



WG Technical Aspects: Presentation of the results

With a view to prepare and to motivate the initiation of a normalisation process of therapeutic hyperbaric Facility (HBO), the WG Technical Aspects has partially conducted a risk analysis, following an European analysis norm of the risk related to medical devices (EN 1441). The aim was, among others, to demonstrate the necessity of a normalisation, by identifying any danger linked to the use of a hyperbaric installation. For this, we have used annex C of the EN 1441 norm, which is a reminder aiming at identifying all possible dangers.

Five (different) types of danger have been studied :

- **Energy Hazards** (Electricity, heat, mechanical force, pressure, ...)
- **Biological hazards** (bio contamination, toxicity, pyrogenicity, ...)
- **Environmental hazards** (inadequate supply of power or coolant, incompatibility with other devices, ...)
- **Hazards related to the use of the device** (inadequate operating instructions, inadequate specification of accessories, use by unskilled/ untrained personnel, ...)
- **Hazards arising from functional failure, maintenance and ageing** (inadequacy of performance characteristics for the intended use, inadequate maintenance,...)

As a complement to this identification of dangers and with a view to make a combination (to cross) of all information findings (collection), a functional analysis has also been realised.

The results, which you can find in annex, are a detail of all dangers linked to the use of the HBO Facility, The general presentation follows the structure of the annex C of the EN 1441 norm. Within each type of danger, every element is identified with its kind of danger and its consequences for the patient (P), the accompanying personnel (A) and the operators (O).

Each identified danger can (may) have implications, follow-up into another type of danger (Cross Ref. Column)

This is a non exhaustive list of dangers. In fact, it's a first step which should bring us to a normalisation process. These results will therefore be integrated into the ongoing normalisation process, as well as into the future work of the WG Safety.

This study, a preliminary *sine qua non* to the settled objective, is a collegial achievement of the WG Technical Aspects members.

On behalf of the members of WGT,

Robert HOUMAN
Secretary

C2: ENERGY HAZARDS

| Items | Hazard/ type of error | Consequences | P | A | O | Cross Ref |
|-----------------------|---|--|---|---|---|-----------|
| ENVIRONMENT | Earthquake zone | Walls crash-collaps | X | X | X | |
| | High risk of flooding | Flooding of the chamber locals | X | X | X | |
| | High risk of pollution | Bad quality of compressed air | X | X | | 3, 4 |
| PREMISES | Room do not fit to receive the chamber | Patient's way is full of difficulties | X | X | X | 4, 6 |
| | Not enough space for ancillary rooms | Bad organization | X | X | X | 4 |
| | Not good foundation | Collapse of the frame | X | X | X | |
| MECHANICAL | Bad construction as cracks on: - steel plates; - forged pieces; - diaphragms; - elliptic ends; - portholes; - medical lock. | Collapse of the frame - crash - explosion when in pressure | X | X | X | 4, 6 |
| ELECTRICAL SERVICE | Short circuit of: - lighting system; - electric devices; - communication system. | Fire - explosion | X | X | X | 2, 4 |
| | Electric spark | Fire - explosion | X | X | X | 4 |
| | Electrostatic spark | Fire - explosion | X | X | X | 4 |
| | Spark from mechanical friction | Fire - explosion | X | X | X | 4 |
| FIRE PROTECTION | Bad working of fire fighting system | No fire extinguishing | X | X | X | 4, 5, 6 |
| COMPRESSED AIR SYSTEM | Bad working | Uncorrected compression or decompression protocole | X | X | | 3, 5, 6 |

| | | | | | | |
|---------------|---------------------------------|-----------|---|---|---|--|
| OXYGEN SYSTEM | Dirt inside circuit | Explosion | X | X | X | |
| | High pressure | Explosion | X | X | X | |
| | Rust inside piping | Explosion | X | X | X | |
| | Build up inside chamber | Explosion | X | X | X | |
| | High temperature inside circuit | Explosion | X | X | X | |
| | Bad lubrication | Explosion | X | X | X | |
| | Wrong gasket | Explosion | X | X | X | |

C3. BIOLOGICAL HAZARDS

1 – Risks linked to hardware : chambers and pressure part design and manufacturing

| Items | Hazard / type of error | Consequences | P | A | O | Cross Ref. |
|------------------------------|--|---|---|---|---|------------|
| | Over pressurisation above the rated working pressure | Damage to structures | X | X | X | 2, 5, 6 |
| | Pressurisation over the stop pressure | Decompression illness | X | X | | 5, 6 |
| | Pressurisation rate too fast | Rise in ambient temperature | X | X | | 2, 5, 6 |
| | Depressurisation rate too fast | Decompression illness Pulmonary barotrauma | X | X | | 2, 5, 6 |
| Chamber paint | Incorrect type | Contamination of chamber atmosphere | X | X | | 4 |
| Adequate Chamber ventilation | Contamination of chamber atmosphere | Inability to complete therapy | X | X | | 4, 6 |
| Reducers | Failure open / free-flow | Damage to pressure vessels / explosion / rupture | X | X | X | 4 |
| Exhausts | Inadequate size / not protected / not well placed to avoid pocketing of O ₂ | Noise / unnecessary ventilation / suction injury / blockage | | | | 4, 6 |
| Noise | Health hazard | Hearing loss | X | X | X | |

