

## ISO TC 121 마취기 및 호흡회로 소개

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### 안 원 식

우리는 의사로서 다양한 의료기기를 사용한다. 그 중에서 마취기와 인공호흡기, 기타 관련된 부속 장치는 마취과 의사들에게 분신과도 같은 존재일 것이다. 마취과 의사들에게도 필수적인 장비이지만, 마취기와 인공호흡기는 경제적 수익이 좋기에 매우 많은 회사에서 매우 다양한 종류의 제품을 생산하고 있다. 다양한 제품의 생산이, 소비자인 마취과 의사들의 선택의 폭을 넓히고, 저렴한 제품을 공급하는데는 기여하지만, 한편으로는 호환성, 안전성의 문제를 제기하게 된다. 이에 국제 표준화 기구(International Organization for Standardization, ISO)의 한 분야로서 마취기와 관련 제품의 표준에 대한 국제적인 합의 노력이 다양하게 진행되고 있다. 마취기에 대한 표준화 작업은 ISO의 기술위원회(Technical Committee, TC) 121에서 다루고 있고, 정식 명칭은 ISO TC 121 Anesthetic and Respiratory Equipment 이다.

ISO TC 121은 1966년에 설립되었고, 매년 총회를 개최하고 있다. 회원 구성으로는 정회원 25개국, 준회원 21개국 등 총 46개국이 활동 중에 있고, 우리나라는 정회원국이다. 다양한 분야를 포괄하여 활동하고 있기에 6개의 분과위원회(SubCommittee, SC)로 나누어 활동을 진행하고 있다. 각 분과를 설명하면, SC1 Breathing attachments and anaesthetic machines, SC2 Tracheal tubes and other equipment, SC3 Lung ventilators and related equipment, SC4 Anaesthesia terminology, SC6 Medical gas systems, SC8 Suction devices for hospital and emergency care use 이다. SC5, SC7은 미래에 개발될 장

비를 위해 유보되어 있다.

ISO 홈페이지는 <http://www.iso.org> 이고, 발간된 규격을 product라고 한다. 2010년 9월 현재 각 분과에서 발간한 국제 규격을 알아보면 별첨한 자료와 같다. 자료 중에 나오는 약자들을 풀어쓰면 다음과 같다. IEC (International Electrotechnical Commission), TR (Technical Report), Cor (Correction).

ISO/IEC 규격들은 고가이고, 영어로 기술되어 있어 관계자들이 한글로 된 것을 저렴하게 구입할 수 있도록 기술표준원에서 국내 실정에 맞게 수정/번역하여 게시하고 있다. 기술표준원 홈페이지는 <http://www.kats.go.kr> 이고, 각종 국가표준으로 지정된 KS규격은 국가표준인증종합센터에서 제공하는, [http://www.standard.go.kr/code02/user/0B/03/SerKs\\_Search.asp](http://www.standard.go.kr/code02/user/0B/03/SerKs_Search.asp)에서 구할 수 있다. 2010년 현재 마취과 관련 KS 규격 제정에 마취과 전문 의사들의 참여가 미약하여, KS 규격 발간 수도 미미하고, 임상적으로 맞지 않는 용어가 배포된 경우도 있다. 기존 발간 ISO 규격의 한글과 사업 뿐 아니라, ISO 등 국제 단체에서 신규 규격 검토 요청이 계속되고 있고, 국내 업체의 이익을 대변하여 표준 회의에서 논리적 의견 개진 등이 결실하여, 기술표준원에서 주관하는 ISO 표준 개발 사업에 마취과 회원들의 적극적 참여가 필요한 실정이다. 참여를 원하는 회원은 상기 홈페이지에서 제공하는 KS 표준 검색에서 담당부서와 담당 공무원을 확인할 수 있고, 참여 의사를 밝히면, 소정의 임명 절차를 거친 후 국가표준 개발 위원으로 위촉되게 된다.

(별첨) ISO TC 121 발간 규격(2010년 8월 기준)

**I. TC 121/SC 1 Breathing attachments and anaesthetic machines**

ISO 5356-1:2004

Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets

ISO 5356-2:2006

Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors

ISO 5358:1992

Anaesthetic machines for use with humans

ISO 5359:2008

Low-pressure hose assemblies for use with medical gases

ISO 5360:2006

Anaesthetic vaporizers -- Agent-specific filling systems

ISO 8835-2:2007

Inhalational anaesthesia systems -- Part 2: Anaesthetic breathing systems

ISO 8835-3:2007

Inhalational anaesthesia systems -- Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems

ISO 8835-4:2004

Inhalational anaesthesia systems -- Part 4: Anaesthetic vapour delivery devices

ISO 8835-5:2004

Inhalational anaesthesia systems -- Part 5: Anaesthetic ventilators

ISO 11195:1995

Gas mixers for medical use -- Stand-alone gas mixers

ISO/TS 18835:2004

Inhalational anaesthesia systems -- Draw-over vaporizers and associated equipment

ISO 21647:2004

Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors

ISO 21647:2004/Cor 1:2005

ISO 26825:2008

Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs used during anaesthesia -- Colours, design and performance

IEC 60601-2-13:2003

Medical electrical equipment -- Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

IEC 60601-2-13:2003/Amd 1:2006

IEC 80601-2-35:2009

Medical electrical equipment -- Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

**II. TC 121/SC 2 Airways and related equipment**

ISO 5361:1999

Anaesthetic and respiratory equipment -- Tracheal tubes and connectors

ISO 5361-4:1987

Tracheal tubes -- Part 4: Cole type

ISO 5362:2006

Anaesthetic reservoir bags

ISO 5364:2008

Anaesthetic and respiratory equipment -- Oropharyngeal airways

ISO 5366-1:2000

Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 1: Tubes and connectors for use in adults

