# Belgian standards for patient safety in anesthesia

## The Belgian Anesthesia Patient Safety Steering-Committee

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### Editorial Comments

Mortality and morbidity related to anesthesia is a continuous threat to the practice of anesthesia (Lauwers, 1978). Fortunately anesthetic mortality has decreased from a death rate of 3.7 per 10 000 anesthetics (Beecher and Todd, 1954) to figures 0.76 per 10 000 anesthetics (Tiret et al., 1986). Even a low figure of 0.066 per 10 000 was mentioned (Eichhorn, 1986).

Elements which contributed to this fortunate decrease of anesthesia-related mortality are multiple. The continuous presence of an anesthesiologist in the operatingroom during the entire diagnostic or surgical procedure is very important, and allows a patient linked individual observation. The more elaborate education and experience of the anesthesiologist, which increased over the last decade, and comprises now in Belgium a full time training of 5 years, is a further important factor. The gradual adaptation of monitoring devices, to improve anesthesia care and to decrease the incidence of anesthesia-related patient injuries is the third crucial factor. Although monitoring is routinely encouraged for every patient under anesthesia, it is even still more mandatory if the vital functions of the patients are disturbed or threatened. Therefore nowadays diverse monitoring devices must be available at all times in each anesthesia location. Nevertheless we may not forget that monitoring and monitoring devices are not end targets, but highly sophisticated means to improve anesthesia care, and that only with a judicious use of them we will reach the final patient safety goal. This also implies that according to the practical situation, which the anesthesiologist is facing, he must decide himself which monitoring he is using and depending on the patients' condition minimal monitoring equipment can be extended. Clinical vigilance remains essential because even highly sophisticated monitoring devices such as capnographs and oximeters may occasionally not function correctly and may even fail to reveal dangerous circumstances !

Standards for patient monitoring were first adopted in 1985 by the Harvard-affiliated hospitals and later in 1986 encouraged by the American Society of Anesthesiologists. There is now already provisional strong suggestion that after the application of these standards anesthesia mortality decreased (Eichhorn, 1989). Standards have also been adopted by the Association of Anaesthesists of Great Britain and the French Society of Anesthesia. Already for years in the Netherlands strict rules for anesthesia monitoring exist. It is therefore timely that Belgian Standards for patient safety in anesthesia now are published. Months of discussion amongst the professors of anesthesiology of the Belgian Universities, togeter with representatives of the scientific and professional anesthesiology societies of Belgium preceeded the present publication.

The adopted standards have to be met latest on 1 January 1995. Indeed for practical reasons each individual hospital, or anesthesia location cannot immediately comply with these rules.

The present standards apply only to anesthesiapractice done by anesthesiologists for diagnostic and/or surgical procedures. Of course this is only part of the professional

activities of the anesthesiologist. For the practice outside the traditional operating theatre and diagnostic examination room, other standards have still to be elaborated in the future. This concerns activities in the delivery unit, pain clinic, acute pain treatment or intensive care unit.

The Board of directors
of the Belgian Society of Anesthesia and Reanimation

**References**


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## Introduction

0.01 The anesthesiologists of the Belgian Society for Anesthesia and Reanimation and of the Belgian Professional Association of Specialists in Anesthesia and Reanimation have undertaken to define safety standards for anesthesia or sedation of patients, undergoing diagnostic or surgical procedures.

0.02 These safety standards should be effective by the first of January 1995.

0.03 The standards are divided as follows :

*Part One : Minimal standards*

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| Section I | General principles. |
| Section II | Departmental organization. |
| Section III | Assistance for the anesthesiologist. Minimal standards. |
| Section IV | General equipment. Minimal standards. |
| Section V | Monitoring equipment. Minimal standards. |
| Section VI | Transport of the patient. |
| Section VII | Post-anesthetic care unit (PACU). Minimal standards. |
| Section VIII | Maintenance of equipment in anesthesia and PACU. |

*Part Two : Safety recommendations for the practice of anesthesia*

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| Section I | General organization. |
| Section II | Preoperative visit. |
| Section III | Basic controls. |
| Section IV | Peroperative patient control. |
| Section V | Transport of the patient. |
| Section VI | Postanesthetic care unit. |
| Section VII | Anesthesia records. |
| Section VIII | Quality control. |
| Section IX | Continuing educational programme. |

0.04 In circumstances where the application of the standards in whole or in part is not possible, the reason is noted on the anesthesia record. A lack of staff, equipment or organization is not an acceptable reason.

