

# Oxygen Firebreaks and Hospices – the Regulatory Position

## How firebreak regulations apply to hospices

- Manufacturers and distributors in the EU are legally bound by the requirements of the Medical Device Directive (MDD). The products that they design, manufacture and distribute must meet the MDD Essential Requirements for safety and performance. Safety is built into medical devices, including labelling and instructions for use.
- Healthcare establishments and healthcare professionals are not strictly obligated by the requirements of the Medical Device Directive (MDD) but would open themselves up to liability if they use medical devices off label.
- The harmonised oxygen concentrator standard (EN ISO 8359:2009+AMD1:2012) requires that for safe use, oxygen concentrators must have a means to prevent the ingress of fire back into the concentrator and a firebreak, fitted close to the patient, to stop the flow of gas in the event of a fire in the tube. If a hospice does not fit a firebreak close to the patient in accordance with the concentrator instructions for use (IFU), then they are defeating an essential requirement for the safe use of that concentrator.
- The MDD also requires that manufacturers apply risk control measures to “reduce the risk as far as possible” and “take account of the generally acknowledged state of the art”, which would suggest that all oxygen modalities should have a firebreak fitted close to the patient. However, unless this is documented by a manufacturer in the IFU, for example for a liquid oxygen Dewar, then the hospice would not be using the device off label.
- Harmonised standards are considered de facto ‘state of the art’.
- The fitting of firebreaks is obviously a very sensible precaution for other modalities even though they may not be specified in the instructions for use provided with them.
- Fitting a firebreak close to the oxygen concentrator is not a requirement. The risk control measures required for oxygen concentrators are clearly given by [EN ISO 8359:2009+AMD1:2012](#).

### For sales contact:

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The following table provides further explanation of the requirements for firebreaks in hospices:

|   | In the cannula close to the patient | In the cannula close to the equipment | Notes  |
|---|-------------------------------------|---------------------------------------|--|
| Oxygen concentrator (introduced after Jan 2015)       | Requirement                         | Not required                          | Concentrator Instructions for Use require a firebreak as an Essential Requirement for performance and safety.  |
| Oxygen concentrator (introduced before Jan 2015)      | Strongly recommended                | Recommended*                          | Firebreaks are not strictly a legal requirement for a hospice, but their use reduces the risk as far as possible in line with the state of the art.<br><br>* Not necessary if the oxygen source has a metal outlet                   |
| Liquid oxygen (LOX) or gaseous oxygen cylinders (GOX) | Strongly recommended                | Recommended*                          |  |
| Wall-mounted flowmeter                                | Strongly recommended                | Recommended*                          |  |
| Bubble humidifier                                     | -                                   | -                                     | Where the outlet from the humidifier is fitted to the standard oxygen supply tubing, a firebreak immediately after the bubble humidifier is recommended. Humidifiers using 22mm (Elephant) tubing cannot be fitted with a firebreak. |

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