Concepts of med. equipment safety and risk management

- Safety is relative
- Hazards and risk
- Process of risk management
- Risk classification schemes
- Risk classification determinants
- Risk/benefit ratio for medical equipment
- Examples of risk classification based on determinants

see also:
MEDICAL DEVICE REGULATIONS
Global overview and guiding principles
WHO 2003

17.1.1 Define the concepts of medical equipment safety and risk management

Unit C 17.1 Medical Equipment Safety

Module 279-17-C Regulations, Standards and Ethics

What is safe? What is risk?

Sort on safety / risk level:

1. a car
2. a race car
3. a truck
4. a bus
5. a bicycle
6. an airplane

1. a screw driver
2. a hammer
3. scissors
4. tongs / pincers
5. an electric drill machine
6. lathe machine

1. injection needle
2. suction machine
3. blood pressure machine
4. anesthesia machine
5. X-ray system
6. surgical knife

Relative Risks in everyday life (USA data)

Activity	What is the risk that a person dies in any given year from this activity ?
Smoking 10 cigarettes per day	
Influenza	
Natural Causes, 40 years old	
Road Accident	
Accident at Home	
Accident at Work	
Hit by Lightning	

Relative Risks in everyday life (USA data)

Activity	What is the risk that a person dies in any given year from this activity ?
Smoking 10 cigarettes per day	1 in 200
Influenza	1 in 500
Natural Causes, 40 years old	1 in 850
Road Accident	1 in 8,000
Accident at Home	1 in 26,000
Accident at Work	1 in 43,500
Hit by Lightning	1 in 10,000,000

What is risk ?

Risk is the potential of losing something of value

Values (such as physical health, social status, emotional well being or financial wealth) can be gained or lost when taking risk resulting from a given action, activity and/or inaction, foreseen or unforeseen.

Risk is the intentional interaction with uncertainty

Uncertainty is a potential, unpredictable, unmeasurable and uncontrollable outcome,
risk is a consequence of action taken in spite of uncertainty.

Risk perception is the subjective judgment people make about the severity and/or probability of a risk, and may vary person to person.

Any human endeavour carries some risk, but some are much riskier than others….

Safety and the chance of dying

Your odds of dying by (in the USA):

- Cardiovascular disease: 1 in 2
- Smoking (by/before age 35): 1 in 600
- Car trip, USA coast-to-coast: 1 in 14,000
- Bicycle accident: 1 in 88,000
- Tornado: 1 in 450,000
- Train, coast-to-coast: 1 in 1,000,000
- Lightning: 1 in 1.9 million
- Bee sting: 1 in 5.5 million
- U.S. commercial jet airline: 1 in 7 million

Sources: Natural History Museum of Los Angeles County, Massachusetts Institute of Technology, University of California at Berkeley

Risk is OK, sort of ….

In general, we are all ok with many of the risks of likelihoods in the range 1 in 10,000 to 1 in 10 million.

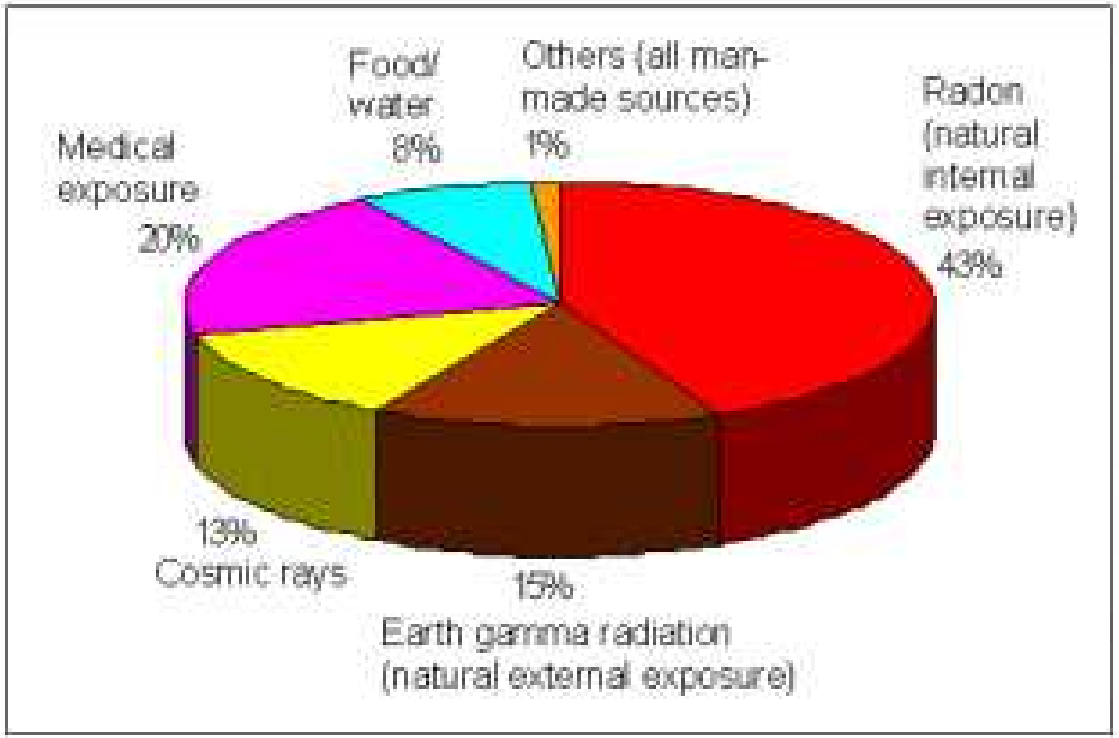
When we stop to consider many of these risks,
we recognize that they are potentially lethal and indeed
could affect people such as ourselves,
but we do not change our behaviour to avoid them.