0.05 Until the standards become effective (the transitional period), the chief of a department of anesthesiology, taking into account all

local relevant circumstances, submits a written plan listing the requirements for compliance with the new standards, to the hospital management.

0.06 During the transitional period, application of the standards receives priority :

1. in workstations outside the main operating theatre area ([1]),
2. in locations where close observation of the patient is difficult, or where lighting is frequently lowered, or where adequate oxygenation of the patient is more difficult to assess or control.

0.07 During the transitional period, it should be useful for the departments of anesthesia to have an independent audit ([2]) performed by qualified professionals from outside the hospital. In the case of a lawsuit, a previously held audit may provide evidence of the correct running of the department and of the efforts that are being, and have already been, made to comply with the standards.

0.08 The standards will be revised in accordance with scientific advances. The upgraded rules will be published in scientific and professional journals.

0.09 In a case where hospital management makes it impossible for the anesthesiologist to put these standards into practice despite a duly written request, the anesthesiologist can no longer be held responsible for the consequences. In this situation, the chief anesthesiologist immediately requests an audit ([2]).

(1) These locations are frequently poorly equipped.
(2) An audit may be requested from either of the current Presidents, at the following addresses : Doctor J. C. DEVOGHEL, President of the Belgian Society of Anesthesia and Reanimation, Service d'Anesthésiologie, Centre Hospitalier Universitaire B35, Domaine Universitaire du Sart Tilman, 4000 Liège and Doctor P. BOLLANSEE-OOSTERWIJCK, President of the Belgian Professional Association of Specialists in Anesthesia and Reanimation, Avenue de la Couronne-Kroonlaan 20, 1050 Bruxelles-Brussel.

## Part One : Minimal standards

### SECTION I : GENERAL PRINCIPLES

1.01 The function "Anesthesiology", which is included in the K.B.-A.R. 30.01.1989, automatically implies the existence of an organized department of anesthesiology.

1.02 The accreditation of a hospital depends on the application of minimal standards in anesthesia. These standards are to be met every time a patient undergoes general anesthesia, major regional anesthesia or sedation given by an anesthesiologist for diagnostic or surgical procedures.

1.03 The hospital manager is responsible for the provision of nursing staff, equipment for anesthesia and monitoring, according to the advice of the department of anesthesiology. The hospital manager is also responsible for the effective maintenance of this equipment.

### SECTION II : DEPARTMENTAL ORGANIZATION

1.04 Each department of anesthesiology has a chief-anesthesiologist who is responsible for the organization and coordination of all activities of the department.

1.05 Staffmembers in each department of anesthesiology define and apply together a common policy in the interests of the patient.

1.06 The department of anesthesiology must have suitable space for its professional and educational activities and sufficient secretarial support.

SECTION III :
ASSISTANCE FOR THE ANESTHESIOLOGIST
MINIMAL STANDARDS

1.07 The anesthesiologist is always assisted by a properly trained nursing staff during induction and emergence periods. During maintenance of anesthesia, assistance is available on demand. This assistance has priority and is given in such a way as to allow the anesthesiologist close contact with the patient, at all times. This also applies to anesthesia care outside the main operating theatre area.

1.08 The department of anesthesiology must request the nursing management to transfer a nurse for reasons of incompetence or unreliability. If this transfer is not made, the anesthesiologist can not be held responsible for the consequences.

1.09 One full time technician is appointed to every department of anesthesiology for each unit of four thousand or less anesthetics performed per year.

