KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINAL AND HEALTH PRODUCTS

Issued

Royal Order designating the guide applicable to the installation and maintenance of medical devices intended for the diagnosis and treatment of sleep apnoea syndrome outside a hospital and laying down the procedures for notifying the companies referred to in Article 60(2), subparagraph 3, of the Law of 15 December 2013 on medical devices

BY THE KING,

The Minister for Public Health,

PHILIPPE, King of the Belgians,

To all those present and to come,

Frank Vandenbroucke

Greetings.

Having regard to the Law of 15 December 2013 on medical devices, Article 60(2), subparagraphs 1 and 3,

Having regard to the Royal Order of 30 October 2018 on the procedure and arrangements for approving the guides referred to in Article 60(1) of the Law of 15 December 2013 on medical devices;

Having regard to the communication to the European Commission, on xxx in accordance with Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the opinion of the Finance Inspector issued on xxx;

Having regard to the opinion of the Council of State No. xxx, given on xxx, pursuant to Article 84(1), subparagraph 1(2), of laws on the Council of State, coordinated on 12 January 1973;

On the proposal of the Minister of Social Affairs and Public Health,

We have decreed and hereby decree:

Annex – Guide for the establishment of a self-monitoring system related to the installation, maintenance and/or removal of medical devices as part of the diagnosis and treatment of sleep apnoea syndrome

1. Preamble

According to Article 59 of the Law of 15 December 2013 on medical devices, companies that install, maintain and/or remove medical devices as part of the medical treatment of a patient outside a hospital (‘STHA actor’) must establish, apply and maintain a self-monitoring system.

This guide is intended to provide STHA actors involved in the treatment of sleep apnoea syndrome (SAS) with a good practice guide outlining the steps needed to implement such a self-monitoring system.

It is based on the criteria set out in Annex I of the Royal Order of 30 October 2018 on the procedure and arrangements for the approval

of the guides referred to in Article 60(1), of the Law of 15 December 2013 on medical devices.

This guide covers medical devices and accessories used in the diagnosis and treatment of sleep apnoea syndrome, outside the hospital. These include PAP devices (CPAP, BPAP, APAP, etc.), humidifiers, masks, chin rests, telemonitoring devices and PAP accessories used in PAP therapy, positional therapy, therapy using mandibular advanced orthotics and diagnostic services (polygraphy or polysomnography) and treatment titration. This list is a snapshot of the current situation and may change in the future.

Means other than those listed in this guide may also be used to the extent that it can be demonstrated that these alternative means enable to achieve the objective pursued by the Regulation.

1.1. Identification of working groups and consultations

The professional association submitting this guide to the FAMHP is beMedTech asbl, the Belgian federation of the medical technology industry. The 200+ members of beMedTech are manufacturers and/or distributors of medical devices.

This guide is the result of consultations within the STHA-SAS working group of the ‘STHA – Services & Technologies Home Assistance’ section of beMedTech. The members of this working group represent a large part of the manufacturers and/or distributors of medical devices.

1.2. Complementarity with other Regulations and guides

This guide is in no way intended to contradict existing Regulations and other relevant guides. It is the responsibility of the STHA actor to verify the applicable Regulations and/or guides. For example, STHA actors who are also distributors should also consult the guide for medical device distributors. This guide covers the use of medical devices in a STHA environment only.

2. QUALITY MANAGEMENT SYSTEM

2.1 General

The STHA actor must establish and maintain a quality management system covering all its activities with the aim of maintaining the required level of quality with regard to the installation, maintenance and/or removal of medical devices.

The quality system consists in entering, documenting, recording and implementing a process to ensure that the service provided meets a certain level of requirements.

The quality system requires sufficient and competent staff to ensure business continuity.

The scope of the STHA actor must be taken into account when developing or modifying the quality management system.

2.2 Documentation

The documentation consists of all written procedures, instructions, agreements, records and data, in paper or electronic form. These documents should reflect the current situation and be updated as they evolve. The documentation must be kept for at least five years and must be easily accessible or recoverable to the competent authorities.

The documentation must contain sufficient information on all activities of the STHA actor and be drafted in a language that the staff can understand.

In addition, the documentation must be drafted in clear and unambiguous language and should not contain errors.