It is as if we recognize that there are just too many possible risks that might kill each one of us
in our daily lives that we just adopt common sense and carry on living our lives.

"Every man dies, not every man really lives" (Braveheart)

Exposure to Medical Radiation is not Insignificant

Radiation is a well-established risk factor for Cancer.
Medical exposure to radiation is caused by X-ray / CT / NM examinations.
The amount of medical exposure (probably) increases the incidence of cancer in the population.
The amount of medical exposure to radiation therefore should be minimized.



But such examinations can still be very 'worthwhile' (versus benefits) for individual patients

Investigation	Effective Dose (mSv)	Equivalent number of Chest X-rays	Equivalent period of natural radiation
Radiography			
Chest	0.02	1	3 days
Skull	0.1	5	2 weeks
Abdomen	1.5	75	9 months
CT examination			
Brain	2.0	100	1 year
Abdomen	8.0	400	4 years

The biggest risk is taking no risks !

Minimizing risks in Healthcare

How do we minimize the (unnecessary) risk that patients and hospital personnel run?

By exploring the sources of all potential accidents (hazards)
and
adapting our behaviour and our actions to avoid these.

Such adapted behaviour is made obligatory for all workers in the healthcare field
by means of
rules and regulations.

Hazards and Risk

A '**hazard**' is a 'danger': a potential source for an adverse event; **something that could go wrong**

in this context, a '**risk**' is a measure of the combination of

1. the **hazard**
2. the **likelihood** of occurrence of the adverse event
3. the **severity** or overall impact

- a punctured tire
- once every four years
- a severe accident

The magnitude of the risk indicates
how much a hazard must be taken into account in practical life

A higher risk means more regulation….

Hazards

List as many as possible hazards associated with a:

car

hammer

X-ray system

Hazards and Risk (examples)

(*) examples only

	hazard	how likely is it to happen (*)	how bad is it when it happens (*)
Injection needle	unintended puncture	+++	++
	infection if non-sterile	+	++
Suction machine	over-suction	+	+
Blood pressure machine	mercury spill	+	+
Anaesthesia machine	wrong dose administered	+	++++
X-ray machine	patient damage from X-ray	+	+++
ECG machine	electrical shock through grounding error	+	++++

There are usually many hazards per device!

Safety is a Risk Management issue

Starting points to consider medical device safety:

- Absolute safety cannot be guaranteed
- It is a risk management issue
- It is closely aligned with device effectiveness / performance
- It must be considered throughout the life span of the device
- It requires shared responsibility among the stakeholders

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a critical shortage of blood for other lifesaving purposes, with a broad impact on patient care.

Risk/benefit ratio for medical equipment

The first requirement of the
"Essential principles of safety and performance of medical devices"
recommended by the GHTF (SG1-N020R5) states that:

Medical devices should be designed and manufactured in such a way that:

and maintained!!

