

201.12.3 ALARM SYSTEMS

Delete the entire subclause, including 201.12.3.101.

201.12.4 Protection against hazardous output

Add, after 201.12.4.103, the following new subclause:

201.12.4.104 * Audible warnings prior to energy delivery

The DEFIBRILLATOR shall include an audible warning signal that indicates the DEFIBRILLATOR is preparing to or is about to deliver energy to the PATIENT. The preparing-to or about-to-deliver-energy-to-the-patient warning shall not be capable of being inhibited by the OPERATOR or RESPONSIBLE ORGANIZATION. The warning shall occur:

a) for manual DEFIBRILLATORS and AEDs with OPERATOR activated discharge control, when the discharge control is active;

b) for AEDs with automatic discharge control, at least 5 s prior to energy delivery.

The effectiveness of the audible warnings to mitigate the risk of unintentional energy delivery to the OPERATOR or bystander shall be included in the RISK MANAGEMENT FILE.

201.15.4.3.101 * Non-rechargeable battery replacement

Replace the existing title by the following new title:

201.15.4.3.101 * Battery replacement

201.101.1 Requirements for FREQUENT USE, MANUAL DEFIBRILLATORS

Replace, in the third paragraph, "201.7.2.101" *by* "201.7.2.102"*.*

201.101.4 * Requirements for INFREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS

Replace the existing paragraph before the last by the following new paragraph:

In case of a DEFIBRILLATOR *with non-rechargeable batteries, the test is to start with a battery depleted by the delivery of the number of charge/discharge cycles after which it is specified as still useable by the MANUFACTURER, or when the ME EQUIPMENT indicates that the battery needs replacement, whichever comes first.*

201.102.3.1 FREQUENT USE AED

Add, after the first paragraph, the following new paragraphs:

If the AED is incapable of meeting one of the above criteria due to the implementation of a fixed protocol which does not meet the above criteria, select and use the available protocol that most closely matches one of the provided criteria.

For a FREQUENT USE AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

201.102.3.2 INFREQUENT USE AED

Add, after the first paragraph, the following new paragraph:

If the AED is incapable of meeting one of the above criteria due to the implementation of a fixed protocol which does not meet the above criteria, select and use the available protocol that most closely matches one of the provided criteria.

201.105.1 ECG signal derived via DEFIBRILLATOR ELECTRODES

Add, after the second paragraph, the following new paragraph:

If the AED incorporates a CPR interval after a shock within the pre-programmed defibrillation sequence, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s after the minimum CPR interval setting.

201.105.3 ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES

Add, after the last paragraph, the following new paragraph:

If the AED incorporates a CPR interval after a shock within the pre-programmed defibrillation sequence, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s after the minimum CPR interval setting.

201.106 * Disturbance to the MONITOR from charging or internal discharging

Add, after item c) of the third paragraph, the following new paragraph:

If necessary, a capacitor may be added in parallel with the 5 kΩ impedance for tests b) and c) above such that the device operates within its valid patient impedance range. If used, the capacitor shall be the minimum value required to achieve a valid patient impedance. The value of the capacitor and the rationale for the selected value shall be disclosed in the test report.

201.108.1.1 * AC small signal impedance

Replace the first two existing paragraphs by the following new paragraphs:

The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak, shall not exceed 3 kΩ. The impedance at 30 kHz shall be less than 10 Ω.

Reference: ANSI/AAMI EC12, Section 4.2.2.1 on sample size and failure rate.

Compliance is checked by connecting a pair of electrodes, gel-to-gel, applying a 10 Hz sinusoidal current of known amplitude not exceeding 100 μA p-p and observing the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a resistor in series with the electrode pair. The value of the resistor should be at least 10 times the value of the electrode impedance.

201.108.1.2 * AC large signal impedance

Replace, in the first paragraph, "3 Ω" *by* "5 Ω".

Replace, in the second paragraph, "3:50" *by* "5:50".

201.108.1.3 * Combined offset instability and internal noise

Delete the entire subclause.

201.108.1.4 * Defibrillation recovery

Replace the existing paragraph by the following new paragraphs:

The potential of a pair of gel-to-gel electrodes in series with a 50 Ω resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 500 mV at 4 s and 400 mV at 60 s after the last shock delivery.

When this test is executed after pacing according to 201.108.1.10 c) the potential shall not exceed 1 000 mV at 4 s and 750 mV at 60 s.

201.108.1.9 * Packaging and shelf life

Replace the existing two paragraphs by the following new paragraphs:

The electrodes shall be manufactured and packaged in such a way that all requirements of this standard shall be met up to the expiration date and under the storage conditions specified by the MANUFACTURER. At a minimum, electrodes shall comply with all performance specifications after storage for 1 year at 35 °C. One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 h at −30 °C and for 24 h at +65 °C. Electrodes shall be returned to a temperature in the range of 15 °C to 35 °C before the test for compliance is performed. Electrodes shall be tested at both 15 °C and 35 °C.

Compliance is checked by conducting the tests of 201.108.1.1 through 201.108.1.8 at the end of the specified shelf life and at both 15 °C and 35 °C.

201.108.1.10 * Universal-function electrodes

Replace the last existing paragraph by the following new paragraph:

Compliance is checked by the electrodes meeting these requirements or shall be met by the disclosure of the performance to each specification: 201.108.1.1 to 201.108.1.4 following an hour of pacing. Tests shall be conducted immediately after the conclusion of pacing.

201.108.1.11 * Cable length

Replace the first sentence of the first existing paragraph by the following new sentence:

The electrode cables shall have an extended length of at least 2 m for monitor/DEFIBRILLATORs (e.g. hospital crash cart), and a length of at least 1 m for AEDs.

201.109 * External pacing (U.S.)

Delete, in the title, the words "(U.S.)"*.*

201.109.2.1 Separate pacing pathway

Replace, in item (1) of the second existing paragraph, the reference "Figure US.2" *by* "Figure 201.109"*.*

201.109.7 Demand pacing

Add, after the last paragraph of the subclause, the following new paragraphs:

Set the pacing rate to its maximum rate. Input ECG with maximum rate +10 %. The unit shall not have pacing activated. Change the ECG signal rate to maximum rate −10 %. The unit shall now have pacing activated.

Set the pacing rate to its minimum rate. Input ECG with minimum rate +10 %. The unit shall not have pacing activated. Change the ECG signal rate to minimum rate −10 %. The unit shall now have pacing activated.

201.109.8 Pacer lead-off indication

Delete Figure 201.109.

Figure 201.110 – Test circuit for DEFIBRILLATOR overload test of pacing output circuitry

Replace, in the key to the figure, the existing L and $R + R_L$ values by the following new values:

L = 500 μH

R + R_L ≤ 10 Ω (R_L represents the d.c. resistance of inductor L)

202 * Electromagnetic compatibility – Requirements and tests

Replace, in the first sentence, the reference "IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014"*.*

202.6.2.3.2 Tests

Add, in the title, an asterisk before the word "Tests".

Replace the first sentence of the existing paragraph before the last by the following new sentences:

** The DEFIBRILLATOR ELECTRODES are terminated in a simulated PATIENT load (1 kΩ resistor in parallel with a 1 μF capacitor) and, if necessary, an additional resistor and capacitor parallel combination in series such that the device operates within its valid patient impedance range. If used, the additional resistor and capacitor values shall be disclosed in the test report.*

Annex AA
(informative)

Particular guidance and rationale

Subclause 201.7.2.101 – Concise operating instructions

Add, after the existing paragraph, the following new paragraph:

The monitoring of a PATIENT's ECG is considered relevant where the ECG is needed to either deliver defibrillation therapy, or to make the determination that the delivery of defibrillation therapy is needed.

Add, after Subclause 201.8.3, the following new paragraph:

Subclause 201.8.5.3 – MAXIMUM MAINS VOLTAGE

This clarifies the definition in order to retain the test voltage of 250 V, which is considered to be sufficient for INTERNALLY POWERED ME EQUIPMENT with no means of connection to the SUPPLY MAINS, or ME EQUIPMENT with a connection to SUPPLY MAINS where the RATED supply voltage is less than 100 V.

Subclause 201.8.8.3 – Dielectric strength

Replace the first existing paragraph by the following new paragraphs:

Voltage spikes on the SUPPLY MAINS will not appreciably affect the voltage on the energy storage capacitor; therefore, a moderate test voltage relative to the PEAK WORKING VOLTAGE of the DEFIBRILLATOR or PACER high-voltage circuits was considered to be sufficient. The removal of defibrillation or pacing voltages from the calculation of WORKING VOLTAGE for the tests of the general standard ensure that all other tests (e.g. between APPLIED PARTS and MAINS PART) remain in effect, while the tests of this standard are appropriate to ensure the safety of the defibrillation and pacing circuits.

In the general standard, earthing of the PATIENT is not considered to be a fault condition; consequently, the situation where one side of the APPLIED PART is connected to earth had to be included.

*Replace, in the existing subclause, the eight occurrences of the term "*DEFIBRILLATOR*" by "*DEFIBRILLATOR or PACER*".*

Subclause 201.8.9.1.5 – ME EQUIPMENT RATED for high altitudes

Delete, in the existing paragraph, the last sentence.

Subclause 201.8.9.1.101 – DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

Add, in item b), the following new text:

The defibrillation and pacing circuits, typically both comprised of CHARGING CIRCUITS, DISCHARGING CIRCUITS, ENERGY STORAGE DEVICES, etc., may be combined or separate depending on the architecture of the DEFIBRILLATOR.

For those pacing circuits which utilize the same energy delivery circuits as the DEFIBRILLATOR, and where the DEFIBRILLATOR WORKING VOLTAGE used in calculating the CREEPAGE DISTANCES and AIR CLEARANCES is larger than the WORKING VOLTAGE for the PACER, there is no need to duplicate the testing at the lower voltage.

For those pacing circuits which have their own dedicated energy delivery circuits separate from the DEFIBRILLATOR, the maximum peak voltage present during pacing in NORMAL USE is used in calculating the CREEPAGE DISTANCES and AIR CLEARANCES. This should include the worst-case level of superimposed ripple and overshoot that can be present during NORMAL USE.

In those cases where a component or insulation which is a sub-part of a combined energy delivery circuit is only exposed to pacing voltages, only pacing voltages should be considered for that particular component or insulation.

Subclause 201.12.3.101 – Audible warnings prior to energy delivery

Delete the entire subclause.

Add, after Subclause 201.12.4.103, the following new paragraph:

Subclause 201.12.4.104 – Audible warnings prior to energy delivery

The term "warning" was chosen to differentiate from an alarm associated with patient monitoring.

Adequate OPERATOR warning prior to discharge is important. However, it is possible to charge safely even though discharge may not be imminent. Because charging may be an internal "background" function of the device, it is more important to the OPERATOR to be warned of impending external events, such as energy delivery. Of more relevance to the OPERATOR is the following.

a) If the DEFIBRILLATOR is manual or semi-automatic, audible warnings are needed when the DEFIBRILLATOR becomes fully armed and ready to shock. This allows the OPERATOR and any bystanders to prepare for the shock.
b) If the DEFIBRILLATOR is fully automatic, audible warnings at least 5 s prior to discharge are needed to allow time to cease touching the PATIENT.

Audible warnings can be provided as voice prompts, audible tones, or both.

It is highly recommended that the audible warnings prior to energy delivery also be accompanied by a visual indication.

Subclause 201.15.4.3.101 – Non-rechargeable battery replacement

Replace the existing title by the following new title:

Subclause 201.15.4.3.101 – Battery replacement

Subclause 201.108.1.3 – Combined offset instability and internal noise

Delete the entire subclause.

Subclause 201.108.1.9 – Packaging and shelf life

Add, after the last existing paragraph, the following new paragraph:

The operating temperature range for AEDs is typically 0 °C to 50 °C. Near freezing, a pair of hydrogel electrodes placed gel-to-gel exhibit very high impedances due to their water content. However, when placed on the chest, they readily equilibrate with body skin temperature (~33 °C). At the higher temperatures, there is less resistance to ionic flow and the gel-to-gel hydrogel electrode pair exhibit lower impedances than at room temperature. Again, when placed on skin, the electrodes' temperature will approach skin temperature. Thus,

DEFIBRILLATOR electrodes will operate in a 0 °C to 50 °C space, as long as the body they are attached to is warm.

Subclause 201.108.1.11 – Cable length

Replace the existing paragraph by the following new paragraphs:

For monitor/DEFIBRILLATORs, to ensure that the user has adequate cable for most purposes, minimum cable length of 2 m (80 in) was specified for those units requiring cables. Although it was recognized that a minimum cable of 3 m (10 ft) might be more useful in some circumstances, it was felt that a 3 m cable would be rather cumbersome for some mobile applications and hence was not specified as a minimum requirement.

For AEDs, the only essential requirement is that the cables reach from a device on the floor or bed to the PATIENT's chest. To allow the DEFIBRILLATOR to be placed out of the way of where the user might perform CPR, and allow for it to be placed on the PATIENT's right (furthest away from the cardiac apex), one may compute the distance for the largest male patient. Consulting [7] and using the largest values from Tables 10.1 to 10.17 (which look at different nationalities), we find that the maximum shoulder height (1 545 mm) minus the maximum hip height (965 mm) is 580 mm, the maximum shoulder breadth is 445 mm and the maximum abdominal depth is 375 mm. The distance is the square root of the sum of the squares, which is equal to 822 mm. Therefore, a minimum cable length of 1 m is appropriate.

Also, note that only medical professionals use coil cords, therefore there need not be a separate requirement for devices used by lay users.

Add, after Clause 202, the following new paragraph:

Subclause 202.6.2.3.2 – Tests

For some DEFIBRILLATORs, the simulated PATIENT load consisting of a 1 kΩ resistor in parallel with a 1 µF capacitor is not within the acceptable/specified range to detect a valid PATIENT is connected. The load showed in Figure AA.1 is proposed and is unique to each device.

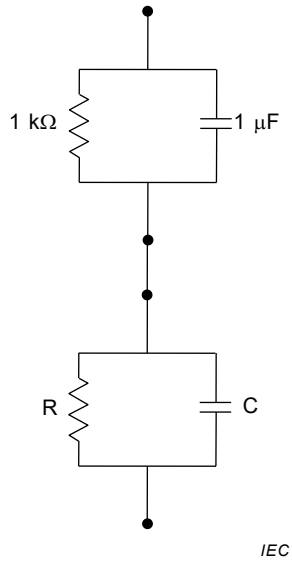

Figure AA.1 – Simulated PATIENT load

This load retains the part of the load in the IEC/AAMI specification, but adds a parallel RC to this in series. The values of this load would be provided by the manufacturer on request to satisfy any PATIENT qualification features within the device. Since the frequencies used to test

EMI are in the tens-of-megahertz to gigahertz range, there should be no effect on the test. The difference in impedance at lower frequencies would be insignificant to either the test or the device. It is not possible for manufacturers to specify loads that would improve their test results because the load that is specified by the MANUFACTURER is in series with the current AAMI/IEC load and any load could only make results worse, not better.

Bibliography

Replace reference [2] by the following new reference:

[2] IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

Add, at the end of the bibliography, the following new reference:

[7] PHEASANT S. HASLEGRAVE C. M. Bodyspace, anthropometry, ergonomics and the design of work. Third edition, CRC Press, 2005.

Index of defined terms used in this particular standard

*Delete the term "*HIGH VOLTAGE*" and its reference.*

*Replace, in the term "*IMMUNITY*", the reference* "IEC 60601-1-2:2007, 3.13" *by* "IEC 60601-1-2:2014, 3.8".

*Replace, in the term "*IMMUNITY LEVEL*", the reference* "IEC 60601-1-2:2007, 3.14" *by* "IEC 60601-1-2:2014, 3.9".

Replace, in the reference to the term "RHYTHM RECOGNITION DETECTOR (RRD)"*, the number* "215" *by* "216".

Replace, in the reference to the term "SELECTED ENERGY"*, the number* "216" *by* "217".

Replace, in the reference to the term "SEPARATE MONITORING ELECTRODE"*, the number* "217" *by "218".*

Replace, in the reference to the term "STAND-BY"*, the number* "218" *by* "219".

Replace, in the reference to the term "STORED ENERGY"*, the number* "219" *by* "220".

Replace, in the reference to the term "SYNCHRONIZER"*, the number* "220" *by* "221".

_____

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IEC 60601-2-4

Edition 3.0 2010-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

Appareils électromédicaux –
Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques

IEC 60601-2-4:2010

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IEC 60601-2-4

Edition 3.0 2010-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

Appareils électromédicaux – Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2002. This edition constitutes a technical revision, revised to structurally align it with IEC 60601-1:2005 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;

- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match IEC 60601-1-2, third edition.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/857/FDIS	62D/878/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27 [2][2]). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for cardiac defibrillators as defined in 201.3.202.

---

1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

2 Numbers in square brackets refer to the bibliography.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general

standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 73.

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

ISO 15223-1:2007, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

Addition:

NOTE An index of defined terms is found beginning on page 74.

201.3.201
AUTOMATED EXTERNAL DEFIBRILLATOR
AED
DEFIBRILLATOR that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the patient's skin identifies shockable cardiac rhythms, and automatically operates the DEFIBRILLATOR when a shockable rhythm is detected, hereinafter referred to as an AED

NOTE AEDs may provide varying levels of automation and be referred to by various terms. A semi-automatic DEFIBRILLATOR requires manual shock activation. A fully automatic DEFIBRILLATOR will provide shock without OPERATOR intervention.

201.3.202
CARDIAC DEFIBRILLATOR
MEDICAL ELECTRICAL EQUIPMENT intended to normalize the rhythm of the heart by an electrical pulse via electrodes applied either to the PATIENT's skin with external electrodes or to the exposed heart with internal electrodes

NOTE 1 A CARDIAC DEFIBRILLATOR can be referred to in this standard as a DEFIBRILLATOR or as ME EQUIPMENT.

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions.

201.3.203
CHARGING CIRCUIT
circuit within the DEFIBRILLATOR intended for charging the ENERGY STORAGE DEVICE. This circuit includes all parts conductively connected to the ENERGY STORAGE DEVICE during the charging period

201.3.204
DEFIBRILLATOR ELECTRODE
electrode intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation

NOTE DEFIBRILLATOR ELECTRODES may also provide other monitoring (e.g. ECG acquisition) or therapeutic (e.g. transcutaneous pacing) functions and may be disposable or reusable.

201.3.205
DELIVERED ENERGY
energy which is delivered through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value

201.3.206
DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which connects the ENERGY STORAGE DEVICE to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

201.3.207
DUMMY COMPONENT
test replacement for moulded components like transformers, resistors, semiconductors etc.

NOTE The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test, but provides dielectric isolation. The volume may lack parts of the original components (for example: semiconductor die, transformer cores and windings). The DUMMY COMPONENT makes it possible to test creepage, clearance and dielectric strength with the correct geometry without exceeding the internal maximum voltage of the part being replaced. The DUMMY COMPONENT shall be identical to the component replaced with respect to conductive external details such as metal legs, pins etc.

201.3.208
DEFIBRILLATOR TESTER
instrument capable of measuring the energy output from a CARDIAC DEFIBRILLATOR while generating a simulated ECG output to the CARDIAC DEFIBRILLATOR

201.3.209
ENERGY STORAGE DEVICE
component that is charged with the energy necessary to deliver an electrical defibrillation pulse to the PATIENT

NOTE A capacitor is a typical example of the component.

201.3.210
FREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure more than 2 500 discharges (see 201.103)

201.3.211
INFREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure less than 2 500 discharges (see 201.103)

201.3.212
INTERNAL DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

201.3.213
MANUAL DEFIBRILLATOR
DEFIBRILLATOR capable of being manually operated by the OPERATOR for selection of energy, charging and discharging

201.3.214
MONITOR
part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this particular standard to distinguish such a MONITOR from one which forms a separate ME EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

201.3.215
RHYTHM RECOGNITION DETECTOR
RRD
a system that analyzes the ECG and identifies whether a cardiac rhythm is shockable

NOTE The algorithm in an AED is designed for sensitivity and specificity for the detection of arrhythmias for which a defibrillation shock is clinically indicated. May be referred to as RRD.

201.3.216
SELECTED ENERGY
energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an automatic protocol

201.3.217
SEPARATE MONITORING ELECTRODE
electrode applied to the PATIENT for the purpose of monitoring the PATIENT

NOTE These electrodes are not used to apply defibrillation pulses to the PATIENT.

201.3.218
STAND-BY
mode of operation in which the ME EQUIPMENT is operational except that the ENERGY STORAGE DEVICE is not yet charged

201.3.219
STORED ENERGY
energy which is stored in the DEFIBRILLATOR ENERGY STORAGE DEVICE

201.3.220
SYNCHRONIZER
device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

201.4.2.101 * Additional RISK MANAGEMENT requirements

MANUFACTURER shall address readiness for use in the RISK MANAGEMENT FILE.

Check compliance by inspection of RISK MANAGEMENT FILE.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Each of the three capabilities listed in Table 201.101, when included in a defibrillator, will be considered ESSENTIAL PERFORMANCE.

Where engineering judgement by the MANUFACTURER specifies performance in excess of ESSENTIAL PERFORMANCE, that performance may be degraded by external factors such as EMC, as long as the RISK MANAGEMENT FILE documents that ESSENTIAL PERFORMANCE is met.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	
Description	**(Sub)clause**
Deliver defibrillation therapy	201.12.1
Deliver synchronized defibrillation therapy	201.104
Accurately differentiate between shockable and nonshockable rhythms	201.107

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition:

aa) The test required in 201.102.2 and 201.102.3 shall be performed at an ambient temperature of 0 °C ± 2 °C.