SECTION IV : GENERAL EQUIPMENT
MINIMAL STANDARDS

1.10 All equipment is in accordance with ISO standards.

1.11 The basic equipment comprises for each anesthesia workstation :

1. A standard anesthesia trolley in the sole form selected by the department of anesthesiology and an anesthesia machine.
2. A suction appliance.
3. Equipment for ventilation with pure oxygen by mask, including an ambu-type system, and instrumentation for tracheal intubation, with at least two laryngoscopes.
4. Specific equipment for the adequate lighting of the patient, the anesthesia machine, the anesthesia trolley and the monitoring equipment.
5. Means of communication including :
   a. a telephone, reserved for the anesthesiologist, and placed so that the user may continue to observe the patient and the monitors.
   b. an intercom.
   c. a "cardiac arrest" call button.
6. Electric power points, connected to an emergency supply source of electricity, in sufficient number so as to allow the functioning of all the necessary appliances and monitors.
7. Outlets for medical gases from the central supply. The tubings which connect wall plugs to the anesthesia machine are manufactured and supplied as single pieces, without any detachable components.

1.12 In addition to this basic equipment :

a. a standard resuscitation cart in the sole form selected by the department of anesthesiology must be available within two minutes. It contains, amongst other things, a defibrillator and a crico-thyrotomy set.
b. a spare tank of oxygen, cool infusion solutions, ice and a minimum of 240 mg of dantrolene must be quickly available, at all times.

SECTION V : MONITORING EQUIPMENT
MINIMAL STANDARDS

1.13 Minimal standard monitoring equipment includes for each anesthesia workstation :

1. An oxygen analyser, incorporating an audible signal to warn of low oxygen concentration, correctly fitted into the breathing system.
2. When an automatic ventilator is in use :
   a. a manometer to display the pressure in the breathing system.
   b. a pressure alarm system including :
      - a high pressure alarm sounding each time the maximum selected pressure is reached.
      - a disconnection alarm, indicating that the minimum selected pressure has not been reached in the last twenty seconds. This delay of twenty seconds may be prolonged temporarily but not perma-

nently. The starting and stopping of the alarm system should be independent to the functions of the respirator.

c. a device to measure the respiratory frequency continuously ([3]).

d. a device to measure the expired gas volume continuously.

3. A device to measure systolic and diastolic arterial pressure with appropriate sizes of inflatable cuffs.
4. Equipment to display the electrocardiogram continuously.
5. Equipment to read the cardiac frequency continuously.
6. Equipment to measure the body temperature continuously.
7. A pulse-oximeter with a minimum alarm setting.
8. A device to measure $CO_2$-concentration of inspiratory and expiratory gases and displaying the tidal curves on a screen continuously.
9. A device to measure the concentration of all inhalation anesthetics used in the respiratory system continuously.
10. A monitor of neuromuscular function.
11. An appropriate printed anesthesia record, fulfilling the specific requirements of the department of anesthesiology.

1.14 In addition to this basic equipment, there must be in the operating theatres or in the hospital, facilities, around the clock, for relevant biochemical and hematological monitoring, including : pH, blod gases, hemoglobin concentration, hematocrit, serum electrolytes, glucose, blood group, cross-match and blood coagulation tests.

## SECTION VI : TRANSPORT OF THE PATIENT

1.15 A battery powered pulse-oximeter and an oxygen delivery system are available.

(3) "Continuously" means without interruption.

## SECTION VII : POST-ANESTHETIC CARE UNIT (PACU) MINIMAL STANDARDS

1.16 The minimal standards for the post anesthetic care unit (PACU) are as follows :

1. 1.5 beds per operating room.
2. One nurse, properly trained and exclusively assigned to the PACU, for each unit of three or less patients in normal conditions of anesthetic recovery.
3. A device for ventilation with pure oxygen, an ambu-like system and the appropriate instrumentation for tracheal intubation.
4. For each patient, the following equipment is available :
   a. an oxygen delivery system.
   b. a suction appliance.
   c. a displayed electrocardiogram.
   d. a blood pressure measurement device.
   e. a device to continuously measure the temperature.
   f. a continuous pulse-oximeter ($SpO_2$), with a lower limit alarm.
   g. a respiratory monitor which operates either :
      - by recording expiratory $CO_2$ concentration ($ETCO_2$), if the patient is intubated, or,
      - by impedance measurement between ECG electrodes, or,
      - by any other reliable system.
   h. Outlets for medical gases from the central supply. All tubings which connect wall plugs to breathing systems, are manufactured and supplied as single pieces, without any detachable components.
   i. Electric power points, connected to an emergency supply source of electricity, in sufficient number so as to allow the functioning of all the necessary appliances and monitors.
5. A standard resuscitation cart in the sole form selected by the department of anesthesiology, available within two minutes. It contains,

amongst other things, a defibrillator and a cricothyrotomy set.