- when used under the conditions and for the purposes intended and,
- where applicable, by virtue of the technical knowledge, experience, education or training of the intended users,

they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons,

provided that any risks which may be associated with their use constitute

- **acceptable risks when weighed against the benefits to the patient** and
- are compatible with **a high level of protection of health and safety**.

Risk needs to be assessed

All devices carry a certain degree of risk and could cause problems in specific circumstances.

Many medical device problems cannot be detected until extensive market experience is gained.
For example:

- an **implantable device** may fail in a manner that was not predictable at the time of implantation
- a failure may reflect conditions unique to certain patients
- a component failure can be unpredictable or random
- .....

The current approach to device safety is to **estimate the potential of a device becoming a hazard** that could result in safety problems and harm.

This estimate is often referred to as: the Risk Assessment

Risk needs to be assessed

Risk Assessment

begins with

Risk Analysis to identify all possible hazards,

followed by

Risk Evaluation to estimate the risk of each hazard.

Risk Assessment
=
Risk Analysis plus Risk Evaluation

Risk Analysis
=
Hazard Identification

Risk Evaluation
=
Sizing the Risk

In general, risk assessment is based on experience, evidence, computation, or even guesswork. Risk assessment is complex, as it can be influenced by personal perception and other factors such as cultural background, economic conditions, and political climates.

Medical Device classification based on risk assessment

The degree of regulation imposed on any device is proportional to its potential hazard (risk class)

‘Medical Devices’ includes more than ‘Medical Equipment’

“**Medical device**” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, **intended by the manufacturer to be used**, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of **disease**
- diagnosis, monitoring, treatment, alleviation of or compensation for an **injury**
- investigation, replacement, modification, or support of the **anatomy** or of a **physiological process**
- **supporting** or **sustaining** life
- **control of conception**
- **disinfection** of medical devices
- providing information for medical purposes by means of **in vitro examination** of specimens derived from the human body

e.g. a bed versus a hospital bed,
a knife versus a surgical knife,

‘Medical Device’ includes most medical items that are not drugs. Regulation is mainly done at Medical Device level….

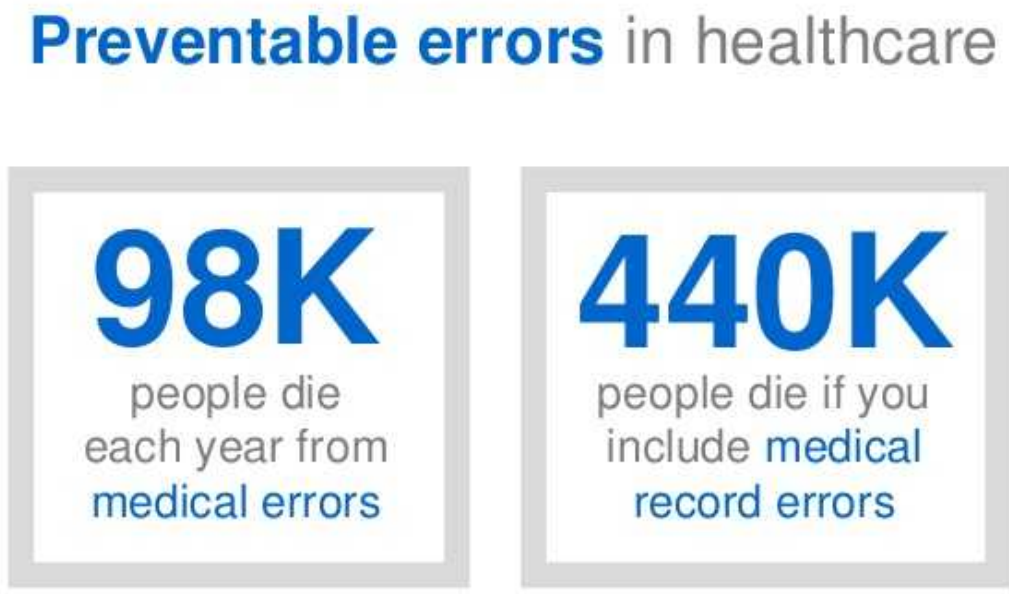
Patient Safety?

In the United States, the public and the medical specialty of anesthesia were shocked in April **1982** by a USA television program entitled The Deep Sleep. Presenting accounts of anesthetic accidents, the producers stated that, every year, 6,000 Americans die or suffer brain damage related to such accidents.