Any changes to the documentation must be signed and dated; the modification must be made in such a way that the original information remains legible. Where appropriate, the reason for the change must be indicated.

Each employee must have direct access to all the necessary documentation relating to the tasks carried out within his competence.

2.3 Procedures

The STHA actor must have working procedures and instructions detailing the services and associated activities it provides. Procedures and work instructions describe the organisation of the activities and tasks performed. There has to be a method to combat uncontrolled copying.

It is important to ensure that valid and approved procedures are applied. Procedures should be reviewed and updated regularly. Procedures must be subject to a version control. Once a procedure has been revised, a system must be put in place to prevent the unintended use of an outdated version. Obsolete or redundant procedures must be removed from workstations and archived.

2.4 Records

Each time an activity (installation, maintenance, replacement, repair, removal of a medical device, handling complaints, incident reporting, etc.) is undertaken, the activity concerned must be recorded with clear notes so that all significant activities or occurrences can be traced.

Records must be kept to demonstrate that the activity carried out complies with the established requirements and to prove the effectiveness of the quality management system.

2.5 Risk analysis

The STHA actor prepares a risk analysis that identifies the causes and effects of a potential failure as well as actions that can eliminate that potential failure (or at least reduce its impact and/or frequency). This is mainly a predictive method to identify malfunctions that can lead to failures before they even occur. These risk assessments should be documented and repeated periodically.

2.6 Internal audit and CAPA plan

An internal audit plan must be drawn up to verify the effectiveness of the STHA actor and compliance with the quality system and legislation. This plan must be drawn up on the basis of a risk analysis for all activities within the company. Internal audits may cover one or more activities simultaneously.

After an internal audit, a report should be prepared which includes the results of the audit. Corrective and preventive actions resulting from the internal audit are also recorded.

All identified non-conformities must be closed as soon as possible.

3. RESPONSIBILITIES

3.1 The responsibilities of the STHA actor

The STHA actor is responsible for the development and implementation of a quality management system. It shall determine the quality objectives to be achieved in accordance with the applicable legislation and ensure that they are achieved and maintained.

The STHA actor ensures the availability of resources to achieve the quality objectives.

The STHA actor shall ensure that only medical devices manufactured or purchased from a legal manufacturer or importer or distributor registered with the FAMHP are installed.

The STHA actor shall ensure that only medical devices complying with European Directives 93/42/EEC and 98/79/EC or European Regulations 2017/745 and 2017/746 are installed.

The responsibilities of all staff and/or subcontractors involved in the activities of the STHA actor must be recorded in writing.

The STHA actor shall ensure that internal audits/self-assessments are carried out at appropriate and regular intervals according to a predetermined schedule. In addition, it shall ensure that the necessary corrective measures are taken in a timely manner.

3.2 Subcontracting of activities

If the STHA actor chooses to subcontract certain activities, it must ensure that the contractor/subcontractor knows and complies with the procedures applicable to this/these activity(ies).

The STHA actor and the contractor must conclude a written quality agreement which clearly defines the obligations of each party in relation to the subcontracted activity(ies).

However, it is important to emphasise that the STHA actor retains final responsibility and must ensure that the activities carried out meet the legal requirements.

The quality agreement, as well as the procedures for subcontracted activities, must be made available during an FAMHP inspection.

4. RESOURCE MANAGEMENT

The STHA actor must have the necessary human and infrastructural resources to implement quality management and comply with legal requirements.

4.1 Personnel & training

The STHA actor shall ensure the level of training, competence and experience of its staff or contractors so that the tasks assigned are carried out correctly and comply with the training requirements of the manufacturer of the medical devices concerned.

The training and skills needed to carry out the different tasks related to the activities must be clearly defined.

A training plan (initial and ongoing training) should be drawn up to enable the tasks assigned to be carried out correctly.

Initial training focuses on the following points:

- the content of this guide;
- the quality management system and the applicable procedures and records;
- the status of the STHA actor in relation to the patient; definition of roles, missions and responsibilities;
- the European and national Regulations applicable to STHA actors;
- materials vigilance, so that any incident or risk of an incident involving a medical device is reported in an appropriate and timely manner;
- traceability to patient level;
- sleep disorders and their treatment;
- all medical devices and accessories that are or may be used in the diagnosis and treatment of sleep apnoea syndrome and its risks;
- ethics and code of conduct, including patient rights and freedoms, professional secrecy and relationships between the medical device industry and healthcare professionals;
- legislation on the protection of personal data;
- liability aspects (including compliance with medical prescriptions) and privacy policy;
- safety protocols and procedures when using medical technology, based on a prior risk analysis.

