

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

CORRIGENDUM 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 m² and 1,5 m², 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 m² and 1,5 m², 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...”