

F29 on Anesthetic and Respiratory Equipment Structure and Work Plan

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SCOPE: The development of terminology, units of measure, identification, dimensions, tolerances, performance, and test methods of anesthetic and respiratory equipment and systems for function and safety.

The work of this Committee will be coordinated with other ASTM Committees and other organizations having mutual interest.

STRUCTURE and WORK PROGRAM

F29.10 on Anesthesia Workstations

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F29.10 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.10.01 Anesthesia Gas Machines (Grabber)				ISO/TC121/SC1
F29.10.02 Breathing Systems/Performance (Grabber)	F1208-89(2005) ISO 5360	Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems Anesthetic Vaporizers – Agent Specific Filling Systems (on MCLB)	Current Adopted with Deviations	ISO/TC121/SC1
F29.10.03 Connectors and Adapters (Grabber)	F1054-01 (Withdrawn) ISO 5359 ISO 5356-1	Specification for Conical Fittings of 15-mm and 22-mm sizes Low-Pressure Hose assemblies for Use with Medical Gases Anaesthetic and Respiratory Equipment- Conical Connectors – Part 1 Cones and Sockets	Withdrawn, replaced with ISO 5356-1 Adopted with Deviations Adopted with Deviations	ISO/TC121/SC1
F29.10.04 Breathing Systems and Anti-Disconnect Fittings (Open)				ISO/TC121/SC1
F29.10.05 Anesthesia Gas Scavenging Systems (AGSS) (Grabber)	F1343-02	Specification for Anesthetic Equipment – Scavenging Systems for Anesthetic Gases	Current	ISO/TC121/SC1
F29.10.06 Lung Ventilators for Use in Anesthesia (Grabber)	F1101-90(2004)	Specification for Ventilators Intended for Use During Anesthesia	Current	ISO/TC121/SC1 ISO/IEC JWG1
F29.10.07 Anesthesia Workstations (Grabber)	F1850-00(2005)	Specification for Particular Requirements for Anesthesia Workstations and Their Components	Current	ISO/TC121/SC 1 IEC/SC62D

F29.11 on Gas Monitors

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F29.11 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.11.01 Capnographs and Anesthetic Agent Analyzers (Goldman)	F1452-01 (Withdrawn)	Specification for Anesthetic Agent Monitors	(Withdrawn) Replaced with ISO 21647	ISO/TC121/SC1/ WG5
	F1456-01 (Withdrawn)	Specification for Capnometers	(Withdrawn) Replaced with ISO 21647	
	ISO 21647	Medical Electrical Equip – Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	Adopted w/ Deviations	
F29.11.02 Nitric Oxide Delivery Devices and Monitors (Goldman)				
F29.11.03 Cutaneous Gas Monitoring (Goldman) (TG has been disbanded)				
F29.11.04 Oxygen Analyzers (Hedley-Whyte)	F1462-93 (Withdrawn)	Specification for Oxygen Analyzers	Withdrawn – Replaced with ISO 7767	ISO/TC121/SC1 WG5
	ISO 7767 (Withdrawn)	Oxygen Monitors for Monitoring Patient Breathing Mixtures-Safety Requirements	Withdrawn, Replaced with ISO 21647	
F29.11.05 Pulse Oximeters (Weitzner)	F1415-92(2000) (Withdrawn)	Specification for Pulse Oximeters	Withdrawn, Replaced with ISO 9919	ISO/TC121/SC3 WG4
	ISO 9919	Medical Electrical Equipment – Part Requirements for Pulse Oximeters Equipment	Adopted w/ Deviations	