201.5.4 Other conditions

Addition:

aa) Unless otherwise specified in this standard, all tests apply to all kinds of DEFIBRILLATOR types (manual, AEDs, INFREQUENT USE and FREQUENT USE DEFIBRILLATORS).

201.5.8 Sequence of tests

Addition:

The endurance test required in Clause 201.103 shall be performed after the test for excessive temperatures (see B.19 of the general standard).

The tests required in Clauses 201.101, 201.102, 201.104, 201.105 and 201.106 shall be performed after test B.35 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 * Electrical input power from the SUPPLY MAINS

Replacement of paragraph beginning "If the rating of ME EQUIPMENT includes ...":

The RATED power input of mains operated ME EQUIPMENT shall be the maximum value attained by averaging the power input over any period of 2 s.

Additional subclauses:

201.7.2.101 * Concise operating instructions

Instructions for defibrillating, and where relevant, monitoring a PATIENT'S ECG, shall be provided by means of either clearly legible markings, or clearly understandable auditory commands.

Check compliance of auditory commands by the following test:

Auditory commands shall be clearly understandable to a person of normal hearing from a distance of 1 m in an ambient white noise (defined as flat ±10 % over the range 100 Hz to 10 kHz) level of 65 dB, as measured with a Type 2 A-weighted sound level meter (see IEC 61672-1).

201.7.2.102 * INTERNALLY POWERED ME EQUIPMENT

INTERNALLY POWERED ME EQUIPMENT and any separate battery charger shall be marked with brief instructions for, as appropriate, the re-charging or replacement of the battery.

If a connection to the SUPPLY MAINS or to a separate battery charger is provided, the ME EQUIPMENT shall be marked to indicate any limitations of operation when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. Such marking shall include a description of the function as well as any limitations of operation of the ME EQUIPMENT with a discharged or missing battery.

201.7.2.103 Disposable defibrillator electrodes

The labelling accompanying the electrode package shall include, at a minimum, the following information:

a) symbols (in accordance with ISO 15223-1:2007) or a statement indicating the date the electrodes will expire (e.g., "use before ____") and the lot number or the date of manufacture;

b) appropriate cautions and warnings, including limits on duration of electrode application and a caution that the unit package shall not be opened until immediately prior to use, if applicable;

c) appropriate instructions for use, including procedures for skin preparation;

d) instructions describing storage requirements, if applicable.

201.7.4 Marking of controls and instruments

Additional subclause:

201.7.4.101 * Selected energy control

The DEFIBRILLATOR shall be provided with a means for choosing the SELECTED ENERGY, unless the ME EQUIPMENT provides an automatic protocol for choosing the SELECTED ENERGY.

If the DEFIBRILLATOR is provided with means for the selection, continuously or in steps, of the SELECTED ENERGY then an indication of the SELECTED ENERGY in joules shall be incorporated, expressed as the nominal DELIVERED ENERGY in joules to a resistive load of 50 Ω.

Alternatively, the DEFIBRILLATOR may deliver a single preset energy, or a sequence of energies according to a preset protocol described in the instructions for use. If the DEFIBRILLATOR is designed to supply a single energy, or a programmed sequence of energies, no indication of the SELECTED ENERGY is required.

Check compliance by inspection.

201.7.9.2 Instructions for use

201.7.9.2.4 * Electrical power source

Replacement:

For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.

If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.

The instructions for use shall provide information on the number of maximum energy discharges (in the case of AEDs, the number of preprogrammed discharges) which are available from a new and fully charged battery at 20 °C ambient temperature.

If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification, and include full details of the charging procedure.

* The instructions for use shall contain advice on the periodic replacement of any primary or rechargeable battery.

If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or other available energy source.

For ME EQUIPMENT that is also capable of connection to the SUPPLY MAINS or to a separate battery charger, the instructions for use shall contain information on any limitations of operation when such a connection is made. This information shall include the case of a discharged or missing battery.

Additional subclause:

201.7.9.2.101 * Supplementary instructions for use

The instructions for use shall additionally contain the following:

a) * warning not to touch the PATIENT during defibrillation;

b) * a description of the correct type and method of handling the DEFIBRILLATOR ELECTRODES in use as well as a prominent warning that DEFIBRILLATOR ELECTRODES shall be kept well clear of other electrodes or metal parts in contact with the PATIENT. The OPERATOR shall be advised that other ME EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts shall be disconnected from the PATIENT during defibrillation;

c) caution for the OPERATOR to avoid contact between parts of the PATIENT's body such as exposed skin of head or limbs, conductive fluids such as gel, blood or saline and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current;

d) * any environmental limitations regarding storing the ME EQUIPMENT (e.g. in a car or an ambulance under severe climatic conditions) immediately prior to use;

e) where means are provided for monitoring via SEPARATE MONITORING ELECTRODES, instructions for the placement of these electrodes;

f) * a recommendation calling the OPERATOR'S attention to the need for periodic maintenance of the ME EQUIPMENT irrespective of usage, especially:

- cleaning of any reusable DEFIBRILLATOR ELECTRODES and the insulating parts of the handles;
- sterilization procedures for any reusable DEFIBRILLATOR ELECTRODES or handles, including recommended sterilization methods and maximum sterilization cycles, if applicable;
- cleaning of any reusable monitoring electrodes;
- inspection of the packaging of any disposable DEFIBRILLATOR ELECTRODES and any disposable monitoring electrodes to ensure integrity of any seals and validity of any expiry date;
- inspection of cables and electrode handles for possible defects;
- functional checks;
- charging of the ENERGY STORAGE DEVICE, if it is of a type requiring periodic charging (e.g. electrolytic or polyvinylidene fluoride (PVDF) capacitors);

g) * information on the time required for charging a fully discharged ENERGY STORAGE DEVICE, when the DEFIBRILLATOR is set to maximum energy,

1) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;

2) with MAINS VOLTAGE of 90 % of the RATED value and for an INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges taken from a new fully charged battery for FREQUENT USE DEFIBRILLATOR or 6 discharges for INFREQUENT USE DEFIBRILLATOR;

3) as 2) but measured from initially switching power on to ready for discharge at maximum energy;

h) for AEDs, information on the maximum time from the initiation of rhythm analysis with a clear ECG signal to readiness for discharge. The defibrillator will indicate if the ECG signal is not presently analyzable.

1) with RATED MAINS VOLTAGE and, for an INTERNALLY POWERED DEFIBRILLATOR, with a new fully charged battery;

2) with MAINS VOLTAGE of 90 % of the RATED value and for AN INTERNALLY POWERED DEFIBRILLATOR after 15 maximum energy discharges taken from a new fully charged battery for a FREQUENT USE DEFIBRILLATOR or 6 discharges for an INFREQUENT USE DEFIBRILLATOR;

3) as 2) but measured from initially switching power on to ready for discharge at maximum energy;

i) * for AEDs, information on whether or not the defibrillator can automatically abort a charged and ready for shock condition as follows:

- the RHYTHM RECOGNITION DETECTOR has detected a shockable rhythm and the DEFIBRILLATOR is charged and ready to shock;
- the RRD has continued analyzing ECG after the initial shockable rhythm detection and has then detected a non-shockable rhythm;

j) a warning that use of a DEFIBRILLATOR in the presence of flammable agents or in an oxygen enriched atmosphere presents an explosion and fire HAZARD;

k) for ME EQUIPMENT intended for INFREQUENT USE, the intent shall be clearly stated and the limitations of the ME EQUIPMENT shall be clearly defined. Recommended or required status tests or preventive maintenance shall also be stated;

l) for ME EQUIPMENT that delivers energy according to a preset protocol, information regarding the automatic selection of DELIVERED ENERGY and the conditions for resetting of the protocol shall be described in the instructions for use. The instruction for use shall also contain information of how to change the protocol if applicable.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 * ESSENTIAL PERFORMANCE data for defibrillation

The technical description shall additionally provide:

a) graphical plots in terms of time and current or voltage of the waveforms of the delivered pulses when the DEFIBRILLATOR is connected in turn to resistive loads of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω 150 Ω and 175 Ω and set to its maximum output, or according to an automatic protocol for the SELECTED ENERGY if applicable;

b) energy accuracy specifications for the DELIVERED ENERGY in a 50 Ω resistor;

c) if the DEFIBRILLATOR has a mechanism to inhibit its output when the PATIENT impedance is outside certain limits, disclosure of those limits.

201.7.9.3.102 * ESSENTIAL PERFORMANCE data of any SYNCHRONIZER

The technical description shall additionally provide:

a) the meaning of any displayed synchronization or marker pulse;

b) the maximum time delay between the synchronization pulse and delivery of the energy, once the output has been activated, including details of how the time delay was measured; and

c) a statement concerning any conditions which will de-select the synchronized mode.

201.7.9.3.103 * ESSENTIAL PERFORMANCE data of the RHYTHM RECOGNITION DETECTOR

The technical description shall additionally provide:

a) ECG database test report, (see 201.107 for database requirements);

A test report describing the recording methods, rhythm source, rhythm selection criteria, and annotation methods and criteria shall be available. The results of detector performance shall be reported in terms of specificity, true predictive value, sensitivity, and false positive rates. See 201.107 for definitions.

The report shall clearly summarize the sensitivity for detecting VF, and the sensitivity for detecting ventricular tachycardia (VT) for those devices designed to treat VT. For those devices designed to treat certain types of VT a description of the requirements for indication of VT as a shockable rhythm shall be included. The positive predictive accuracy, the false positive rate and overall specificity of the device shall also be reported. Reporting the specificity of the device for each non-shockable rhythm group (i.e. normal

sinus rhythm, supraventricular rhythms such as atrial fibrillation and atrial flutter, ventricular ectopy, idioventricular rhythms and asystole) is recommended but not required.

b) if the detector initiates analysis of the rhythm either automatically or following manual initiation by the OPERATOR, this shall be described;

c) if the DEFIBRILLATOR incorporates a system that detects and analyzes physiological information other than the ECG, in order to increase the sensitivity or specificity of the AED, the technical description shall explain the method of operation of this system and the criteria for recommending shock delivery.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Addition:

aa) Any APPLIED PART consisting of SEPARATE MONITORING ELECTRODES for monitoring the ECG shall be a TYPE CF APPLIED PART.

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 * Defibrillation protection

- Differential-mode test

Replacement of the third paragraph ("After the operation of S, the peak….") by the following:

After the operation of S, the peak voltage between the points Y_1 and Y_2 is measured. Each test is performed both with the ME EQUIPMENT energized and not energized in turn and is repeated with V_T reversed in each case.

Additional subclauses:

201.8.5.5.101 * Isolation of DEFIBRILLATOR ELECTRODES

Arrangements to isolate the DEFIBRILLATOR ELECTRODES from other parts shall be so designed that, during the discharge of the ENERGY STORAGE DEVICE, hazardous electrical energies are excluded from the following:

a) the ENCLOSURE;

b) all PATIENT CONNECTIONS belonging to other PATIENT circuits;

c) any SIGNAL INPUT/OUTPUT PART;

d) a metal foil on which the ME EQUIPMENT is placed and which has an area at least equal to that of the base of the ME EQUIPMENT (CLASS II ME EQUIPMENT or ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE).

Check compliance by the following test:

The above requirement is met when, after a discharge of the DEFIBRILLATOR connected as shown in Figure 201.101, the peak voltage between the points Y_1 and Y_2 does not exceed 1 V. Transients might be imposed on the measurement during the energy discharge. These are to be excluded from the measurement. This voltage corresponds to a charge of 100 µC from the part under test.

In the case where an active signal output part would affect the measured voltage between Y_1 and Y_2, the specific signal output port is excluded from the measurement. However, the ground reference of such a signal output port is to be measured.

In the case where the connection of the measurement circuit of Figure 201.101 to an input/output port would create a failure of the device to function properly, the specific input/output port is excluded from measurement. However, the ground reference of such an input/output signal shall be measured.

DEFIBRILLATORS requiring an impedance within a certain range to be present at the output of the DISCHARGE CIRCUIT are to be tested connected to a 50 Ω resistive load. In the case of DEFIBRILLATORS requiring the detection of a shockable ECG in order to deliver a shock, an ECG simulator incorporating a 50 Ω resistive load is to be used.

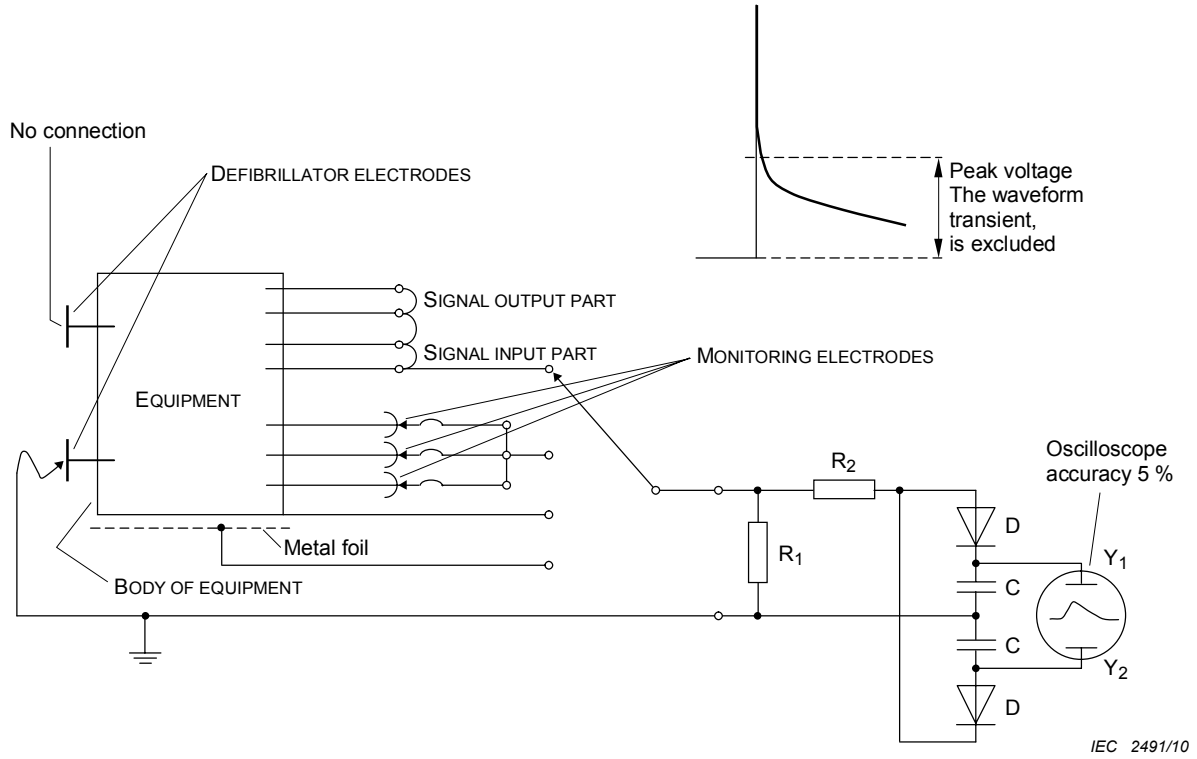
Measurements are to be done at the maximum energy level of the device.

CLASS I ME EQUIPMENT is tested while connected to the protective earth.

CLASS I ME EQUIPMENT which is capable of operation without a SUPPLY MAINS, e.g. having an internal battery, shall also be tested without the protective earth connection.

Any connection to a FUNCTIONAL EARTH TERMINAL is to be removed.

The test is repeated with the earth connection transferred to the other DEFIBRILLATOR ELECTRODE.



R_1 = 1 kΩ ± 2% (≥ 2 kV)
R_2 = 100 kΩ ± 2% (≥ 2 kV)
C = 1 μF ± 5%
D: Small signal silicon diodes

Figure 201.101 – Dynamic test for limitation of energy from different parts of the ME EQUIPMENT
(see 201.8.5.5.101)

201.8.5.5.102 * APPLIED PARTS not being DEFIBRILLATOR ELECTRODES

Any APPLIED PARTS not being DEFIBRILLATOR ELECTRODES shall be DEFIBRILLATION-PROOF APPLIED PARTS unless the MANUFACTURER has taken steps to prevent their use at the same time as performing defibrillation with the same DEFIBRILLATOR.

201.8.5.5.103 Charging of the ENERGY STORAGE DEVICE

In keeping with subclause 201.13.1.3, unintentional charging of the ENERGY STORAGE DEVICE shall not occur when testing.

201.8.7 * LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 * General requirements

Replacement of b) indent 3 with:

– with ME EQUIPMENT energized in STAND-BY condition and fully operating and with any switch in the MAINS PART in any position;

For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT, the ME EQUIPMENT shall be operated in turn:

1) in STAND-BY;
2) while the ENERGY STORAGE DEVICE is being charged to maximum energy;
3) while the ENERGY STORAGE DEVICE is maintained at maximum energy until internal energy discharge is automatically performed, or for 1 min;
4) for 1 min, starting 1 s after the commencement of the output pulse into a 50 Ω load (the period of discharge being excluded).

201.8.7.3 * Allowable values

Addition:

aa) For DEFIBRILLATOR ELECTRODES that are TYPE CF APPLIED PARTS, the allowable value of the PATIENT LEAKAGE CURRENT for the special test condition identified in 8.7.4.7 of the general standard with MAXIMUM MAINS VOLTAGE on the DEFIBRILLATOR ELECTRODES is 0,1 mA.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition to item b) as the forth paragraph:

For DEFIBRILLATOR ELECTRODES, the voltage at the transformer T_2 in Figure 16 is applied between earth and, in turn, the external DEFIBRILLATOR ELECTRODES connected together and any internal DEFIBRILLATOR ELECTRODES connected together, metal foil being wrapped around, and in intimate contact with, the electrode handles and connected to earth and to the parts of 8.7.4.7 g) as modified by this particular standard.

Addition to item g):

For DEFIBRILLATOR ELECTRODES the PATIENT LEAKAGE CURRENT is measured with the DEFIBRILLATOR ELECTRODES connected to a 50 Ω load. The measurement is to be made from either DEFIBRILLATOR ELECTRODE to earth, the following parts being connected together and to earth:

1) conductive ACCESSIBLE PARTS;

2) metal foil on which the ME EQUIPMENT is positioned and which has an area at least equal to that of the base of the ME EQUIPMENT;

3) any SIGNAL INPUT/OUTPUT PARTS which may be connected to earth in NORMAL USE.

201.8.8.3 * Dielectric strength

Replace the third dash:

– *after reaching a temperature equivalent to the steady state operating temperature reached during the heating test of 11.1.1 of the general standard with the ME EQUIPMENT operating in STAND-BY.*

Addition:

For the DEFIBRILLATOR high-voltage circuit (for example DEFIBRILLATOR ELECTRODES, CHARGING CIRCUIT and switching devices) the following requirements and tests shall apply in addition to those of the general standard.

The insulation of the above circuit shall withstand a d.c. test voltage of 1,5 times the highest PEAK WORKING VOLTAGE *U* occurring between the parts concerned during discharging in any mode of normal operation. The insulation resistance of the above insulation shall not be less than 500 MΩ.

Compliance shall be checked by the following combined dielectric strength and insulation resistance test:

The external d.c. test voltage is applied:

Test 1: With the switching devices of the DISCHARGE CIRCUIT activated between each pair of DEFIBRILLATOR ELECTRODES connected together and all of the following parts connected together:

a) *conductive ACCESSIBLE PARTS;*

b) *the protective earth terminal in the case of CLASS I ME EQUIPMENT or metal foil on which the equipment rests in the case of CLASS II ME EQUIPMENT or ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE;*

c) *metal foil in intimate contact with non-conductive parts liable to be handled in NORMAL USE; and*

d) *any isolated discharge control circuit including the manually operated discharge controls and all parts conductively connected to them and any isolated SIGNAL INPUT/ OUTPUT PART.*

If the CHARGING CIRCUIT is floating and is isolated from the DEFIBRILLATOR ELECTRODES during discharging, it shall be connected to them during this test.

Any resistors forming the isolating means between the DEFIBRILLATOR and other PATIENT circuits shall be replaced by a DUMMY COMPONENT.

Any other PATIENT CONNECTIONS, their cables and associated connectors shall be disconnected from the ME EQUIPMENT during this test.

Any switching arrangements used to isolate the high-voltage circuit of the DEFIBRILLATOR from the other PATIENT circuits, other than those activated in NORMAL USE by the connection of their respective cables and PATIENT CONNECTIONS, shall be held in the open-circuit position.

Any resistors bridging the insulation under test (e.g. components of a metering circuit) shall be replaced by a DUMMY COMPONENT during this test provided that their effective value in the test configuration is not less than 5 MΩ. Any components which are known not to withstand the test voltage of 1,5 U, but which have been demonstrated to be safe by the test at the end of this subclause, are accepted as meeting the requirements of this subclause.

NOTE "Pair" here refers to any two DEFIBRILLATOR ELECTRODES used together in NORMAL USE.