2 – Risks linked to hardware : Respiratory gases

| | | | | | | |
|---------------------------|--|---|---|---|---|---------|
| Medical Gases | Correct label/type/purity | Poisoning/Hypoxia | X | X | | 4, 5, 6 |
| Purity of gases | Contamination | Poisoning of inside personnel/hypoxia. Fire | X | X | | 4 |
| Purity of Air | Contamination | Poisoning of inside personnel/hypoxia. Fire | X | X | | 4 |
| Compressor air intakes | Incorrect position height etc. | Contamination of atmosphere | X | X | | 2 |
| Compressor high pressure | Faulty contaminated air | Poisoning of chamber personnel | X | X | | 2 |
| Compressor Low pressure | Faulty contaminated air | Poisoning of chamber personnel | X | X | | 2 |
| Purity of oxygen | Contamination | Poisoning of inside personnel/hypoxia. Fire | X | X | | 4 |
| Liquid Oxygen | Position / safe distances Cleanliness | Injury / off-gassing / Fire | | | X | |
| Purity of helium | Contamination | Poisoning of inside personnel/hypoxia. Fire | X | X | | |
| Quality calibration gases | Incorrect specification | Inaccurate analysers | X | X | | |
| Mixing of gases | High oxygen level | Cerebral/pulmonary oxygen toxicity | X | | | 4, 5, 6 |
| Mixing of gases | High Nitrogen partial pressure | Nitrogen narcosis | X | X | | 4, 5, 6 |

3 - Risks linked to hardware : gas breathing devices and associated pipes

| | | | | | | |
|-------------------------|--|--|---|---|---|---------|
| Reducers | Failure open / free-flow | Damage to BIBSs / explosion / rupture of pipes / damage to the patient | X | X | X | 4, 5 |
| BIBS | Contaminated/poor fitting/leaking. Breathing resistance | Raised ppO ₂ in chamber Fire risk Patient not receiving 100% O ₂ | X | X | X | 4, 5 |
| BIBS tracking regulator | Malfunction | Vacuum injury/pressure loss | X | | | 2, 4, 6 |
| | Allergenic substances | Allergic reaction | X | | | |
| | Transmission of infectious diseases | Infectious cutaneous, broncho-pulmonar or general diseases | X | | | 4, 5 |

4 - Risks linked to hardware : accessories / others

| | | | | | | |
|---|--|---|---|---|---|---------|
| Plastic | Non chamber compatible | Burning/off gassing Contamination | X | X | | 4, 6 |
| Inappropriate Materials/ furnishings | Static electrical discharge. Off gassing if burning | Fire | X | X | X | 4, 6 |
| Chamber Lights | Too Hot / Not bright enough | Fire/ heat source Medical procedures difficult | X | X | X | 2, 4, 5 |
| Speakers | Electrical short | Sparks / Fire | X | X | X | 2, 4, 6 |
| Heat Source | Over heating | Fire / Burn risk | X | X | X | 4 |
| Fire extinguishers | Incorrect type | Not function at depth/contaminated atmosphere | X | X | X | 5 |
| Equipment charging areas | Fumes/off gassing Electrical faults Heat | Electrical shock/ Fire | X | X | X | 4 |
| Loose Cables/Wires | Trapped/ Chaffing/Arching/Fire | Electrical Shock | X | X | X | 4 |

5 - Risks linked to chamber operations

| | | | | | | |
|--|---|--|---|---|---|------|
| Control panel alarms | Lack of function/ settings to high | Contamination/ Fire risk Hypoxia / Poisoning | X | X | X | 5, 6 |
| Humidity control | Incorrect safe level | Sparks /Fire/ Uncomfortable | X | X | X | 6 |
| Compression rates | Injury to personnel inside chamber | Barotrauma / Heat | X | X | | 5, 6 |
| Decompression rates | Injury to personnel inside chamber | DCI | X | X | | 5, 6 |
| Incorrect / Dirty Clothing | Contamination | Fire | X | X | X | 4 |
| Dirt/ Dust / Contamination | Poor house keeping | Contamination / Fire / Explosion / | X | X | X | 4, 6 |
| Banned Substances | Contamination | Fire / Off gassing | X | X | | 4, 6 |
| Banned equipment / Substances inside Chamber | Biggest single causes of accidents / Fire | Injury / Fire | X | X | X | 4 |
| Inappropriate cleaning chemicals | Contamination | Contamination of atmosphere. Scratching of view ports | X | X | | 4 |

| | | | | | | |
|--------------|--------------------------------|--|---|---|--|---|
| Water supply | Insufficient Volume/ clean/ | Unable to fight O ₂ rich fire Contamination / diseases | X | X | | 6 |
|--------------|--------------------------------|--|---|---|--|---|