F29.12 on Airways, Bronchoscopes and Laryngoscopes

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F29.12 Standards and Status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.12.01 Tracheal Tubes (Graham)	F1242-96 (Withdrawn)	Specification for Cuffed and Uncuffed Tracheal Tubes	Withdrawn – Replaced with ISO 5361	ISO/TC121/SC2
	F1243-89(1995) (Withdrawn)	Specification for Tracheal Tube Connectors	Withdrawn – Replaced with ISO 5361	
	ISO 5361 – Adopted no deviations	Anaesthetic and Respiratory Equipment – Tracheal Tubes and Connections	ISO 5361 – Adopted no deviations	
	New Standard WK 7763	Specification for Tracheal Tubes and Other Airway Devices	Being Balloted Intended for ISO Use	
F29.12.02 Naso/Oropharyngeal Airways	F1573-95(2000)	Specification for Anesthetic Equipment – Oropharyngeal and Nasopharyngeal Airways	Current	ISO/TC121/SC2
F29.12.03 Breathing Tubes/Bags (Graham)	F1204-88(1998) (Withdrawn)	Specification for Anesthesia Reservoir Bags	Withdrawn, replaced with ISO 5362	ISO/TC121/SC2
	ISO 5362 – Adopted no deviations	Anesthesia Reservoir Bags	Adopted, no deviations	
	F1205-88(1999)	Specification for Anesthesia Breathing Tubes		
F29.12.04 Tracheostomy Tubes – Adult (Graham)	F1590-95 (Withdrawn)	Specification for Tracheostomy Tube Connectors	Replaced with ISO 5366-1 and ISO 5366-3	ISO/TC121/SC2
	F1666-95E1 (Withdrawn)	Specification for Adult Tracheostomy Tubes	Replaced with ISO 5366-1	
	ISO 5366-1 Adopted no deviations	ISO 5366-1 Anesthetic and Respiratory Equipment – Tracheostomy Tubes – Part 1: Tubes and Connectors for Use in Adults	Adopted no deviations	
F29.12.05 Tracheostomy Tubes – Pediatric (Graham)	F1627-95 Withdrawn	Specification for Tracheostomy Tubes – Pediatric Tracheostomy Tubes	Withdrawn, replaced with ISO 5366-3	ISO/TC121/SC2
	ISO 5366-3 Adopted no deviations	ISO 5366-3 Anesthetic and Respiratory Equipment – Tracheostomy Tubes – Part 3: Paediatric Tracheostomy Tubes	Adopted no deviations	
F29.12.06 Suction Catheters (Graham)	F1981-99	Specification for Suction Catheters for Use in the Respiratory Tract	Review needed	ISO/TC121/SC2
F29.12.07 Supralaryngeal Airways (Goldman/Virag)	F2560-06	Specification for Supralaryngeal Airways and Connectors	Current (Intended for ISO as New Work Item)	ISO/TC121/SC2

F29.12 Standards and status (Continued)

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.12.08 Laryngoscopes – Bulbs/Handles/ Blades (Rigid) (Graham)	F965-99	Specification for Rigid Laryngoscopes for Tracheal Intubation – Hook-on Fittings for Laryngoscope Handles and Blades with Lamps	Review needed	ISO/TC121/SC2
	F1195-99	Specification for Rigid Laryngoscopes for Tracheal Intubation – Hook-on Fittings for Fiber-illuminated Blades and Handles	Review needed	
F29.12.09 Laryngoscopes and Bronchoscopes (Flexible) (Graham)	F896-90(1999) (Withdrawn)	Specification for Flexible Fiberoptic Bronchoscopes	(Withdrawn – no replacement)	ISO/TC121/SC2
F12.12.10 Bronchoscopes (Rigid) (Graham)	F1218-89(2007)	Specification for Bronchoscopes Rigid	Current	ISO/TC121/SC2
F29.12.11 Tracheal Tubes for Laser Surgery	F1497-99A	Test Method for Determining Laser Resistance of the Shaft of Tracheal Tubes	Review needed	ISO/TC172/SC9/ WG42 and ISO/TC121/SC9 2/ WG2
	F1628-95(2000)	Specification for Labeling and Marking of Cuffed and Uncuffed Tracheal Tubes and Related Treatments Intended for Use During Laser Surgery	Being Balloted for Withdrawal	
	ISO 14408:2005	Tracheal Tubes Designed for Laser Surgery	Being balloted for adopted as ANS	