Newer circuit topologies for DEFIBRILLATORS may make it difficult to carry out the test outlined above. Components which are not rated at 1,5 U, or which are known to fail at less than 1,5 U, are acceptable if they pass the following test. The highest peak voltage U is determined by circuit analysis, making allowances for circuit component tolerances. The distribution of breakdown voltages for the component under test is obtained from the supplier, or is determined by testing to breakdown a sample of sufficient size, to yield 90 % confidence that the probability of failure of the component at U is less than 0,0001. In addition, MANUFACTURERS, through fault mode and effect analysis (see IEC 60300-3-9 [1]), demonstrate that the implemented circuit topology does not create a HAZARDOUS SITUATION in SINGLE FAULT CONDITION and that the OPERATOR is made aware of such a failure.

Test 2: Between the defibrillator electrodes of each pair—external and internal in turn—while:

a) *the ENERGY STORAGE DEVICE is disconnected;*

b) *the switching devices of the DISCHARGE CIRCUIT are activated;*

c) *any switching arrangements used to isolate the high-voltage circuit of the DEFIBRILLATOR from other PATIENT circuits are held in the open-circuit position; and*

d) *any components which would provide a conductive pathway between the DEFIBRILLATOR ELECTRODES during this test are disconnected.*

Newer circuit topologies for DEFIBRILLATORS may make it difficult to carry out the test outlined above. Components which are not rated at 1,5 U, or which are known to fail at less than 1,5 U, are acceptable if they pass the following test. The highest peak voltage U is determined by circuit analysis, making allowances for circuit component tolerances. The distribution of breakdown voltages for the component under test is obtained from the supplier, or is determined by testing to breakdown a sample of sufficient size, to yield 90 % confidence that the probability of failure of the component at U is less than 0,0001. In addition, MANUFACTURERS are to demonstrate, through fault mode and effect analysis (see IEC 60300-3-9 [1]), that the implemented circuit topology do not create a HAZARDOUS SITUATION in SINGLE FAULT CONDITION and that the OPERATOR is made aware of such a failure.

Test 3: Across each switching device in the DISCHARGE CIRCUIT and in the CHARGING CIRCUIT.

In the case of switches in the DISCHARGE CIRCUIT intended to operate in series as a single functional group, the following tests shall be performed.

a) *Place the test voltage across each functional group in the polarity consistent with that of the ENERGY STORAGE DEVICE and verify d.c. withstand per the provisions of the section.*

b) *Disconnect the ENERGY STORAGE DEVICE and substitute with a test voltage source set per the calculations above, with polarity consistent with the ENERGY STORAGE DEVICE.*

By shorting functional groups, simulate cascade-failures of each series functional switching group in turn. Demonstrate that, under simulated cascade failure conditions, energy discharge to the PATIENT CONNECTION does not occur.

Test 4: Between the MAINS PART and the DEFIBRILLATOR electrodes connected together while the switching devices of the discharge circuit are activated.

NOTE It may not be possible to activate the switching means for extended periods of time. In such cases the switching procedure may be simulated for this test.

This test is not to be performed if the MAINS PART and the APPLIED PART containing the DEFIBRILLATOR electrodes are effectively separated by a protectively earthed shield or a protectively earthed intermediate circuit.

Where the effectiveness of the separation is in doubt (e.g. the protective shielding is incomplete) the shield is to be disconnected and the dielectric strength test performed.

The test voltage is initially set at U and the current is measured. The voltage is raised to 1,5 U in a time of not less than 10 s and then maintained constant for a period of 1 min during which no breakdown or flashover is to occur.

Current increasing more than 20 %, in proportion to applied test voltage, is not allowed (see Figure 201.102), unless one of the following alternate methods to linearity is met. Any transient increase in the current due to non-linearity of the increase of the test voltage shall be ignored. The insulation resistance shall be calculated from the maximum voltage and the steady-state current.

– The calculated resistance at 1,5 *U* is greater than or equal to 1 GΩ.
– The dielectric voltage is increased to 1,7 *U* in a time not less than 10 s and maintained for a constant period of 1 min during which no breakdown or flashover is to occur.
– Four additional samples are dielectric tested at 1,5 *U* for a period of 1 min during which no breakdown or flashover is to occur and they meet the 500 MΩ resistance requirement.

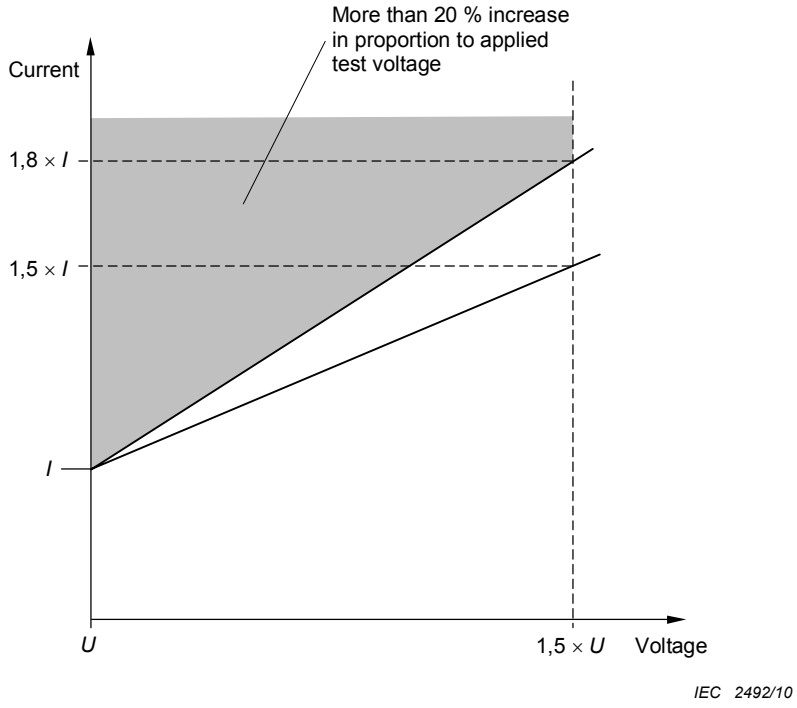


Figure 201.102 – Allowed current versus applied test voltage
(see 201.8.8.3)

During the tests specified in the general standard, that portion of the test voltage appearing across any switching device in the charging circuit or in the discharge circuit shall be restricted so as not to exceed a peak value equal to the d.c. test voltage specified above.

201.8.9.1 Values

201.8.9.1.5 * ME EQUIPMENT RATED for high altitudes

Addition:

General standard Subclause 8.9.1.5 does not presently apply to defibrillators rated for use at altitudes up to 5 000 m but is under consideration for future application.

Additional subclause:

201.8.9.1.101 * DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

NOTE *General standard Subclause 8.9.1.5 "ME EQUIPMENT RATED for high altitudes" does not presently apply to this subclause for defibrillators rated for use at altitudes up to 5 000 m but is under consideration for future application.

a) * Between energized parts of DEFIBRILLATOR ELECTRODES and parts of any associated handle and any switches or controls likely to be touched in NORMAL USE there shall be a CREEPAGE DISTANCE of at least 50 mm and an AIR CLEARANCE of at least 25 mm.

b) * Except for components where the adequacy of ratings can be demonstrated (e.g. by component manufacturers' ratings or by the dielectric strength tests of 8.8.3 of the general standard) the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the high-voltage circuit and other parts, and between different parts of the HIGH-VOLTAGE circuit, shall be at least 3 mm/kV.

   This requirement shall also apply to the isolating means between the HIGH-VOLTAGE circuit of the DEFIBRILLATOR and other PATIENT circuits.

   Check compliance by measurement.

c) * Non-reusable DEFIBRILLATOR ELECTRODES are not required to comply with the CREEPAGE DISTANCE and AIR CLEARANCE requirements of b) above and are not required to comply with the dielectric strength requirements of 8.8.3 of the general standard.

d) * The cable connecting the DEFIBRILLATOR to the DEFIBRILLATOR ELECTRODES shall have double insulation (two separately moulded insulation layers). For a non-reusable cable included as part of non-reusable DEFIBRILLATOR ELECTRODES, where the non-reusable cable has a length of less than 2 m, there is no requirement of double isolation. The insulation resistance of the cable shall not be less than 500 MΩ. The dielectric strength of the cable shall be tested using a voltage of 1,5 times the highest voltage occurring between the DEFIBRILLATOR ELECTRODES in any normal mode of operation.

   Check compliance by the following test.

   A length of 100 mm of the outside of the cable is wrapped with conductive foil. The test voltage is applied between the high voltage conductor and the outside conductive wrapping. The voltage is raised to 1,5 U in a time of not less than 10 s and then maintained constant for a period of 1 min during which no breakdown or flashover is to occur. The leakage current between the high voltage conductor and the wrapping is to demonstrate an insulation resistance of more than 500 MΩ.

201.9 Protection against MECAHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.3 Measurements

c) Thermal stabilization

Replacement:

The ME EQUIPMENT is operated in STAND-BY until temperature equilibrium is attained. For MANUAL DEFIBRILLATORS, the DEFIBRILLATOR is alternately charged and discharged with its maximum energy 15 times at the rate of three per minute into a resistive load of 50 Ω. For AEDs the number and rate of discharges shall be the maximum specified by the MANUFACTURER for normal operation.

201.11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

Addition:

The ME EQUIPMENT shall be so constructed that, in the event of spillage of liquids (accidental wetting), no HAZARDOUS SITUATION shall result.

Check compliance by the following test:

One sample of the ME EQUIPMENT is placed in the least favorable position of NORMAL USE with the DEFIBRILLATOR ELECTRODES in the stored position. The ME EQUIPMENT is then subjected for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the ME EQUIPMENT. The ME EQUIPMENT shall not be energized during the test. PATIENT cables, mains cables etc., are placed in the least favorable position during the test.

A test apparatus is shown in Figure 3 of IEC 60529.

An intercepting device may be used to determine the duration of the test.

Immediately after the 30 s exposure, visible moisture on the ENCLOSURE is removed. Immediately after the above test, verify that any water which might have entered the ME EQUIPMENT cannot result in a HAZARDOUS SITUATION. In particular the ME EQUIPMENT shall be capable of meeting the dielectric strength test in 8.8.3 of the general standard.

The DEFIBRILLATOR is alternately charged and discharged with its maximum energy 15 times at the rate of three per minute into a resistive load of 50 Ω. For AEDs, the maximum number of discharges and rate of discharge may be limited to the MANUFACTURER'S specifications for normal operation.

After the test, the DEFIBRILLATOR is disassembled to inspect for water ingress. The ME EQUIPMENT is to show no signs of wetting of electrical insulation, which is liable to be adversely affected by such liquid. There is to be no sign of water in the high-voltage circuitry.

The ME EQUIPMENT is to function normally.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

For DEFIBRILLATOR portion of ME EQUIPMENT, immediately after the exposure, visible moisture on the ENCLOSURE is removed. Immediately after the above test, verify that any water which might have entered the ME EQUIPMENT cannot result in a HAZARDOUS SITUATION. In particular the ME EQUIPMENT shall be capable of meeting the dielectric strength test in 8.8.3 of the general standard.

The DEFIBRILLATOR is alternately charged and discharged with its maximum energy 15 times at the rate of three per minute into a resistive load of 50 Ω. For AEDs, the maximum number of discharges and rate of discharge may be limited to the MANUFACTURER'S specifications for normal operation.

After the test, the DEFIBRILLATOR is disassembled to inspect for water ingress. The ME EQUIPMENT is to show no signs of wetting of electrical insulation, which is liable to be adversely affected by such liquid. There is to be no sign of water in the high-voltage circuitry.

The ME EQUIPMENT is to function normally.

201.11.6.7 * Sterilization of ME EQUIPMENT and ME SYSTEMS

Addition:

Internal DEFIBRILLATOR ELECTRODES including handles, any incorporated controls or indicators, and associated cables shall be sterilizable. See 201.7.9.2 for requirements for instructions for use.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Replacement:

The RATED DELIVERED ENERGY (according to ME EQUIPMENT settings) into loads of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω, and 175 Ω shall be specified. The measured DELIVERED ENERGY into these load resistances shall not vary from the DELIVERED ENERGY for that impedance by more than ± 3 J or ± 15 %, whichever is greater, at any energy level.

Check compliance by measurement of DELIVERED ENERGY in load resistances of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω, and 175 Ω at energy levels as above or by measurement of the internal resistance of the DEFIBRILLATOR output circuit and hence calculation of the DELIVERED ENERGY.

201.12.2 USABILITY

Addition:

201.12.2.101 * ELECTRODE energizing controls

a) The ME EQUIPMENT shall be so designed as to prevent the external and internal DEFIBRILLATOR ELECTRODES being energized simultaneously.

Check compliance by inspection and functional test.

b) * The means for triggering the DEFIBRILLATOR DISCHARGE CIRCUIT shall be so designed as to minimize the possibility of inadvertent operation.

   Acceptable arrangements are:

   1) for anterior-anterior DEFIBRILLATOR ELECTRODES, two momentary switches, one located on each DEFIBRILLATOR ELECTRODE handle;

2) for anterior-posterior DEFIBRILLATOR ELECTRODES, a single momentary switch located on the anterior electrode handle;
3) for internal DEFIBRILLATOR ELECTRODES, a single momentary switch located on one of the electrode handles or one or two single momentary switches on the panel only; and
4) for external self-adhesive DEFIBRILLATOR ELECTRODES, one or two single momentary switches located on the panel only.

Foot-operated switches shall not be used to trigger the defibrillation pulse.

Check compliance by inspection and functional test.

201.12.2.102 Display of signals

A DEFIBRILLATOR with monitoring capability shall not display signals from more than one input simultaneously unless the origin of the signals is labelled unambiguously.

Check compliance by inspection.

201.12.3 Alarm systems

Addition:

201.12.3.101 * Audible warnings prior to energy delivery

The DEFIBRILLATOR shall be equipped with an ALARM SYSTEM that includes a HIGH PRIORITY ALARM CONDITION that indicates when the DEFIBRILLATOR is preparing to or is about to deliver energy to the PATIENT. This ALARM CONDITION shall be provided with either verbal or auditory alarm signals. The preparing-to or about-to-deliver-energy-to-the-PATIENT ALARM shall not be capable of being AUDIO PAUSED or AUDIO OFF. The ALARM CONDITION shall be:

a) for AEDs with OPERATOR activated discharge control, when the RHYTHM RECOGNITION DETECTOR has reached a determination that a shockable rhythm is detected and the discharge control is active;
b) for AEDs with automatic discharge control, at least 5 s prior to energy delivery;
c) for manual DEFIBRILLATORS, when the device is ready to be discharged by the OPERATOR.

201.12.4 Protection against hazardous output

201.12.4.1 * Intentional exceeding of safety limits

Replacement:

The control for SELECTED ENERGY shall not allow:

a) the SELECTED ENERGY to exceed 360 J;
b) for internal DEFIBRILLATOR ELECTRODES, the SELECTED ENERGY to exceed 50 J.

Check compliance by inspection and functional test.

Additional subclauses:

201.12.4.101 * Output voltage

The output voltage of the DEFIBRILLATOR across a 175 Ω load resistance shall not exceed 5 kV.

Check compliance by measurement.

201.12.4.102 * Unintentional energy

The ME EQUIPMENT shall be so designed that in the event of a power failure (either of the supply mains or of the internal electrical power source) or when the ME EQUIPMENT is switched off, no unintentional energy shall be available at the DEFIBRILLATOR electrodes.

Check compliance by functional test.

201.12.4.103 * Internal discharge circuit

A DEFIBRILLATOR shall be provided with an internal discharge circuit whereby STORED ENERGY that for some reason is not to be delivered through the DEFIBRILLATOR electrodes can be dissipated without energizing the DEFIBRILLATOR electrodes.

This INTERNAL DISCHARGE CIRCUIT may be combined with that required by 201.12.4.102.

Check compliance by functional test.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies, except as follows:

201.13.1.3 * Exceeding LEAKAGE CURRENT or voltage limits

Addition:

– * inadvertent charging or discharging of the energy storage device.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 * ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

Additional subclauses:

201.15.4.3.101 * Non-rechargeable battery replacement

Means shall be provided to indicate clearly when non-rechargeable batteries require replacement or rechargeable batteries require recharging. These means shall not make the ME EQUIPMENT inoperative, and the ME EQUIPMENT shall be capable of delivering three maximum energy discharges after that indication is initially provided.

For ME EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 3 defibrillation discharges at the pre-programmed settings after that indication is initially provided. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION the AED shall be able to deliver 3 defibrillation discharges at the maximum energy setting sequence selectable.

Check compliance by inspection and functional test at 20 °C ± 2 °C.

201.15.4.3.102 Battery charging indicator

Means shall be provided to indicate clearly when any rechargeable battery is being charged.

Check compliance by inspection and functional test.

201.15.4.3.103 * Rechargeable battery

Any rechargeable new battery shall enable the ME EQUIPMENT to pass the following test:

a) *Test requirements for MANUAL DEFIBRILLATOR:*

After fully charging the battery, the ME EQUIPMENT is stored while switched off for 168 h (7 days) at a temperature of 20 °C ± 5 °C and at a relative humidity of 65 % ± 10 %. The ME EQUIPMENT is then charged and discharged with the maximum DELIVERED ENERGY of the ME EQUIPMENT, 14 times into a 50 Ω load at the rate of one charge-discharge per minute. The charging time for the 15th charge is not to exceed 15 s (25 s for INFREQUENT USE MANUAL DEFIBRILLATOR).

If the DEFIBRILLATOR can perform a wake-up self-test that is automatically started with pre-selectable intervals when the DEFIBRILLATOR is powered off, the test is to be performed with the wake-up self-test enabled with the shortest possible interval.

b) *Test requirements for AUTOMATED EXTERNAL DEFIBRILLATORS:*

After fully charging the battery, the ME EQUIPMENT is stored while switched off for 168 h (7 days) at a temperature of 20 °C ± 5 °C and at a relative humidity of 65 % ± 10 %. The ME EQUIPMENT is then charged and discharged, with the maximum DELIVERED ENERGY of the ME EQUIPMENT, 14 times into a 50 Ω load at the rate of the pre-programmed defibrillation sequence. For discharge number 15, the time measured from application of the shockable cardiac rhythm to when the DEFIBRILLATOR is ready for discharge is not to exceed

- *30 s for FREQUENT USE AEDS;*
- *40 s for INFREQUENT USE AEDS.*

For ME EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the pre-programmed energy setting sequence. In a case of the pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the maximum energy setting sequence selectable.

If the DEFIBRILLATOR can perform a wake-up self-test that is automatically started with pre-selectable intervals when the DEFIBRILLATOR is powered off, the test is to be performed with the wake-up self-test enabled with the shortest possible interval**.**

Additional subclause:

201.15.4.101 * DEFIBRILLATOR ELECTRODES and their cables

a) Any DEFIBRILLATOR ELECTRODE handles shall have no conductive ACCESSIBLE PARTS.

This requirement does not apply to small metal parts such as screws in or through insulating material which cannot become live under SINGLE FAULT CONDITIONS.

Check compliance by inspection and the dielectric strength test (see 201.8.8.3, test 1).

b) * DEFIBRILLATOR ELECTRODE cables and their anchorages shall be capable of satisfactorily passing the following tests. Additionally the anchorages for reusable DEFIBRILLATOR

ELECTRODES shall comply with the requirements for POWER SUPPLY CORDS as described in 8.11.3.5 a) through d) of the general standard. For single use cables or cable/electrode assemblies the number of cycles of flexing in Test 2 shall be divided by 100. For sterilizable internal paddles the number of cycles of flexing in Test 2 shall be the maximum number of sterilization cycles allowable for the paddles times 5. Each cable to ME EQUIPMENT/DEFIBRILLATOR ELECTRODE and each cable to ME EQUIPMENT/DEFIBRILLATOR ELECTRODE connector, where relevant, in turn shall be subjected to the tests as for DEFIBRILLATOR ELECTRODES, unless two or more connectors have identical construction, in which case only one of these shall be tested. Where a connector is fitted with two or more cables these shall be tested together, the total tension on the connector being the sum of the tensions appropriate to each cable individually (see Annex AA and Figure 201.103 for guidance on identification of anchorages that require testing).

Check compliance by inspection and by the following tests:

Test 1: For rewirable cable, the conductors are introduced in the terminals in the DEFIBRILLATOR ELECTRODES, any terminal screws being tightened just sufficiently to prevent easy displacement of the conductors. The cord anchorage is then tightened in the normal way. For all cables, to measure the longitudinal displacement a mark is made on the cable at a distance of approximately 2 cm from the cord anchorage.

Immediately afterwards, the cable shall be subjected to a pull of 30 N, or the maximum force that can be applied to the anchorage before the connector becomes disconnected, or the electrode is pulled off the PATIENT, where applicable, for 1 min, whichever is the least. At the end of this period the cable is not to have been displaced longitudinally by more than 2 mm. For rewirable cables, the conductors are not to have moved by more than 1 mm in the terminals nor is there be appreciable strain on the conductors while the pull is still being applied. For non-rewirable cables not more than 10 % of the total number of conductor strands in each wire of the cable can be broken.