In **2004**, the Canadian Adverse Events Study found that **adverse events** occurred in more than 7% of hospital admissions, and estimated that 9,000 to 24,000 Canadians die annually after an **avoidable medical error**.

These and other reports have led the World Health Organization to estimate that **one in ten persons receiving health care will suffer preventable harm.**

Hospital Errors are the Third Leading Cause of Death in U.S.



Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press; 2000.
James, JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013 Sep;9(3):122-8. doi: 10.1097/PTS.0b013e3182948a69.

Patient Safety?

A Report on Quality and Safety in 2007 found that **inadequate communication** between healthcare providers, or between providers and the patient and family members, was the root cause of over half the serious adverse events in accredited hospitals. **Handwritten reports, manual order entry, and poor legibility** lead to substantial errors and injuries.

Other leading causes included **inadequate assessment of the patient's condition, poor leadership** or **training**.

Similarities and contrasts have been noted between the "cultures of safety" in medicine and aviation. Pilots and medical personnel both operate in complex environments, interact with technology, and are subject to fatigue, stress, danger, and loss of life and prestige as a consequence of error.

Given the excellent record of aviation in accident prevention, a similar medical adverse event system would include

- **non-punitive reporting**,
- **teamwork training**,
- **feedback on performance** and
- **institutional commitment to data collection and analysis**.

Medical Device Risk Classification in the USA

The Food and Drug Administration (FDA) has established risk classifications for approximately **1,700** different **generic** types of devices.
Each of these generic types of devices is assigned to **one of three regulatory classes** based on the **level of control necessary** to assure the safety and effectiveness of the device. The risk classification is based on **expert recommendation** from members of 16 medical 'panels', together covering all devices.

Device classification depends on the **intended use of the device** and also upon indications for use.
For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labelling such as, "for making incisions in the cornea".

Indications for use can be found in the device's labelling, but may also be conveyed orally during sale of the product.

Device classification is **risk based**, that is, the risk the device poses to the patient and/or the user is the major factor in the class it is assigned (see next page).

FDA Class I includes devices with the lowest risk and FDA Class III includes those with the greatest risk

Risk classification determinants

In classifying devices, potential areas of hazard that are considered include:

- **the degree of invasiveness**
  - an invasive device is usually considered to have higher potential hazard than an equivalent non-invasive device (e.g. there are invasive and non-invasive blood pressure monitors)
- **duration of contact**
  - long versus short
- **the body system affected**
  - more or less vital organs affected; e.g. the heart is considered vital
- **local versus systemic effects**
  - systemic means involving the ‘total’ body

Examples of risk classification (FDA)

Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls.
For example, **dental floss** is classified as Class I device.

Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness. For example, **condoms** are classified as Class II devices.

Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices **must typically be approved by FDA before they are marketed**. For example, replacement heart valves are classified as Class III devices.

Examples of risk classification (FDA)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--**MEDICAL DEVICES**
PART 870 -- **CARDIOVASCULAR DEVICES**

Subpart C--**Cardiovascular Monitoring Devices**

Sec. 870.2340 **Electrocardiograph.**
(a) Identification. An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.

(b) Classification. **Class II** (performance standards).

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Subpart B--**Cardiovascular Diagnostic Devices**

Sec. 870.1130 **Noninvasive blood pressure measurement system.**
(a) Identification. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of tranducers placed on the surface of the body.

(b) Classification. **Class II** (performance standards).

Examples of risk classification (FDA)

Sec. 892.1000 **Magnetic resonance diagnostic device**.
(a) Identification. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) Classification. **Class II**.

Sec. 868.1100 **Arterial blood sampling kit**.
(a) Identification. An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

(b) Classification. **Class I**

Sec. 864.3600 **Microscopes and accessories.**
(a) Identification. Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes. Variations of microscopes and accessories (through a change in the light source) used for medical purposes include the following:

(b) Classification. **Class I**

Risk Classification in the European Union (EU)

