Investigation of selected examples of practical guiding principles used in emergency situations as quality and safety instrument for use of medicines

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Annotation

Devices and equipment used in the emergency health service must meet strict technical criteria which has to be adhered and regularly verified. The types of verification procedures, whether internal or external, have to be compiled in accordance with the technical characteristics of the devices and meet the criteria of prescribed regulations and procedures. Based on these facts, we will show some important technical information and operating equipment that are one of the major operating systems for using individual devices and medical aids. These sequences can then be evaluated in other branched steps according to the prescribed criteria, identify individual branches for regular revisions and technical inspections, and then perform these technical inspections and sequencing at specified intervals.

Keywords: quality control, technical criteria, verification procedure, medical aid.

Introduction. In the above article we will list some types, forms of manuals and user controls to meet the basic requirements for putting aids and devices into operation as well as meeting the safety and operating regulations of the devices. This article can make a significant contribution to the introduction of technical verification for other aids and devices of medical nature as well as technical objects of different scope, with the important aim of fulfilling the required qualitative, safety and legislative requirements in the event of a growing tendency to continually improve individual technical, technological, working sequences. Based on these information, we can compile this article as an informative guide to some medical emergency medical aids, such as: instructions for operating a contour universal head immobilizer, displaying the flow of the infusion pump volume as well as certification of an organization for the production and distribution of medical devices meeting the criteria for the management system quality as well as operational and safety requirements as a complex.

Material and methods. There are several types of verification and approval options for individual devices and it can be categorized according to whether it is and internal (intradepartmental) quality control, or performing an internal audit based on legislative requirements, the prescribed revision and certification procedures. Based upon this, we will show some examples of both technical and progressive use of medical devices, for example, during the inspection as well as in operating conditions and tests with practice practices.

From the point of view of legal and other requirements, the purpose of this element is to ensure that the organization has permanent access to up-to-date security regulations. The area of OSH is much more related to legislation, standards and technical requirements than other areas of management. Therefore, it is necessary to ensure an adequate overview, permanent availability and timeliness of such documents. The introduction of this element does not mean the establishment of legal documentary libraries but the establishment of a system (along with the training element) to keep staff informed of security requirements to understand their legal obligations and to identify them. It should also be determined who should know what information, how to monitor, implement and control new regulatory requirements and how to ensure access to texts.

The introduction of this element means:

- to develop and implement an algorithm (procedure) for monitoring, updating and access to legal and other OHS prescriptions;
- to prepare a register of legislation, an STN-related register, a register of internal regulations and a register of good practice principles of OSH, including the availability of texts.

Inputs:

- introductory analysis,
- OSH and STN regulations,
- internal safety-technical regulations,
- documentation.

Outputs:

- training courses,
- OSH policy,
- objectives,
- risk management,
- control, monitoring.

The documents that create the organization's documentation can be divided into two basic groups:

- specifications,
- records.

The specifications describe or define the products of the organization, their processes, procedures or activities. Examples of such documents are production documentation, drafting or prescriptions, management guidelines and regulations, control procedures, decisions or notifications, and so on.

The records are evidence of the carried out activity. Examples of documents in this group include accounting documents, minutes of meetings, records of delivered and dispatched mail, records of the training performed, records of incoming intermediate and final inspections, records of the measures taken, etc.

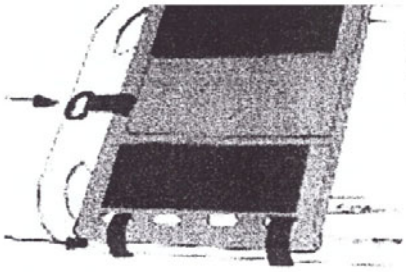
Maintenance can be defined as a set of activities performed to ensure the technical conditions of the specified operating state of a technical facility as well as to define and assess its actual state. The basis for defining basic concepts for all types of maintenance and for maintenance management is the European Standard EN 13306. "Maintenance" means a way to measure and maintain the status and functionality of the equipment or the whole in order to meet the desired objectives.

Maintenance definitions:

a) maintenance is a summary of activities ensuring the technical capability, readiness and economical operation of the core funds of production modules;

b) maintenance is a set of activities to ensure the technical conditions of the examined operating state as well as the definition and assessment of its research state.

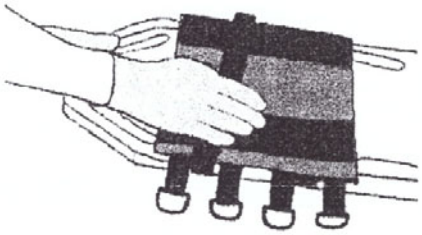
Results and discussion. The following results are presented by some of the above-mentioned types of documentation, instructions and certification that can significantly contribute to the regular improvement of safety and quality in practice, both in terms of new mutual knowledge and possible new universal instructions. Individual medical manuals can be used as a guide to the use and quality control of medical devices in this article, as well as the possibility of compiling new instructions from either a qualitative, safety, operational and medical focus.

