

ISO Standards for MDI / DPI and Nebulizers

ISO CD 27427 – Nebulizers and nebulizing systems

11/7/06

Breakout Session
Track D

ISO CD 27427 – Nebulizers and nebulizing systems

- n New work item proposal (NWIP) submitted by the ISO Italian member body.
- n Based on *European Committee for Standardization. Respiratory therapy equipment. Part 1: nebulizing systems and their components. Lisbon: European Committee for Standardization; 1999 (2006).*
- n The original series of European standards consisted of three parts: nebulizers, connectors, and nebulizer compressors.
- n International Organization of Standardization (ISO) circulated the NWIP in 2006
- n International Electrical Committee (IEC) circulated the NWIP in 2006

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|-------------|----------------------|
| n Australia | n Italy |
| n Belgium | n Japan |
| n Brazil | n Korea |
| n Canada | n Russian Federation |
| n Denmark | n Sweden |
| n France | n Switzerland |
| n Germany | n United Kingdom |
| n Ireland | n United States |

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Concerns were raised by both ISO 84 and ISO 121 members about potential overlap of the scope between ISO CD20072 (ADDD) and ISO CD 27427 (Nebulizers).

A telecon was held between ISO TC/84 WG/5 (managing ISO CD 20072) and ISO TC/121 SC/2 (managing ISO CD 27427) and review of the scope of both standards was undertaken.

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ISO CD 27427 – Nebulizers and nebulizing systems - Comments

The first ISO meeting for nebulizers was held in Helsinki Finland, June, 2006. During the ballot period, comments were received and these were discussed in a general way with the technical experts present.

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ISO CD 27427 – Nebulizers and nebulizing systems-participants

W. John Russell (AU) HOD	Adele Bindon (NZ)
Mark Fajgren (AU)	Brett Whiston (NZ)
Jeremy Sloan (CA) HOD	erry Longman (UK) HOD
John Dennis (CA)	John Stevens (UK) CEN TC/215
Jolyon Mitchell (CA)	Ronnie Greenbaum (UK) Chair ISO TC/121
Markus Tservistas (DE) HOD	Julian Goldman (US) Chairman ISO TC/121 SC/2
Niels Lomholt (DK) HOD	Ann Graham (US) Secretary ISO TC/121 SC/2
Gilles Chantrel (FR)	Robert Virag (US)
Francois Simondet (FR) HOD	Len Berman (US) HOD
Laurent Vecellio (FR)	Lana Lyapustina (US)
Giorgio Fusato (IT) HOD	Kirt Nikander (US)
Alberto Rivetti (IT)	Tim Hancox (ISO/CS)
Tetsuo Inoue (JP) HOD	David Upstone (UK) Secretary ISO TC/121
Akinori Sueoka (JP)	

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The subcommittee agreed to use *prEN 13544-1 Respiratory Therapy Devices – Nebulizing systems*, as amended in Lubeck, April 23, 2006, as the base document for the ISO draft standard development.

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ISO CD 27427 – Nebulizers and nebulizing systems – Scope

The scope and recommendations are consistent with and complementary to those of the TC 84/ WG 5 document.

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ISO CD 27427 – Nebulizers and nebulizing systems - Scope

- n This draft International standard specifies requirements for nebulizing systems used for the delivery of drugs in an aerosol form to humans through the respiratory system. It includes gas-powered nebulizers which may be derived from e.g. compressors, pipeline systems, cylinders etc., or electrically-powered nebulizers (e.g. ultrasonic) or manually-powered nebulizers.
- n This draft International standard does not include nebulizers precharged or intended for use with a specific medicinal product (ISO CD 20072).

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ISO standard for nebulizers should be built on risk management and Quality-by-Design initiatives

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The standard should make it clear that its intention is to assist in design verification of the device not the medicinal product. Testing of the medicinal product will be addressed by the monographs for nebulization products, which are being developed by the US and European Pharmacopeias.

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Meaningful methods for characterization of nebulizer performance should be described in principle, but reflect use of a range of validated technologies that can provide acceptable data.

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Manufacturers should be allowed to test nebulization with an appropriate range of pharma products (not sodium fluoride).

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- n Nebulizers should be tested with compressors that are designed to be used with the specific nebulizer.**
- n Mouthpieces should more accurately reflect the intended population.**
- n Breath-actuated testing should be more representative (1:2 I/E ratio rather than 1:1).**

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ISO CD 27427 – Nebulizers and nebulizing systems –Next steps

n Meeting January 16-18, 2007

AAMI Headquarters

Alexandria, VA

n ISO target dates:

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FDIS 03-01-2008

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If you wish to get involved in the development of this standard or in the work of ISO TC/121, please email me at:

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