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Medical electrical system – Input interface for haemodialysis equipment for use of external alarming device

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL SYSTEM – INPUT INTERFACE FOR HAEMODIALYSIS EQUIPMENT FOR USE OF EXTERNAL ALARMING DEVICE

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Draft PAS	**Report on voting**
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INTRODUCTION

The effort to standardize an INPUT INTERFACE is based on the request to connect an EXTERNAL ALARMING DEVICE to the HAEMODIALYSIS EQUIPMENT in order to stop the extracorporeal circuit.

This PAS establishes a unique interface for connection of an EXTERNAL ALARMING DEVICE.

In extracorporeal treatment different hazardous situations may occur. One major concern is blood loss to the environment. In 12.4.4.104.1 of IEC 60601-2-16:2012, different technical solutions are given.

The relevant excerpt concerning this issue from 201.12.4.4.104.1 of IEC 60601-2-16:2012 reads as follows:

“a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment that may cause a HAZARD.

NOTE 1 Today no system has been developed that can totally be relied upon to detect blood loss to the environment. The following recommendation is the best known system to detect blood loss to the environment.

If a PROTECTIVE SYSTEM is utilizing measurement of the VENOUS PRESSURE, the OPERATOR should have at least the possibility to adjust the lower ALARM LIMIT manually as closely as possible to the current measurement value. The single needle treatment mode needs additional measures.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment caused by a rupture or separation in the EXTRACORPOREAL CIRCUIT due to excessive pressure, unless this is prevented by inherent safe design.

NOTE 2 This is not related to separation of the PATIENT CONNECTION or access needle but related to the potential pressure that can be generated by the pump which could cause tubing rupture or joint separation in the EXTRACORPOREAL CIRCUIT.

c) Operation of the PROTECTIVE SYSTEM shall achieve thefollowing safe condition:

- activation of an audible and visual alarm signal (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101;
- stoppage of the blood flow to the environment caused by the HAEMODIALYSIS EQUIPMENT, even under SINGLE FAULT CONDITION;
- in the case of HAEMOFILTRATION or HAEMODIAFILTRATION, stoppage of the SUBSTITUTION FLUID flow.”

Concerning Subclause 201.12.4.4.104.1 a) of IEC 60601-2-16:2012

Monitoring of the VENOUS PRESSURE is not always suitable for detecting a blood loss in time, in case the venous puncture cannula slips out. The VENOUS PRESSURE is determined mainly by the hydraulic resistance of the venous puncture cannula, particularly with today's usual high blood flow rates of up to 500 ml/min. Hence a VENOUS PRESSURE ALARM SYSTEM is not always able to detect whether or not the puncture cannula slips out.

If dialysis is performed in the single-needle mode with only one blood pump ("single-needle single pump", "SN click-clack"), the VENOUS PRESSURE measurement is an integral part of the control system. An error in this control system (e.g. pressure sensor stuck to low value) might lead to the upper changeover point of the VENOUS PRESSURE never being reached. As a result, the pressure becomes too high, the tubing system may burst, and the PATIENT may lose a great amount of blood. This may require a PROTECTIVE SYSTEM that is independent of the control system, e.g. monitoring of the phase duration by an independent microprocessor.

Inherent safe design is e.g. a pump rotor that is spring-mounted so smoothly that bursting of the tubing is not possible. However, in this case the HAZARD of haemolysis may exist.

Other measures for prevention of overpressure are holders for the EXTRACORPOREAL CIRCUIT lines and the DIALYSER which make kinking sufficiently unlikely.

Blood loss to the environment caused by disconnections or faults in the EXTRACORPOREAL CIRCUIT cannot be prevented by any PROTECTIVE SYSTEM. The PROTECTIVE SYSTEM should be designed so that blood loss is detected and major blood loss is prevented. Most reported cases of fatal blood loss are caused by blood access cannulas slipping from the fistula or graft. This cannot be prevented by the HAEMODIALYSIS EQUIPMENT. Traditionally, VENOUS PRESSURE monitors have been used for protection of blood loss to the environment. These sensors detect a drop of the pressure in the return bloodline. In case of a bloodline rupture or disconnection of the bloodline from the blood access device (cannula or central venous catheter) the pressure will drop considerably because of the high flow resistance in the blood access device. When the venous cannula slips from a fistula the pressure change is usually too low to be detected by the VENOUS PRESSURE monitor. The pressure drops only by the amount of the fistula pressure, which is typically 5 mmHg – 20 mmHg. To avoid frequent nuisance alarms caused by PATIENT movement the difference between the actual VENOUS PRESSURE and the lower pressure ALARM LIMIT is usually adjusted to 10 mmHg – 20 mmHg.

Monitors employing pressure pulses or other parameters may offer greater sensitivity but may also require up to a minute to detect the fault condition and switch off the blood pump. With high blood flow this may cause blood losses of 500 ml, which are usually not fatal for adults.

The effects of haemorrhage are described by [1][1].

Concerning Subclause 201.12.4.4.104.1 c) of IEC 60601-2-16:2012

As alarm reaction, the stopping of an occluding blood pump is considered as sufficient. The additional closing of the safety clamp adds only little value, because a rupture will occur most likely at the point of highest pressure, which normally is between the blood pump and the DIALYSER. In this case “retrograde” blood loss via the venous bloodline is negligible compared to the direct blood loss through the arterial bloodline.

If staff is not present (e.g. home PATIENT) or delayed for a long period, in the case of venous puncture cannula slippage, the blood loss from the venous access (backwards) may become hazardous to the PATIENT.

An EXTERNAL ALARMING DEVICE could detect blood loss to the environment from venous needle disconnection. The alarm reaction of the HAEMODIALYSIS EQUIPMENT via the input interface avoids further blood loss.

The solution in this PAS is given by hardware and software with regard to the behaviour of the HAEMODIALYSIS EQUIPMENT in case of activation by an EXTERNAL ALARMING DEVICE.

It is the understanding of the standard committee that initially as little as possible should standardized. It is hoped that a quasi-standard evolves, which can then be standardized.

The design of the socket and plug is under the responsibility of the manufacturers.

[1] Numbers in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL SYSTEM – INPUT INTERFACE FOR HAEMODIALYSIS EQUIPMENT FOR USE OF EXTERNAL ALARMING DEVICE

1 Scope

This PAS establishes a unique INPUT INTERFACE for connection of an EXTERNAL ALARMING DEVICE to HAEMODIALYSIS EQUIPMENT.

The INPUT INTERFACE of the HAEMODIALYSIS EQUIPMENT is designed as a simple solution, which takes a SINGLE FAULT CONDITION of the INPUT INTERFACE into account, to stop the extracorporeal blood flow in case of needles slipping out from the fistula or graft detected by the EXTERNAL ALARMING DEVICE.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-16:2012, *Medical electrical equipment – Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.*