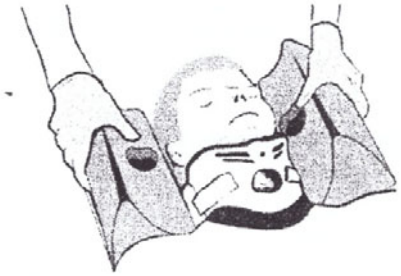


Place the Head Immobiliser on the supplied spine board following the universal system or by means of the adhesive stripes on the back of the Head Immobiliser's base.

Check position and straps to be secured before use.

The Head Immobiliser can be applied to adult or paediatric patients. For adults, the supplied rectangular pillow should be placed on the base, between the two lateral supports. For children, the pillow should not be employed.





Moving the lined up patient. Immobilise the patient – avoiding pressure – the anatomic supports of the head immobiliser should adhere symmetrically to the sides of the patient's head.

Secure the headblocking straps. Start with the "chin holder": pass it over the cervical collar chin support; bend it upwards and fasten it using the fastening-System with buttomhole and hook. Secure the "forehead strap" in the same way by crossing it over the "chin holder".

Before transport, it's necessary to fix the patient to the board by means of belts to immobilise the patient shoulders and avoid cervical spine compression.

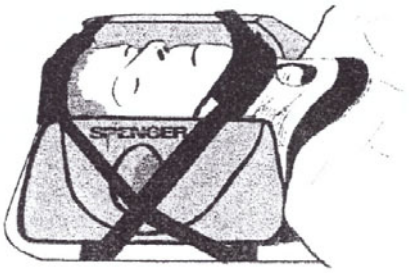
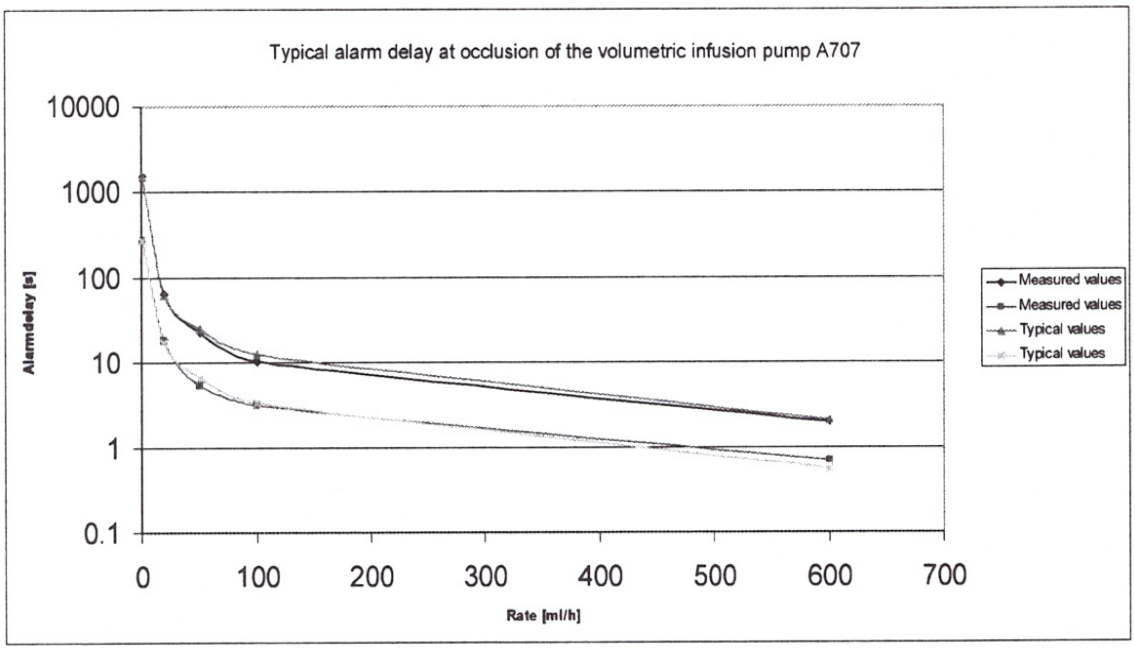


