Supplementary information and frequently asked questions relating to MDA/2010/040 – All chest drains when used with high-flow, low-vacuum suction systems (wall mounted).

In response to queries that the MHRA has received relating to this MDA, the following further advice is provided.

Current guidelines for the use of suction with chest drains are published by the British Thoracic Society (BTS) - BTS guidelines for the insertion of a chest drain. D Laws, E Neville, J Duffy, on behalf of the British Thoracic Society Pleural Disease Group, a subgroup of the British Thoracic Society Standards of Care Committee. Thorax 2003;58(Suppl II):ii53–ii59. Section 14.3 Suction states:

'• When chest drain suction is required, a high volume/low pressure system should be used
• If suction is required, this may be performed via the underwater seal at a level of 10–20 cm H2O. (1-2 kPa)'

The full document can be found at http://www.brit-thoracic.org.uk/Portals/0/Guidelines/PleuralDiseaseGuidelines/PleuralDiseaseChestDrain.pdf

The current standards for suction equipment operated from wall vacuum sources are contained in BS EN ISO 10079-3:2009 Medical suction equipment – Part 3*. Suction equipment typically used for chest drain suction is described as follows:

'**8.6 Low vacuum/high flowrate equipment**
… suction … marked 'low vacuum/high flow' shall produce a free air flowrate of not less than 20 l/min and a vacuum of not more than 20 kPa below atmospheric pressure.

8.7 Thoracic drainage equipment for adults
… suction equipment marked 'thoracic drainage' shall produce a free air flowrate of not less than 15 l/min at the inlet of the collection container, and the level of vacuum developed shall not exceed 7 kPa below atmospheric pressure.

Note: In some situations, e.g. broncho-pleural fistula, a higher flowrate such as 25 l/min may be required.

Both systems should incorporate a filter and a shut off valve to prevent contamination of hospital suction pipelines and both require high gas flows to prevent pressure build up in the system in the event of a significant air leak from the lungs. Usually both can be adjusted to the required vacuum level.
The risk of aspirating fluid or froth into the vacuum regulator and so producing inadvertent shut-off and blockage of the chest drain is dependent on several factors including the volume of fluid loss, the size and stability of the primary drain bottle, the use of de-foaming agents and the gas flow rate and suction pressures. If vacuum pressures are regulated to the BTS guidelines, then the risks of aspiration will be similar between regulators.

Inadvertent aspiration is therefore possible with all types of suction regulator and is not prevented by the use of regulators marked 'Thoracic Drainage'.

If the vacuum regulator is not adequately protected from aspiration of fluid or froth, users are advised to add a canister/collection jar to the system between the chest drain unit and the vacuum regulator.

Frequently asked questions

Q. Is an additional collection jar or canister needed between the chest drain bottle and the regulator when a 1 chamber chest drain bottle is used?
A. If the device only has a combined collection/underwater seal chamber then an additional collection device is required.

Q. Is an additional collection jar or canister needed between the chest drain bottle and the regulator when a 2, 3 or 4 chamber chest drain bottle is used?
A. There maybe may be some 2, 3 or 4 chamber chest drain bottles where an additional collection device might not be necessary as the water seal, collection, or vacuum control chambers, or other features of the device offer adequate protection. Where this is believed to be the case users are advised to carry out a risk assessment and document reasons for not using an additional collection jar or canister.

Q. Are the small chambers that are sometimes an integral part of the high-flow, low-vacuum pressure regulator adequate, or is an additional collection jar or canister also required?
A. The recommendation is to use an additional collection jar or canister. The small chamber integral with the pressure regulator is unlikely to have a volume large enough to offer adequate protection against fluid from the chest drain system.

Q Would an extra collection jar or canister affect the suction that is applied?
A. The additional collection jar or canister will reduce the suction if it is open to the atmosphere but suction is restored when the drain is connected unless there is a leak in the collection jar or canister.

Q. Is an extra collection jar or canister required if de-foaming agent is used?
A. The recommendation is to use an additional collection jar or canister as de-foaming agents will not offer adequate protection against fluid from the chest drain system.

Q. Does MDA/2010/040 apply both to suction systems using high-flow, low-vacuum regulators and to suction systems using thoracic regulators?
A. The potential for contamination of the hospital pipework, and the risk of aspirate activating the regulator safety valve to prevent contamination of the pipework leading to shut off of the vacuum to the chest drain unit is dependent on several factors, and can be higher when a high-flow low-vacuum regulator is used in the suction system than when a thoracic regulator is used, but inadvertent aspiration is possible with both types of suction regulator.
So, there would not be a safety issue if the advice in MDA/2010/040 was followed by those using a thoracic regulator. Indeed the MHRA would recommend that a local risk assessment is carried out when using a thoracic regulator to ensure that the suction system being used includes protection against the incident described in

MDA/2010/040, and users should be aware that some manufacturers of thoracic regulators may recommend the inclusion of an intermediate collection jar or canister in the suction system.

Q. What sort of additional container should be used?
A. MDA/2010/040 is advising that a collection jar or canister is included in wall mounted high-flow, low-vacuum systems connected to chest drainage bottles, similar to the collection jars or canisters which are a standard feature of the systems described in MDA/2005/035 - Suction systems including suction tubing, collection jar/canister and suction controller.

If you require further information or clarification regarding MDA/2010/040 or any of the above please contact:

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