SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-39:2023

01-januar-2023

Medicinska električna oprema - 2-39. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za trebušno dializo

Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

Medizinische elektrische Geräte - Teil 2-39: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Peritoneal-Dialyse-Geräten

Appareils électromédicaux - Partie 2-39: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de dialyse péritonéale

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-39:2022**

ICS:

11.040.99	Druga medicinska oprema	Other medical equipment

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62D/1992/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-39 ED4**	
DATE OF CIRCULATION: **2022-11-11**	CLOSING DATE FOR VOTING: **2023-02-03**
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IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

FOREWORD

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International standard IEC 60601-2-39 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This edition cancels and replaces the third edition of IEC 60601-2-39 published in 2018. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-

10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;

b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;

c) including the information given in the document 62D/1771A/INF regarding clause 201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT;

d) including the information given in the document 62D/1734/INF regarding technical issues of the previous edition;

e) including SECURITY (CYBERSECURITY) requirements;

f) additions related to online PD SOLUTION generation (ONLINE PD);

g) improvements regarding the definition of the APPLIED PART;

h) improvement of the essential performance requirements clause/subclauses;

i) improvements for labelling;

j) other minor technical improvements;

k) editorial improvements.

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

FDIS	Report on voting
62D/xxxx/FDIS	62D/xxxx/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 document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of PERITONEAL DIALYSIS ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PERITONEAL DIALYSIS ME EQUIPMENT, hereafter referred to as PD EQUIPMENT. It applies to PD EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including PD EQUIPMENT operated by the PATIENT, regardless of whether the PD EQUIPMENT is used in a hospital or domestic environment.

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.

This document does not take into consideration specific safety details of the DIALYSING SOLUTION control system of PD EQUIPMENT using regeneration of DIALYSING SOLUTION or CENTRAL DELIVERY SYSTEMS for DIALYSING SOLUTION. It does, however, take into consideration the specific safety requirements of such PD EQUIPMENT concerning electrical safety and PATIENT safety.

This document specifies the minimum safety requirements for PD EQUIPMENT. These PD EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision.

This document includes all ME EQUIPMENT that is intended to deliver a PERITONEAL DIALYSIS treatment to a PATIENT, independent of the treatment duration and location.

These particular requirements do not apply to pre-manufactured DIALYSING SOLUTION bags, DIALYSING SOLUTION CIRCUITS and DIALYSING SOLUTION CONCENTRATE.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PD EQUIPMENT.

201.1.3 Collateral standards

Addition:

[1] The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/ AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 208, 210 and 211.

IEC 60601-1-3 does not apply. IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 does not apply as noted in Clause 209.

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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are 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 document 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 3.154, additional definitions in this document 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, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" 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.

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

Addition:

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
Amendment 1:2013
Amendment 2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
Amendment 1:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering method in an essentially free field over a reflecting plane*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

IEC Electropedia: available at http://www.electropedia.org/

ISO Online browsing platform: available at http://www.iso.org/obp

NOTE Refer to section “Index of defined terms used in this particular standard” for the index of defined terms.

201.3.8
*** APPLIED PART**

Replacement:

DIALYZING SOLUTION CIRCUIT and all parts permanently and conductively connected to it

Note 1 to entry: See Annex AA Figure AA.1 in Informative Annex Subclause 201.16 and Clause 201.16.6.3.

Note 2 to entry: One example of an APPLIED PART is the DIALYSING SOLUTION CIRCUIT including pre-manufactured DIALYSING SOLUTION bags, extension lines, and drain bags in a stand-alone system connected during treatment.

Note 3 to entry: Another example of an APPLIED PART is the DIALYSING SOLUTION CIRCUIT including connected DIALYSING SOLUTION bags, that are online prepared before treatment without the PATIENT connected and drain bags. During treatment the online preparation part of the PD EQUIPMENT is conductively disconnected.

Note 4 to entry: Another example of an APPLIED PART is the DIALYSING SOLUTION CIRCUIT including all PD EQUIPMENT used for online production of DIALYSING SOLUTION bags and/or the connection to a drain during the treatment.