ISO 5366-3:2001

Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 3: Paediatric tracheostomy tubes

ISO 5366-3:2001/Cor 1:2003

ISO 5367:2000

Breathing tubes intended for use with anaesthetic apparatus and ventilators

ISO 7376:2009

Anaesthetic and respiratory equipment -- Laryngoscopes for tracheal intubation

ISO 8836:2007

Suction catheters for use in the respiratory tract

ISO 11712:2009

Anaesthetic and respiratory equipment -- Supralaryngeal airways and connectors

ISO/TR 11991:1995

Guidance on airway management during laser surgery of upper airway

ISO 14408:2005

Tracheal tubes designed for laser surgery -- Requirements for marking and accompanying information

ISO 16628:2008

Tracheobronchial tubes -- Sizing and marking

ISO 27427:2009

Anaesthetic and respiratory equipment -- Nebulizing systems and components

### III. TC 121/SC 3 Lung ventilators and related equipment

ISO 8185:2007

Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems

ISO 8359:1996

Oxygen concentrators for medical use -- Safety requirements

ISO 9360-1:2000

Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 1: HMEs for use with minimum tidal volumes of 250 ml

ISO 9360-2:2001

Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml

ISO 9919:2005

Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

ISO 10651-2:2004

Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 2: Home care ventilators for ventilator-dependent patients

ISO 10651-3:1997

Lung ventilators for medical use -- Part 3: Particular requirements for emergency and transport ventilators

ISO 10651-4:2002

Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators

ISO 10651-5:2006

Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 5: Gas-powered emergency resuscitators

ISO 10651-6:2004

Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 6: Home-care ventilatory support devices

ISO/TR 13154:2009

Medical electrical equipment -- Deployment, implementation and operational guidelines for indentifying febrile humans using a screening thermograph

ISO 17510-1:2007 Sleep apnoea breathing therapy -- Part 1: Sleep apnoea breathing therapy equipment	systems IEC 60601-1-8:2003/Amd 1:2006
ISO 17510-2:2007 Sleep apnoea breathing therapy -- Part 2: Masks and application accessories	IEC 60601-1-10:2007 Medical electrical equipment -- Part 1-10: General requirements for basic safety and essential performance -- Collateral standard: Requirements for the development of physiologic closed-loop controllers
ISO 18777:2005 Transportable liquid oxygen systems for medical use -- Particular requirements	IEC/DIS 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 18778:2005 Respiratory equipment -- Infant monitors -- Particular requirements	IEC 60601-2-12:2001 Medical electrical equipment -- Part 2-12: Particular requirements for the safety of lung ventilators -- Critical care ventilators
ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures -- Particular requirements	ISO/DIS 80601-2-12 Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use -- Part 1: Salt test method to assess filtration performance	IEC 80601-2-30:2009 Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 23328-2:2002 Breathing system filters for anaesthetic and respiratory use -- Part 2: Non-filtration aspects	ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 23747:2007 Anaesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	IEC 80601-2-59:2008 Medical electrical equipment -- Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening
ISO 26782:2009 Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans	ISO 81060-1:2007 Non-invasive sphygmomanometers -- Part 1: Requirements and test methods for non-automated measurement type
ISO 26782:2009/Cor 1:2009	
IEC 60601-1-8:2006 Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical	

ISO 81060-2:2009

Non-invasive sphygmomanometers -- Part 2: Clinical validation of automated measurement type

**IV. TC 121/SC 4 Anaesthesia terminology**

ISO 4135:2001

Anaesthetic and respiratory equipment -- Vocabulary

**V. TC 121/SC 6 Medical gas systems**

ISO 7396-1:2007

Medical gas pipeline systems -- Part 1: Pipeline systems for compressed medical gases and vacuum

ISO 7396-1:2007/Amd 1:2010

Requirements for terminal units for vacuum fitted on medical supply units with operator-adjustable portions and connected to the pipeline through flexible hoses

ISO 7396-1:2007/Amd 2:2010

ISO 7396-2:2007

Medical gas pipeline systems -- Part 2: Anaesthetic gas scavenging disposal systems

ISO 9170-1:2008

Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum

ISO 9170-2:2008

Terminal units for medical gas pipeline systems -- Part 2: Terminal units for anaesthetic gas scavenging systems

ISO 10083:2006

Oxygen concentrator supply systems for use with medical gas pipeline systems

ISO 10524-1:2006

Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices

ISO 10524-2:2005

Pressure regulators for use with medical gases -- Part 2: Manifold and line pressure regulators

ISO 10524-3:2005

Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves

ISO 10524-4:2008

Pressure regulators for use with medical gases -- Part 4: Low-pressure regulators

ISO 11197:2004

Medical supply units

ISO 15001:2010

Anaesthetic and respiratory equipment -- Compatibility with oxygen

ISO 15002:2008

Flow-metering devices for connection to terminal units of medical gas pipeline systems

ISO 19054:2005

Rail systems for supporting medical equipment

ISO 21969:2005

High-pressure flexible connections for use with medical gas systems

**VI. TC 121/SC 8 Suction devices for hospital and emergency care use**

ISO 10079-1:1999

Medical suction equipment -- Part 1: Electrically powered suction equipment -- Safety requirements

ISO 10079-2:1999

Medical suction equipment -- Part 2: Manually powered suction equipment

ISO 10079-3:1999

Medical suction equipment -- Part 3: Suction equipment powered from a vacuum or pressure source