F29.14 on Ventilators

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F29.14 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.14.01 Lung Ventilators (Other than for Anesthesia) (Hedley-Whyte)	F1100-90(1997) (Withdrawn)	Specification for Ventilators Intended for Use in Critical Care	(Withdrawn)	ISO/IEC JWG ISO/TC121/SC3 and IEC/SC62D
	Adopt IEC/ISO 60601-2-12	Medical Electrical Equipment 2-12 Particular Requirements for the Safety of Lung Ventilators -- Critical Care Vent	Adopted w/ Deviations	
F29.14.02 Gas Mixers (Hedley-Whyte)	ISO 11195 - Adopted With Deviations	Gas Mixers for Medical Use- Stand-Alone Gas Mixers -	Adopted With Deviations	ISO/TC121/SC3
F29.14.03 Humidifiers (Carstensen)	F1690-96(2004)	Specification for Humidifiers for Medical Use -- Part 1: General Requirements for Active Humidification Systems	Current	ISO/TC121/SC3
F29.14.04 Home Care Ventilators (Hedley-Whyte)	F1246-91(2005)	Specification for Electrically Powered Home Care Ventilators, Part 1: Positive-Pressure Ventilators and Ventilator Circuits	Current	ISO/TC121/SC3
F29.14.05 Oxygen Concentrators (Hedley-Whyte)	F1464-93(2005)	Specification for Oxygen Concentrators for Domiciliary Use	Current	ISO/TC121/SC3
F29.14.06 Resuscitators (Hedley-Whyte)	F920-93(1999)	Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans	Withdrawn Replaced with ISO 10651-4 and ISO 10651-5	ISO/TC 121/SC3
	ISO 10651-4 Adopted with Deviations	Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators	Adopted With Deviations	
	ISO 10651-5 Adopted with Deviations	Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 5: Gas-powered emergency resuscitators	Adopted With Deviations	
F29.14.07 Sleep Apnea (Hedley-Whyte)	Corresponding ISO Standards ISO 17510-1	ISO 17510-2 Sleep apnea breathing therapy -- Part 1		ISO/TC 121/SC3
	ISO 17510-2	ISO 17510-2 Sleep apnea breathing therapy - Part 2: Masks and application accessories		

F29.15 on Harmonization of Alarms

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F29.15 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.15.01 Harmonization of Alarms (Hedley-Whyte)	F1463-93(1999) (Withdrawn)	Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	Superseded by IEC 60601-1-8	ISO/IEC JWG ISO/TC121/SC3 and IEC/SC62A

F29.16 on Terminology

Chair: Vacant

F29.16 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.16 Terminology	F2002-01C (Withdrawn) ISO 4135 Adopted w/ Deviations	Terminology Relating to Anesthesia and Respiratory Equipment Anesthesia and Respiratory Equipment - Vocabulary	Withdrawn – Replaced with ISO 4135 Adopt ISO Standard w/ Deviations	ISO/TC121/SC4

F29.17 on Medical Surgical Suction and Drainage

Chair: Vacant

F29.17 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.17.01 Medical Surgical Suction and Drainage	F960-86(2000) (Withdrawn) ISO 10079-1 ISO 10079-2 ISO 10079-3	Specification for Medical and Surgical Suction and Drainage Systems Medical Suction Equip Parts 1, 2, 3	(Withdrawn) Replaced with ISO 10079-1 ISO 10079-2 ISO 10079-3 Adopted with deviations	ISO/TC121/SC8

F29.19 on Warming Devices

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F29.19 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
F29.19.01 Patient Warming Equipment -- Warming Blankets (Virag)	F2196-02	Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices	- Current -Submitted as IEC/ISO New Work Item Proposal	ISOTC121 IEC SC62D
F29.19.02 Patient Warming Equipment -- Blood and Fluid Warmers (Virag)	F2172-02	Specification for Blood and Fluid IV / Irrigation Fluid Warmers	- Current - Submitted as IEC/ISO New Work Item Proposal	ISOTC121 IEC SC62D

F29.20 Medical Gas Systems

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F29.20 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
Flow Meters (S. Dorsch)	ISO 15002	Flow-Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems	Adopted with deviations	ISO TC121/ SC 6

F29.21 Closed-Loop Controllers

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F29.21 Standards and status

Task Group	Standard Designation	Title	Status	ISO Relationship
Closed-Loop Controller	Draft standard being prepared			ISO TC121 IEC TC 62

