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MEGA

MEDICAL GAS CYLINDERS COLOUR CODING

TD 09/15/E

MIDDLE EAST GASES ASSOCIATION (MEGA)

European Business Center, Office BC – 25

Dubai Investments Park, PO Box: 166 Dubai-UAE

Tel: +971-4-8135525 / Fax: +971-4-8135575 / E-mail: info@megases.org, www.megases.org

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1. INTRODUCTION

Across the Middle East, there are no clear standards for colour coding of cylinders for different product lines and specifically for medical use. The prevalence of large numbers of different colour codes for the same product line within the companies under MEGA is regarded as misleading and being potentially hazardous. Hence there is a high risk of the wrong product(s) being filled if the labels are not legible.

The hazards associated with filling a wrong product into cylinders can result in loss of production, property damage and injury to personnel. The adoption of this guideline should mitigate the risks. Whilst the product label fitted to a medical gas cylinder remains the primary means of identifying the product it contains, cylinder colour coding is routinely used as the secondary means of identification to ensure that the correct product is chosen to administer to the patient. European standard EN 1089-3 2011, Transportable gas cylinders - Gas cylinder identification (excluding LPG) - Part 3: Colour coding, has been published to provide the details about the colours that should be used to identify the gas contained in cylinders, including those used for medical purposes.

An essential requirement for all medical gas cylinder users, in order to promote patient safety, is that a harmonised approach should be adopted across the Middle East for the colour coding of gas cylinders.

This document deals with the colour coding of medical gas cylinders and provides information to both the suppliers and the users of the medical gas cylinders.

It also provides an interpretation of the EN standard and how it should be applied to all cylinders dedicated for medical use.

2. SCOPE AND PURPOSE.

2.1. Scope

The aim of this document is to propose to all member companies under MEGA to follow this guideline for colour coding for cylinders and achieve a fully harmonised colour coding system. It applies specifically to medical gases and mixtures for medical use.

The term 'medical gas cylinder' is used in this document to define any cylinders containing a gas or mixture of gases intended to be:

- Administered to patients for therapeutic, diagnostic or prophylactic purposes, with or without pharmacological action (medical gas);
- Used as a medical device, where it can be used to drive surgical tools or administered to the patient where its intended use is not for pharmacological effect (medical gas) .

Therefore in this document the term 'medical' stands for both 'medicinal' and 'medical device' gases.

The industrial gases, such as gases used as Active Pharmaceutical Ingredient (API) and Excipients used in the pharmaceutical industry, are considered as industrial gases and colour coded accordingly.

2.2. Purpose

The purpose is to unify the colour coding for medical gas cylinders.

All new cylinders to be put into service after publication and approval of concerned Authorities of this guideline shall follow it immediately.

All existing cylinders should follow this guideline after its publication and approval of concerned Authorities by latest 31st December 2019.

The purpose of this document is to provide guidance to all medical gas cylinder suppliers on how to apply the colour coding principles.

It is also intended that this document shall provide guidance to national Regulatory Authorities about the correct use of colour coding to identify the gas contained in a medical gas cylinder.

3. CYLINDER COLOUR CODING PRINCIPLES

This guideline was introduced as a regional guideline covering the countries under MEGA in order to replace (or establish) national standards/local practices or the colour coding of gas cylinders, so that there could be a common approach to colour coding of all cylinders across Middle East.

The basic principles used in this guideline for the colour coding of cylinders was that only the shoulder of the cylinders should be used to define either the product or the hazard associated with the gas . The basic principles used in EN 1089-3 for the colour coding of cylinders was that only the shoulder of the cylinders should be used to define either the product or the hazard associated with the gas .

For cylinders in medical gas service, this new guideline document now defines both the specific colours to be used for the shoulders of most common medical gas / gas mixtures as well as specifying that the bodies of all medical gas cylinders shall be painted white. For those medical gases / gas mixtures not specified in the standard, it defines that the colours used for the cylinder shoulder shall relate to the associated hazards of the gas or gas mixture.

