

MEDICAL GAS CYLINDERS COLOUR CODING

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MEDICAL GASES CYLINDERS COLOUR CODING

Prepared by WG-7 Medical and Breathing Gases

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Amendments to 177/13

Section	Change
5.2	Reference to Medical Device Regulation
8	Update reference to EN ISO 10961
9	Change of title

NOTE Technical changes from the previous edition are underlined

1 Introduction

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.

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

This publication deals specifically 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 scope of this publication covers the colour coding of cylinders used for medicinal and medical gas use, used within Europe where EN standards are applied. It may also be used in other countries / territories, where there is no national colour coding standard.

The term 'medical gas cylinder' is used in this publication 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 (medicinal 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 publication the term 'medical' stands for both 'medicinal' and 'medical device' gases.

The gases used as Active Pharmaceutical Ingredient (API) and excipients, used in the pharmaceutical industry, are considered as industrial gases according to the colour coding requirements and therefore appropriately colour coded accordingly, unless there are specific national requirements.

2.2 Purpose

The purpose of this publication is to provide guidance to all medical gas cylinder suppliers on how to apply the colour coding principles outlined in EN 1089-3.

It is also intended that this publication 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 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

4 Cylinder colour coding principles

EN 1089-3 was introduced as a European standard in order to replace all national standards for the colour coding of gas cylinders, so that there could be a common approach to colour coding of all cylinders across Europe.

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 medical gases, specific colours were assigned to the commonly used medicinal gases.

In the previous revision of the standard (published in 2003), the cylinder body colour was not defined, leaving it to the gas cylinder owner to use whichever colour they wanted provided it did not create any confusion with the shoulder colour.

For cylinders in medical gas service, it 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.

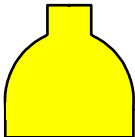

This has the benefit of differentiating between medical and non-medical gas cylinders as well as identifying the gas contained in the cylinder.

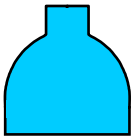
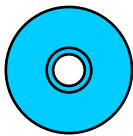

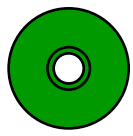
5 Colour coding – cylinder shoulder

5.1 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	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, the colour coding of the shoulder is defined by highest hazard as above

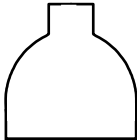
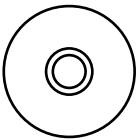
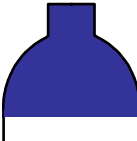
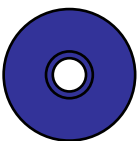
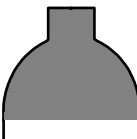

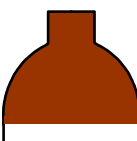
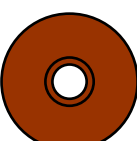


5.2 Cylinder shoulder colours




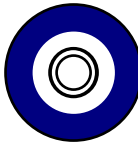

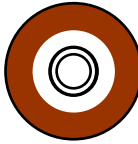
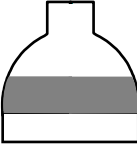
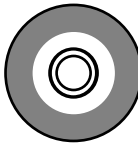
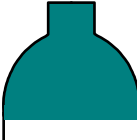
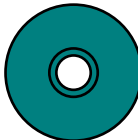
EN 1089-3 specifies the colour coding for the most commonly used medical gases and medical gas mixtures.

This includes:

- medicinal gases, as defined in EC Directive 2001/83 and used to administer to the patient (such as oxygen and nitrous oxide), and
- medical gases, defined as in the Medical Device Regulation (EU) 2017/745 and used as a medical device (such as carbon dioxide)

The colour coding specified for the gases covered by the standard include:

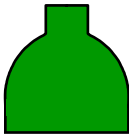
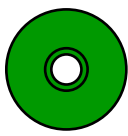

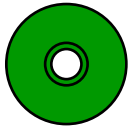

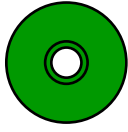
Gas / gas mixture for medical use	Shoulder colour			RAL number
Oxygen	White			9010
Nitrous Oxide	Blue			5010
Carbon Dioxide	Grey			7037
Helium	Brown			8008
Argon	Dark Green			6001

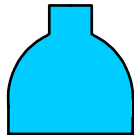
Gas / gas mixture for medical use	Shoulder colour			RAL number
Medical Air / Synthetic Air	White/Black			9010/9005
Nitrous Oxide/Oxygen	Blue/White			5010/9010
Helium/Oxygen	Brown/White			8008/9010
Carbon Dioxide/Oxygen	Grey/White			7037/9010
Nitric Oxide/Nitrogen	Turkish Blue if NO <= 1000 ppm (V/V)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