In addition, an annual programme of ongoing training and knowledge validation should be established, based on the risk analysis included in the quality management system.

All training activities must be recorded in detail, including: a description of the training, the date, duration and location of the training, the provider and the follower of the training, including the success rate.

4.2 Infrastructure

Medical devices must be stored and transported in conditions that do not adversely affect the quality and safety of products or patients. To do this, the manufacturer's instructions must be followed.

The STHA actor shall document the requirements relating to maintenance activities, including the time interval considered necessary to carry out these maintenance activities.

The storage areas for medical devices used in STHA activities must be clearly distinguished and designated.

A clear distinction should also be made between medical devices removed from a patient and returned to the STHA actor and other goods in inventories. The different storage areas may vary in size but must be marked.

5. THE MANAGEMENT OF THE SERVICES PROVIDED AND THE ASSOCIATED RISKS

5.1 Technical installation, maintenance and removal services

For any technical installation, maintenance and/or removal of a medical device from a patient, the STHA actor or its contractor shall carry out its task strictly in accordance with the instructions of the doctor (referrer/attending physician) and the manufacturer's instructions for use. The intervention of the STHA actor or its contractor shall be of a purely technical nature and shall not affect medical or pharmaceutical services provided by approved healthcare professionals. The STHA actor cannot modify the therapy (or the type of mask) without the prior consent of the doctor (referrer/attending physician).

The technical services of installation, maintenance and removal from the patient can be carried out in several phases:

- The diagnostic phase
- The initiation phase to familiarise the patient with the equipment
- The follow-up phase after the first 6 months of treatment
- Removal after completion of treatment

The technical service of the STHA actor must take place outside the hospital, i.e. it can take place either in the patient's home or in another location (for example, in the premises of the STHA actor, etc.) if there are no specific requirements for the activity to be carried out in the patient's home. Non-technical services, such as supply of equipment for home use, are not part of STHA activities.

A. Diagnostic phase

In this phase, a home diagnostic test will be carried out on the basis of a medical prescription. For this purpose, the STHA actor or its contractor will deliver and collect the equipment for the home diagnostic test at the patient's home, give the patient (and, if necessary, his entourage) the necessary instructions on the correct use of the diagnostic equipment and prepare the patient for the test. The STHA actor will place the sensors in the right place in the patient's home. The STHA actor must test the equipment and check the quality of the signals to ensure proper recording.

B. Initiation phase

This initiation phase includes the installation of the medical device given to the patient for the treatment prescribed.

The choice of medical device and accessories for the treatment of sleep apnoea syndrome is made in accordance with the request of the doctor (referrer/attending physician).

Each medical device is checked before being made available to the patient. The following checks shall be carried out as a minimum: compliance, functionality and cleanliness. These checks are recorded.

The patient is informed of the collection and processing of his personal data, which requires his prior consent. The criteria for including this consent are documented and maintained.

The installation of the equipment by an expert should ensure the safety of the patient and his entourage and promote the correct use of the medical technology provided.

This operation is carried out according to the steps described below:

- communication and awareness to motivate the patient (and his entourage) to follow the prescribed therapy;
- the provision of equipment in accordance with the doctor's prescription and in the language recommended by the doctor (French, Dutch, German and/or English)
- the supply of a manual and/or instructions for the use of the equipment in French, Dutch, German and/or English
- providing the patient with the contact details of the STHA actor and/or its contractor, the number of any on-call service (see 5.4 continuity of service);
- information and technical training of the patient and, where appropriate, of his entourage; this includes the following:
  - the operation of the equipment, in accordance with the medical prescription;
  - fitting and adjusting the mask;
  - information on hygiene instructions for the equipment and its accessories (e.g. mask);
  - information on health and safety instructions;

- confirmation that the patient (or his entourage) has understood all the information and instructions in order to use the equipment in accordance with the medical prescription and in compliance with safety rules.

The equipment must be locked in such a way that the patient cannot access features requiring medical opinion or approval.