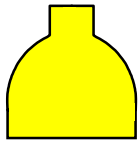
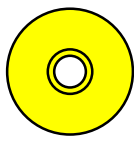
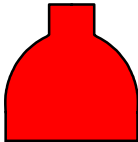
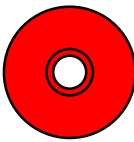
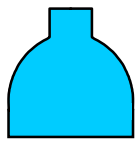
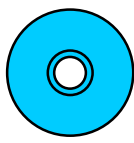
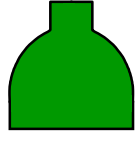
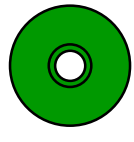
This has the benefit of differentiating between medical and non-medical gas cylinders as well as identifying the gas contained in the cylinder.

4. COLOUR CODING – CYLINDER SHOULDER

4.1. Basic hazard colour coding

For those medical gases gas mixtures not specified within the standard, the colour coding of the cylinder shoulder is determined by the hazard associated with the contents as prescribed by the transport labels.

The four categories are defined below:

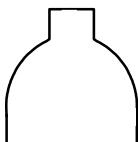
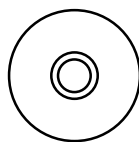
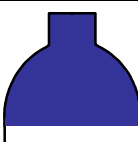
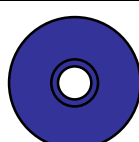
| Gas property ² | Shoulder colour | | RAL number | |
|---------------------------|-----------------|---|--|------|
| Toxic and/or corrosive | Yellow |  |  | 1018 |
| Flammable | Red |  |  | 3000 |
| Oxidising | Light Blue |  |  | 5012 |
| Inert ¹ | Bright Green |  |  | 6018 |

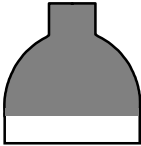

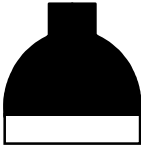


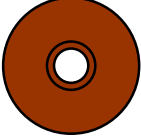




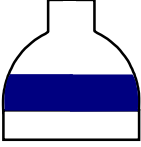
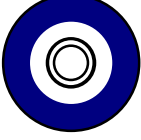

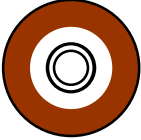
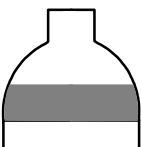
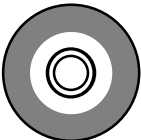
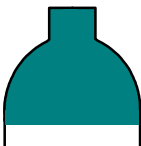

Note 1 Inert is considered to be a non-toxic and/or non-corrosive, non-flammable and non-oxidizing gas with an oxidising potential of less than 23.5%. However, for medical gases, inert usually means having less than 20.0% oxygen within the medical gas mixture.

Note 2 The table gives the scale of hazard in descending order. When a gas has more than one hazard, colour coding of the shoulder is defined by highest hazard as above.

4.2. Cylinder shoulder colours

This guideline specifies the colour coding for the most commonly used medical gases and medical gas mixtures as described in section 2.1 :

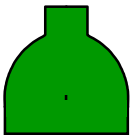
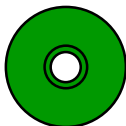

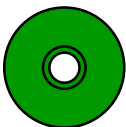

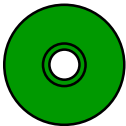
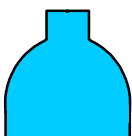

| Gas / gas mixture for medical use | Shoulder colour | | RAL number | |
|-----------------------------------|-----------------|--|---|------|
| Oxygen | White |  |  | 9010 |
| Nitrous Oxide | Blue |  |  | 5010 |

