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Identification of Intensive Care Unit planning criteria during a COVID-19 emergency: ICU Reorganizational Protocol

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ABSTRACT

Italian version

L'attuale emergenza sanitaria legata a COVID-19 ha posto particolare pressione sul Sistema Sanitario Nazionale italiano, richiedendo un aumento delle postazioni in reparti di Terapia Intensiva di oltre il 50% rispetto alla situazione ordinaria. La mancanza di linee guida per la riorganizzazione delle strutture sanitarie ha creato un'ulteriore criticità nella gestione dell'emergenza, lasciando alle singole cliniche il compito di valutare possibili modifiche. Da qui l'esigenza di creare un protocollo, in collaborazione con il servizio di Ingegneria Clinica dell'ASST-FBF-SACCO, che definisca i requisiti necessari e ideali riguardanti i dispositivi medici, le strutture e gli impianti ospedalieri, relativi al ricovero di pazienti COVID-19 in Terapia Intensiva, con attenzione ai cambiamenti legislativi e di pratica clinica attuati in fase emergenziale.

Si rende quindi in primo luogo necessaria un'analisi riguardante gli aspetti generali relativi a Dispositivi Medici e Impianti Ospedalieri nelle strutture sanitarie, per poi definire la loro applicazione in Terapia Intensiva.

Poiché l'immissione nel mercato di **Dispositivi Medici** e la loro successiva accettazione in strutture ospedaliere è vincolata al soddisfacimento di **Direttive Europee**, è necessario conoscere il quadro normativo e i criteri di classificazione e certificazione dei dispositivi medici, che dimostrino, tramite l'ottenimento della Marcatura CE, il rispetto stringente di standard di sicurezza ed efficacia e permettano il successivo accreditamento presso le cliniche ospedaliere.

Le strutture sanitarie devono adempiere a specifici requisiti riguardanti gli **Impianti Ospedalieri**. Vengono dunque presi in analisi regolamentazioni legislative, standard tecnici di progettazione e criteri di sicurezza e controllo relativi ai principali impianti, necessari alla costruzione di unità di Terapia Intensiva: impianto elettrico, impianto di distribuzione dei gas medicali, impianto idraulico e impianto di ventilazione e condizionamento. Inoltre, vengono brevemente descritti i sistemi per la gestione dei flussi informativi dei pazienti e della struttura, insieme al sistema di supervisione e controllo del network ospedaliero.

La realizzazione di unità di **Terapia Intensiva** segue precisi criteri relativi agli aspetti strutturali e impiantistici e riguardanti i dispositivi medici. La progettazione strutturale richiede la presenza di specifiche zone che assicurino un supporto clinico specializzato,

mentre gli impianti precedentemente descritti devono garantire adeguate condizioni: il sistema di ventilazione e condizionamento mantiene caratteristiche ambientali definite e la corretta purezza dell'aria; l'impianto di distribuzione dei gas medicali assicura l'erogazione dei gas a determinati valori di pressione e flusso tramite specifici terminali; l'impianto elettrico garantisce le misure di sicurezza definite per la relativa categoria di locale ad uso medico. Infine, ulteriori criteri definiscono l'insieme dei dispositivi medici necessari, di cui si evidenziano la composizione, il funzionamento e la classificazione, insieme agli standard tecnici che ne assicurano la corretta performance e la tempistica di manutenzione.

Definiti i requisiti relativi ad unità di terapia intensiva standard, vengono in seguito identificate le possibili **Misure d'Emergenza per Terapia Intensiva COVID-19**. Un confronto tra le due condizioni, a livello strutturale, impiantistico e nella gestione dei dispositivi medici, è evidenziato all'interno delle seguenti tabelle: *COVID-19 Structural modifications* (Table 13), *COVID-19 HVAC setting* (Table 14), *COVID-19 Medical gases setting* (Table 15), *COVID-19 Medical Devices recommendations* (Table 16), *COVID-19 Cleaning and Disinfection measures* (Table 20). A livello strutturale (Table 13), si delineano cambiamenti riguardanti la definizione di percorsi clinici e una diversa gestione di pazienti e reparti. In ambito impiantistico (Table 14, Table 15), il sistema di ventilazione e condizionamento si regola su differenti livelli di pressione e di ricircolo d'aria, mentre per la distribuzione di gas medicali è necessaria una verifica della capacità dell'impianto e l'utilizzo di particolari collegamenti d'emergenza per i sistemi di supporto respiratorio, che possano far fronte ad un elevato numero di ricoveri. Per i dispositivi medici (Table 16), sono invece individuati cambiamenti sul set di apparecchiature per posto letto e sulle procedure di manutenzione, con particolare attenzione alla ventilazione polmonare. Rispetto ai protocolli di disinfezione (Table 20), si applicano specifiche considerazioni relativamente a superfici, lavanderia, rifiuti ospedalieri e apparecchiature medicali. Infine, la grande richiesta di dispositivi medici ha implicato problematiche nel rispetto del regolatorio legislativo, per cui la *Proposta Interassociativa* (AIIC, AIIGM, ANTEV, ANTAB) rappresenta una possibile soluzione.