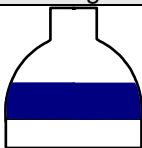
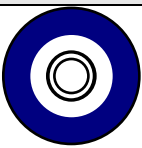
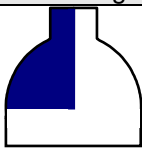
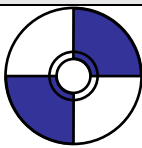
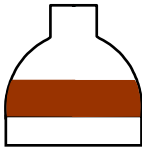
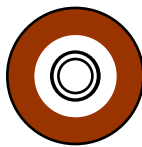

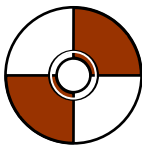

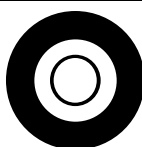
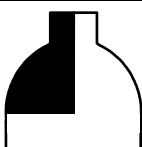

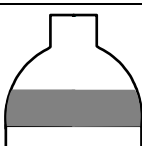
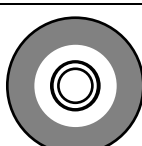
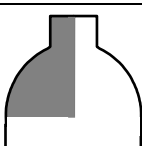
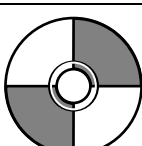
The colour of the secondary hazard property may also be given in the form of a band or segment, but in most cases for medical gases only the colour of the principal hazard is used.

5.3 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:

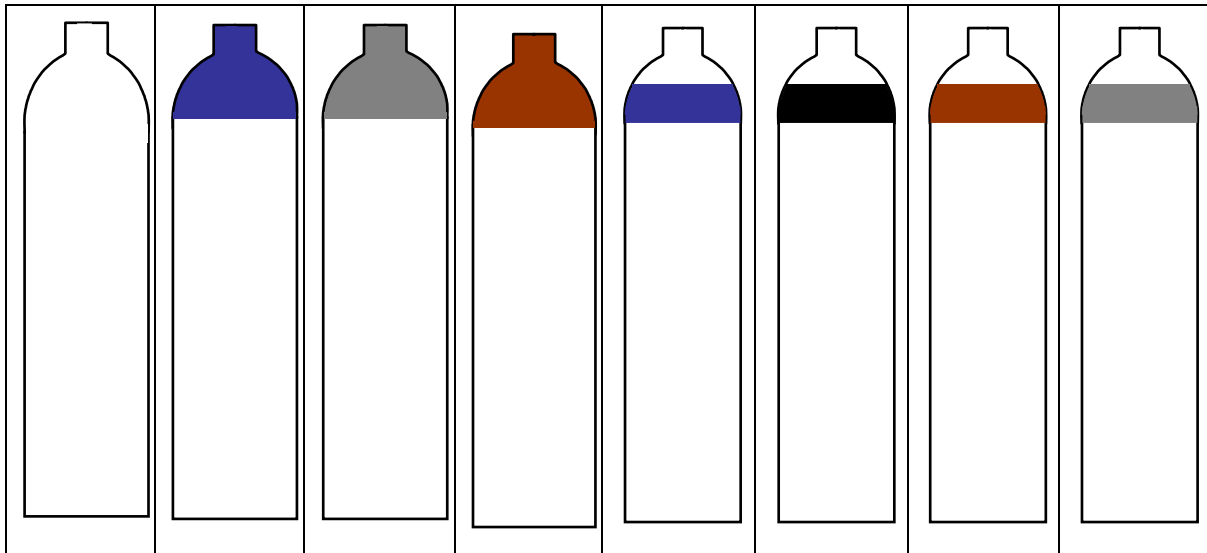
Medicinal gas mixture cylinder shoulder painting options				
	Banding		Quartering	
Oxygen / Nitrous Oxide				
Oxygen / Helium				
Medical Air / Synthetic Air				
Oxygen/ Carbon Dioxide				

6 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 medical device gases, in some countries this a not a regulatory requirement.

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.

7 Cylinder valve guard colour coding

There is no requirement within EN 1089-3 to colour code the cylinder valve guard or protection cap in accordance with the colours defined for the cylinder shoulder.

8 Cylinder bundles

There is no requirement in EN 1089-3 to colour code the cylinders used in cylinder bundles.

EN ISO 10961, Gas cylinders — Cylinder bundles — Design, manufacture, testing and inspection, does not specify any rules for painting the shoulder or the body of cylinders. For transport within Europe the applicable requirements of the European Agreement on the Carriage of Dangerous Goods, (ADR), shall be followed for marking for transport, and for labelling for use the requirements of the Classification, Labelling and Packaging, (CLP) Regulations shall be followed.

If it is decided to colour code the cylinders in cylinder bundle, then the principles of EN 1089-3 shall be followed.

9 Medical gas mixture with oxygen content below 23.5%

For the hazard identification in EN 1089-3, 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 an inert.

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 only breath 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 EN 1089-3, they do require being 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.

10 References

Unless otherwise specified, the latest edition shall apply.

Document 177 can be found on www.eiga.eu