| Gas / gas mixture for medical use | Shoulder colour | | RAL number | |
|--------------------------------------|---|--|---|-----------|
| Carbon Dioxide | Grey |  |  | 7037 |
| Nitrogen | Black |  |  | 9005 |
| Helium | Brown |  |  | 8008 |
| Argon | Dark Green |  |  | 6001 |
| Medical Air / Synthetic Air | White/Black |  |  | 9010/9005 |
| Nitrous Oxide/Oxygen | Blue/White |  |  | 5010/9010 |
| Helium/Oxygen | Brown/White |  |  | 8008/9010 |
| Carbon Dioxide/Oxygen | Grey/White |  |  | 7037/9010 |
| Nitric Oxide/Nitrogen | Turkish Blue if NO < 1000 ppm (V/V) |  |  | 5018 |

There are a number of other gases used for medicinal purposes. The colour coding used for these gases shall be defined by the basic hazard codes defined above.

As examples, the most commonly used non-specified products, listed below, shall have the following colour coding for the cylinder shoulder colour, based on the product hazard and shall have white bodies to signify that they are for medical use.

The principles used to define the colour coding for these gases / mixtures can be applied to any gas / mixture.

| Gas / gas mixture for medical use | Shoulder colour | | RAL number | |
|--|-----------------|--|---|------|
| Xenon | Bright Green |  |  | 6018 |
| Sulphur Hexafluoride | Bright Green |  |  | 6018 |
| 0.3% Carbon Monoxide/ 9% Helium/ 21% Oxygen/Balance Nitrogen | Bright Green |  |  | 6018 |
| 9% Helium/ 35% Oxygen/Balance Nitrogen | Light Blue |  |  | 5012 |

When a medical gas has more than one hazard property, the greatest hazard (see note 2 table 4.1) is used to define the colour code.


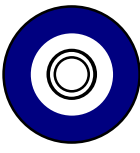
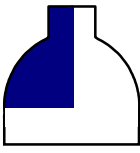
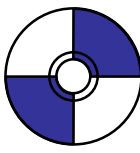

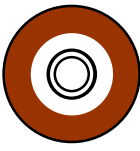
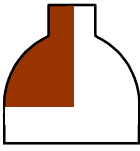
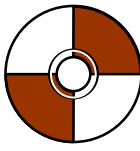




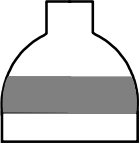
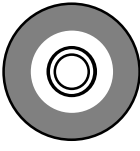
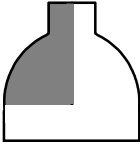
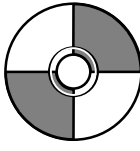
The colour of the secondary hazard property may also be given in the form of a band or segment, but in most cases for medical gases only the colour of the principal hazard is used.

4.3. Cylinder shoulder banding

Where the colour coding requires two colours to be applied to cylinders, this may be done either by applying the colours by banding or by quartering.

Banding requires the colour to be applied as a solid band (approximately half the depth of the shoulder) around the circumference of the cylinder. Where one of the bands signifies that oxygen is present in the mixture, the white band should be at the top (so as not to be confused with the cylinder body colour).



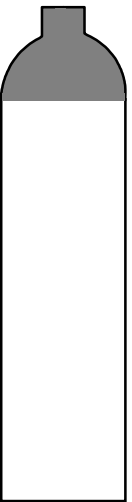
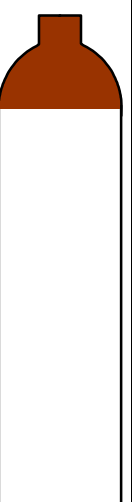


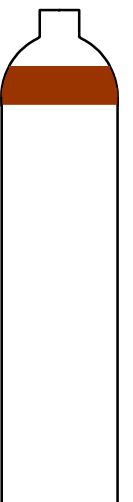
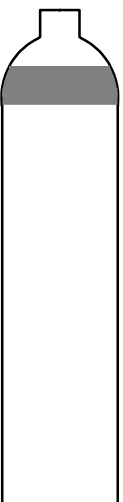
Typical examples of banding and quartering are shown in the table below :

| Medicinal gas mixture cylinder shoulder painting options | | | | |
|--|--|--|--|--|
| | Banding | | Quartering | |
| Oxygen / Nitrous Oxide |  |  |  |  |
| Oxygen / Helium |  |  |  |  |
| Medical Air / Synthetic Air |  |  |  |  |
| Oxygen/ Carbon Dioxide |  |  |  |  |

5. CYLINDER BODY

All cylinders used for medical gases / medical gas mixtures shall be painted with a white body, with only the shoulder being painted to the defined product colour code requirements.