Summary of Actions Regarding Adoption/Withdrawal/ ISO-IEC Intended

Adoption of ISO Standards

- Adoption of ISO 5359, *Low Pressure Hose Assemblies for Use with Medical Gases* – With Deviations (F29.10)
- Adoption of ISO 7767, *Oxygen Monitors for Monitoring Patient Breathing Mixtures-Safety Requirements* - With Deviations (F29.11)
- Adoption of ISO 5361, *Anaesthetic and Respiratory Equipment –Tracheal Tubes and Connections* – No Deviations (F29.12)
- Adoption of ISO 5366-1, *Anesthetic and Respiratory Equipment – Tracheostomy Tubes – Part 1: Tubes and Connectors for Use in Adults* - No Deviations (F29.12)
- Adoption of ISO 5366-3, *Anaesthetic and Respiratory Equipment – Tracheostomy Tubes – Part 3: Paediatric Tracheostomy Tubes* – No Deviations (F29.12)
- Adoption of ISO 5362, *Anaesthesia Reservoir Bags* – No Deviations (F 29.12)
- Adoption of IEC/ISO 60601-2-12 *Medical Electrical Equipment Parts 2-12, Requirements for the Safety of Lung Ventilators – Critical Care Ventilators* - With Deviations (F29.14)
- Adoption of ISO 4135, *Anaesthesia and Respiratory Equipment Vocabulary* – With Deviations (F29.16)
- Adoption of ISO 10079 Parts 1, 2 and 3, *Medical Suction Equipment* – With Deviations (F29.17)
- Adoption of ISO 5360, *Anesthetic Vaporizers-Agent Specific Filling Systems* - With Deviations (F29.10)
- Adoption of ISO 11195, *Gas Mixers for Medical Use-Stand-Alone Gas Mixers* – With Deviations (F29.14)
- Adoption of ISO 15002, *Flow-Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems* – With Deviations (F 29.20)
- Adoption of ISO 9919, *Medical Electrical Equip – Pulse Oximeter Equipment* – With Deviations (F 29.11)
- Adoption of ISO 5356-1, *Anaesthetic and Respiratory Equipment-Conical Connectors – Part 1 Cones and Sockets* – With Deviations (F 29.10)
- Adoption of ISO 21647 – *Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Respiratory* – With Deviations (F29.11)
- Adoption of ISO 10651-4, *Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators* – With Deviations (F 29.14)
- Adoption of ISO 10651-5 *Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas-powered emergency resuscitators* – With Deviations (F 29.14)

Withdrawn

- F1462-93, Replaced with ISO 7767(F29.11)
- F1242-96, Replaced with ISO 5361 (F29.12)
- F1243-89(1995), Replaced with ISO 5361 (F29.12)
- F1204-88(1998), Replaced with ISO 5362 (F29.12)
- F1666-95 Replaced with ISO 5366-1 (F29.12)
- F1627-95, Replaced with ISO 5366-3 (F29.12)
- F1590-95, Replaced with ISO 5366-1 and ISO 5366-3 (F29.12)
- F896-89(1999), No replacement (F29.13)
- F2002-01C, Replaced with ISO 4135 (F29.16)
- F960-86(2000) – Replace with ISO 10079-1-3 (F29.17)
- F1100-90(1997), Replace with IEC/ISO 60601-2-12
- F1415-92(2000), Replaced with ISO 9919 (F29.11)
- F1054-01, Replaced with ISO 5356-1 (F29.10)
- F1452-01, Replaced with ISO 21647 (F29.11)
- F1456-01, Replaced with ISO 21647 (F29.11)
- F920-93(1999), Replaced with ISO 10651-4, and ISO 10651-5 (F29.14)
- ANS/ISO 7767- Replaced with ISO 21647 (F29.11)

Intended for ISO/IEC Use

F2196-02 - *Spec for Circulating Liquid and Forced Air Patient Temp Man Devices (F29.19)*

F2172-02 - *Spec for Blood and Fluid IV / Irrigation Fluid Warmers (F29.19)*

F2560-06 - *Specification for Supralaryngeal Airways and Connectors (F29.12)*