A report on the installation will be made available to the doctor (referrer/attending physician).

During the initiation period, the patient has several moments of contact with the STHA actor. The purpose of these moments of contact is:

- to ensure proper handling of the appliance and its accessories;
- to answer any questions or issues raised by the patient;
- to monitor compliance with the medical prescription;
- to monitor compliance by the STHA actor at the request of the doctor (referrer/attending physician): the device must be used for an average of at least 4 hours per night;
- to check the effectiveness of the therapy according to the criteria defined by the doctor (referrer/attending physician).

The dates of these moments of contact are fixed and recorded by the STHA actor and made available to the doctor (referrer/attending physician).

C. Follow-up phase

During this phase the STHA actor will take charge of the following steps and procedures:

- the annual summary with the device data. This step includes the preparation of a follow-up report, adherence to the medical prescription as well as reports on compliance (if requested by the physician) for the physician (referrer/attending physician).
- ensure that the monitoring parameters meet the objectives of the different monitoring parameters mentioned on the prescription and, if not, report it in writing to the doctor (referrer/attending physician) and his team.
- Checking that the mask is well tolerated (including absence of injury) and correctly adjusted by the patient and adaptation of a new mask if necessary;
- monitoring compliance with observance of hygiene and safety rules;
- monitoring and technical maintenance of equipment. The frequency and nature of this work must comply with the manufacturer’s specifications and must take place at least once a year. In addition, they must be recorded in a register that can be consulted by the competent authorities.

D. Removal

When it is decided by the doctor (referrer/attending physician) to stop the use of the installed equipment, the STHA actor takes care of the removal of all the equipment. The removal shall include the following operations:

- the return of the equipment, with the exception of single-use accessories, on the understanding that the equipment taken back will follow the cleaning, disinfection and control procedures in accordance with the manufacturer's requirements
- checking the conformity of the equipment with the manufacturer's specifications, including:
  - the release of compliant equipment, the overhaul and repair of defective equipment by a qualified technician or by the manufacturer or its designated representative;
  - destruction of non-compliant devices and accessories.

A STHA actor which recovers a medical device must, before putting back into service on another patient, carry out and document the following actions:

- cleaning and disinfection of equipment in accordance with an established and documented procedure, in particular ensuring the use of the appropriate products, the safety of flows and the suitability of the premises
- description and implementation of a maintenance procedure, preventive or curative, and tests that ensure the proper functioning of the equipment when it leaves to another patient
- description and implementation of a procedure for the deletion of personal data present on the machine and setting up parameters for a return to the initial configuration of the equipment
- packaging and storage of medical devices in accordance with the conditions defined by the manufacturer

5.2 Administrative services

The STHA actor is responsible for the following administrative services:

- opening the patient's administrative file;
- management of the patient's administrative file;
- management of continuity of services by the authorised staff of the STHA actor, on Belgian territory;
  - in this respect, the conditions of use of the device outside the home (e.g. in a car, when camping or on a cruise) must be specified to the patient, if necessary
- for air transport a certificate of conformity for air transport in English must be provided to the patient on request.

All data and information collected during each phase of the technical service provided by the STHA actor must always be available to the doctor (referrer/attending physician).

Whenever a report or certain data may be of interest to the doctor, the STHA actor must communicate this information to the doctor (referrer/attending physician).

The STHA actor must define and apply methods to protect confidential (health) patient information in accordance with applicable legal requirements and, in particular, Belgian and European legislation on the protection of personal data. This last obligation, however, does not fall within the competence of the FAMHP.

5.3 Traceability

Traceability is the implementation of a system to track the medical device at all stages of the process and use.

To ensure optimal traceability, the following must be recorded:

- Name of medical device +type
- Serial number
- Unique identification number
- Customer name
- Customer address
- Date of the particular activity (installation, maintenance, removal of the medical device, etc.)

At all times, the STHA actor has information about the medical devices in circulation and the equipment and accessories that accompany each patient. Records are also kept for each device, with information on maintenance and its schedule.

5.4 Continuity of services

The STHA actor must set up a telephone hotline (24 hours a day; 7 days a week) to ensure safe and adequate service. The provision of services shall include: receiving and handling (technical) complaints and incidents; answering questions from patients and doctors; etc.