6 - Risks linked to medical devices

| | | | | | | |
|--|--|---|----------|---|---|------|
| Equipment touch key pads | All come on together with compression / faulty | Patient vital equipment inoperable | X | | | |
| Laryngoscopes /Battery equipment | Incorrect batteries / sparking switch | Fire risk | X | X | X | 4 |
| Patient Ventilator | Affected by pressure / density of ambient pressure | Patient inadequately ventilated | X | | | 4, 5 |
| Artificial ventilation | Resistance of patient | Pulmonary barotrauma | X | | | 5 |
| Infusion Pumps | Affected by pressure / density of ambient pressure | Patient inadequately supplied with drug doses prescribed | X | | | 4, 5 |
| Intravenous infusions | Lack of sealing Ingress of bubbles | Gaseous embolisations | X | | | 5 |
| Bed/trolley type | Rams/Oil/ pneumatic | Contamination, loss of height of bed | X | X | | 4, 6 |
| Diabetic monitors | Affected by pressure | Inaccurate | <u>X</u> | | | 4, 6 |
| Patient Monitoring | Affected by pressure / density of ambient pressure | Inaccurate / can not change settings / failure | X | | | 4, 6 |

7 - Risks linked to managing the patient

| | | | | | | |
|---------------------------|-------------------------------------|--|---|---|---|------|
| Patient Changing areas | Lack off | Contamination of chamber environment/ Fire risk | X | X | X | 4, 6 |
| Infection Control | Poor standards/ inadequate | Cross infection of patients / Staff | X | X | | 4, 6 |
| Shoes/Overshoe s | Lack off / dirt / Oil in Chamber | Contamination / Fire | X | X | X | 4 |
| Patient Lockers | Lack off/ not lockable | Will mean patient will take banned substances into chamber/ Fire / Contamination | X | X | X | 4, 6 |

C4. ENVIRONMENTAL HAZARDS

| Items | Hazards/type of error | Consequences | P | A | O | Cross Ref. |
|--|---|--|---|---|---|------------|
| ENTRANCE TO CHAMBER | | | | | | |
| Entrance into the chamber | Inadequate construction, improper use, | Personnel injury, damage of material | X | X | X | 4, 6 |
| Incorrect/ Dirty Clothing | Contamination, electrostatic spark | Cross infection, Fire | X | X | X | 3, 4 |
| Shoes/Overshoes | Lack off / dirt / Oil in Chamber | Infection, Fire | X | X | X | 3, 4, 5 |
| Prohibited items | Contamination, Spark, malfunction | Cross infection, injury, fire | X | X | X | 3, 4 |
| BUILDING & CHAMBER | | | | | | |
| Building/ housing | Combustible/ insufficient fire protection | Inability to escape. Burns, lack of protection | X | X | X | 2, 4 |
| Building Architecture | Design | Injury / lack of safety / Lifting / Fire protection | X | X | X | 2, 4, 6 |
| Chamber ergonomics | Inadaptable device | Personnel Injury, damage of material | X | X | X | 4 |
| Medical lock size | Unable to quickly lock in/ out essential equipment | Poor quality care to patients/ dangerous due to delays with essential drugs More items inside than strictly necessary | X | | | 4 |
| Chamber paint | Non compatible | Poisoning | X | X | | 3, 4 |
| Plastic | Non compatible | Burning/off gassing, Contamination | X | X | X | 2, 3, 4 |
| Inappropriate cleaning chemicals | Contamination | Poisoning, damage of equipment | X | X | X | 3, 4, 6 |
| Environmental control unit/ Regenerator of air | Failure/ lack of regular maintenance | Infection, intoxication, Hypo and hyperthermia, sparks, fire | X | X | X | 4, 6 |
| Communication systems/External assistance | Inadequate, malfunctions, Can not call for assistance | Early termination of treatment, Poor quality care to patients Inability to call for urgent or any assistance | X | X | X | 2, 4, 6 |
| BIBS exhaust | Free flow/ Malfunction | Vacuum injury, leak into chamber atmosphere | X | X | | 2, 4, 6 |
| Mains electrical systems | Break down/ power cuts. | Inability to complete exposition safely | X | X | | 2, 4, 6 |
| Battery electrical systems | Hydrogen gas/ insufficient power / time | Explosion, Fire, Inability to complete exposition safely | X | X | X | 2, 4, 6 |
| UPS electrical systems | Not working when required, Sufficient time/power for emergency requirements | Inability to complete exposition safely | X | X | | 2, 4, 6 |