For the main gases, the following overall colour coding of the cylinder shall be as defined below:

| Medical cylinder body colours | | | | | | | |
|---|---|---|---|---|--|---|---|
| Oxygen | Nitrous Oxide | Carbon Dioxide | Helium | Oxygen / Nitrous Oxide | Medical Air / Synthetic Air | Oxygen / Helium | Oxygen/ Carbon Dioxide |
|  |  |  |  |  |  |  |  |

White bodied cylinder shall not be used for any other non-medical application (including breathing gas mixtures)

Gases and gas mixtures used as starting material or intermediates in the manufacturing of gases for medical use shall not be painted with a white cylinder body.

PS. Cylinders from USA (examples M and E types) made of aluminium only have the shoulder colour coded, and the body left unpainted or painted with an excess-temperature-indicating-coating. Painting the body of such cylinders would diminish rather than enhance safety.

6. CYLINDER VALVE GUARD COLOUR CODING

There is no colour code in this guideline for the cylinder valve guard or protection cap in accordance with the colours defined for the cylinder shoulder. When applicable cylinder cap/guard may be painted to white colour to match the cylinder body.

7. CYLINDER BUNDLES

Cylinder bundles should have the same colour code as individual cylinders as described in this guideline.

8. MEDICAL GAS MIXTURE: MIXTURES USED FOR INHALATION (WITH OXYGEN CONTENT BELOW 23.5%)

For the hazard identification in this guideline, an oxidising gas is defined as a gas containing more than or equal to 23.5% oxygen. If the gas has no other associated hazards (not toxic or flammable), the gases with oxygen below 23.5% are considered to be inert.

Medical gas mixtures, intended for the patient to breath, will often contain oxygen at a level below 23.5%. Typical mixtures used for medical purposes include:

- Lung Function Test Gases – where the oxygen content is normally specified at 21.0%. These mixtures are intended for the patient to breath.

Note: These mixtures can also contain toxic or flammable gases at low levels (normally at 0.3%), such as carbon monoxide, methane and/or acetylene, but the concentration of the flammable gas is normally well below the flammable limit and do not require the cylinder to be colour coded as either flammable or toxic.

- Fitness to fly medical test gases, with a typical composition of 15% oxygen, balance nitrogen. These mixtures are intended for the patient to breath, only under the supervision of a Healthcare Professional.
- Standard blood gas testing gases, with a typical composition of 20% oxygen, 5% carbon dioxide, balance nitrogen. These gases are not intended for breathing.
- Aerobic blood culture gases, with a typical composition of 20.7% oxygen, 2.5% carbon dioxide, balance nitrogen. These gases are not intended for breathing.

Although some of these gases are intended for breathing, so as to be in accordance with this guideline, they do require to be colour coded as inert (with a bright green shoulder).

This does not indicate that the gas is an asphyxiant and they are suitable for administration to patients (where relevant) by a Healthcare Professional.

9. GAS COMPANIES' RESPONSIBILITIES

Prior to fill and delivery of cylinders, gas companies have the responsibility to ensure that the cylinders are correctly labelled and painted accordingly as per above.

10. REFERENCES

- EIGA Document – MGC Doc 177/13/E, Medical Gas Cylinders Colour Coding
www.eiga.eu
- European standard EN 1089-3 2011 Transportable gas cylinders - Gas cylinder identification (excluding LPG) - Part 3: Colour coding