Fig. 1. An example of instructions for contour universal head immobilizer



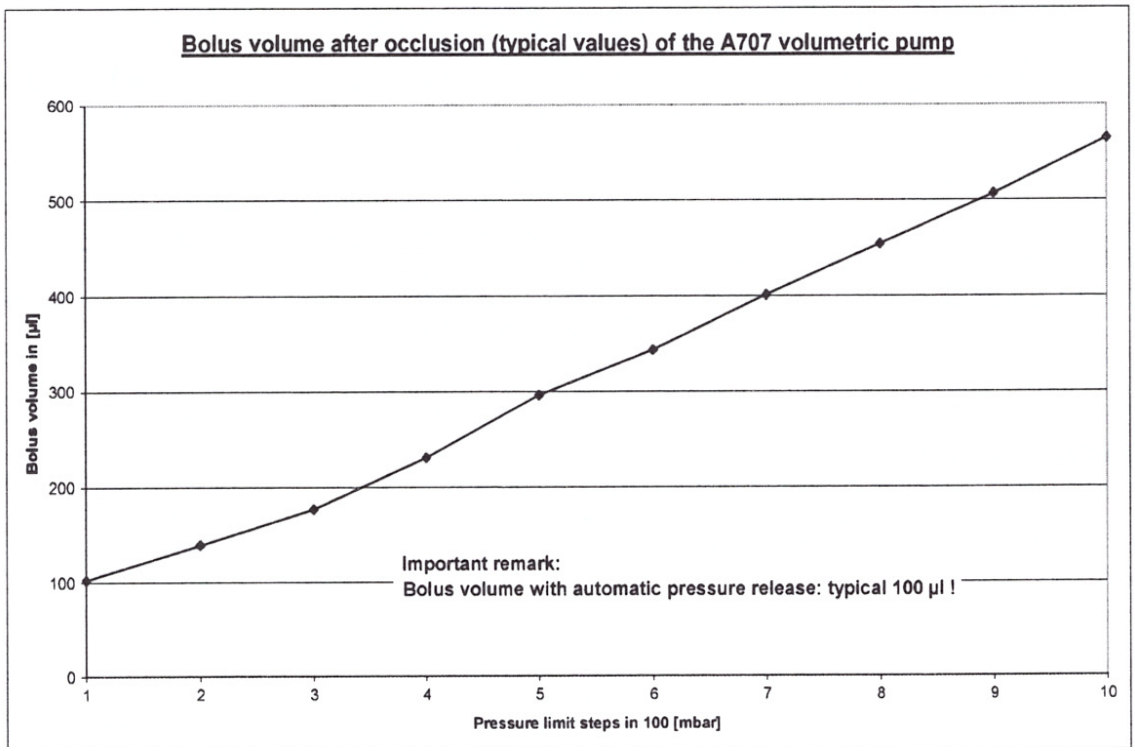


Fig. 2. An example of two performance tests for a volumetric infusion pump

Certification Bodies certifying management systems focus on assessing the compliance of management systems within the scope of accreditation conditions for accreditation, according to the nominal standards of the management systems. Each certification body can be accredited for different management systems (e.g., according to ISO 9001: 2015), as long as it demonstrates compliance with all accreditation conditions, in particular all requirements for professional competence of auditors (quality manual, documented certification procedures, etc.)

Certificate

The Certification Body of

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has established and applies a quality system for medical devices for the following scope:

Manufacturing, Distribution and Servicing of Defibrillator/Pacemaker (external) with Monitor

Proof has been furnished that the requirements specified in

EN ISO 13488:2000*

* Quality systems – Medical devices – Particular requirements for the application of

EN ISO 9002

are fulfilled. This approval is subject to periodic surveillance.

Certificate Registration No.: SX 60005314 0001

An audit was performed. Report No.: 21106112 002

This Certificate is valid until: 06.07.2008

Certification Body

Fig. 3. An example form of an organization's certification for the manufacture and distribution of medical devices under international guidelines

Conclusion. Typical attributes of the EU approach to quality assurance include the application of some social conformity assessment processes. Conformity activities mean, in particular, the determination of product conformity requirements, which are then defined in standards, regulations and other types of specifications. Confirmation of conformity is obtained by various processes in which, for example mechanical testing or certification is demonstrated either by compliance or non-compliance with the defined requirements. A declaration of conformity is the official declaration of the organization that carries out the conformity assessment in such a way that a particular product is fully in conformity with the prescribed conformity specifications.

Based on this information, it is possible to distinguish the conformity assessment processes:

- testing,
- calibration,
- certification,
- inspection activity (market surveillance),
- accreditation,
- notification.

An overview of the information and illustrations provided in this article can make a significant contribution to possible conformity assessment procedures, whether functional, legislative or qualitative, and this information can be a major step forward in improving the individual operational and technical procedures for the use of medical devices.

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