| | | | | | | |
|--|---|--|---|---|---|---------------|
| Emergency generator electrical systems | Not working when required, Sufficient time/power for emergency requirements | Inability to complete exposition safely | X | X | | 2, 4, 6 |
| Chamber ventilation | Inadequate ventilation, failure | Intoxication, | X | X | | 3, 4, 5, 6 |
| Infection Control | Poor standards/ inadequate | Cross infection | X | X | X | 3, 4, 5, 6 |
| Door seals/ "O" rings | Damage | No Compression / loss of pressure | X | X | | 2, 4, 5, 6 |
| Door weight/handles | Lack of door stops / doors not hung correctly | Physical Injury | X | X | X | 2, 4, 6 |
| Silencers | Dirty/ Blocked / corroded | Explosion, physical Injury | X | X | X | 2, 4, 6 |
| Pipework | Inadequate | Injury/ damage/ explosion | X | X | X | 2, 4, 6 |
| Pressure relief valves | Not large enough / incorrectly set / Faulty | Explosion, Damage to pressure hull, Injury | X | X | X | 2, 4, 6 |
| Reducers | Failure open / free-flow | Unintentional Increase of pressure | X | X | | 2, 3, 4, 5,6 |
| Equipment charging areas | Fumes/off gassing Electrical faults Heat | Intoxication, electrical shock, fire | X | X | X | 2, 3, 4, 6 |
| Exhausts | Inadequate construction, malfunction | Noise, O2 pockets, suction injury, DCS | X | X | | 2, 3, 4, 6 |
| Chamber Lights | Malfunction, short-circuit | Poor quality care to patients, fire | X | X | X | 2, 3, 4, 5, 6 |
| Heat Source | Over, lack of heat | Fire / Burn risk / Hypothermia | X | X | X | 2, 3, 4, 5, 6 |
| Loose Cables/Wires | Trapped/ Chaffing/Sparks | Electrical Shock, fire | X | X | X | 2, 3, 4, 5, 6 |
| Compressor high pressure | Faulty, contaminated air | Infection, intoxication | X | X | | 2, 3, 4, 5, 6 |
| Compressor Low pressure | Faulty, contaminated air | Infection, intoxication | X | X | | 2, 3, 4, 5, 6 |
| Oxygen supply | Malfunction, purity, amount | Hypoxia, DCI, fire | X | X | X | 2, 3, 4, 6 |
| Computers outside | Failure | Inability to complete treatment safely | X | X | | 2, 4, 5, 6 |
| Manifolds | Wrong position / inappropriate material / rating / erroneous labeling | Asphyxia, hypoxia, intoxication, DCI | X | X | | 2, 4, 5, 6 |
| INTERNAL EQUIPMENT | | | | | | |
| Internal fixed equipment | Not ergonomic | Personnel injury | X | X | X | 4 |
| Internal equipment | Un-allowed air pockets, malfunction | Damage, health hazard | X | X | | 4, 5, 6 |
| Internal battery equipment | Malfunction, sparks | Fire, health hazard | X | X | X | 2, 3, 4, 6 |
| Patient Ventilator | Malfunction, affected by pressure & density of gas | Hypo- hyperventilation, lung overpressure | X | | | 3, 4, 5, 6 |

| | | | | | | |
|--------------------|---|--|---|--|--|------------|
| Infusion Pumps | Malfunction, affected by pressure / density of ambient pressure | Patient inadequately supplied with drug doses prescribed | X | | | 3, 4, 5, 6 |
| Patient Monitoring | Malfunction, affected by pressure / density of ambient pressure | Poor quality care to patients | X | | | 3, 4, 5, 6 |
| Diabetic monitors | Affected by pressure | Inaccurate | X | | | 3, 4, 5, 6 |

