IEC 60601-2-16
(Third edition – 2008)

Medical electrical equipment –
Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

C O R R I G E N D U M 1

Page 17

201.7.9.2.5 ME EQUIPMENT description

In the sixth dashed item, instead of:

"…PHYSIOLOGICAL CLOSED LOOP CONTROLLER…"

read:

"…PHYSIOLOGIC CLOSED-LOOP CONTROLLER…"

Page 26

201.12.4.4.105 * Air infusion

In item b), on page 27, in the first and seventh dashed items of the bullet point entitled "Continuous air infusion", instead of:

"*…g cannula…*"

read:

"*…gauge cannula…*"

In item b), on page 28, in the first dashed item of the bullet point entitled "Bolus air infusion", instead of:

"*Set up the HAEMODIALYSIS EQUIPMENT with a DIALYSER with a standard capillary DIALYSER with a surface area between 1 m^2 and 1,5 m^2, the recommended EXTRACORPOREAL CIRCUIT and 16 g cannulas.*"

read:

"*Set up the HAEMODIALYSIS EQUIPMENT with a standard capillary DIALYSER with a surface area between 1 m^2 and 1,5 m^2, the recommended EXTRACORPOREAL CIRCUIT and 16 gauge cannulas.*"

In Note 7, following the second dashed item of the bullet point entitled "Bolus air infusion", instead of:

"*…If degassed dialysate is…*"

read:

"*…If degassed DIALYSING FLUID is…*"

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208.6.3.3.2 Volume of auditory ALARM SIGNALS and INFORMATIONS SIGNALS

In the title of this subclause, instead of:

"...INFORMATIONS SIGNALS..."

read:

"...INFORMATION SIGNALS..."

Page 41

201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

In item a)1) step (3), on page 42, instead of:

"...but sucking a coloured test liquid..."

read:

"...but using a coloured test liquid..."

In the second paragraph of item b, on page 43, instead of:

"...is sucked instead of disinfectant..."

read:

"...is used instead of disinfectant..."

Page 43

Clause 12 Accuracy of controls and instruments and protection against hazardous outputs

In the title of this rationale, instead of:

"Clause 12..."

read:

"Clause 201.12..."

Page 45

Subclause 201.12.4.4.104.1 a) Extracorporeal blood loss to the environment

In the second paragraph, instead of:

"...the PATIENT may loose a great amount of blood..."

read:

"...the PATIENT may lose a great amount of blood..."

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Subclause 201.12.4.4.105 Air infusion

In the first paragraph, instead of:

"...air of less than 0,03 ml/(kg*min)..."

read:

"...air of less than 0,03 ml/(kg·min)..."

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Index of defined terms used in this particular standard

Add the following new term:

PHYSIOLOGIC CLOSED-LOOP CONTROLLER.....IEC 60601-1-10:2007, 3.20

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