In the event of failure or malfunction of a medical device, the STHA actor must repair or replace the device as quickly as possible so as not to interrupt the patient’s treatment.

The patient should be informed of how continuity of services can be ensured during a temporary stay abroad.

6. COMPLAINTS AND INCIDENT REPORTS

6.1 Handling of complaints

The STHA actor sets up a system for handling, managing and archiving complaints.

All oral or written complaints must be recorded in order to assess trends in complaints, the regularity of product-related complaints, and the seriousness of complaints with a view to taking further action and, where appropriate, immediate corrective action. These records must be made available to the competent authorities during their inspections.

The register of complaints must contain at least the following information:

- Identification of the complainant unless he/she explicitly requests anonymity;
- The nature of the complaint, including the name of the medical device with batch number/serial number/UDI;
- Date of receipt of the complaint;
- The measures taken;
- If the manufacturer or a third party has been contacted, the communication relating thereto;
- The reply provided to the complainant, including the date on which the reply was sent;
- The final decision in relation to the complaint.

6.2 Incident report

The STHA actor designates a person responsible for the materials vigilance who is responsible for analysing an identified problem. This person may be the actor itself, or this activity can be entrusted to an employee or an external partner.

On the basis of the decision tree provided by the FAMHP, it is appropriate to decide whether an incident should be reported to the FAMHP. Any incident that may lead to a serious incident as well as any recall of a medical device installed, maintained and/or removed by the company or service provider representing it must be reported to the FAMHP. Any communication with the FAMHP relating to incidents is done via the email address vigilance.meddev@fagg-afmps.be.

The person responsible for the materials vigilance shall also report any potential incidents or incidents to the manufacturer and/or importer and doctor (referrer/attending physician).

Once the incident is identified and analysed, incidents or risks of incidents should be reported as soon as possible.

Each incident and risk of an incident must be reported in the STHA actor’s materials vigilance register.

7. APPLICABLE LEGISLATION

This guide has been developed taking into account the requirements of the current legislation, namely

- Articles 59 and 60 of the Law of 15 December 2013 on medical devices.
- Royal Order of 30 October 2018 on the procedure and arrangements for drawing up the guides referred to in Article 60(1), of the Law of 15 December 2013 on medical devices.
- Royal Order of 10 October 2021 establishing the principles on which the self-monitoring system and the criteria for exemption from the system of self-monitoring of foreign companies referred to in Articles 59 and 60(2), second subparagraph, of the Law of 15 December 2013 and amending the Royal Order of 18 March 1999 on medical devices should be based.

8. DEFINITIONS

For the purposes of this guide, the following definitions apply:

Medical device: Any instrument, apparatus, equipment, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, in humans for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or mitigation of a disease;
- diagnosis, monitoring, treatment, mitigation of or compensation for an injury or disability;
- investigation, replacement or modification of an anatomical structure or function or physiological or pathological process or condition;
- provision of information by means of an in vitro examination of samples from the human body, including donations of organs, blood and tissues, whose main intended action in or on the human body is not obtained by pharmacological or immunological means or by metabolism, but whose function may be assisted by such means.

The following products are also deemed to be medical devices:

- devices intended to control or assist conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices referred to in Article 1(4) of Regulation (EU) 2017/745 on medical devices and those referred to in the first subparagraph of this definition.

(Article 2(1) of Regulation (EU) 2017/745 on medical devices)

Accessories: Any article which, although not itself a medical device, is intended by its manufacturer to be used with one or more given medical devices to enable the latter to be used in accordance with its intended purpose or to contribute specifically and directly to the medical function of the medical device(s) depending on its/their intended purpose.

(Article 2(2) of Regulation (EU) 2017/745 on medical devices)

STHA actor: Companies which, as part of the medical treatment of a patient outside a hospital, install, maintain and/or remove medical devices, as referred to in Article 59(1) of the Law of 15 December 2013 on medical devices (including hospitals as defined in Article 2(1) of the Coordinated Law of 10 July 2008 on hospitals and other healthcare facilities, if they carry out the above-mentioned activities outside a hospital).

CPAP: Continuous Positive Airway Pressure

APAP: Automatic Positive Airway Pressure

BiPAP: Bilevel Positive Airway Pressure

PAP: Positive Airway Pressure

SAS: Sleep Apnoea Syndrome