201.3.78
PATIENT CONNECTION

Addition:

Note 1 to entry: The PATIENT connector(s) is/are the individual point(s) on the APPLIED PART through which a current can flow between the PATIENT and the PD EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additional terms and definitions:

201.3.201
APD ME EQUIPMENT

ME EQUIPMENT used to perform AUTOMATED PERITONEAL DIALYSIS

201.3.202
AUTOMATED PERITONEAL DIALYSIS
APD

method to perform dialysis with automated fluid exchanges in the peritoneum

201.3.203
CENTRAL DELIVERY SYSTEM

part of a ME SYSTEM which proportions DIALYSING SOLUTION CONCENTRATE and DIALYSIS WATER for distribution as DIALYSING SOLUTION to the PD EQUIPMENT or distributes DIALYSING SOLUTION CONCENTRATE

201.3.204
DIALYSING SOLUTION
PD SOLUTION

aqueous fluid containing electrolytes and, usually, buffer and glucose, and which is intended to exchange solutes during PERITONEAL DIALYSIS

Note 1 to entry: The DIALYSING SOLUTION could be pre-manufactured in bags as pharmaceuticals according to the relevant pharmacopoeia monograph or be prepared by the PD EQUIPMENT or be influenced in composition by the PD EQUIPMENT.

201.3.205
DIALYSING SOLUTION CIRCUIT

part of the fluid circuit that conveys DIALYSING SOLUTION from the PD EQUIPMENT to the peritoneal cavity of the PATIENT, from the PATIENT to the PD EQUIPMENT, and from the PD EQUIPMENT to a drainage bag or drain.

201.3.206
DIALYSING SOLUTION CONCENTRATE

substances which, when appropriately diluted or dissolved with DIALYSIS WATER, produce the DIALYSING SOLUTION

201.3.207
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3:2019 [13] and which is suitable for use in PD applications, including the preparation of DIALYZING SOLUTION and preparation of DIALYSING SOLUTION CONCENTRATE

Note 1 to entry: The words "water for dialysis", "permeate", "reverse osmosis water" and "purified water" are commonly used as synonyms of DIALYSIS WATER.

[SOURCE: ISO 23500-1:2019 [11], 3.17, modified – The reference number "[13]" has been added in the definition, as well as the note.]

201.3.208
INFLOW
phase during which the peritoneal cavity is filled

Note 1 to entry: The term "fill" is commonly used as a synonym for "INFLOW".

201.3.209
ONLINE PD

PERITONEAL DIALYSIS PROCEDURE where the PD EQUIPMENT produces the DIALYSING SOLUTION for the PERITONEAL DIALYSIS treatment

201.3.210
OUTFLOW
phase during which the peritoneal cavity is emptied

Note 1 to entry: The term "drain" is commonly used as a synonym for "OUTFLOW".

201.3.211
PERITONEAL DIALYSIS
PD
PROCESS whereby a DIALYSING SOLUTION is introduced into the peritoneal cavity of the PATIENT and is subsequently removed

Note 1 to entry: The DIALYSING SOLUTION may be left in the peritoneal cavity for a dwell time or may be continuously exchanged.

201.3.212
PERITONEAL DIALYSIS ME EQUIPMENT
PD EQUIPMENT
ME EQUIPMENT used to perform PERITONEAL DIALYSIS including APD ME EQUIPMENT

201.3.213
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

201.4 General requirements

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

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

If applicable, the ESSENTIAL PERFORMANCE of PD EQUIPMENT includes, but is not limited to, the functions found in the subclauses listed in Table 201.101, which shall be met within the tolerances specified by the MANUFACTURER under NORMAL CONDITION,

The behaviour of the PD EQUIPMENT for ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION shall be determined by the MANUFACTURER'S RISK MANAGEMENT.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW	201.4.3.102
DIALYSING SOLUTION volume balancing (INFLOW/OUTFLOW volume)	201.4.3.103
PERITONEAL DIALYSIS dwell time	201.4.3.104
DIALYSING SOLUTION composition	201.4.3.105
DIALYSING SOLUTION temperature	201.4.3.106

NOTE 1 Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposables used.

NOTE 2 The general standard clause 7.9.2.5 requires giving the specifications for the ESSENTIAL PERFORMANCE in the instruction for use.

201.4.3.102 * DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

The accuracy of the DIALYSING SOLUTION flow rate administered by the PD EQUIPMENT during INFLOW/OUTFLOW to and from the PATIENT shall be as specified by the MANUFACTURER.