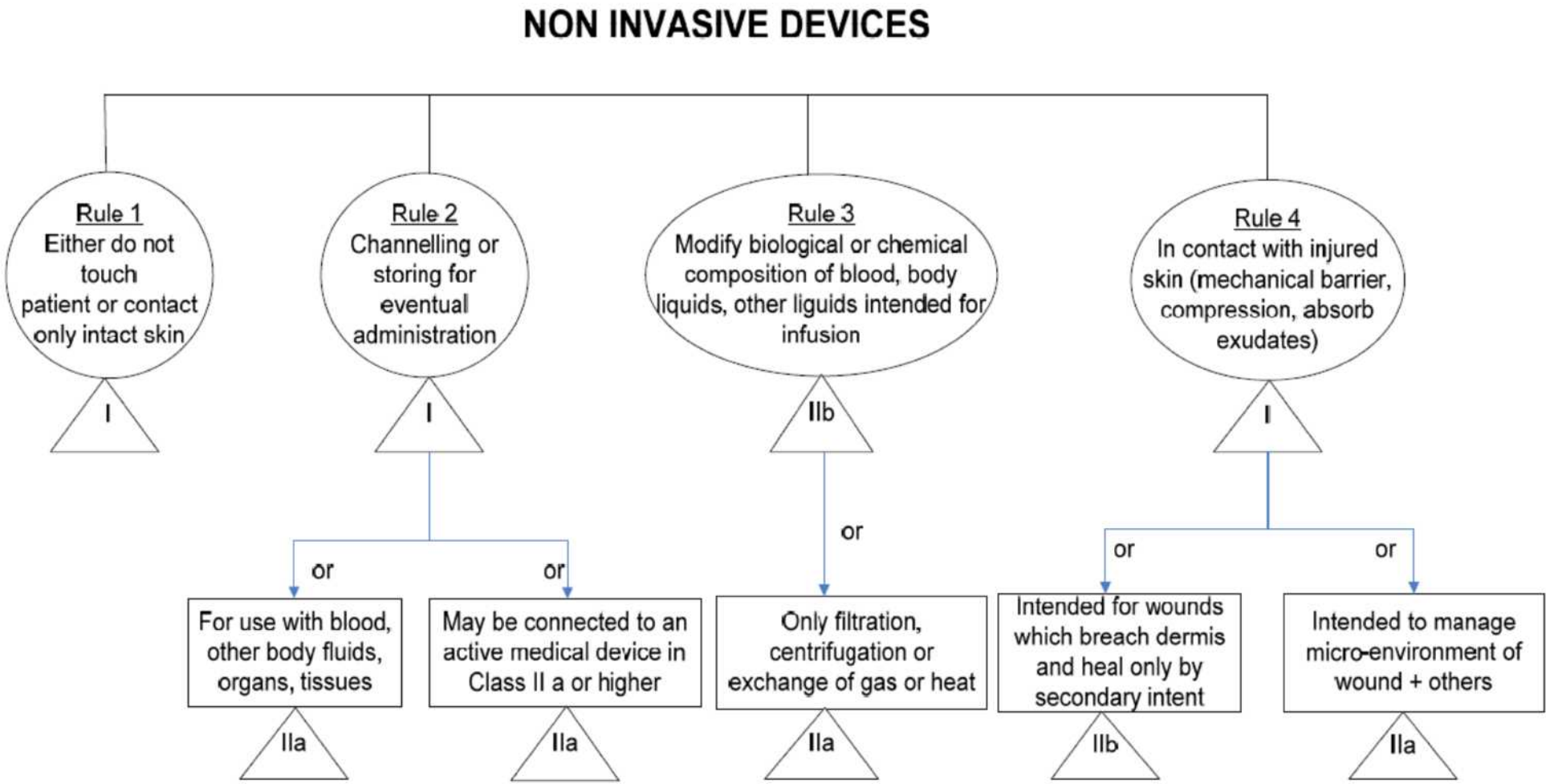
The classification of medical devices in the European Union is outlined in Annex IX of the Council Directive 93/42/EEC.

There are basically four classes, ranging from low risk to high risk.

- Class I
- Class IIa
- Class IIb
- Class III

The classification is **'rule based':** rules categorize medical devices according to their perceived potential hazards (see next page).

EU Rule Based device classification (example)



Examples of risk classification

Risk Class	Risk Description	Example
Active Implantable Medical Device (AIMD)	High	Implantable pacemaker
Class III	High	Drug eluting cardiac stents
Class IIb	Medium-High	Ventilators, orthopaedic implants
Class IIa	Medium-Low	Hypodermic needles, suction equipment
Class I sterile	Low	Sterile dressings, non-medicated
Class I measuring	Low	Volumetric urine bag
Class I basic	Low	Reusable surgical instruments

(GHTF guidelines)

END

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