C5. HAZARDS RELATED TO THE USE OF THE DEVICE

a) Inadequate labelling

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | CROSS REF. |
|------------------------|---|--|---|---|---|------------|
| Chamber | Main chamber with patient lock | No compression | X | | | 6 |
| | Confusion inlet valve with outlet valve | No compression | X | | | |
| Fire suppression | Confusion main chamber and personnel lock | Inability to stop a fire, accidental deluge | X | X | | 6 |
| Electrical power | Main chamber light | Darkness, panic, inability to observe patients | X | X | | 6 |
| | Alarms, warnings | Inability to detect technical problem: Overpressure, high PPO ₂ of the chamber atmosphere etc | X | X | X | 6 |
| | Loss of different functions i.e. TcPO ₂ , communication devices, TV, panel illumination etc. | Inability to perform the corresponding functions | X | X | | 6 |
| Breathing place number | If different gases are simultaneously used | Treatment failure, incorrect patient statistic, treatment evaluation etc | X | X | | 3 |
| Gases | Confusion O ₂ with air | DCI for personnel | X | X | | 3, 6 |
| | Confusion air with O ₂ | Fire risk, Oxygen toxicity | X | X | X | 3, 6 |
| | Confusion Helium with O ₂ | Asphyxia for personnel | X | X | | 3, 6 |
| | O ₂ with Mix | Therapeutic failure in patients, risk of DCI for personnel | X | X | | 3, 6 |
| | Mix with O ₂ | Oxygen toxicity | X | X | | 3, 6 |

b) Inadequate operating instructions

| Items | Hazard/Type of error | HARM/CONSEQUENCES | P | A | O | Cross Ref. |
|-------------|--|---|---|---|---|------------|
| Chamber | Fast compression Fast decompression Overpressurization | Barotrauma Oxygen toxicity | X | X | | 3, 6 |
| Gas: Air | Starting a treatment without enough supply | Aborted treatment | X | X | | 3, 6 |
| Gas: Oxygen | Starting a treatment without enough supply | Fire if use of lubricants, Aborted treatment | X | X | X | 3, 6 |
| Gas: Helium | Starting a treatment without enough supply | Inability to perform a saturation or deep treatment | X | | | 3, 6 |
| Gas: Gasmix | Starting a treatment without enough supply | Inability to perform a saturation or deep treatment | X | | | 3, 6 |
| Electricity | Unplugged device | No function, malfunction of device before or during treatment | X | X | X | 6 |
| Patients | Patient instructions | Barotrauma Oxygen toxicity Risk of fire if patients carry banned substances | X | X | X | 6 |

c) Inadequate specification of accessories

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | CROSS REF. |
|-------------------|---|--|---|---|---|------------|
| Fire suppression | Malfunction | Inability to stop a fire, accidental deluge | X | X | X | 2, 6 |
| Electrical power | Main chamber light | Darkness, panic, inability to observe patients | X | X | X | 6 |
| | Alarms, warnings | Inability to detect technical problem: Overpressure, high PPO ₂ of the chamber atmosphere etc | X | X | X | 6 |
| | Loss of different functions i.e. TcPO ₂ , communication devices, TV, panel illumination etc. | Inability to perform the corresponding functions | X | X | X | 6 |
| BIBS | If different gas are simultaneously used | Treatment failure, incorrect patient statistic, treatment evaluation etc | X | X | | 3 |
| Hoods | Reuse of old hoods | Rupture of the hood, risk of fire, interruption of treatment | X | X | X | 6 |
| Vacuum bottles | Not suitable for high pressure, Rupture of Glass/plastic | Lack of suction | X | | | 6 |
| Respirator | Not suitable for high pressure | Inefficient patient ventilation | X | | | 3, 6 |
| Infusion pumps | Not suitable for high pressure | False volume delivery | X | | | 3, 4, 6 |
| Infusions | Unsuitable for overpressure | Rupture, air insufflations in the patient's vein | X | | | 3, 4, 6 |
| TcPO ₂ | No or false readings under hyperoxia | False wound evaluation of TcPO ₂ | X | | | 4, 6 |
| EKG | No or false readings under pressure | Misinterpretation of results | X | | | 4, 6 |
| Blood pressure | No or false readings under pressure | Misinterpretation of results | X | | | 4, 6 |

g) Use by unskilled/untrained personnel

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|------------------|--|------------------------|---|---|---|------------|
| Chamber | Overpressure, prolonged exposure | Oxygen toxicity DCI | X | X | | 3, 6 |
| Compression rate | Fast compression or decompression | Barotrauma | X | X | | 3, 6 |
| IV lines | Introduction of air bubbles in the iv line | Air embolism | X | | | 3, 4, 6 |

h) Reasonably foreseeable misuse

| ITEMS | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|----------|----------------------|----------------------------------|---|---|---|------------|
| Oxygen | Sparks in chamber | Fire, explosion, oxygen toxicity | X | X | X | 2, 6 |
| Pressure | Overpressurization | Damage to chamber | X | X | X | 2, 3, 6 |

i) Insufficient warning of side effects

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|----------|---|---|---|---|---|------------|
| Patients | Missing selection of high risk patients | Increase of side effect (Oxygen toxicity, Claustrophobia, Barotrauma) | X | X | | 6 |