NOTE 1 A DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW lower than the set value is considered detrimental for a typical treatment.

Compliance is checked under the following test conditions:

– *Set up the* DIALYSING SOLUTION containers as specified *by the ACCOMPANYING DOCUMENTS*, otherwise at the same height as the PD EQUIPMENT.

– *Set the PD EQUIPMENT to a total therapy volume of 10 Litres, or to an appropriate volume specified by the MANUFACTURER.*

– *Set the PD EQUIPMENT to a fill volume or cycle volume of 2,0 Litres, or to an appropriate fill or cycle volume specified by the MANUFACTURER.*

– *Connect the PD EQUIPMENT to a simulated PATIENT comprising the following elements:*

  - *An appropriately sized empty or partially filled fluid bag simulating the PATIENT's peritoneal cavity and*
  - *A flow restrictor in line between the PD EQUIPMENT and the fluid bag, simulating the combined flow resistance of the peritoneal catheter, transfer set and fluid connector according to the MANUFACTURER'S recommendation. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*

– *Set the DIALYSING SOLUTION temperature to 37 °C, if applicable.*

– *Set the PD EQUIPMENT to the minimum cycle time, or to a dwell time of 0 min.*

– *Set the PD EQUIPMENT to operate until all DIALYSING SOLUTION processing components are primed.*

– *Place the simulated PATIENT on a weighing scale located 50 cm above the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*

– *Set the highest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*

– *Measure the DIALYSING SOLUTION flow during at least 2 INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*

– *Set the lowest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*

– *Measure the DIALYSING SOLUTION flow during at least 2 INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*

– *Place the simulated PATIENT on a weighing scale located 50 cm below the PD EQUIPMENT, or at the minimum allowable height, as specified by the MANUFACTURER.*

– *Set the highest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*

– *Measure the DIALYSING SOLUTION flow during at least 2 INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*

– *Set the lowest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*

– *Measure the DIALYSING SOLUTION flow during at least 2 INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*

NOTE 2: It is acceptable for the simulated PATIENT to be in an enclosure controlled to approximately 37°C to simulate the PATIENT'S body temperature, which may be needed for the PD EQUIPMENT to maintain thermal equilibrium required for pumping accuracy.

NOTE 3: It is acceptable for the minimum cycle (dwell) time to also include time needed for the PD EQUIPMENT to reach and maintain thermal equilibrium required for pumping accuracy.

The values of the DIALYSING SOLUTION flow rate shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.103 DIALYSING SOLUTION volume balancing (INFLOW/OUTFLOW volume)

The DIALYSING SOLUTION INFLOW and OUTFLOW volume accuracy of the PD EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE 1 A DIALYSING SOLUTION volume imbalance larger than the set value is considered as more negative for a typical treatment.

Compliance is checked under the following test conditions:

Test for APD ME EQUIPMENT

– *Set up the* DIALYSING SOLUTION containers as specified *by the ACCOMPANYING DOCUMENTS*, otherwise at the same height as the PD EQUIPMENT.

– *Set the PD EQUIPMENT to maximum fill volume or cycle volume.*

– *Connect the PD EQUIPMENT to a simulated PATIENT comprising the following elements:*

  - *An appropriately sized empty or partially filled fluid bag simulating the PATIENT's peritoneal cavity and*
  - *A flow restrictor in line between the PD EQUIPMENT and the fluid bag, simulating the combined flow resistance of the peritoneal catheter, transfer set and fluid connector according to the MANUFACTURER'S recommendation. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*

– *Set the DIALYSING SOLUTION temperature to 37 °C, if applicable.*

– *Set the PD EQUIPMENT to the minimum cycle time, or to a dwell time of 0 min.*

– *Set the PD EQUIPMENT to operate until all DIALYSING SOLUTION processing components are primed.*

– *Place the simulated PATIENT on a weighing scale located 50 cm above the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*

– *Measure the DIALYSING SOLUTION volume of 5 INFLOW and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*

– *Place the simulated PATIENT on a weighing scale located 50 cm below the PD EQUIPMENT, or at the minimum allowable height, as specified by the MANUFACTURER.*