Test 2: One DEFIBRILLATOR ELECTRODE is fixed in an apparatus similar to that shown in Figure 201.104, so that when the oscillating member of the apparatus is at the middle of its travel, the axis of the cable, where it leaves the electrode or electrode handle, is vertical and passes through the axis of oscillation. Tension is applied to the cable as follows:

1) *for extensible cables a tension equal to that necessary to extend the cable to three times its natural (unextended) length, or to the weight of one DEFIBRILLATOR ELECTRODE, whichever is the greater, is applied and the cable is clamped at a distance of 300 mm from the axis of oscillation;*
2) *for non-extensible cables, the cable is passed through an aperture 300 mm from the axis of oscillation and a weight equal to the weight of one DEFIBRILLATOR ELECTRODE, or 5 N, whichever is the greater, is fixed to the cable below this aperture.*

The oscillating member is rotated through an angle of

- *180 ° (90 ° on each side of the vertical) for internal electrodes;*
- *90 ° (45 ° on each side of the vertical) for external electrodes.*

The number of cycles shall be 10 000 at the rate of 30 cycles per minute. After 5 000 cycles the DEFIBRILLATOR ELECTRODE is turned through 90° about the centre line of the cable entry point and the remaining 5 000 cycles are completed in this plane.

After the test, the cable is not to have worked loose and neither the cord anchorage nor the cable show any damage, except that not more than 10 % of the total number of conductor strands in each wire of the cable can be broken.

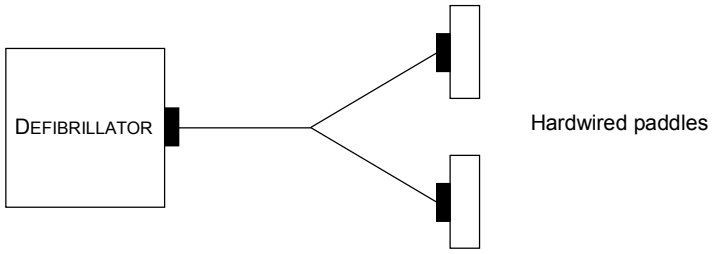
c) Minimum DEFIBRILLATOR ELECTRODE area

The minimum area of each of the DEFIBRILLATOR ELECTRODES shall be:

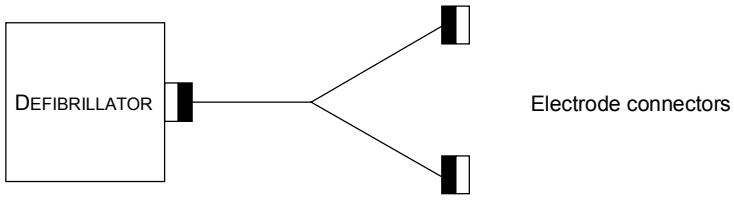
- 50 cm^2 for adult external use;
- 32 cm^2 for adult internal use;
- 15 cm^2 for pediatric external use; or
- 9 cm^2 for pediatric internal use.

Check compliance by inspection.

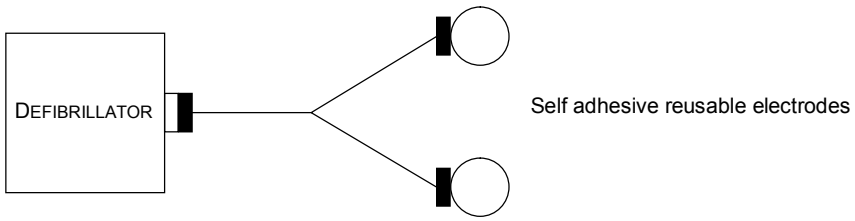
Hardwired reusable cable and electrodes:



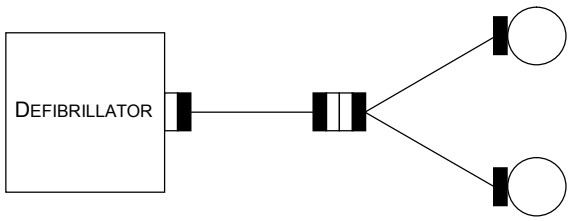
Reusable cable and single use electrodes:



Single use electrodes and cable:



Reusable extension cable and single use electrodes with connecting cables:



Cable anchorage requiring testing

Connector to defibrillator or electrode where relevant

IEC 2493/10

Figure 201.103 – Examples of cord anchorages that require testing
(see 201.15.4.101 b))

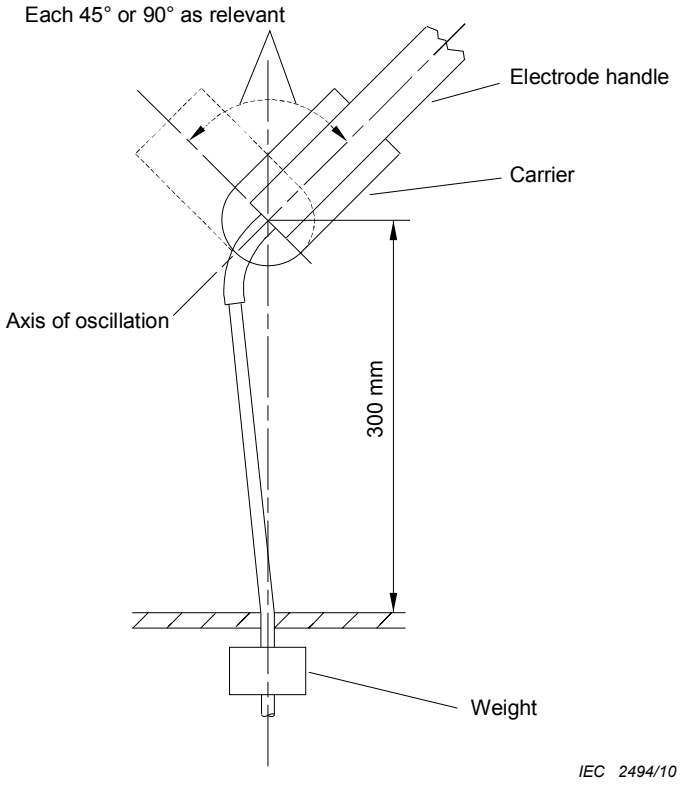


Figure 201.104 – Test apparatus for flexible cords and their anchorages
(see 201.15.4.101 b), Test 2)

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

NOTE See also Clause 202 of this standard.

Additional clauses:

201.101 * Charging time

201.101.1 Requirements for FREQUENT USE, MANUAL DEFIBRILLATORS

a) The time needed to fully recharge a completely discharged ENERGY STORAGE DEVICE shall not exceed 15 s under the following conditions:
   - when the DEFIBRILLATOR is operated on 90 % of the rated mains voltage;
   - with batteries depleted by the delivery of 15 discharges at maximum energy.

b) The time from initially switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 25 s. This requirement shall apply to charging a completely discharged ENERGY STORAGE DEVICE to maximum energy under the following conditions:
   - when the DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE,

– with batteries depleted by the delivery of 15 discharges at maximum energy.

Check compliance with a) and b) above by measurement. In the case of INTERNALLY POWERED ME EQUIPMENT, the test is to start with a new and fully charged battery. In the case of such ME EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is checked when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 201.7.2.101.

In case of a DEFIBRILLATOR with non-rechargeable batteries, the test is to start with a battery depleted by the delivery of the number of charge/discharge cycles after which it is specified as still useable by the MANUFACTURER, or when the ME EQUIPMENT indicates that the battery needs replacement, whichever comes first.

201.101.2 Requirements for INFREQUENT USE, MANUAL DEFIBRILLATORS

a) The following charge time requirements apply.

– When the DEFIBRILLATOR is operated on 90 % of the rated mains voltage, the time for charging a completely discharged energy storage device to maximum energy shall not exceed 20 s**.**

– With batteries depleted by the delivery of 6 discharges at maximum energy, the time for charging a completely discharged ENERGY STORAGE DEVICE to maximum energy shall not exceed 20 s.

– With batteries depleted by the delivery of 15 discharges at maximum energy, the time for charging a completely discharged ENERGY STORAGE DEVICE to maximum energy shall not exceed 25 s.

b) For the time from initially switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy the following applies.

– When the DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 30 s.

– With batteries depleted by the delivery of 6 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 30 s.

– With batteries depleted by the delivery of 15 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 35 s.

Check compliance with a) and b) above by measurement. In the case of INTERNALLY POWERED ME EQUIPMENT, the test is to start with a new and fully charged battery. In the case of such ME EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is also checked when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 201.7.2.102.

In case of a DEFIBRILLATOR with non-rechargeable batteries, the test is to start with a battery depleted by the delivery of the number of charge/discharge cycles after which it is specified as still useable by the MANUFACTURER, or when the ME EQUIPMENT indicates that the battery needs replacement, whichever comes first.

201.101.3 * Requirements for FREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS

a) The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to the DEFIBRILLATOR being ready for discharge at maximum energy, shall not exceed 30 s under the following conditions:

- when the AED is operated on 90 % of the RATED MAINS VOLTAGE;
- with batteries depleted by the delivery of 15 discharges at maximum energy.

b) * The time from initially switching power on, or from within any OPERATOR programming mode, to the DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 40 s. This requirement shall apply to charging a completely discharged ENERGY STORAGE DEVICE to maximum energy under the following conditions:

- when the AED is operated on 90 % of the RATED MAINS VOLTAGE;
- with batteries depleted by the delivery of 15 discharges at maximum energy.

201.101.4 * Requirements for INFREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS

a) The following charge time requirements for INFREQUENT USE AUTOMATED EXTERNAL DEFIBRILLATORS apply.

- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 35 s when the AED is operated on 90 % of the RATED MAINS VOLTAGE.
- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 35 s with batteries depleted by the delivery of 6 discharges at maximum energy.
- The maximum time from activation of the RHYTHM RECOGNITION DETECTOR to ready for discharge at maximum energy, shall not exceed 40 s with batteries depleted by the delivery of 15 discharges at maximum energy.

b) For the time from initially switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy the following applies.

- When the AED is operated on 90 % of the RATED MAINS VOLTAGE, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 45 s.
- With batteries depleted by the delivery of 6 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 45 s.
- With batteries depleted by the delivery of 15 discharges at maximum energy, the time from switching power on, or from within any OPERATOR programming mode, to ready for discharge at maximum energy shall not exceed 50 s.

Check compliance with 201.101.3 a) and b) and 201.101.4 a) and b) by the following test:

A shockable simulated PATIENT rhythm signal as defined by the MANUFACTURER is applied to the SEPARATE MONITORING ELECTRODES or the DEFIBRILLATOR ELECTRODES. The visual or audible instructions given by the DEFIBRILLATOR are followed. The charge time is measured from RRD activation (for 201.101.3 a)) and 201.101.4 a)) or initial power on (for 201.101.3 b)) and 201.101.4 b)) to ready for discharge.

In the case of INTERNALLY POWERED ME EQUIPMENT, the test is to start with a new and fully charged battery. In the case of such ME EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is checked when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 201.7.2.102.

In case of a DEFIBRILLATOR with non-rechargeable batteries, the test is to start with a battery depleted by the delivery of the number of charge/discharge cycles after which it is specified as still useable by the MANUFACTURER, and when the ME EQUIPMENT indicates that the battery needs replacement.

For ME EQUIPMENT with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the pre-programmed energy setting sequence. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the requirement for depletion of batteries with the delivery of maximum energy discharges is relaxed to the number of discharges at the worst case energy setting sequence selectable.

201.102 INTERNAL ELECTRICAL POWER SOURCE

201.102.1 General

The requirements of this clause apply whether or not the ME EQUIPMENT can also be operated from a SUPPLY MAINS.

201.102.2 * Requirements for MANUAL DEFIBRILLATORS

The capacity of a new and fully charged battery shall be such that at 0 °C the ME EQUIPMENT can provide at least 20 defibrillation discharges having each the maximum DELIVERED ENERGY of the ME EQUIPMENT, performed in cycles, each of which comprising three discharges in 1 min and 1 min rest. For INFREQUENT USE MANUAL DEFIBRILLATORS, each cycle shall consist of three discharges in 90 s with 1 min rest.

Where ME EQUIPMENT contains the possibility to insert more than one battery which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.

For any extra batteries that may be available for use in the DEFIBRILLATOR but are not actually mounted in the DEFIBRILLATOR, the extra batteries shall not be included in the test.

Check compliance by a functional test at 0 °C ± 2 °C, the ME EQUIPMENT having first been prepared as follows:

a) *The battery is to be fully charged in accordance with the MANUFACTURER'S instructions (or until the ME EQUIPMENT indicates that the battery is fully charged) at an ambient temperature of 0 °C ± 2 °C, 20 °C ± 2 °C and 40 °C ± 2 °C, or according to environmental operating conditions as specified by the MANUFACTURER according to 7.9.3.1 of the general standard, whichever constitutes the most severe conditions.*

b) *The ME EQUIPMENT including the battery is cooled to 0 °C ± 2 °C until it reaches thermal equilibrium.*

201.102.3 * Requirements for AUTOMATED EXTERNAL DEFIBRILLATORS (AED)

201.102.3.1 FREQUENT USE AED

For a FREQUENT USE AED, the capacity of a new and fully charged battery shall be such that at 0 °C the ME EQUIPMENT can provide at least 20 defibrillation discharges at the maximum DELIVERED ENERGY of the AED performed using the pre-programmed defibrillation sequence. The rate of discharge shall meet one of the following criteria:

- delivered in cycles, each comprising three discharges in 105 s and 1 min rest,
- delivered equally spaced with 55 s between discharges,
- delivered at any spacing so that all 20 are delivered within 1 100 s.

Where a FREQUENT USE AED contains the possibility to insert more than one battery at the same time which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.

For any extra batteries that may be available for use in the DEFIBRILLATOR, but are not actually mounted in the DEFIBRILLATOR, the extra batteries shall not be included in the test. For an AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

201.102.3.2 INFREQUENT USE AED

For an INFREQUENT USE AED, a new and fully charged battery shall be capable of providing at least 20 maximum energy discharges at the maximum DELIVERED ENERGY of the ME EQUIPMENT performed using the pre-programmed defibrillation sequence. The rate of discharge shall meet one of the following criteria:

- delivered in cycles, each comprising three discharges in 135 s and 1 min rest,
- delivered equally spaced with 65 s between discharges,
- delivered at any spacing so that all 20 are delivered within 1 300 s.

For an INFREQUENT USE AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

Check compliance with 201.102.3.1 and 201.102.3.2 by a functional test at 0 °C ± 2 °C, the ME EQUIPMENT having first been prepared as follows:

a) *The battery is to be fully charged in accordance with MANUFACTURER'S instructions (or until the ME EQUIPMENT indicates that the battery is fully charged) at an ambient temperature of 0 °C ± 2 °C, 20 °C ± 2 °C and 40 °C ± 2 °C, or according to environmental operating conditions as specified by the MANUFACTURER according to 7.9.3.1 of the general standard, whichever are the most severe conditions.*

b) *The ME EQUIPMENT including the battery is cooled to 0 °C ± 2 °C until it reaches thermal equilibrium.*

A shockable cardiac rhythm signal is applied to the SEPARATE MONITORING ELECTRODES or the DEFIBRILLATOR ELECTRODES. The visual or audible instructions given by the DEFIBRILLATOR are followed ensuring that DEFIBRILLATOR discharges is performed in cycles as specified above.

Where ME EQUIPMENT contains the possibility to insert more than one battery at the same time which can be selected randomly by the OPERATOR, the requirement of 20 discharges is the total amount of discharges available when the DEFIBRILLATOR is equipped with the maximum amount of batteries.

For any extra batteries that may be available for use in the DEFIBRILLATOR, but are not actually mounted in the DEFIBRILLATOR, the extra batteries shall not be included in the test.

201.103 * Endurance

The ME EQUIPMENT shall be capable of meeting the following endurance test which shall be carried out after the test for excessive temperatures as specified in 201.11.1.3 c) of this standard:

a) *A FREQUENT USE DEFIBRILLATOR shall be charged and discharged 2 500 times into a 50 Ω load at maximum energy or according to a programmed energy protocol. A DEFIBRILLATOR intended for INFREQUENT USE is to be charged and discharged 100 times into a 50 Ω load*

at maximum energy or according to a programmed energy protocol. During this test, forced cooling of the ME EQUIPMENT and the load is permitted. The accelerated test procedure shall not be allowed to produce temperatures in excess of those obtained in the test of 201.11.1.3 c) of this standard. INTERNALLY POWERED ME EQUIPMENT can be supplied from an external power source during this test.

b) *The DEFIBRILLATOR is charged and discharged ten times at maximum energy or according to an internal protocol, with the DEFIBRILLATOR ELECTRODES short-circuited. The intervals between consecutive discharges are not to exceed 3 min.*

Where short-circuited discharge is not possible, this test does not apply.

c) *The DEFIBRILLATOR is then charged and discharged five times at maximum energy with the DEFIBRILLATOR ELECTRODES open-circuited, but with one electrode and any conductive ENCLOSURE connected to earth. The test is then repeated with the other electrode and this ENCLOSURE connected to earth. In the case of a non-conductive ENCLOSURE, each electrode in turn is connected to earthed metal on which the ME EQUIPMENT is positioned as in NORMAL USE. The earthed metal is to have an area at least equal to that of the base of the ME EQUIPMENT.*

The intervals between consecutive discharges are not to exceed 3 min.

Where open-circuited discharge is not possible, this test does not apply.

d) *For FREQUENT USE DEFIBRILLATORS, each INTERNAL DISCHARGE CIRCUIT is tested 500 times at the maximum STORED ENERGY. The INTERNAL DISCHARGE CIRCUIT used in INFREQUENT USE DEFIBRILLATORS shall be tested 20 times at the maximum STORED ENERGY. During this test, forced cooling of the ME EQUIPMENT and the load is permitted. The accelerated test procedure shall not be allowed to produce temperatures in excess of those obtained in the test of 201.11.1.3 c) of this standard. INTERNALLY POWERED ME EQUIPMENT can be supplied from an external power source during this test.*

After completion of these tests, the ME EQUIPMENT is to comply with all other requirements of this standard.

201.104 * SYNCHRONIZER

Where a SYNCHRONIZER is provided, the following requirements shall be met:

a) There shall be a clear indication by a visible and optionally audible signal when the DEFIBRILLATOR is in the synchronized mode.

b) A defibrillation pulse shall occur only if a synchronization pulse occurs while the discharge control(s) is/are operated.

c) The maximum time delay from the peak of the QRS or the onset of an external triggering pulse to the peak of the DEFIBRILLATOR output waveform shall be:

   1) 60 ms where the ECG is derived via an APPLIED PART or a SIGNAL INPUT PART of the DEFIBRILLATOR, or

   2) 25 ms where the synchronizing triggering signal (not being an ECG) is derived via a SIGNAL INPUT/OUTPUT PART.

d) The DEFIBRILLATOR shall not default to synchronization mode on power up or on selection of defibrillation mode from any other mode.

201.105 * Recovery of the MONITOR and/or ECG input after defibrillation

201.105.1 ECG signal derived via DEFIBRILLATOR ELECTRODES

When the DEFIBRILLATOR is tested as described below, after a maximum period of 10 s following the DEFIBRILLATOR pulse, the test signal shall be visible on the MONITOR display (if

applicable) and the peak-to-valley amplitude of the displayed signal shall not deviate from the original amplitude by more than 50 %.

In addition to the above requirement, the RHYTHM RECOGNITION DETECTOR, if present, shall be able to detect a shockable rhythm 20 s after the defibrillation pulse. In this case, the signal applied to the DEFIBRILLATOR ELECTRODES shall be a signal recognizable by the DEFIBRILLATOR as shockable.

Check compliance test using the following apparatus, as shown in Figure 201.105. Self-adhesive electrodes are attached directly to the metal plates. Metal hard paddle surfaces, with conductive gel, as supplied or recommended by the MANUFACTURER if relevant, are applied directly onto the sponges without the metal plates, with an appropriate force. The force should be constant and be sufficient to provide a stable ECG signal without deforming the sponges. A weight shall be used to produce this force for repeatability and stability. A weight of at least 400 grams has been shown to obtain these results.

a) Two open cell synthetic sponges having a diameter or length and width approximately 15 mm greater than the diameter or length and width of the DEFIBRILLATOR ELECTRODES and a thickness of approximately 40 mm.

b) Two silver electrodes for the introduction of the test signal.

c) Switch S_1, double pole, of suitable rating.

d) Sine wave 10 Hz signal generator or shockable rhythm signal generator.

e) Non-conductive tank having dimensions not less than 250 mm × 150 mm × 60 mm.

f) "Normal" saline solution (9 g/l of NaCl) sufficient to fill the tank to an approximate depth of 30 mm so that the surface of the liquid is up to but not covering the top of the sponge.

g) Two metal plates made of high-nickel stainless steel or equivalent, type AISI 316 for example, slightly larger than electrode surface area, and of sufficient thickness to support electrodes.

The sponges are saturated with saline and the DEFIBRILLATOR ELECTRODES are placed on the metal plates and weighted to provide uniform contact with sponges.

With S_1 open, the DEFIBRILLATOR output current and voltage are measured during a maximum energy discharge, for example using a separate oscilloscope. The positions of the sponges and/or the level of the solution in the tank are adjusted so that the apparatus presents a (50 ± 5) Ω load to the defibrillation pulse.

Any input selector is set so that the MONITOR input is derived from the DEFIBRILLATOR ELECTRODES. Any selectable sensitivity control is set so that the MONITOR sensitivity is adjusted to 10 mm/mV. Any control affecting the MONITOR frequency response is set to the widest frequency response.

With S_1 closed, the signal generator output is adjusted to give a displayed signal of 10 mm peak-to-valley on the monitor display (if applicable). For a DEFIBRILLATOR with a RHYTHM RECOGNITION DETECTOR, the amplitude of the applied shockable rhythm signal is adjusted to enable the DEFIBRILLATOR to reliably detect a shockable rhythm.