6. The following means of communication :
   a. a telephone placed so that the user may continue to observe the patients.
   b. an intercom.
   c. a "cardiac arrest" call button at each bed.

SECTION VIII :
MAINTENANCE OF EQUIPMENT
IN ANESTHESIA AND PACU

1.17 Systematic control and maintenance is carried out bi-annually for anesthesia machines and respirators and annually for monitoring appliances.

1.18 These duties are undertaken either by commercial firms or by the biotechnical department of the hospital. In both situations, a detailed written maintenance contract is agreed upon. Whenever maintenance is carried out it is reported in writing to the chief-anesthesiologist.

1.19 A label is attached to each appliance, showing the dates of controls, maintenance and repairs, and the data of the next control due. A technical journal of every appliance is kept by the department of anesthesiology.

1.20 The technical department and the hospital pharmacist ensure that the chief of the department of anesthesiology or his acting deputy is informed of any work carried out on the medical gas distribution system.

1.21 The technical department ensures that the chief of the department of anesthesiology or his acting deputy is informed of any work carried out on the electricity power supply.

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## Part Two : Safety recommendations for the practice of anesthesia

SECTION I : GENERAL ORGANIZATION

2.01 The anesthesiologist takes part in the setting up of the operating list. The interest of the patient is paramount in the compilation of the list.

2.02 The anesthesiologist ensures that the surgical activity is homogeneously spread over the working hours, in order to make the best possible use of anesthesiologists, nurses and operating theatre facilities.

2.03 The anesthesiologist devotes the necessary time to the induction of and the emergence from anesthesia.

SECTION II : PREOPERATIVE VISIT

2.04 A preoperative examination of the patient in conjunction with the consultation of the patient's file is essential. Thereafter the anesthetic can be planned in accordance with the patient's particular problems and needs.

2.05 Consequently, the anesthesiologist must be informed of the surgeons schedule. This information must be given in good time and at the very latest, the day before the operation.

SECTION III : BASIC CONTROLS

2.06 Basic controls comprise :

1. Identity of the patient : before commencing, the anesthesiologist ascertains the patient's identity, the scheduled operation and, if relevant, the site of the operation. This control made by the anesthesiologist does not discharge the surgeon from his responsibility for the same control.
2. Drugs : the anesthesiologist verifies the label of all drugs before loading the syringe. If the anesthesiologist is wearing sterile garments, the drug is shown to him in such a way as to allow him to read the label.

3. Syringes : each syringe is labelled with the name of the drug and the concentration. A national system of syringe labelling is used.
4. Perfusions : each container, to which a drug has been added, is clearly labelled with the required information.
5. Transfusions : for all preparations supplied by the blood bank for which the compatibility with the patient needs to be tested, the anesthesiologist ascertains whether this test has been done. Before connecting the blood bank product to the patient's perfusion set, the anesthesiologist notes on the anesthesia record the references of the patient's blood group and those of the blood bank container.
6. Before starting the first case of the day, the anesthesiologist checks the equipment and completes a printed checklist made for that purpose.
   Before starting each anesthetic or sedation, the anesthesiologist checks :
   - the oxygen supply,
   - the artificial ventilation systems, means of intubation and suction equipment,
   - the presence of the emergency drugs on the anesthesia trolley.
7. Prior to general anesthesia, all patients are preoxygenated, except when this is contraindicated ; verification is made that the effects of the inhaled gas are those of oxygen and not of nitrous oxide.

## Section IV : Peroperative patient control

2.07 From the beginning of te anesthetic to the post-anesthetic care unit or the intensive care unit, an anesthesiologist attends the patient in close vicinity. This attendance is continuous ([4]). A permanent physical contact, cardiac beat by cardiac beat, links the anesthesiologist to the patient. The anesthesiologist continually monitors the patient's condition and tailors the anesthetic to the patients' particular needs.