j) Inadequate warning of hazards likely with the reuse of a single use device

| ITEMS | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|---------|-----------------------|-------------------|---|---|---|------------|
| Filters | Reuse of mask filters | Contamination | X | | | 3, 4, 6 |

k) Incorrect measurement and other methodological aspects

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|-----------------------------|---------------------------|---|---|---|---|------------|
| Chamber pressure gauge | Pressure lower than real | Insufficient treatment | X | | | 6 |
| | Pressure higher than real | Risk of DCI in tenders Oxygen toxicity in patients | X | X | | 6 |
| Air supply gauge | Pressure lower than real | Premature interruption of treatment | X | | | 6 |
| | Pressure higher than real | None | | | | 6 |
| O ₂ supply gauge | Pressure higher than real | None | | | | 6 |
| | Pressure lower than real | Premature interruption of treatment | X | | | 6 |

l) Incorrect diagnosis

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|----------|--|---|---|---|---|------------|
| Patients | Insufficient response to complications | Oxygen toxicity, Barotrauma | X | X | | 6 |
| | Choice of treatment protocol | Ineffective treatment, risk of complication | X | X | | 6 |

m) Erroneous data transfer

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|--------------------|------------------------------|--|---|---|---|------------|
| Treatment number | False reporting (under/over) | Unjustified Treatment failure, false billing | X | | | 6 |
| Pressure | False reporting (under/over) | Medico legal implications in case of permanent disability in patient | X | X | X | 6 |
| Treatment duration | False reporting (under/over) | Medico legal implications in case of permanent disability in patient | X | X | X | 6 |

o) Incompatibility with consumables/accessories/other devices

| Items | Hazard/Type of error | Harm/Consequences | P | A | O | Cross Ref. |
|---------------------------|-----------------------------|--|----------|----------|----------|-------------------|
| Ventilator | Insufficient ventilation | Insufficient treatment | X | | | 3, 4, 6 |
| Infusion pumps | False volume delivery | Insufficient treatment | X | | | 3, 5, 6 |
| Infusions | Unsuitable for overpressure | Rupture, gas embolism | X | | | 3, 5, 6 |
| Vacuum bottles | Unsuitable for overpressure | Rupture, gas embolism / gas emphysemas | X | | | 3, 6 |
| IV lines | Air entrapment | Gas embolism | X | | | 3, 6 |
| Pomades, creams, oil pads | Flammable topical creams | Risk of fire | X | X | X | 4, 6 |
| Various | Flammability | Fire | X | X | X | 4, 6 |

C6. HAZARDS ARISING FROM FUNCTIONAL FAILURE, MAINTENANCE AND AGEING

1. Inadequacy of performance characteristics for the intended use

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF. |
|---|--|--|---|---|---|------------|
| Air compression | Failure on compression system: too fast, too slow, not enough, no compression | Overpressure, Unable to complete therapies, injury, Barotrauma / Heat | X | X | | 2, 3, 5 |
| Cylinder gas storage HP | Lack of volume / size | Unable to complete therapies if power cut | X | X | | |
| Cylinder gas storage LP | Lack of volume / size | Unable to complete therapies if power cut | X | X | | |
| Pipework for all gases | Inadequate / size / pressure rating / material | Unable to carry on treatment / injury damage/ explosion | X | X | X | 4 |
| Reducers | Failure open / free-flow | Damage to pressure vessels / explosion / rupture | X | X | X | 4 |
| Air decompression | Failure on decompression, Too slow, too fast, no decompression | DCI, | X | X | | 5 |
| Air ventilation | Not adequate, failure, Inadequate size / not protected / not well placed to avoid pocketing of O ₂ | FO ₂ increase, Fire danger, Hyperoxia, Noise / unnecessary ventilation / suction injury / blockage | X | X | X | 5 |
| Heating /Cooling | Insufficient / poor | Inability to complete treatments safely | X | X | | 4 |
| Humidification | Incorrect levels | Static/Sparks/ Fire /Shocks/Comfort | X | X | X | |
| Distribution of therapeutic gas | Not adequate, failure, leak O ₂ inside chamber | Fire danger, Hyperoxia | X | X | X | 3 |
| Self contained Breathing Apparatus (SCBA) | Not available/malfunction/ Staff not trained in its use. | Operators unable to stay to assist in the emergency evacuation of chamber personnel | X | X | X | |
| BIBS tracking regulator | Malfunction | Vacuum injury/pressure loss | X | X | | 4 |
| Gas distribution Panels | Poor design / Maintenance/ failure | Lack of gas inability to treat Incorrect gas/ hypoxia/ poisoning | X | X | | 3 |

