Fédération Européenne de l'Industrie de l'Optique et de la Mécanique de Précision

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Enhancing the health of the public European wide and world wide and
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Advisory opinion from EUROM VI

Safe use and operation of oxygen concentrators in the home

Berlin, November 29, 2011

In recent years long-term oxygen therapy for patients has become firmly established as a method of home healthcare all over in Europe. However, the constant need for oxygen and the risks simultaneously associated with this presents a special problem for long-term oxygen therapy, in particular when used by patients at home: The patient's concerned need a supply of oxygen at a concentration of over 90% that is virtually continuous throughout the day. This is unavoidably associated with a major increase in the level of oxygen at the oxygen supply to the patient, i.e. with administration via a nasal cannula fitted to the patient's head. Here it is not only the patient's hair and clothing that becomes highly enriched with oxygen, but also pillows/cushions, coverings, upholstery or other flammable materials in the immediate environment.

It is known fact that the energy necessary to ignite such flammable materials is considerably reduced in an oxygen-enriched atmosphere. Often all that is needed here is a small spark to set these materials alight. And the plastics used as application accessories for the administration of oxygen therapy, e.g. nasal cannulas, also ignite very easily. This risk of fire is especially great in the case of patients who, despite all warnings, persist in smoking during oxygen therapy. Once ignition has taken place, the fire will spread along the oxygen supply tube very quickly, setting alight everything in its path, e.g. beds, furniture, carpets, curtains etc., as the flow of oxygen that is continued to be supplied will especially promote the combustion.

Although the accompanying documentation - in particular the operating instructions and warnings attached to the device - makes explicit reference to such hazards, and the risks resulting from the use of oxygen are also emphasised when instructing the patient or carers or relatives during set-up of these products at the patient's home, major fires still continue to occur, in most cases caused by the patient smoking during oxygen therapy. Such fire accidents generally end in serious burns to the patient, sometimes with fatalities, and frequently also have a major impact on the patient's environment, possibly causing severe damage to property or involving other persons.

Three stages can generally be identified whenever a fire occurs in the course of oxygen therapy:

Stage 1:

Firstly, the materials enriched with oxygen in the patient's immediate vicinity catch alight, possibly causing serious burns to the patient. Preventing such an ignition in the oxygen-enriched environment of the patient is not technically feasible as flammable materials can always be found in the immediate vicinity of administration of the oxygen therapy, e.g. hair, clothing, pillows/cushions, bed/mattress coverings, etc., which become massively enriched with oxygen in the course of such therapy. The risk of ignition can thus only be reduced by the inclusion of information to this effect in the accompanying documentation - in particular the instructions for use - and warnings attached to the device, and supplemented by an emphasis on this aspect when instructing the patient or carers or relatives during set-up of

these products, together with explicit warnings about the risks of smoking during oxygen therapy.

Stage 2:

Once ignition has taken place, the fire will propagate along the oxygen supply tube very quickly. When this frequently very lengthy tube burns, it can set the patient's surroundings alight, e.g. carpets, curtains, furniture etc. The propagation of the fire is further supported by the uninterrupted supply of oxygen.

Considering the entire system for the supply of oxygen to patients, from the patient through the nasal cannula, the supply tube, the humidifier up to the oxygen concentrator, this stage represents the earliest possible and most effective option to reduce the likelihood of propagating the fire.

In technical terms this could be achieved for example by equipping the oxygen supply tube with a valve system that interrupts the flow of oxygen in the event of a fire while simultaneously stopping the supply tube from burning any further. Although such valve systems do exist, they are not currently available on the market in the necessary quantities. To prevent a large-scale fire from breaking out, such valve systems need to be installed as close to the patient as possible. Integration ad the Y-piece of the nasal cannula would be advisable here.

Stage 3:

If the fire can propagate down the oxygen supply tube into the oxygen concentrator, there is the risk of deflagration.

According to current knowledge the probability of a fire propagating up to this point without already having caused devastating injury and material damage is extremely low (< 1 of 1000 fires). Measures designed to prevent the fire spreading into the concentrator represent also an option for minimising the severity of risk, but ultimately the contribution they can make to risk minimisation overall is very limited.

According to the state of the art, such measures would prevent the fire propagating into the concentrator via the outlet connector. Although such devices are technically feasible, they are not commercially available at present.

Measures:

In view of the possible fire scenarios described above and the fact that patients persist in smoking during oxygen therapy despite all information and warnings to the contrary, the following catalogue of measures is recommended by the European Federation EUROM VI “Medical Technology“ in consultation with the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and the majority of companies concerned by this problem:

- Systematic continuation and intensification of the labelling procedure used on systems, inclusion of warnings in operating instructions and above all, increased emphasis of the risks involved during the initial instruction when such systems are set up at patients' homes, in particular if patient's are assumed to be smokers. For this purpose EUROM VI will provide homecare providers with suitable information material so that patients can be explicitly warned about the resulting risks if they smoke during oxygen therapy. In addition, this material refers patients to video clips which will be put online by EUROM VI and are designed to deter them from smoking while using oxygen.
- Independently of current revision of the relevant EN ISO 8359 standard *Oxygen concentrators for medical use - Safety requirements*, EUROM VI supports the international initiative to add the following safety requirements to the existing EN ISO 8359 via the international fast-track procedure:
    - The outlet connector of the oxygen concentrator must be provided with a means that prevents fire spreading via this connection into the oxygen concentrator. This means must not be removable without the use of a tool.
    - The application accessory used to supply oxygen from the concentrator to the patient must be equipped with a means that stops the flow of oxygen should the application accessory ignite.
- The additional requirements amended to EN ISO 8359 via the fast-track procedure shall immediately come into force from the date given in the standard amendment with regard to new products, i.e. new products placed on the market after this date must incorporate these means.
- The introduction of these changes is also recommended for devices already in service from the date specified in this standard amendment. Given the limited level of risk minimisation resulting from these measures and the considerable cost which would be incurred by public health systems by an on-site implementation of this means, it is not recommended to retrofit devices already in use. Modification of devices in use should be carried out within the next technical procedure scheduled for the oxygen concentrator concerned, e.g. during preventive maintenance or when the oxygen concentrator is transferred to the next patient.

One aspect of special significance is that the specification of safety requirements for application systems, namely the call for an oxygen cut-out device as an integral part of the application system, is taking place by initiation within the responsible standardisation committee ISO TC 121, e.g. a nasal cannula with an oxygen cut-out incorporated in the Y-piece, i.e. in the immediate vicinity of the patient. These systems will make the greatest contribution to minimising risk with all types of long-term oxygen therapy and will in future ensure maximum protection for patients.