2.08 When several anesthesiologists take care of one patient at the same time, one of them is specifically designated to conduct the anesthetic and to be formally responsible for the patient's safety ([5]).

2.09 The anesthesiologist is not permitted to leave an anesthetised patient to deal with a life threatening emergency nearby, unless another person has been instructed to observe continuously the patient's vital signs and the overall responsibility has been delegated to and accepted by another doctor.

2.10 When primary responsibility for the anesthetic is handed over to another anesthesiologist, that anesthesiologist is made aware of all relevant information concerning the patient, the conduct of the anesthetic and the apparatus used. The patient's condition and the proper functioning of the apparatus is checked before and after the hand over, and this is noted on the anesthesia record.

2.11 If the doctor in charge is a trainee the degree of supervision by a qualified specialist which he requires is in accordance with his level of competence and the complexity of the case.

2.12 Clinical observation by the anesthesiologist is of the utmost importance. For this, access to some part of the patient's body is required. If, in particular circumstances, this access does not exist, the reasons are noted on the anesthesia record. Other causes making clinical observation impossible are also noted.

2.13 As far as indicated and technically possible, the continual clinical observation of the patient throughout the anesthetic comprises the observation of :

1. Ventilation. Auscultation of breathing sounds is performed when necessary.
2. Circulation. This includes peripheral pulse and heart sounds when necessary.
3. Mucosae, and/or feeling of the skin, including at the extremities.

(4) The word "continuous" is used to describe an action which is carried out without interruption, whereas the word "continual" is used to describe an action which is performed on a regular basis throughout the procedure.
(5) Complex inductions are particularly prone to breed confusion.

4. Urinary flow.
5. Surgical field.

2.14 Whenever the patient's position is changed, the anesthesiologist proceeds to a complete verification of equipment and clinical observation, before allowing surgery to be started or resumed.

## Section V : Transport of the patient

2.15 After general anesthesia, sedation or major regional blocks, transfer of the patient to the post-anesthetic care unit or the intensive care unit is done with oxygen administration and with pulse oximetry ($SpO_2$), in accordance to the patient's needs and the duration of the journey.

## Section VI : Post anesthetic care unit (PACU)

2.16 Supervision of the patient in the PACU is delegated to nurses, properly trained and exclusively assigned to the PACU. However an anesthesiologist is available at all times.

## Section VII : Anesthesia records

2.17 The anesthesiologist records the preoperative examination, the anesthetic and the post anesthetic phases by completing the appropriate printed forms. These anesthesia records are added to the patient's file.

2.18 All the documents are clear, complete, accurate and readable.

2.19 All automated printed records from monitoring equipment are considered as part of the anesthesia records and are safely retained (6).

2.20 Circumstances may arise which prevent the anesthesiologist from completing the records on the spot. Short notes of events and times will then help the anesthesiologist to fully report the case at a later and quieter moment.

2.21 If severe complications arise, the unfolding of events is described with the greatest precision, without stating any responsibility there may be (7).

## Section VIII : Quality control

2.22 For all cases in which unexpected clinical events have arisen, which could have been or have been harmful to the patient, a complementary report is prepared.

2.23 Such reports, which may be filed anonymously, are discussed during staff-meetings.

2.24 The patient is seen postoperatively by an anesthesiologist in order to ascertain his degree of satisfaction or otherwise, with the anesthetic and any side effects he has experienced.

## Section IX : Continuing educational programme

2.25 The anesthesiologist takes part in a continuing educational programme, for which certification is given.

This programme involves attendance at national and international meetings, seminars and courses.

It comprises also of periods of practice, each of them of at least of one week duration, in a well known teaching department.

2.26 Appropriate study leave is provided for this purpose, and the hospital administration accepts that it is the hospital and ultimately the patients who are the beneficiaries of this continuing educational programme.

2.27 The scientific society will set up a system of credits for participation in the continuing educational programme.

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(6) Such automatic recording is strongly recommended.
(7) A similar situation applies in cases of road traffic accidents.