| | | | | | | |
|--|---|---|---|---|---|---------|
| Control panel | Not adequate (ergonomic), failure, | Positioning, accident | X | X | X | 3, 5 |
| Control panel alarms | Lack of function/ settings to high | Contamination/ Fire risk Hypoxia / Poisoning | X | X | X | 3, 5 |
| Watch systems and alarms (passive), Analyzers, ... | Not adequate, failure, Lack of function | Contamination/ Fire risk Hypoxia / Poisoning | X | X | X | 3, 5 |
| Protective systems (active), Sprinkler | Not adequate, failure, Lack of function | Contamination/ Fire risk Hypoxia / Poisoning | X | X | X | 2, 3, 5 |
| Fire extinguishers | Incorrect type | Not function at depth/contaminated atmosphere | X | X | X | 2, 3, 5 |
| Fire suppression Outside chamber | Lack of function/ Maintenance | Inability to fight fire Injury to personnel | X | X | X | 2, 3, 5 |
| Fire explosive hazards | Lack of care in following standard operating procedures | Fire / Hazards/ Injury | X | X | X | 2 |
| Temperature control | Hyper-/ Hypothermia | May require early termination of treatment | X | X | | 3, 4, 5 |
| Software | Malfunction | Therapy terminated early | X | X | | 3, 4, 5 |
| Equipment touch key pads | All come on together with compression / faulty | Patient vital equipment inoperable | X | | X | 3, 5 |
| Communications/ Primary | Poor quality | Confusion / Errors / Panic | X | X | | 3, 5 |
| Communications/ Secondary | Not functioning | Panic / incorrect actions / injury / lack of communications | X | X | | 3, 5 |
| Speakers | Electrical short | Sparks / Fire | X | X | X | 2, 3, 5 |
| Lighting primary | Inadequate | Mistakes at work | X | X | | 5 |
| Lighting secondary | Lack of maintenance | Inability to complete treatments safely | X | X | | 5 |
| Ergonomics in and outside the chamber | Not adequate | Injuries to personnel | X | X | X | 2, 3 |
| Patient Access | Steps / Door widths / Wheel chair access | Delays / Lifting / Injury | X | X | | 2, 3, 4 |
| Door weight/handles | Lack of door stops / doors not hung correctly | Injury to personnel | X | X | X | 2, 3, 4 |
| Silencers | Dirty/ Blocked / corroded | Explode / fracture / Injury | X | X | X | 4 |

| | | | | | | |
|-------------------------------|---|--|---|---|---|------|
| Pressure Gauges | Inaccurate | Decompression Illness | X | X | | 5 |
| Equipment tagging & numbering | Inadequate/ incorrect | Break down / failure Unable to treat patients | X | X | | 5 |
| Equipment charging areas | Fumes/off gassing Electrical faults Heat | Electrical shock/ Fire | X | X | X | 4 |
| Accessories | Not adequate, failure | Explosion, Fire, Injury | X | X | X | 3, 5 |
| Medical records | Incorrect for patient / Inadequate / not complete / up to date /available | Poor quality of care | X | X | | 5 |
| Mains electrical systems | Break down/ power cuts/ Not adequate | Inability to complete treatments safely | X | | X | 2, 5 |
| Battery electrical systems | Hydrogen gas/ insufficient power / time | Inability to complete treatments safely | X | | X | 4 |
| UPS electrical systems | Sufficient time/power for emergency requirements | Inability to complete treatments safely | X | | X | 4 |
| Generator electrical systems | Not working when required | Inability to complete treatments safely | X | | X | 4, 5 |
| Personal | No adequate education | Accident, safety not assured | | X | X | 5 |

2. Lack of, or inadequate specification for maintenance, including inadequate specification of post maintenance functional checks,

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|--|---|--|---|---|---|-----------|
| Safety inspection | Not adequate/ regularly | Potentially harmful conditions | X | X | X | 5 |
| User manual | Not adequate, (no identification of each element) | Damage, Injury, failure | X | X | X | 5 |
| Technical Documentation | Not adequate | Damage, Injury, failure | X | X | X | 5 |
| Compressor filtration system | Failure/ lack of regular maintenance | Contamination/ Injury | X | X | X | 3 |
| Environmental control unit/ Rain | Failure/ lack of regular maintenance | Contamination/ Injury | X | X | X | 4 |
| View Ports | Damage /Scatched/ Out of date | Severe pressure loss Decompression Illness | X | X | X | |
| Back up machinery | Inadequate/ lack off Not serviced. maintained | Break down / failure Unable to treat patients | X | | X | 4 |
| Patient monitoring | Failure/ lack of regular maintenance | Inaccurate / injury | X | X | X | 3, 4, 5 |
| O ₂ Analyzers/ Primary | Failure cell expired Inaccurate / maintenance | Too high PP0 ₂ Fire risk | X | X | X | 3, 4, 5 |
| O ₂ Analyzers/ Secondary | As above & Needs to agree with primary | Too high PP0 ₂ Fire risk | X | X | X | 3, 4, 5 |
| CO ₂ analyzers | Failure/ inaccurate | Contamination/ inadequate flushing/ ventilation/ poisoning | X | X | X | 3, 4, 5 |