With S_1 opened, a maximum energy pulse is delivered into the apparatus. S_1 is immediately closed and the MONITOR display is observed. The period of 10 s specified above is measured from this closure of S_1. In addition, the ECG RHYTHM RECOGNITION DETECTOR, if relevant, is to have detected a shockable rhythm within 20 s after closure of S_1.

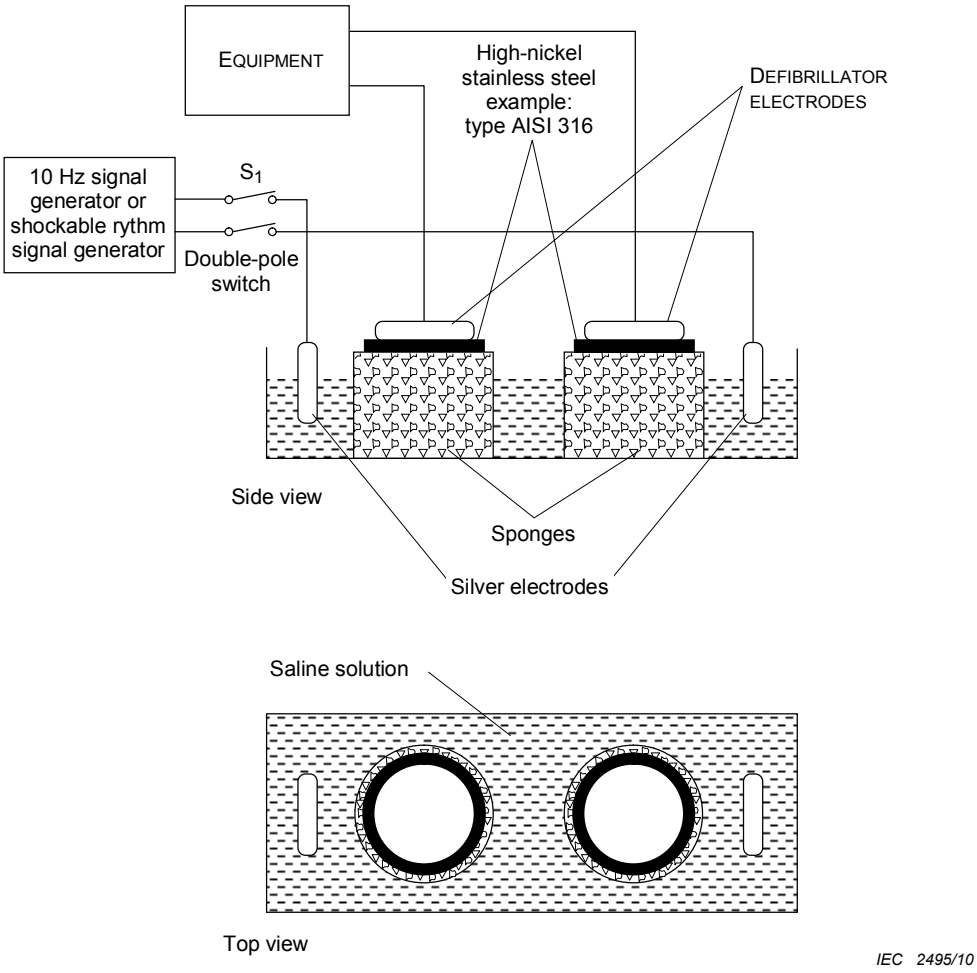
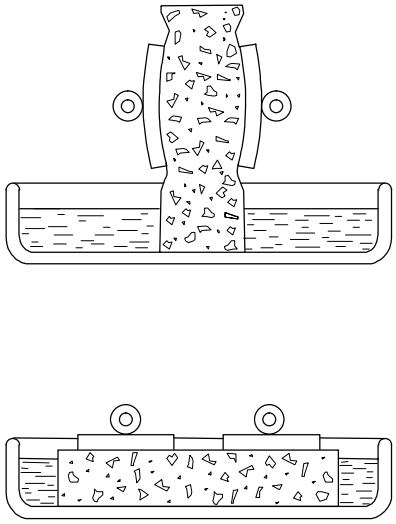


Figure 201.105 – Arrangement for test of recovery after defibrillation
(see 201.105.1)

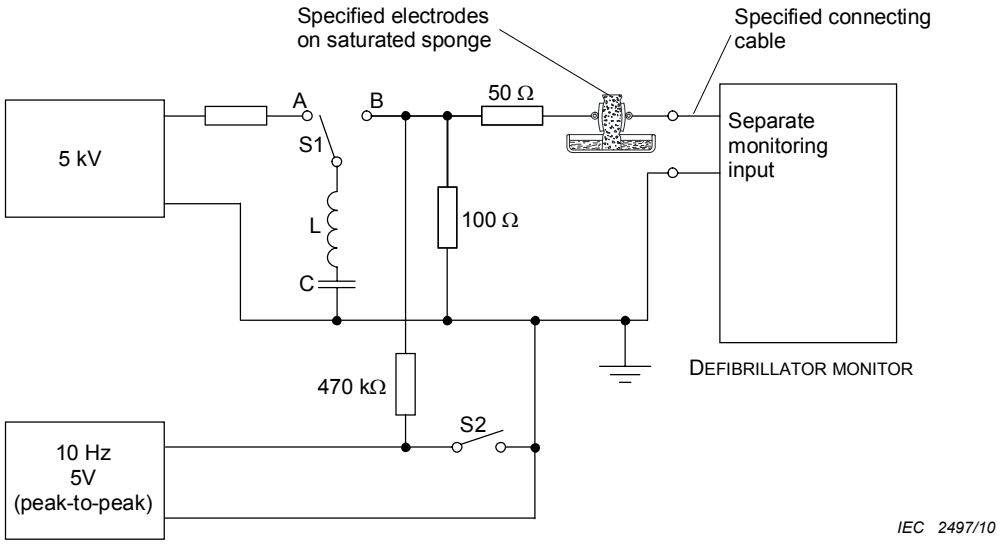
201.105.2 ECG signal derived via any SEPARATE MONITORING ELECTRODES

The test of 201.105.1 is performed with the SEPARATE MONITORING ELECTRODES attached to metal plates and then to a saturated sponge. Use electrodes specified by the MANUFACTURERS and the apparatus shown in Figures 201.106 and 201.107. The same compliance criteria apply.



IEC 2496/10

Figure 201.106 – Arrangement of monitoring electrodes on sponge
(see 201.105.2)



L = 500 μH
$R_L \leq 10\ \Omega$ (R_L represents the d.c. resistance of inductor L)
C = 32 μF

Figure 201.107 – Arrangement for recovery test after defibrillation
(see 201.105.2)

201.105.3 ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES

When the DEFIBRILLATOR is tested as described below, after a maximum period of 10 s following the defibrillation pulses the ECG shall be visible on the MONITOR display and the peak-to-peak amplitude of the displayed signal shall not deviate from the original amplitude by more than 50 %. For a DEFIBRILLATOR not incorporating a MONITOR, but where the ECG input is used for the ECG RHYTHM RECOGNITION DETECTOR, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s following the defibrillation pulse.

Check compliance by the test described below:

A pair of non-reusable DEFIBRILLATOR ELECTRODES of the type(s) recommended by the MANUFACTURER are connected back-to-back (conductive surface against conductive surface). The DEFIBRILLATOR ELECTRODES are connected to the DEFIBRILLATOR in series with a DEFIBRILLATOR TESTER incorporating an ECG simulator. The ECG simulator is set to ventricular fibrillation. Ten energy pulses are delivered at the highest energy output of the device, or according to a fixed protocol if such is incorporated in the device. The energy pulses are delivered at the highest rate obtainable with the device.

201.106 * Disturbance to the MONITOR from charging or internal discharging

NOTE This clause does not apply to DEFIBRILLATORS which do not incorporate a MONITOR.

During charging or internal discharging of the ENERGY STORAGE DEVICE, with the MONITOR display sensitivity set to 10 mm/mV ± 20 %:

a) any interference visible on the MONITOR display shall not exceed 0,2 mV peak-to-valley; and

b) the displayed amplitude of a 10 Hz sine wave input of 1 mV peak-to-valley shall not change by more than 20 %.

Any disturbances having a total duration of less than 1 s shall be ignored. A baseline shift shall be ignored provided that the entire signal remains visible on the display.

The above requirement shall be met with the MONITOR input derived as shown in Figure 201.108:

a) from any SEPARATE MONITORING ELECTRODES;

b) from the DEFIBRILLATOR ELECTRODES, any SEPARATE MONITORING ELECTRODES being disconnected;

c) from the DEFIBRILLATOR ELECTRODES, the SEPARATE MONITORING ELECTRODES being connected to the ME EQUIPMENT, if applicable.

Check compliance by measurement.

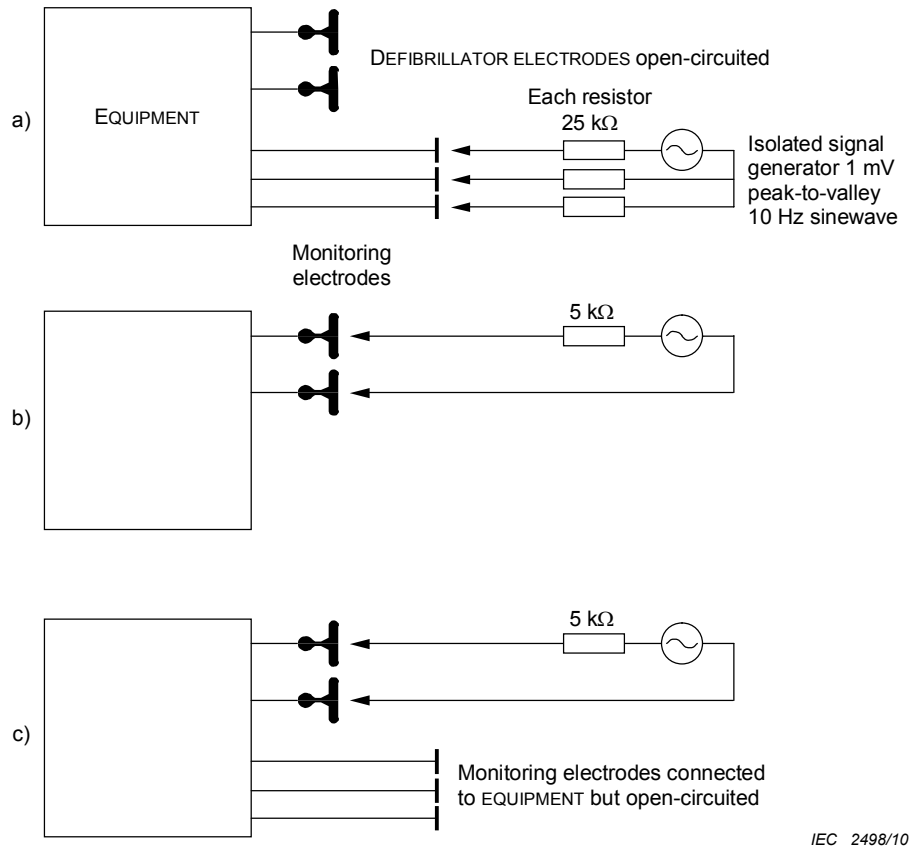


Figure 201.108 – Arrangement for test of disturbance from charging and internal discharging
(see 201.106)

201.107 * Requirements for RHYTHM RECOGNITION DETECTOR

The ECG database for validation of rhythm recognition performance shall include, at a minimum, ventricular fibrillation (VF) rhythms of varying amplitudes, ventricular tachycardia (VT) rhythms of varying rates and QRS width, various sinus rhythms including supraventricular tachycardias, atrial fibrillation and atrial flutter, sinus rhythm with PVC (premature ventricular contraction), asystole and pacemaker rhythms. All rhythms shall have been collected using electrode systems and ECG signal processing characteristics similar to the device being tested, and shall be of appropriate length to allow decisions to be made by the detector system.

The parameters describing rhythm recognition detector performance are as follows: specificity, true predictive value, sensitivity, and false positive rates (see Table 201.102).

Table 201.102 – RHYTHM RECOGNITION DETECTOR categories

	VF and VT	All other ECG rhythms
Shock	A	B
No shock	C	D

A true positive (A) is a correct classification of a shockable rhythm. A true negative (D) is a correct classification of all rhythms for which a shock is not indicated. A false positive (B) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable rhythm. A false negative (C) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

The sensitivity of the device for shockable rhythms is A/(A+C). The true predictive value is expressed as A/(A+B). The specificity of the device for non-shockable rhythms is D/(B+D). The false positive rate is expressed as B/(B+D).

The sensitivity of the device to recognize VF at maximum peak to peak amplitude of 200 μV or greater shall exceed 90 % in the absence of artifacts (e.g., induced by cardiopulmonary resuscitation). For those devices which detect VT, the sensitivity shall exceed 75 %. The specificity of the detector in correctly differentiating non-shockable rhythms shall exceed 95 % in the absence of artifacts.

The ECG database used to establish compliance with these requirements shall be different than the ECG database used for development of the RHYTHM RECOGNITION DETECTOR.

d) To define the performance of the RHYTHM RECOGNITION DETECTOR, the classification described in the literature indicated in the Annex AA can also be used as an alternative.

Check compliance by measurement.

201.108 DEFIBRILLATOR ELECTRODES

201.108.1 * DEFIBRILLATOR ELECTRODES for monitoring and defibrillation, and (optionally) pacing

201.108.1.1 * AC small signal impedance

The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak, shall not exceed 3 K Ω. The impedance at 30 kHz shall be less than 5 Ω.

Compliance is checked by connecting a pair of electrodes, gel-to-gel, applying a 10 Hz sinusoidal current of known amplitude not exceeding 100 μA p-p and observing the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a 1 MΩ resistor in series with the electrode pair.

The test is repeated with a 30 kHz current.

201.108.1.2 * AC large signal impedance

The impedance of an electrode pair connected gel-to-gel, in series with a 50 Ω load and measured at the maximum rated energy of the DEFIBRILLATOR shall not exceed 3 Ω.

Compliance is checked by placing a pair of electrodes gel-to-gel in series with a 50 Ω load across the output of the DEFIBRILLATOR. While monitoring the voltage across both the electrode pair and the resistor, the DEFIBRILLATOR is set to 360 J or its maximum rated energy and discharged through the circuit. The ratio of the peak voltages impressed across the electrodes should be less than or equal to 3:50.

201.108.1.3 * Combined offset instability and internal noise

A pair of electrodes connected gel-to-gel shall generate, after a 1 min stabilization period, a voltage no greater than 100 μV peak-to-peak in the pass band of 0,5 Hz to 40 Hz, for a period of 5 min following the stabilization period.

Compliance is checked after a 1 min stabilization period, the output voltage of the test circuit (see Figure US.1) shall not exceed 100 μV p-p over 5 min. Output voltage shall be measured

with an instrument having a frequency response of 0,1 Hz to 1,000 Hz and a minimum input impedance of 10 MΩ.

201.108.1.4 * Defibrillation recovery

The potential of a pair of gel-to-gel electrodes in series with a 50 Ω resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 400 mV at 4 s and 300 mV at 60 s after the last shock delivery

201.108.1.5 * Biological response

The electrode shall be biocompatible. For this application, with the electrode in continuous contact with the skin for the maximum duration specified by the manufacturer, biocompatibility requires evaluation of cytotoxicity, skin irritation, and skin sensitization.

Compliance is checked by a variety of acceptable methods. It is recommended that procedures and techniques provided in the ISO 10993 standards be considered when addressing these requirements.

201.108.1.6 * DC offset voltage

A pair of electrodes connected gel-to-gel shall, after a 1 min stabilization period, exhibit an offset voltage no greater than 100 mV.

Compliance is checked by connecting the electrodes gel-to-gel to form a circuit with a DC voltmeter having a minimum input impedance of 10 MΩ and a resolution of 1 mV or better. The measuring instrument shall apply less than 10 nA of bias current to the electrodes under test. The measurement shall be made after a 1 min stabilization period but before 1,5 min have elapsed.

201.108.1.7 * Electrode active area

The minimum active (gel) area of self-adhesive electrodes used for defibrillation and pacing shall be

each	**together**	**purpose**
50 cm^2	150 cm^2	adult transthoracic
15 cm^2	45 cm^2	pediatric (less than 10 kg) trans-chest

201.108.1.8 * Electrode adhesion and contact to patient

The electrode materials and construction shall ensure good adhesion and electrical contact with the patient when the electrodes are placed properly. Data on the characteristics of the adhesive (peel strength, setting time, response to perspiration, effect of temperature on these characteristics) should be available from the vendor.

There is no reliable bench test for this characteristic. Testing is best performed in a controlled clinical environment.

201.108.1.9 * Packaging and shelf life

The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the expiration date and under the storage conditions specified by the manufacturer. At a minimum, electrodes shall comply with all performance specifications after storage for 1 year at 35 °C. One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 h at -30 °C and +65 °C. Electrodes shall be returned to a temperature in the range of 15 °C to 35 °C before the test

for compliance is performed. Electrodes shall be tested at both 15 °C and 35 °C or the operating temperature extremes defined by the manufacturer.

Compliance is checked by conducting the tests of 201.108.1.1 through 201.108.1.8 at the end of the specified shelf life and at the extremes of the temperature ranges specified.

201.108.1.10 * Universal-function electrodes

If the electrodes are designed and intended for use in multiple modes, i.e., monitoring, defibrillation, and pacing, the following requirements apply.

a) The electrode package shall clearly identify all functions that the electrode will perform.
b) The electrode package shall provide specific instructions for the connection, placement, and operation of the electrodes for their various functions.
c) The electrode shall meet all requirements or disclose the results, in the instructions for use, of 201.108.1 after 60 min of pacing at the maximum current output and maximum pacing rate through a pair of gel-to-gel electrodes in series with a 50 Ω resistor.

Compliance is checked by the electrodes meeting these requirements or will be met by the disclosure of the performance to each specification: 201.108.1.1 – 201.108.1.4; 201.108.1.6 – 201.108.1.7 following an hour of pacing. Tests shall be conducted immediately after the conclusion of pacing.

201.108.1.11 * Cable length

The electrode cables shall have an extended length of at least 2 m. If coiled cords are used, the extension force shall be 18 N (4 lb) or less per paddle electrode at a distance of 2 m.

Compliance is checked by measurement.

201.109 * External pacing (U.S.)

External pacing may be provided as an optional feature.

201.109.1 Pacing mode activation

The pacing mode shall only be activated manually by the mode selector and shall be clearly labeled. The DEFIBRILLATOR shall be disarmed and the defibrillation mode disabled when the pacing mode is operative.

201.109.2 Pacing delivery

The pacing output may be delivered to the patient through either the defibrillation electrode pathway or a separate pacing electrode pathway.

201.109.2.1 Separate pacing pathway

If a separate pacing electrode pathway is provided, the following requirements apply.

a) Pacing electrode placement and connection shall be described in the operating instructions.
b) The pacing output circuitry shall be able to withstand, without damage, three 360 J defibrillation discharges 1 min apart across the pacing electrode pads shunted by a 100 Ω load.

Compliance is checked by performing the following test:

(1) Connect the pacer circuit to the test circuit as indicated in Figure US.2. A DEFIBRILLATOR test load of 100 Ω, or its equivalent, shall be used.

(2) Charge the capacitor to 5,000 V, with switch S1 in position A. Discharge is accompanied by actuating S1 to position B for a period of 200 ms ± 100 ms. The capacitor shall be disconnected in order to remove residual voltages and to allow recovery to commence.

(3) After 10 s, verify that the pacer circuit correctly displays the test signal at an amplitude at least 50 % of its normal amplitude before the test.

(4) After the test, the pacer circuit shall meet all performance requirements of this standard.

(5) Perform the test three times with at least 30 s separation between successive discharges. The switch S1 shall withstand peak currents of 60 A in the closed position, and in the open position it shall not break down for voltages up to 5 000 V.

201.109.2.2 Combined pathway

If the defibrillation/pacing electrode pathway also is used for ECG monitoring, the following requirements shall apply:

a) the electrode package shall clearly identify all functions that the electrode will perform;

b) electrode placement and connection shall be described in the operating instructions;

c) the electrodes shall meet all the requirements of 201.108.1.

Compliance is checked by performing the tests in 201.108.1.10 c).

201.109.3 Pacing pulse shape and duration

201.109.3.1 Pace pulse duration accuracy

The pacing pulse shape (waveform) and duration shall be specified in the operating instructions. The output waveform shall be within the limits specified in the operating instructions.

Compliance is verified by the following test:

a) Connect a 50 Ω resistive test load and an oscilloscope between the pacing electrode connectors.

b) Activate the pacing mode.

c) The pacing pulse shape and duration shall fall within the limits specified for these parameters in the operating instructions.

201.109.3.2 Pace pulse duration stability

a) If the pacemaker is battery-operated, the pulse duration shall not change by more than ±10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

Compliance is checked by continuing the pacer operation in 201.109.3.1 for the duration equivalent to the nominal operating time of the battery. Measure duration every 15 min. The duration shall not change by more than 10 % from the initial reading for any measurement.

b) If the pacemaker is powered off AC-mains, the pulse duration shall not change by more than ±10% over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Compliance is checked by continuing the pacer operation in 201.109.3.1 for the duration equivalent to the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. Measure duration every 30 min. The duration shall not change by more than 10 % from the initial reading for any measurement.

201.109.4 Pacing pulse current

201.109.4.1 Pacing pulse current accuracy

If predetermined within the pacer, the pacing pulse current shall be described in the operating instructions.

The output waveform shall be within the limits specified in the operating instructions.

Compliance is checked as follows:

a) Perform steps a) and b) of 201.109.3.1.

b) The pacing pulse current shall fall within the limits specified for this parameter in the operating instructions. If a pacing control is provided, the pacing pulse current shall be measured at each setting for compliance. If the pacing current control is continuously variable, measurement of the minimum and maximum settings and at least one other setting corresponding to the control's labeling shall be performed.

201.109.4.2 Pacing pulse current stability

a) If the pacemaker is battery-operated, the pulse current shall not change by more than ± 10 % over the duration equivalent to the nominal operating time of the battery specified in the operating instructions.

b) If the pacemaker is powered off AC-mains, the pulse current shall not change by more than ± 10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Compliance is checked as follows:

a) Perform steps a) and b) of 201.109.3.1.

b) With current set to maximum, verify that the pacing pulse current does not exceed ± 10 % from its original setting.

201.109.5 Pacing rate

201.109.5.1 Pacing rate accuracy

The output waveform shall be within the limits specified in the operating instructions.

Compliance is checked as follows:

a) Perform the steps a) and b) of 201.109.3.1.

b) The pacing rate shall fall within the limits specified for this parameter in the operating instructions. If a pacing rate control is provided, the pacing rate shall be measured at each setting for compliance. If the pacing rate control is continuously variable, measurement of the minimum and maximum settings and at least one other setting corresponding to the controls labeling shall be performed.

c) Compliance with the labeling requirement for a pacing rate control, if present, can be verified by inspection.

201.109.5.2 Pacing rate stability

a) If the pacemaker is battery-operated, the pulse rate shall not change by more than ± 10 % over the duration equivalent to the nominal operating time of the battery as specified in the operating instructions.

Compliance:

If the pacemaker is battery-operated, continue the pacer operation in 201.109.5.1 for the duration equivalent to the nominal operating time of the battery. If a pacing rate control is

provided, it should be set to mid-range. Measure duration every 15 min. The rate shall not change by more than 10 % from initial reading for any measurement.

b) If the pacemaker is powered off AC-mains, the pulse rate shall not change by more than ±10 % over the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions.

Compliance:

If the pacemaker is powered off AC-mains, continue the pacer operation in 201.109.5.1 for the duration of the maximum length of treatment with a given set of electrodes as specified in the operating instructions. If a pacing rate control is provided, it should be set to mid-range. Measure duration every 30 min. The rate shall not change by more than 10 % from the initial reading for any measurement.

201.109.6 Pacing protocol

Pacing may be provided in either a continuous or intermittent sequence. If predetermined within the pacer, the pacing protocol shall be described in the operating instructions. If operator selection is provided, the control that selects the pacing protocol shall be labeled with the available selections.

Compliance is checked by inspection.

201.109.7 Demand pacing

Demand pacing is not a required feature of DEFIBRILLATORS including external pacing capability. If demand pacing is available, the heart rate at which pacing begins, in a down-trending heart rate, shall be between 90 % and 100 % of the pacing rate selected on the unit. If the unit has rate settings below 40 ppm, the unit shall begin pacing when the heart rate drops below the rate setting minus 4 ppm.

Compliance:

For units with the capability of monitoring and pacing through the same set of electrodes, the ECG/pacing leads are connected to a DEFIBRILLATOR tester capable of providing a 1 mV ECG signal to the pacing/ECG cable at a variable rate. For other units not capable of this multifunction operation, the ECG leads are connected to a DEFIBRILLATOR tester capable of providing an ECG signal at a variable rate. An oscilloscope probe should be placed across the inputs to the DEFIBRILLATOR tester to measure the pacing energy delivered into the 50 Ω load of the tester. The ECG signal rate is set to 120 beats per minute (bpm), and the pacing rate of the unit is set to 68 ppm. The unit shall not have pacing activated. Change the ECG signal rate to 60 bpm. The unit shall now have pacing activated.

Set the ECG signal rate to a rate of 180 bpm and the pacing rate of the unit to 134 ppm. The unit shall not have pacing activated. Change the ECG signal rate to 120 bpm. The unit shall now have pacing activated.

201.109.8 Pacer lead-off indication

There shall be a clear indication by means of either a display or an indicator light that the unit is unable to deliver the pacing current because of a pacing leads-off condition. It is recommended, though not required, that the unit also provide an audible indicator of this condition.

Compliance:

Connect the pacer output cable to a 250 Ω power resistor, and pace at the maximum amplitude allowed by the unit. The unit shall not indicate that a pacer lead-off condition is present.

Set the output to 20 mA and disconnect the pacer output cable from the load resistor. The unit shall indicate that a pacer lead-off condition is present.

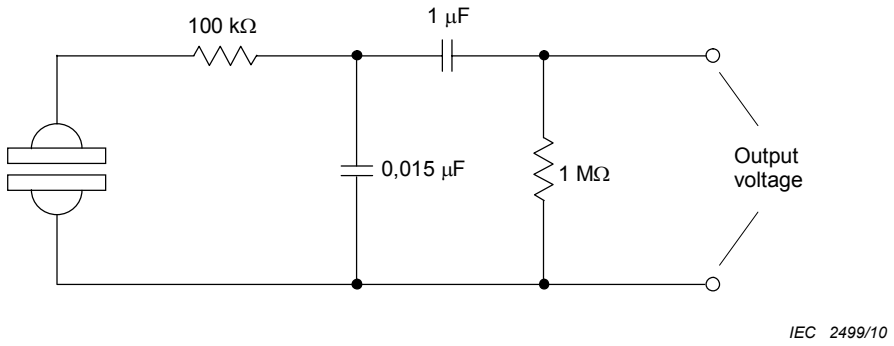
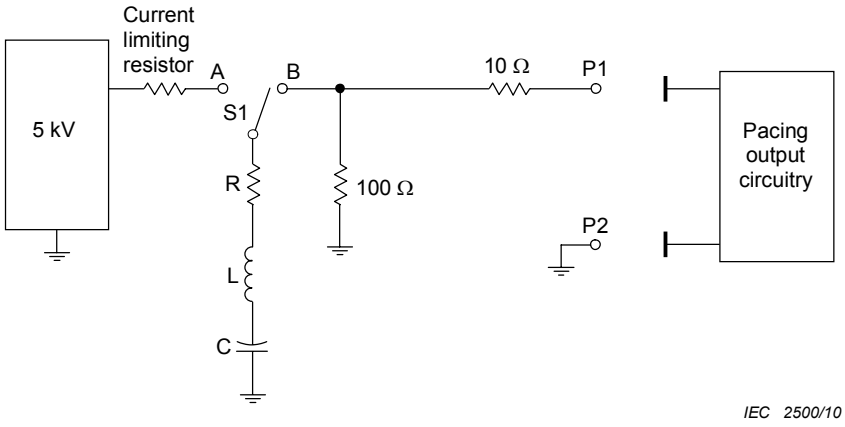


Figure 201.109 – Test circuit for offset instability/internal noise determination



C = 32 μF
L = 25 μH
R + R_L =11 Ω (R_L represents the d.c. resistance of inductor L)

NOTE 1 The values of the resistors are ± 2 %. The value of the inductor is ± 5 %.

NOTE 2 The 100 Ω test load may consist of a 50 Ω load in series with the 50 Ω load of a DEFIBRILLATOR tester; with such a circuit, the total energy delivered to the 100 Ω load is twice the energy indicated by the DEFIBRILLATOR tester.

Figure 201.110 – Test circuit for DEFIBRILLATOR overload test of pacing output circuitry

202 * Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows:

202.6.1 Emissions

Addition:

The requirements of 6.1 of IEC 60601-1-2 are waived during a DEFIBRILLATOR charge/discharge cycle.

202.6.1.1 Protection of radio services

202.6.1.1.1 Requirements

Replacement:

The DEFIBRILLATOR shall comply with the requirements of CISPR 11, group 1, in all configurations and operating modes. DEFIBRILLATORS are classified as class B equipment for determining applicable CISPR 11 requirements. Emission levels measured 10 m from the instrument shall not exceed 30 dB µV/m from 30 MHz to 230 MHz and shall not exceed 37 dB µV/m from 230 MHz to 1 000 MHz.

202.6.2.2 Electrostatic discharge (ESD)

Replacement:

202.6.2.2.1 Requirements

For open air discharges of ±2 kV and ±4 kV and direct contact discharges of ±2 kV, the OPERATOR shall not notice any change in ME EQUIPMENT operation. The ME EQUIPMENT shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is allowed. However, ECG spikes, pacemaker pulse detection, display glitches, or momentary light-emitting diode (LED) flashes are acceptable during an ESD discharge.

For open air discharges of ±2 kV, ±4 kV and ±8 kV or direct contact discharges of ±2 kV, ±4 kV and ±6 kV, the ME EQUIPMENT may exhibit momentary loss of functionality but shall recover within 2 s without OPERATOR intervention. There shall be no unintended energy delivery, unsafe failure mode, or loss of stored data.

202.6.2.2.2 Tests

The test methods and instruments specified in IEC 61000-4-2 apply with the following addition:

The ME EQUIPMENT is exposed, at any point on its surface accessible to the OPERATOR or PATIENT, including APPLIED PARTS, to the discharges described in 202.6.2.2.1.

202.6.2.3 Radiated RF electromagnetic fields

Replacement:

202.6.2.3.1 Requirements

The ME EQUIPMENT is exposed to a modulated RF field with the following characteristics:

- field strength: 10 V/m or 20V/m as test indicates;
- carrier frequency range: 80 MHz to 2,5 GHz;
- AM modulation, 80 % index, at 5 Hz.

202.6.2.3.2 Tests

The test methods and instruments specified in IEC 61000-4-3, apply with the following modifications:

Check compliance by the following test:

The DEFIBRILLATOR ELECTRODES are terminated in a simulated PATIENT load (1 kΩ resistor in parallel with a 1 µF capacitor). The ME EQUIPMENT is tested with all its faces sequentially exposed to the RF field. When exposed to a field strength of 10 V/m, no inadvertent discharge or other unintended change of state shall occur. No inadvertent activation of the RRD (false positive) is allowed. When exposed to a field strength of 20 V/m, no inadvertent energy delivery is allowed.

Certain PATIENT cable configurations can cause failure to meet these IMMUNITY requirements. In such a case, the MANUFACTURER is to disclose the reduced IMMUNITY LEVELS which are met.

202.6.2.4 Electrical fast transients and bursts

Replacement:

202.6.2.4.1 Requirements

Mains connectable ME EQUIPMENT shall test using level 3 at the MAINS PLUG. Only transient loss of functionality is allowed. No inadvertent energy delivery or other unintentional change of state is allowed. The device shall revert to its condition just prior to the burst without OPERATOR intervention.

202.6.2.4.2 Tests

The test methods and instruments specified in IEC 61000-4-4 apply.

202.6.2.5 Surges

202.6.2.5.1 Requirements

Addition:

Mains connectable ME EQUIPMENT shall be tested according to installation Class 3 according to Annex A of IEC 61000-4-5 incorporating amendment Nos. 1 and 2. Compliance criteria: no inadvertent energy delivery or other unintentional change of state is allowed. The device shall revert to its prior condition without OPERATOR intervention.

202.6.2.6 Conducted disturbances, induced by RF fields

202.6.2.6.1 Requirements

Addition:

No inadvertent discharge or other unintentional change of state shall occur during this period. No loss of functionality is allowed.

202.6.2.6.2 Tests

Replacement of the third bullet under the fourth dashed line of item a):

- *When a DEFIBRILLATOR can be operated from line power as well as a battery, an RF voltage with the following characteristics is injected into the input power cord (not in the signal input):*
  - *RF voltage amplitude: 3 V r.m.s.;*
  - *carrier frequency: 150 kHz to 80 MHz;*
  - *AM modulation, 80 % index, at 5 Hz.*

202.6.2.8.1 Power frequency magnetic fields

Replacement:

202.6.2.8.1.1 Requirements

No inadvertent discharge or other unintentional change of state shall occur during this test. Some display jitter is allowed, however the displayed information shall be readable and stored data shall not be lost or corrupted.

202.6.2.8.1.2 Test

The test methods and instruments specified in IEC 61000-4-8 are applied as follows:

The ME EQUIPMENT is exposed on all axes. The ECG leads and electrodes are short-circuited at the ME EQUIPMENT.

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of a CARDIAC DEFIBRILLATOR are found in the subclauses listed in Table 201.C.101.

Table 201.C.101 – Marking on the outside of a CARDIAC DEFIBRILLATOR or its parts

Description of marking	Subclause
Battery charger	201.7.2.102
Concise operating instructions	201.7.2.101
DEFIBRILLATOR ELECTRODES, disposable	201.7.2.103
RATED power input	201.7.2.7

201.C.3 Marking of controls and instruments

Addition:

Additional requirements for marking of controls and instruments of a CARDIAC DEFIBRILLATOR are found in the subclause listed in Table 201.C.102.

Table 201.C.102 – Marking of controls and instruments of a CARDIAC DEFIBRILLATOR

Description of marking	Subclause
SELECTED ENERGY control	201.7.4.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table 201.C.103.

Table 201.C.103 – ACCOMPANYING DOCUMENTS, general

Description of marking	Subclause
Electrical power source	201.7.9.2.4
Supplemental instructions for use	201.7.9.2.101

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Addition:

Additional requirements for information to be included in the instructions for use are found in the subclause listed in Table 201.C.104.

Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use

Description of marking	Subclause
PATIENT cables that do not meet IMMUNITY requirements, disclosure of	202.6.2.3.2

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

Additional requirements for information to be included in the technical description are found in the subclauses listed in Table 201.C.105.

Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description

Description of marking	Subclause
Defibrillation, ESSENTIAL PERFORMANCE data	201.7.9.3.101
DEFIBRILLATOR ELECTRODES, disposable	201.7.2.103
RHYTHM RECOGNITION DETECTOR, ESSENTIAL PERFORMANCE data	201.7.9.3.103
SYNCHRONIZER, ESSENTIAL PERFORMANCE data	201.7.9.3.102

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of this standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

From the standpoint of safety, CARDIAC DEFIBRILLATORS pose special problems not only because of the possible shock hazard to the OPERATOR, but because the DEFIBRILLATOR has to deliver the selected output even after a long period of disuse, otherwise the PATIENT's safety may be at RISK. Thus CARDIAC DEFIBRILLATORS require a high order of reliability.

The minimum safety and reliability requirements as specified in this standard are considered to provide for an acceptable level of safety in operation and reliability in use.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The requirements of this standard are specified for the commonly used DEFIBRILLATOR with or without an incorporated MONITOR, that is, an ME EQUIPMENT containing a capacitor as an ENERGY STORAGE DEVICE. This capacitor is charged to a HIGH VOLTAGE and connected to the output electrodes either directly or via a series inductor or resistor.

The first edition of this standard made a distinction between a DEFIBRILLATOR and a DEFIBRILLATOR-MONITOR. This was due to development of a draft specification for the latter being developed in parallel with that for DEFIBRILLATORS and the two specifications being combined in a later draft. This distinction is no longer necessary and has been eliminated in this edition.

This particular standard does not address requirements for implantable DEFIBRILLATORS since they are considered to have sufficient differences to merit separate treatment.

Since publication of the first edition of this standard, AUTOMATED EXTERNAL DEFIBRILLATORS (AEDs) have come into widespread use. Several requirements of this standard have been revised or created to standardize these devices.

A variety of therapeutic waveforms have been used to terminate cardiac fibrillation including damped sine, biphasic, and truncated exponential. DEFIBRILLATOR designers, RESPONSIBLE ORGANIZATIONS and evaluators should take into consideration that clinical studies have demonstrated that defibrillator termination efficacy varies widely with waveshape as well as other parameters including voltage amplitude, DELIVERED ENERGY, tilt, and total duration. Waveform technology is evolving rapidly. This precludes stating specific safety requirements in this standard. However, due to the efficacy sensitivity to variations in these parameters, adequate clinical validation should be considered essential. Particular validation attention

should be given to the efficacy of waveforms with insufficient current or protracted duration, and the safety of waveforms with excessive peak current.

Subclause 201.4.2.101 – Additional RISK MANAGEMENT requirements

INFREQUENT USE AEDs are deployed in an idle condition for long periods of time without operation or manual maintenance. While the endurance test of 201.103 ensures some level of defibrillator reliability, there are no explicit requirements to guarantee INFREQUENT USE AEDs are maintained in a state of readiness. The MANUFACTURER needs to identify methods to ensure readiness for use, such as periodic self tests and battery capacity monitoring. Methods of providing state of readiness to users should be considered by the MANUFACTURER. This clause emphasizes the importance of considering this unique aspect of INFREQUENT USE AEDs during the risk management process.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

Defibrillators are sufficiently similar that ESSENTIAL PERFORMANCE can be recommended. Where the ME EQUIPMENT contains other functions, such as an ECG waveform display used to determine therapy (IEC 60601-2-27), additional ESSENTIAL PERFORMANCE may apply.

The intent of the subclauses listed in Table 201.101 is that the ME EQUIPMENT operate as specified to provide essential therapy. Degraded operation under misuse and single fault condition is addressed through the risk management system. Where ESSENTIAL PERFORMANCE requirements are repeated to show compliance with other requirements, it is expected that a representative subset of test conditions may be used.

Subclause 201.5.3 – Ambient temperature, humidity, atmospheric pressure

In accordance with the environmental conditions (see 201.5.3), battery powered ME EQUIPMENT also has to be type-tested at 0 °C to reveal any temperature-dependent characteristics which may adversely affect safety.

If ME EQUIPMENT for an extended range of environmental temperatures is needed (for example in ambulances or helicopters) this requires special agreement between the MANUFACTURER and the OPERATOR.

Subclause 201.6.2 – Protection against electric shock

Reference to TYPE B APPLIED PARTS is deleted, as the output circuit has to be isolated from earth to avoid unwanted current paths if the PATIENT has another earth connection. An isolated output circuit is also essential for the safety of the OPERATOR.

Subclause 201.7.2.7 – Electrical input power from the SUPPLY MAINS

A large surge of current may be drawn from the SUPPLY MAINS during charging of the DEFIBRILLATOR. The OPERATOR should operate the ME EQUIPMENT on a suitably RATED mains circuit. This is particularly a problem with a d.c. SUPPLY MAINS.

Subclause 201.7.2.101 – Concise operating instructions

As a DEFIBRILLATOR is frequently needed in an emergency situation, the essential operating information has to be available without recourse to the instructions for use.

Subclause 201.7.2.102 – Internally powered ME EQUIPMENT

Here the same rationale as in 201.7.2.101 applies. Additionally, the marking should indicate whether the DEFIBRILLATOR with a discharged or missing battery can be used effectively from a built-in or separate battery charger.

Subclause 201.7.4.101 – Selected energy control

Values for the PATIENT resistance reported in the literature vary over a range from 25 Ω to 175 Ω in clinical situations. A significant portion of the STORED ENERGY is dissipated in the resistance of the DISCHARGE CIRCUIT or may remain in the storage capacitor. The value of 50 Ω used here represents a suitable reference value rather than a normal or typical value.

In order not to restrict design unnecessarily, no stricter requirements regarding numbers of steps are specified. For easy and safe use, all ME EQUIPMENT are required to be calibrated in joules of DELIVERED ENERGY. However, it is recognized that many newer DEFIBRILLATORS are incorporating sophisticated techniques for optimizing defibrillation output by waveform adjustments based on PATIENT impedance measurements. It is widely recognized that many parameters of defibrillation waveforms, not just total energy, can affect efficacy.

Some AEDs are simple, single energy devices. As long as the accuracy of the device is within the provisions of this standard, no advantages are available to the OPERATOR from a quantitative DELIVERED ENERGY indication. Also, most AEDs have a programmed sequence of energy settings, precluding the OPERATOR from energy selection during PATIENT use. Therefore, a SELECTED ENERGY control is not appropriate.

It is an essential safety feature that the OPERATOR can clearly see or hear the ready for discharge indication from normal distance from PATIENT to device or in typical noise ambient levels. Devices with both audible and visual indicators are preferred.

Subclause 201.7.9.2.4 – Electrical power source

A rechargeable battery has a limited lifetime and should be replaced periodically.

Subclause 201.7.9.2.101 – Supplementary instructions for use

a) and b) This information is necessary for the protection of OPERATOR and PATIENT as well as of other ME EQUIPMENT. Many AEDs include features to allow defibrillation only if the impedance load falls within a predetermined range, as a safety technique to prevent inappropriate shocks.

d) Adverse environmental conditions immediately prior to use may affect the reliable operation of the ME EQUIPMENT.

f) As the reliable function of a DEFIBRILLATOR is essential for the PATIENT'S safety, this maintenance is considered important. Inspection of the packaging of disposable electrodes is necessary because loss of packaging seal could lead to drying of electrolyte and resulting increase in electrode impedance which may result in degradation in performance of the DEFIBRILLATOR.

g) Knowledge of the charging time under best and worst conditions is considered to be essential.

i) Caregivers must be prepared to interpret such a discontinuation of AED shock delivery as a logical RRD decision based on appearance of a non-shockable rhythm and not indication of ME EQUIPMENT malfunction.