| | | | | | | |
|--|---|---|---|---|---|---------|
| CO ₂ Scrubbers | Noise/chemical burns/ corrosion. Electrical faults. | Contamination/ inadequate flushing/ ventilation/ poisoning | X | X | X | 4 |
| Door seals/ "O" rings | Damage | No Compression / loss of pressure | | X | X | 2, 4, 5 |
| Valves needle | Lack of maintenance | Lack of compression / Supply | | X | X | |
| Fire suppression Inside chamber | Tested/function for hyperbaric environment And gas density. Electrical connection trip | Inadequate fire suppression & electrical shock | X | X | X | 2, 3, 5 |
| Power fuses Switchboards | Bad position / incorrect rating / faulty trips / resets | Lack of power for life support | | | X | 2, 3, 5 |
| Liquid Oxygen | Position / safe distances Cleanliness | Injury / off-gassing / Fire | X | X | X | 4 |
| Computers & VDU's | Failure inside or outside chamber. Affected by pressure. Heat | Lack of compression Inability to treat patients Inability to finish treatment Heat/ Fire | | | X | 2, 3, 5 |
| Unauthorized chamber equipment | Malfunction / Fire. Contamination / Electric Shock | Malfunction / Fire. Contamination / Electric Shock | X | X | X | 4, 5 |
| Humidity control | Incorrect safe level | Sparks /Fire/ Uncomfortable | X | X | X | 3, 5 |
| Banned equipment / Substances inside Chamber | Biggest single causes of accidents / Fire | Injury / Fire | X | X | X | 3, 4, 5 |
| Patient Lockers | Lack off/ not lockable | Will mean patient will take banned substances into chamber/ Fire / Contamination | X | X | X | |
| Patient Ventilator | Affected by pressure / density of ambient pressure | Patient inadequately ventilated | X | X | | 3, 4, 5 |
| Infusion Pumps | Affected by pressure / density of ambient pressure | Patient inadequately supplied with drug doses prescribed | X | X | | 3, 4, 5 |
| Patient Monitoring | Affected by pressure / density of ambient pressure | Inaccurate / can not change settings / failure | X | X | | 3, 4, 5 |
| Bed/trolley type | Rams/Oil/ pneumatic | Contamination, loss of height of bed | X | X | X | 3, 4 |
| Diabetic monitors | Affected by pressure | Inaccurate | X | X | | 3, 4, 5 |
| Loose Cables/Wires | Trapped/ Chaffing/Arching/Fire | Electrical Shock | X | X | X | 2 |

3. Inadequate maintenance,

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|-------------------------|--|--|---|---|---|-----------|
| User manual | No determination of each responsibility, | Lack of planned maintenance/ breakdown | | | X | 5 |
| Duties of staff | Personnel unclear of their duties | Injury/ damage | | X | X | 5 |
| Equipment maintenance | Break down | Unable to treat patients | X | X | X | 5 |
| Equipment documentation | Lack of adequate records | Lack of planned maintenance/ breakdown | | | X | 5 |

4. Lack of adequate determination of end of device life,

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|-------------|-----------------------------|--------------------|---|---|---|-----------|
| User manual | Work safety of the facility | Damage, injury | | | X | 5 |

5. Loss of mechanical integrity,

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|------------------------|---|---------------------------------------|---|---|---|-----------|
| Mechanical elements | Work safety of the facility | Damage, injury | X | X | X | 2 |
| Valves 1/4 turn | Lack of maintenance | Lack of compression / Supply/ Exhaust | | | X | |
| Non Return Valves | Lack of maintenance | Reduced gas flow too slow compression | | | X | |
| Pressure relief valves | Insufficient size/ faulty | Damage to pressure hull | | | X | 4 |
| Manifolds | Position / material / rating / labeling | Incorrect gases supplied / Injury | X | X | X | 4, 5 |

6. Inadequate packaging (contamination and/ or deterioration of the device),

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|-------|---|--|---|---|---|-----------|
| BIBS | Contaminated/poor fitting/leaking. Breathing resistance | Raised PPO ₂ in chamber Fire risk, Patient not receiving 100% O ₂ | X | X | X | |

7. Improper re-use

| ITEMS | HAZARDS/ TYPE OF ERROR | HARM/ CONSEQUENCES | P | A | O | CROSS REF |
|-------------|------------------------|--------------------|---|---|---|-----------|
| Accessories | Contamination | Cross infections | X | X | | 3, 4 |