Subclause 201.7.9.3.101 – ESSENTIAL PERFORMANCE data for defibrillation

As the PATIENT resistance is subject to variation, details of the waveform and the effect of changes in load resistance should be made available to the OPERATOR.

Subclause 201.7.9.3.102 – ESSENTIAL PERFORMANCE data of any SYNCHRONIZER

The data listed for SYNCHRONISER performance is based on problems which have arisen in practice.

Subclause 201.7.9.3.103 – ESSENTIAL PERFORMANCE data of the RHYTHM RECOGNITION DETECTOR

The essential performance of RHYTHM RECOGNITION DETECTORS has been the object of considerable clinical/industry collaboration recently, and has resulted in useful, insightful, and statistically meaningful methods of specifying the performance of such system. The standard should simply adopt the results of these efforts:

"*Automatic external DEFIBRILLATORS for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety*," a statement for health professionals from the American heart association task force on automatic external defibrillation, subcommittee and AED safety and efficacy.

Subclause 201.8.3 – Classification of APPLIED PARTS

TYPE CF APPLIED PART requirements are necessary, because a DEFIBRILLATOR providing for the connection of SEPARATE MONITORING ELECTRODES may be used for intracardiac monitoring.

Subclause 201.8.5.5.1 – Defibrillation protection

It is also necessary for the requirement of 201.8.5.5.101 to apply, if other PATIENT circuits of a DEFIBRILLATOR are used and the PATIENT is treated with another DEFIBRILLATOR. The requirements for DEFIBRILLATION-PROOF APPLIED PARTS given in the general standard generally provide adequate protection for other PATIENT circuits which have been specifically included in the DEFIBRILLATOR. The amendments given here take account of other APPLIED PARTS which may be connected to the ME EQUIPMENT but not connected to the PATIENT. In addition to testing with the power off, they are tested with power on, which is the normal operating condition.

Subclause 201.8.5.5.101 – Isolation of DEFIBRILLATOR ELECTRODES

The severity of electric shock a person receives when touching ACCESSIBLE PARTS during defibrillation is limited to a value which can be felt and which may be unpleasant, but which is not dangerous. SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote recording and other ME EQUIPMENT could otherwise carry voltage surges which could cause hazardous shocks from such ME EQUIPMENT.

Subclause 201.8.5.5.102 – Applied parts not being DEFIBRILLATOR ELECTRODES

Where the MANUFACTURER has made use of an APPLIED PART at the same time as performing defibrillation impossible, such an APPLIED PART need not be a DEFIBRILLATION-PROOF APPLIED PART.

Subclause 201.8.7 – Leakage currents and patient auxiliary currents

Subclause 201.8.7.1 – General requirements

Due to capacitive coupling between the DEFIBRILLATOR APPLIED PART and other (possibly earthed) parts, a certain amount of LEAKAGE CURRENT is unavoidable. During discharge, LEAKAGE CURRENTS may be higher, but will be much smaller than the intended defibrillating pulse current and will not present a HAZARD to the PATIENT or the OPERATOR. The period of 1 s for this exemption was chosen in order to include all possible waveforms and to allow any mechanical contactor to reset.

Subclause 201.8.7.3 – Allowable values

The lower limit specified in the general standard is valid for small-area contacts with the myocardium whereas the internal DEFIBRILLATOR ELECTRODES have a relatively large area. Furthermore the special test condition, i.e. MAINS VOLTAGE on the PATIENT for which this value applies, is unlikely to occur during open-chest surgery.

Subclause 201.8.8.3 – Dielectric strength

Voltage spikes on the SUPPLY MAINS will not appreciably affect the voltage on the energy storage capacitor; therefore a moderate test voltage was considered to be sufficient. In the general standard, earthing of the PATIENT is not considered to be a fault condition; consequently, the situation where one side of the APPLIED PART is connected to earth had to be included.

A high insulation resistance together with the other insulation requirements prevents the appearance of dangerous voltages on conductive ACCESSIBLE PARTS. In most insulating materials, a breakdown is preceded by a non-linear increase of the current.

Resistors bridging this insulation should have a value high enough not to conflict with the principle of an isolated DEFIBRILLATOR APPLIED PART.

The purpose of test 1 is to investigate the insulation between the high-voltage circuit of the DEFIBRILLATOR and other ACCESSIBLE PARTS.

The purpose of test 2 is to investigate the isolation between the basic wiring and conductive parts of the high-voltage circuit of the DEFIBRILLATOR.

The purpose of test 3 is to investigate if the isolation across components in the CHARGING CIRCUIT and the DISCHARGE CIRCUIT safely can handle the voltage levels present in the DEFIBRILLATOR.

The linearity test arose out of dielectric testing of only one sample and then not having confidence in being able to show any design margin. Since there is almost always a non-linear increase in current before a breakdown, it is considered an acceptable way to tell if the sample is near breakdown. However, test currents that are below the range of linearity of the measurement equipment, or certain pre-conditioning tests, such as humidity testing, may produce a non-linearity indication when breakdown is not close. To allow for these cases, alternative tests are provided that meet the same intent while bolstering confidence in the design margin.

- Calculated resistance of 1 GΩ demonstrates that the design resistance easily meets the 500 MΩ minimum resistance requirement.
- If a single device is tested to a 1,7 *U* dielectric level with no breakdown or flashover then it was not near breakdown at the 1,5 *U* dielectric level.
- If four additional devices (for a total of five) are tested at 1,5 *U* dielectric level, and they meet the 500 MΩ requirement without breakdown, then there is more confidence in the design margin.

The high voltage switching elements in a DEFIBRILLATOR provide a barrier between the energy storage element and the PATIENT, and this subclause is specifically designed to assure the integrity of those switching elements. The essential need is to assure that PATIENT safety is not compromised due to inadvertent energy discharge.

In many traditional DEFIBRILLATOR designs, the switch under test is simply a relay, which either passes the high-voltage test or not. However, newer DEFIBRILLATOR designs may include more complex switching methods. These methods permit for example, the generation of new defibrillation waveforms and provide improved ability to monitor the integrity of the internal systems.

Series-connected switching devices offer useful design advantages in these newer systems, but care must be taken to assure that faults in any one switching element do not lead to compromise of safety. Accordingly, the intent of this requirement is to subject the DEFIBRILLATOR switching system to over-voltage stresses in conjunction with single-fault

conditions. The MANUFACTURER must demonstrate that, while gaining the versatility of newer switching techniques, PATIENT safety is not compromised in the event of failure.

Subclause 201.8.9.1.5 – ME EQUIPMENT RATED for high altitudes

Provisions of subclause 8.9.1.5 of the general standard are new to the general standard as of edition 3. An installed base of defibrillators, rated for and in use at altitudes up to 5 000 m, currently exists with no indication that additional spacing is needed beyond provisions of the general standard edition 2 and compatible revisions of this standard. The need for greater spacings at higher altitudes is accepted and applied for ME EQUIPMENT rated for altitudes greater than 5 000 m. Refinements in application of 8.9.1.5 of the general standard may be included in subsequent revisions of this standard.

Subclause 201.8.9.1.101 – DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

a) Relatively large distances are specified to allow for the probable spread of conductive gel.
b) Voltage spikes on the mains voltage will not significantly influence the voltage on the storage capacitor; therefore relatively small distances are considered to provide enough safety.
d) Double insulation for reusable cables that may become worn with time and rough handling provides a margin of safety for the operator to protect from high voltage exposure. For single use cables of moderate length, this risk is remote and the requirement is relaxed.

Subclause 201.11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

The ME EQUIPMENT is likely to be carried and used outside medically used rooms and therefore a certain degree of protection against rainfall and spillage was deemed to be necessary. During the functionality test of the DEFIBRILLATOR, it is allowed that secondary functionality (e.g. a recorder) does not operate after the test, as long as this does not adversely affect the DEFIBRILLATOR functionality.

Especially for AEDs, it is required that voice prompts (if applicable) are still functional after the test.

For some ME EQUIPMENT there may be more than one position of NORMAL USE.

Subclause 201.11.6.7 – Sterilization of ME EQUIPMENT and ME SYSTEMS

This requirement was deemed to be essential as the internal DEFIBRILLATOR ELECTRODES are used during open-chest surgery.

Clause 201.12 – Accuracy of controls and instruments and protection against hazardous outputs

Many quite different waveforms are currently used for the treatment of cardiac dysrhythmias. The energy levels used with these different waveforms also vary widely and there is at present no general agreement in the medical profession on an optimum form of electrical output for a CARDIAC DEFIBRILLATOR. This standard therefore does not specify output parameters in any detail.

Subclause 201.12.1 – Accuracy of controls and instruments

The specified accuracy is considered adequate and is practical with existing technology. It was noted that the accuracy tolerance is quite broad for lower energy selections (e.g. < 10 J). It is important that an increase (or decrease) in SELECTED ENERGY produce a corresponding increase (or decrease) in DELIVERED ENERGY. The absolute accuracy of the DELIVERED ENERGY is somewhat less important. DEFIBRILLATORS should meet the output accuracy requirements even when the OPERATOR waits for a while before deciding to deliver a shock.

When the standard was first written, most defibrillators used a damped sinusoidal waveform. Consequently the DELIVERED ENERGY (for a given STORED ENERGY) increased with PATIENT impedance, which may range from 25 Ω to 175 Ω. For example, with a DEFIBRILLATOR internal impedance of 10 Ω and a DELIVERED ENERGY into 50 Ω equal to ED_{50}, the DELIVERED ENERGY into 25 Ω is 0,86 ED_{50}, into 100 Ω is 1,09 $ED_{50,}$ into 175 Ω is 1,135 $ED_{50.}$ If the DEFIBRILLATOR internal impedance were 15 Ω, the range would be 0,81 ED_{50} to 1,20 ED_{50}, i.e. ± 20 % of ED_{50}. This variation is systematic, reproducible and easily calculated and verified. Hence in the previous standard, the required energy accuracy was ± 15 % at 50 Ω, and ± 30 % over the whole range of impedance, not because the DEFIBRILLATOR was less accurate, but to accommodate the known variation of DELIVERED ENERGY with impedance.

The present standard takes a more logical approach. It requires that the dependence of DELIVERED ENERGY on impedance be disclosed for the entire range of PATIENT impedances, 25 Ω to 175 Ω, and that the accuracy requirement be ± 3 J or ± 15 %, whichever is greater, for any impedance; i.e., the actual DELIVERED ENERGY at any impedance must be within ± 15 % of the expected (nominal) DELIVERED ENERGY for that impedance. As an example, if the DELIVERED ENERGY is 200 J (in a 50 Ω PATIENT) and the PATIENT has a very low impedance of 25 Ω, we know that the DELIVERED ENERGY should be 172 J, and we require that the actual DELIVERED ENERGY must be within ± 15 %, i.e., ± 26 J, of 172 J.

Subclause 201.12.2.101 – ELECTRODE energizing controls

The simultaneous energizing of two pairs of electrodes would create a HAZARDOUS SITUATION.

Paragraph 201.12.2.101 b)

This safety requirement may be fulfilled by a design employing a recessed push-button or by similar means. In view of the difficulty of producing a sterilizable internal electrode containing a momentary switch in the electrode handle, a push-button on the panel was deemed to be satisfactory. Furthermore, it may be operated by an assistant during open-chest surgery. The risk of accidental operation of a foot switch is considered unacceptable. Example 4) addresses the advent of self-adhesive DEFIBRILLATOR ELECTRODES since the first edition of this particular standard and presents the same degree of safety as example 2).

Subclause 201.12.3.101 – Audible warnings prior to energy delivery

Adequate OPERATOR warning prior to discharge is important. However, it is possible to charge safely even though discharge may not be imminent. Because charging may be an internal "background" function of the device, it is more important to the OPERATOR to be warned of impending external events, such as energy delivery. Of more relevance to the OPERATOR are:

a) The DEFIBRILLATOR senses a "shockable" rhythm and reaches a "shock" decision. This decision needs to be announced by voice or other audible or visual warning to the OPERATOR. This announcement allows the OPERATOR and any bystanders to prepare for the shock.

b) If the DEFIBRILLATOR is of the "advisory" type, further audible warnings are needed when the DEFIBRILLATOR becomes fully armed and ready to shock.

If the DEFIBRILLATOR is fully automatic, voice or warning sound warnings at least 5 s prior to discharge are needed to allow time to cease touching the PATIENT.

Subclause 201.12.4.1 – Intentional exceeding of safety limits

As very high output current or voltage may cause irreversible damage to the myocardium, its inadvertent application should be avoided by additional safety precautions. The problem of the dosage level necessary for defibrillation versus that which may damage the heart is currently the subject of study and discussion in medical literature.

Subclause 201.12.4.101 – Output voltage

It has been considered necessary to impose an upper limit on the peak output voltage in order to reduce the risk of damage to other ME EQUIPMENT which may be connected to the PATIENT when the DEFIBRILLATOR is used.

Subclause 201.12.4.102 – Unintentional energy

This requirement is necessary in order to prevent the unexpected availability of energy when the SUPPLY MAINS is restored or the ME EQUIPMENT is switched on again.

Subclause 201.12.4.103 – Internal discharge circuit

The INTERNAL DISCHARGE CIRCUIT is needed, for example, when the DELIVERED ENERGY selected has to be reduced after charging the storage capacitor.

Subclause 201.13.1.3 – Exceeding LEAKAGE CURRENT or voltage limits

Inadvertent discharge can be accepted if the likelihood of the fault condition to occur is negligible. An example where the DEFIBRILLATOR will discharge inadvertently is in a case where the means for triggering the discharge circuit described in 201.12.2.101 b) 4) short circuit during the ready period with self-adhesive electrodes attached to the PATIENT. The likelihood of this occurring is considered to be negligible and therefore the risk must be accepted.

Subclause 201.15.4 – ME EQUIPMENT components and general assembly

Any connector for DEFIBRILLATOR ELECTRODES should withstand the pulling forces expected in NORMAL USE.

Subclause 201.15.4.3.101 – Non-rechargeable battery replacement

This requirement is specified to avoid unexpected depletion of the battery.

Subclause 201.15.4.3.103 – Rechargeable battery

Rechargeable batteries should provide for a satisfactory number of discharges after a week's storage without recharging the battery. This requirement is specified to avoid unexpected depletion of the battery.

Subclause 201.15.4.101 – DEFIBRILLATOR electrodes and their cables

External DEFIBRILLATOR ELECTRODE handles should be so designed as to minimize the possibility of contact between the electrodes and the OPERATOR in NORMAL USE. The use of electrode jelly should be taken into account. Controls should be so constructed and positioned that inadvertent operation is unlikely.

Subclause 201.15.4.101 b)

These requirements are specified because in practice the cables and their anchorages are subject to considerable stress. The cables of external paddles have several lines; therefore, if required to meet the test for internal cables, they would become thick and loose flexibility.

Sterilizable internal paddles have a different use model than hard paddles and as such require less flex testing cycles than defibrillator and other patient electrodes.

- They are not transported with the defibrillator – so they don’t have the abuse hard paddles are subjected to every day
- They are not used in the field – They are not wound around the device, used to pull the device, dropped or impacted as hard paddles are.

- They are only used in the sterile operating field of an operating room. – They are only used under controlled conditions.
- The patient is stationary and not moving. – They are not extended or moved around as much as hard paddles because of this.
- They must be sterile – They are sterilized and left in the sterile wrap/tray, typically in a drawer until use so they do not get abused before use.
- If they are dropped they must be inspected for damage and if still functional and safe, re-sterilized. If not, they are removed from use earlier.
- They have very limited life based on the maximum number of allowable sterilization cycles.

Based upon this usage model, a factor of 5 times the maximum number of sterilization cycles provides a more than adequate number of maximum total flexes for a lifetime of use.

Clause 201.101 – Charging time

A delay in delivery of shock is undesirable: even under unfavourable conditions, an excessively long charging time is not acceptable. The time from power-on to having this energy ready becomes a significant problem where self-diagnostics on power-on take more time and check more facilities, particularly when they are repeated if the system re-boots. From within any RESPONSIBLE ORGANIZATION programming mode (once starting to adjust filter settings for instance), if the software were to require completion of a lengthy procedure before returning to normal mode this could lead to further delays.

Subclauses 201.101.3 – Requirements for frequent use, automated external defibrillators, and 201.101.4 – Requirements for infrequent use, automated external defibrillators

Due to requirements of a 5 s audible tone or voice prior to energy delivery for fully AUTOMATED EXTERNAL DEFIBRILLATORS (see 201.12.3.101) the charge time requirement in 201.101.3 and 201.101.4 actually tightens the requirements for fully AUTOMATED EXTERNAL DEFIBRILLATORS.

Paragraph 201.101.3 b)

The 40 s requirement is derived from the following assumptions: 10 s self-test + 15 s ECG-analysis + 15 s charge time. In many cases the background analysis should be confirmed by a manually activated analysis period where the charging of the ENERGY STORAGE DEVICE is started during this manually started analysis.

Subclauses 201.102.2 – Requirements for MANUAL DEFIBRILLATORS and 201.102.3 – Requirements for AUTOMATED EXTERNAL DEFIBRILLATORS (AED)

This minimum battery capacity is a compromise between number of discharges and portability.

The test assumes that operational ME EQUIPMENT is normally stored and charged at room temperature but may need to be used at colder temperatures. Battery powered ME EQUIPMENT should be tested at 0 °C, the lowest temperature specified in the environmental conditions (see 201.5.3) to reveal temperature-dependent deficiencies.

The requirements should be fulfilled in the situation where the battery has been charged at minimum and maximum temperature as specified in the MANUFACTURER'S instructions in the ACCOMPANYING DOCUMENTS. This is due to the fact of charge acceptance for batteries at various temperatures. It is reasonable to expect that the battery will be charged in environments varying between 0 °C and 40 °C (or at the limits set by the MANUFACTURER).

Subclause 201.102.2 – Requirements for MANUAL DEFIBRILLATORS

For INFREQUENT USE DEFIBRILLATORS, it can not be required to perform three defibrillations in 1 min, since the charging time from discharge No. 7 – 5 should be within 25 s (see 201.101.2). The 90 s will assure a break between each of the three discharges and "recovery" of the battery.

Subclause 201.102.3 – Requirements for AUTOMATED EXTERNAL DEFIBRILLATORS (AED)

This measure is the best way to look at the shock-to-shock cycle time of an AED, since the ECG analysis period will always be included in the pre-programmed defibrillation sequence.

Clause 201.103 – Endurance

As reliability of the ME EQUIPMENT has important safety implications, an endurance test is necessary.

Discharge of the DEFIBRILLATOR into open- or short-circuited electrodes is considered to be misuse. Nevertheless, it may occur in practical use and hence the DEFIBRILLATOR should he able to withstand a limited number of such operations. Where such misuse is not possible, the relevant short- and/or open-circuit test is unnecessary.

Clause 201.104 – SYNCHRONIZER

As different synchronization systems exist, only features influencing safety are specified:

1) It has to be clearly apparent if the DEFIBRILLATOR is in the synchronized mode; otherwise operation in an emergency is delayed.
2) The discharge has to be under the full control of the OPERATOR.
3) This requirement is based on ANSI/AAMI DF2-1989 [3] (4.3.17). The reduced time permitted for an ECG derived by another ME EQUIPMENT allows for up to 35 ms processing/detection prior to signaling to the DEFIBRILLATOR.
4) As a safety feature, the DEFIBRILLATOR should always enter a mode where synchronization is disabled after power-on or when the DEFIBRILLATOR mode is entered from a mode different from the DEFIBRILLATOR mode.

A DEFIBRILLATOR and a monitor are normally needed to perform synchronized cardioversion. It is strongly recommended that the defibrillator monitor be integrated into a single instrument to ensure proper interfacing. However such integrated instruments are not available everywhere, and a separate defibrillator and a stand-alone monitor will inevitably be used in many instances. In such cases the RESPONSIBLE ORGANIZATION is responsible for exercising proper care and for ensuring that the two instruments are properly interfaced and satisfy the timing requirements for safe synchronized cardioversion.

Clause 201.105 – Recovery of the MONITOR and/or ECG input after defibrillation

In order that the success or failure of an attempt to defibrillate a PATIENT may be determined as soon as possible, a rapid recovery is necessary from the amplifier overload and electrode polarization produced by the pulse. This applies with the monitoring signal derived via the DEFIBRILLATOR ELECTRODES or via any SEPARATE MONITORING ELECTRODES.

Clause 201.106 – Disturbance to the MONITOR from charging or internal discharging

The requirements allow for a level of interference which is unlikely to cause difficulties in interpretation of the ECG display.

Clause 201.107 – Requirements for RHYTHM RECOGNITION DETECTOR

The essential performance of RHYTHM RECOGNITION DETECTORS has been the object of considerable clinical/industry collaboration recently, and has resulted in useful, insightful, and statistically meaningful methods of specifying the performance of such system. The standard should simply adopt the results of these efforts:

"*Automatic external DEFIBRILLATORS for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety*," a statement for health professionals from the American heart association task force on automatic external defibrillation, subcommittee and AED safety and efficacy.

Subclause 201.108.1 – DEFIBRILLATOR ELECTRODES for monitoring and defibrillation, and (optionally) pacing

With conventional DEFIBRILLATORS, it has been customary to use separate pregelled ECG electrodes for monitoring and DEFIBRILLATOR paddle electrodes for defibrillation. The monitoring electrodes are not capable of effectively delivering a defibrillation shock, and the paddle electrodes have only limited monitoring capability. For recent applications, particularly automatic external defibrillation, it is very desirable to use self adhesive pregelled disposable combination electrodes that perform well in the dual monitoring and defibrillation functions. These electrodes may also be used for delivery of transcutaneous pacing. Recent studies (Stults et al., 1987) also indicate that such combination electrodes may perform better than paddle electrodes for defibrillation. Hence, combination electrodes may become preferred for defibrillation, and it is appropriate in a standard for DEFIBRILLATORS to consider their use and to outline a few requirements for them.

Attenuator devices for pediatric electrodes used with automatic external DEFIBRILLATORS have been introduced. The supporting rationale for the dosing attenuation: automatic external DEFIBRILLATORS generally have energy ranges available beginning at 150 J. Since AEDs were not originally designed for pediatric use, the high energy doses exceed recommended clinical standards for pediatric patients (e.g., 2 J/kG) and may be potentially damaging. To cope with this problem, special electrodes with a high intrinsic resistance have been introduced. When used with standard AEDs (i.e., AEDs intended for adult use), the high resistance electrodes result in a lower energy and current being delivered to the child. This should enhance safety while maintaining effectiveness. Because of the extremely infrequent occurrence of ventricular fibrillation in pediatric patients and difficulties in obtaining informed consent for unpredictable emergency medical procedures, there are no clinical data to directly support the use of these electrodes. However, several animal studies have been conducted using swine models to simulate the pediatric subject. These studies have observed both safety (post-defibrillation cardiac function) and efficacy (defibrillation success and return of spontaneous circulation) to provide reasonable assurance of performance on pediatric patients. Furthermore, post-market surveillance studies are currently underway to capture and record actual clinical performance for future evaluation.

Subclause 201.108.1 .1 – AC small signal impedance

The rationale for this requirement was derived from the performance criteria in ANSI/AAMI EC12:2000, with particular attention to the provision that 5 kΩ is acceptable where skin preparation is minimal.

Subclause 201.108.1.2 – AC large signal impedance

Impedance for self-adhesive electrodes may be higher than for standard hand-held electrode paddles used with manual DEFIBRILLATORS. This requirement provides a reasonable limit on impedance contributed by the electrode pair during defibrillation (less than 6 %).

Subclause 201.108.1.3 – Combined offset instability and internal noise

This requirement is derived from ANSI/AAMI EC12:2000, with the added recognition that cardiac monitor bandwidth is more appropriate.

Subclause 201.108.1.4 – Defibrillation recovery

The fundamental rationale for this requirement is consistent with ANSI/AAMI EC12:2000 and ANSI/AAMI EC13:2002. The requirement and test are stated in terms more directly applicable to DEFIBRILLATORS; that is, in terms of actual exposure to defibrillation energies rather than simulated DC offsets.

Subclause 201.108.1.5 – Biological response

This requirement is derived from ANSI/AAMI EC12:2000. Application to broken skin is to be avoided, therefore the requirement for intracutaneous reactivity is not applicable.

Subclause 201.108.1.6 – DC offset voltage

This requirement is unchanged from ANSI/AAMI EC12:2000.

Subclause 201.108.1.7 – Electrode active area

For electrodes intended for adult use, the requirements, test, and rationale are taken exactly from ANSI/AAMI DF39:1993. The 15 cm2 requirement for individual electrodes intended for pediatric use is retained from ANSI/AAMI DF2:1989. Following the logic of DF39:1993, the pediatric requirement is extended to include a combined electrode area of three times the individual area.

Subclause 201.108.1.8 – Electrode adhesion and contact to patient

Good adhesion and electrical contact between the electrodes and the patient are essential for defibrillation efficiency. They must be achieved for a variety of patient and environmental conditions and maintained over an extended period of time prior to electrode use. However, test and evaluation experience indicates that a bench test for evaluating adhesion performance is not practical or reliable. Proper performance assessment is best done in a controlled clinical environment. This reasoning is consistent with the committee conclusions described in ANSI/AAMI EC12:2000.

Subclause 201.108.1.9 – Packaging and shelf-life

Two conditions are considered: long-term storage in a presumably well-controlled environment and short-term transportation either from manufacturer to customer storage site or from storage site to site of use. For accelerated age testing according to the Van't Hoff rule, a Q10 of 2.0 may be used.

Short-term extreme conditions may be encountered during shipment from manufacturer to purchaser or during transportation with caregivers to the site of use, which could be any accident location. A duration of 12 hours, as specified in ANSI/AAMI DF39:1993, may be too short in this context. A duration of 24 hours at both extreme temperatures of –30 °C and +65 °C is considered more adequate.

Subclause 201.108.1.10 – Universal-function electrodes

DEFIBRILLATORS may incorporate external transcutaneous pacing as either a distinct separate treatment mode or as part of a combined defibrillation/pacing/monitoring operation. Because no general performance standards exist for combination pacing/defibrillation/monitoring

electrodes, the requirements define the basic minimum controls necessary to ensure safe and reliable operation.

Subclause 201.108.1.11 – Cable length

To ensure that the user has adequate cable for most purposes, minimum cable length of 2 m (80 in) was specified for those units requiring cables. Although it was recognized that a minimum cable of 3 m (10 ft) might be more useful in some circumstances, it was felt that a 3 m cable would be rather cumbersome for some mobile applications and hence was not specified as a minimum requirement.

Clause 201.109 – External pacing

A DEFIBRILLATOR may incorporate external pacing either as a distinct pacing treatment mode, separate from the defibrillation treatment mode, or as part of a combined defibrillation/pacing operating protocol. No consensus has been reached on the waveform characteristics providing greatest efficacy due to patent infringement issues and other legal concerns. Therefore, rather than requiring conformance to a specific pacing waveform shape, the standard specifies that the manufacturer should make available clinical test data to demonstrate efficacy of the device with regard to pacing. Except for this area of waveform characteristics, specific requirements are made in this standard with regard to pacing labeling, controls, indicators, and operation.

This standard includes a section on pacing stability. In the clinical setting, capture is determined empirically; in addition, the patient may be left unattended while external pacing is in progress. Therefore, absolute accuracy is not as important as stability when there is the potential that capture may be lost if the amplitude, rate, or waveform duration decreases over the length of time the patient is being paced.

This standard also includes a section on pacing leads-off indication. In the clinical setting, the leads-off indicator is important, because failure of either the pacing leads or of electrode/patient contact will result in no pacing current being delivered to the patient. While there are other component failures that may also result in this condition, improper connection or electrode placement is common enough that a clear indication needs to be provided to the clinician of the viability of the pacing electrical connection.

Clause 202 Electromagnetic compatibility – Requirements and tests

DEFIBRILLATORS are life-saving ME EQUIPMENT and are often used in the field, or in ambulances, where the electromagnetic environment may be particularly severe. This makes it necessary to expand upon the general requirements of IEC 60601-1-2 in order to provide a reasonable assurance that DEFIBRILLATORS will perform well and safely in all of their intended uses.

Immunity to radiated RF fields is generally insured by requiring that the ME EQUIPMENT meets all its specifications when exposed to a field strength of 3 Vm^{-1} which is seldom exceeded in hospitals. However, DEFIBRILLATORS used in transport or ambulances are likely to be used in the vicinity of powerful RF sources (mobile radio transmitters, cellular phones,...) where the field strength may reach or exceed 10 Vm^{-1}. An 8 W GSM transmitter, for instance, produces a field of 20 Vm^{-1} at a distance of 1 m. State of the art technology does not ensure that DEFIBRILLATORS meet all specifications in the presence of a modulated 10 Vm^{-1} RF field but a minimum safety requirement is that such intense fields should not result in a HAZARDOUS SITUATION.

Examples of HAZARDOUS SITUATIONS include failures involving changes in operating state (e.g., unintended charge or discharge), irrecoverable loss or change of stored data, or clinically serious errors in control software (e.g., unintended change in discharge energy level).

Annex BB
(informative)

Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010

This annex contains a mapping of the clauses and subclause of the second edition of IEC 60601-2-4 to the comparable clauses and subclauses in this edition. Table BB.1 is intended to provide a tool to assist users of IEC 60601-2-4 to trace requirements between this edition and their source in the second edition.

Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010

IEC 60601-2-4 Second edition		IEC 60601-2-4:2010	
(Sub)clause	**Title**	**(Sub)clause**	**Title**
1	Scope and object	201.1	Scope, object and related standards
1.1	Scope	201.1.1	Scope
1.2	Object	201.1.2	Object
1.5	Collateral Standards	201.1.3	Collateral standards
1.3	Particular Standards	201.1.4	Particular standards
2	Terminology and definitions	201.3	Terms and definitions
2.1.101	CARDIAC DEFIBRILLATOR	201.3.202	CARDIAC DEBIBRILLATOR
2.1.102	MONITOR	201.3.214	MONITOR
2.1.103	CHARGING CIRCUIT	201.3.203	CHARGING CIRCUIT
2.1.104	DEFIBRILLATOR ELECTRODES	201.3.204	DEFIBRILLATOR ELECTRODE
2.1.105	DISCHARGE CIRCUIT	201.3.206	DISCHARGE CIRCUIT
2.1.106	DISCHARGE CONTROL CIRCUIT		
2.1.107	INTERNAL DISCHARGE CIRCUIT	201.3.212	INTERNAL DISCHARGE CIRCUIT
2.1.108	SYNCHRONIZER	201.3.220	SYNCHRONIZER
2.1.109	AUTOMATED EXTERNAL DEFIBRILLATOR (AED)	201.3.201	AUTOMATED EXTERNAL DEFIBRILLATOR AED
2.1.110	ENERGY STORAGE DEVICE	201.3.209	ENERGY STORAGE DEVICE
2.1.111	SEPARATE MONITORING ELECTRODES	201.3.217	SEPARATE MONITORING ELECTRODE
2.1.112	RHYTHM RECOGNITION DETECTOR	201.3.215	RHYTHM RECOGNITION DETECTOR
2.12.101	DELIVERED ENERGY	201.3.205	DELIVERED ENERGY
2.12.102	STAND-BY	201.3.218	STAND-BY
2.12.103	STORED ENERGY	201.3.219	STORED ENERGY
2.12.104	DUMMY COMPONENT	201.3.207	DUMMY COMPONENT
2.12.105	ENERGY METER / DEFIBRILLATOR TESTER	201.3.208	DEFIBRILLATOR TESTER
2.12.106	SELECTED ENERGY	201.3.216	SELECTED ENERGY

Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010 *(continued)*

IEC 60601-2-4 Second edition		IEC 60601-2-4:2010	
Clause	**Title**	**Clause**	**Title**
2.12.107	FREQUENT USE	201.3.210	FREQUENT USE
2.12.108	INFREQUENT USE	201.3.211	INFREQUENT USE
2.12.109	MANUAL DEFIBRILLATOR	201.3.213	MANUAL DEFIBRILLATOR
4	General requirements for tests	201.5	General requirements for testing of ME EQUIPMENT
4.5	Ambient temperature, humidity, atmospheric pressure	201.5.3	Ambient temperature, humidity, atmospheric pressure
4.6	Other conditions	201.5.4	Other conditions
4.11	Sequence	201.5.8	Sequence of tests
5	Classification	201.6	Classification of ME EQUIPMENT and ME SYSTEMS
5.2	According to the degree of protection against electric shock...	201.6.2	Protection against electric shock
6	Identification, marking and documents	201.7	ME EQUIPMENT identification, marking and documents
6.1	Marking on the outside of EQUIPMENT or EQUIPMENT parts	201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts
6.1 j)	Power input	201.7.2.7	Electrical input power from the SUPPLY MAINS
6.1 aa)	Concise operating instructions	201.7.2.101	Concise operating instructions
6.1 bb)	Internally powered EQUIPMENT	201.7.2.102	Internally powered ME EQUIPMENT
6.1 cc)	Disposable DEFIBRILLATOR electrodes	201.7.2.103	Disposable defibrillator electrodes
6.3	Marking of controls and INSTRUMENTS	201.7.4	Marking of controls and instruments
6.3 aa)	The DEFIBRILLATOR shall be provided....	201.7.4.101	Selected energy control
6.8	Accompanying documents		
6.8.2	Instructions for use	201.7.9.2	Instructions for use
6.8.2 e)	e) full details of the charging procedure....	201.7.9.2.4	Electrical power source .. If an INTERNAL ELECTRICAL POWER SOURCE is replaceable....
6.8.2 f)	f) advice on the periodic replacement....	201.7.9.2.4	Electrical power source .. The instructions for use shall include a warning statement....
6.8.2 g)	g) the number of maximum energy discharges....	201.7.9.2.4	Electrical power source .. The instructions for use shall provide information on the number of maximum energy discharges....
6.8.2 h)	h) for EQUIPMENT also capable...	201.7.9.2.4	Electrical power source .. For ME EQUIPMENT that is also capable....
6.8.2 aa)	aa) Supplementary instructions for use	201.7.9.2.101	Supplementary instructions for use
6.8.3	Technical description	201.7.9.3	Technical description
6.8.3 aa) 1)	1) essential performance data for defibrillation	201.7.9.3.101	ESSENTIAL PERFORMANCE data for defibrillation
6.8.3 aa) 2)	2) essential performance data of any SYNCHRONIZER	201.7.9.3.102	ESSENTIAL PERFORMANCE data of any SYNCHRONIZER
6.8.3 aa) 3)	3) essential performance data of the RHYTHM RECOGNITION DETECTOR	201.7.9.3.103	ESSENTIAL PERFORMANCE data of the RHYTHM RECOGNITION DETECTOR

Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010 *(continued)*

IEC 60601-2-4 Second edition		IEC 60601-2-4:2010	
Clause	**Title**	**Clause**	**Title**
6.8.101	Accompanying documents related to electromagnetic compatibility		Covered by the requirement in IEC 60601-1-2.
10	Environmental conditions		Deleted during preparation of IEC 60601-1:2005
10.2.1	Environment		Deleted during preparation of IEC 60601-1:2005
14	Requirements related to classification		
14.6	TYPES B, BF and CF applied parts	201.8.3	Classification of APPLIED PARTS
17 h)	First dash: APPLIED PARTS of other PATIENT CIRCUITS	201.8.5.5.102	Applied parts not being DEFIBRILLATOR ELECTRODES
17 h)	Delete sixth dash ("the EQUIPMENT shall not be energized;")		Requirement not present in IEC 60601-1:2005
17 h)	Replace second to last paragraph	201.8.5.5.1	Defibrillation protection .. *Differential-mode test*
17 aa)	Arrangements to isolate the DEFIBRILLATOR ELECTRODES….	201.8.5.5.101	Isolate the DEFIBRILLATOR ELECTRODES
17 bb)	Any applied parts not being DEFIBRILLATOR ELECTRODES….	201.8.5.5.102	Applied parts not being defibrillator electrodes
17 cc)	Unintentional charging of the ENERGY STORAGE DEVICE….	201.8.5.5.103	Charging of the ENERGY STORAGE DEVICE
19	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	201.8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS
19.1	General requirements	201.8.7.1	General requirements
19.2	Single fault conditions	201.8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT .. For the DEFIBRILLATOR ELECTRODES ..
19.3	Allowable values	201.8.7.3	Allowable values
20	Dielectric strength	201.8.8.3	Dielectric strength
20.2	Requirements for equipment with an applied part	201.8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS
20.3	Values of test voltages	201.8.8.3	Dielectric strength / *Addition*: .. For the DEFIBRILLATOR high-voltage circuit….
20.4 a)	First dash: Change *"warming up to operating temperature"*	201.8.8.3	Dielectric strength .. *after reaching a temperature equivalent to the steady state operating temperature*
36	Electromagnetic compatibility (EMC)	202	Electromagnetic compatibility – Requirements and tests
36.201	Emissions	202.6.1	Emissions
36.201.1	Protection of radio services	202.6.1.1	Protection of radio services
36.202.2	Electrostatic discharge (ESD)	202.6.2.2	Electrostatic discharge (ESD)
36.202.3	Radiated RF electromagnetic fields	202.6.2.3	Radiated RF electromagnetic fields
36.202.4	Electrical fast transients and bursts	202.6.2.4	Electrical fast transients and bursts
36.202.5	Surges	202.6.2.5	Surges
36.202.6	Conducted disturbances, induced by RF fields	202.6.2.6	Conducted disturbances, induced by RF fields
36.202.8	Magnetic fields	202.6.2.8.1	Power frequency magnetic fields

Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010 *(continued)*

IEC 60601-2-4 Second edition		IEC 60601-2-4:2010	
Clause	**Title**	**Clause**	**Title**
42	Excessive temperatures	201.11	Protection against excessive temperatures and other HAZARDS
42.3 3)	Duty cycle	201.11.1.3 c)	Thermal stabilization
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	201.11	Protection against excessive temperatures and other HAZARDS
44.6	Ingress of liquids	201.11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS
44.7	Cleaning, sterilization and disinfection	201.11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS
46	Human errors	201.12.2	USABILITY
46.101	ELECTRODE energizing controls	201.12.2.101	ELECTRODE energizing controls
46.102	Display of signals	201.12.2.102	Display of signals
46.103	Audible warnings prior to energy delivery	201.12.3.101	Audible warnings prior to energy delivery
50	Accuracy of operating data	201.7	ME EQUIPMENT identification, marking and documents
		201.12	Accuracy of controls and instruments and protection against hazardous outputs
50.1	Marking of controls and INSTRUMENTS	201.7.4	Marking of controls and instruments
50.2	Accuracy of controls and INSTRUMENTS	201.12.1	Accuracy of controls and instruments
51	Protection against hazardous output	201.12	Accuracy of controls and instruments and protection against hazardous outputs
51.1	Intentional exceeding of safety limits	201.12.4.1	Intentional exceeding of safety limits
51.101	The output voltage of the DEFIBRILLATOR....	201.12.4.101	Output voltage
51.102	The EQUIPMENT shall be so designed....	201.12.4.102	Unintentional energy
51.103	A DEFIBRILLATOR shall be provided....	201.12.4.103	Internal discharge circuit
52	Abnormal operation and fault conditions	201.13	HAZARDOUS SITUATIONS and fault conditions
52.4.101	Inadvertent charging or discharging....	201.13.1.3	Exceeding LEAKAGE CURRENT or voltage limits
56	Components and general assembly	201.15	Construction of ME EQUIPMENT
56.101	DEFIBRILLATOR ELECTRODES and their cables....	201.15.4.101	DEFIBRILLATOR ELECTRODES and their cables
57	MAINS PARTS, components and layout		
57.10	CREEPAGE DISTANCES and AIR CLEARANCES	201.8.9.1.101	DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables
101	Charging time	201.101	Charging time
101.1	Requirements for frequent use, manual defibrillators	201.101.1	Requirements for FREQUENT USE, MANUAL DEFIBRILLATOR
101.2	Requirements for infrequent use, manual defibrillators	201.101.2	Requirements for INFREQUENT USE, MANUAL DEFIBRILLATORS
101.3	Requirements for frequent use, automated external defibrillators	210.101.3	Requirements for FREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS

Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010 *(continued)*

IEC 60601-2-4 Second edition		IEC 60601-2-4:2010	
Clause	**Title**	**Clause**	**Title**
101.4	Requirements for infrequent use, automated external defibrillators	201.101.4	Requirements for INFREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS
102	Internal electrical power source	201.102	INTERNAL ELECTRICAL POWER SOURCE
102.1	General	201.102.1	General
102.2	Requirements for MANUAL DEFIBRILLATORS	201.102.2	Requirements for MANUAL DEFIBRILLATORS
102.3	Requirements for automated external defibrillators	201.102.3	Requirements for AUTOMATED EXTERNAL DEFIBRILLATORS (AED)
102.3.1	For a FREQUENT USE AED....	201.102.3.1	FREQUENT USE AED
102.3.2	For an INFREQUENT USE AED....	201.102.3.2	INFREQUENT USE AED
102.4	Means shall be provided to indicate....	201.15.4.3.101	Non-rechargeable battery replacement
102.5	Means shall be provided to indicate....	201.15.4.3.102	Battery charging indicator
102.6	Any rechargeable new battery shall....	201.15.4.3.103	Rechargeable battery
103	Endurance	201.103	Endurance
104	SYNCHRONIZER	201.104	SYNCHRONIZER
105	Recovery of the MONITOR/ECG input after defibrillation	201.105	Recovery of the MONITOR and/or ECG input after defibrillation
105.1	ECG signal derived via DEFIBRILLATOR ELECTRODES	201.105.1	ECG signal derived via DEFIBRILLATOR ELECTRODES
105.2	ECG signal derived via any SEPARATE MONITORING ELECTRODES	201.105.2	ECG signal derived via any SEPARATE MONITORING ELECTRODES
105.3	ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES	201.105.3	ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES
106	Disturbance to the MONITOR from charging or internal discharging	201.106	Disturbance to the MONITOR from charging or internal discharging
Annex L		201.2	Normative references
Annex AA		Annex AA	

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[1] IEC 60300-3-9, *Dependability management – Part 3: Application guide – Section 9: Risk analysis of technological systems*

[2] IEC 60601-2-27, *Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment*

[3] ANSI/AAMI DF2-1989, *Cardiac defibrillator devices, Second Edition: monitoring equipment*

[4] ANSI/AAMI DF39-1993, *Automatic, external defibrillators and remote control Defibrillators*

[5] ANSI/AAMI EC12:2000, *Disposable ECG electrodes*

[6] ANSI/AAMI EC13:2002, *Cardiac monitors, heart rate meters, and alarms*

Index of defined terms used in this particular standard

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