In conclusione, l'insieme delle soluzioni evidenziate (Table 13, Table 14, Table 15, Table 16, Table 20, *Proposta Interassociativa*) costituisce il ***COVID-19 ICU Reorganizational Protocol***, utile per rispondere in modo tempestivo ed efficace alla necessità di riorganizzare un reparto di Terapia Intensiva in caso di eventuali seconde ondate di COVID-19 o simili emergenze infettive.

English version

The current COVID-19 health emergency has placed particular stress on the Italian National Health System, requiring an increase in the number of beds in Intensive Care Units (ICUs) by more than the 50% compared to the ordinary situation. The lack of guidelines for the reorganization of healthcare structures has increased the difficulties in the management of the emergency, leaving to the facilities the evaluation of possible changes. Hence the need to create a protocol, in collaboration with the Clinical Engineering service of the ASST FBF-SACCO, which defines the essential and ideal requirements regarding Medical Devices, hospital structures and implants, related to the hospitalization of COVID-19 patients in ICUs, with attention to legislative and clinical practice changes implemented during the emergency phase.

An analysis is firstly necessary regarding the general aspects related to Medical Devices and Hospital Implants in healthcare facilities, to then define their application in Intensive Care.

The distribution of **Medical Devices** and their following acceptance in hospitals is bound to the fulfillment of **European Directives**. Thus the need to recognize the regulatory framework and the classification and certification criteria for Medical Devices, which demonstrate, by obtaining the CE marking, conformity to the stringent safety and efficacy standards, allowing for the subsequent accreditation in hospitals.

Healthcare facilities must fulfill specific **Healthcare Structures Requirements**. Therefore, legislative regulations, technical design standards, safety and control criteria related to the main implants, necessary for the construction of ICUs, are analyzed: electrical system, medical gas distribution system, hydraulic system, ventilation and air conditioning system. In addition, the data systems for managing patients and facility information flows are briefly described, together with the supervision and control system of the hospital network.

The creation of **Intensive Care Units** follows definite criteria related to structural and implant systems aspects and regarding Medical Devices. The structural design requires the presence of specific areas to ensure specialized clinical support, while the aforementioned hospital implants must guarantee adequate conditions: the ventilation and conditioning system maintains defined environmental characteristics and the correct air quality; the medical gas distribution system ensures the delivery of gases at certain pressure and flow values through specific terminals; the electrical system guarantees the safety measures

defined for the respective premises category. Finally, further requirements define the set of necessary Medical Devices, whose composition, function and classification are highlighted, together with the technical standards that certify the correct performance and maintenance planning.

Once the requirements related to standard ICUs have been defined, possible **ICUs Measures in COVID-19 Emergency** are identified. A comparison between the two conditions on the structural, implant and Medical Devices management levels is highlighted in the following tables: *COVID-19 Structural modifications* (Table 13), *COVID-19 HVAC setting* (Table 14), *COVID-19 Medical gases setting* (Table 15), *COVID-19 Medical Devices recommendations* (Table 16), *COVID-19 Cleaning and Disinfection measures* (Table 20). On the structural level (Table 13), changes regard the definition of clinical pathways and a different management of patients and departments. In the implant systems field (Table 14, Table 15), the ventilation and conditioning system set different levels of pressure and air recirculation, while for the distribution of medical gases it is necessary to check the capacity of the system and to use particular emergency connections for respiratory support systems, which can cope with a large number of hospitalizations. Regarding Medical Devices (Table 16), changes involve the bedside equipment set and the maintenance procedures, with particular attention to lung ventilation. Moreover, specific considerations on surfaces, laundry, hospital waste and medical equipment are mentioned for disinfection protocols (Table 20). Finally, the great demand for Medical Devices has led to problems regarding the compliance with legislative regulations and the *Interassociative Proposal* (AIIC, AIIGM, ANTEV, ANTAB) is identified as a possible solution.

The set of highlighted solutions (Table 13, Table 14, Table 15, Table 16, Table 20, *Interassociative Proposal*) constitutes the **COVID-19 ICU Reorganizational Protocol**, useful for responding in a timely and effective way to the need for restructuring an Intensive Care Unit, in case of any second waves of COVID-19 or similar infectious emergencies.

INTRODUCTION

1. Pandemic

1.1 Rise of the pandemic

December 2019, Hubei province, China. The city of Wuhan became the focus of Chinese and worldwide attention due to a pneumonia outbreak of unknown origin. On 31st December, date of the first notification to the WHO (*World Health Organization*), the Wuhan Municipal Health Commission identified and reconducted the aetiology of 27 cases to the urban Huanan Seafood Wholesale Market [1], anticipating the compatibility of the disease with a viral nature. The possibility of animal-to-human transmission, related to the sale of wild bushmeat at the market in doubtful hygiene conditions, was assumed.

The analysis of the main symptoms (fever and dry cough, eventually respiratory problems and distress) and clinical data rapidly led to the exclusion of SARS-CoV, MERS-CoV, avian influenza and other typical respiratory viruses as causes of the unknown pneumonia. On 7th and 12th January 2020, respectively, Chinese scientists isolated and sequenced the *2019 novel Coronavirus* (then renamed ***SARS-CoV-2***, *Severe Acute Respiratory Syndrome-Coronavirus-2*), which showed a strong similarity to SARS-CoV [2], confirming its zoonotic origin. By this time, diagnostic test were aimed to detect early pneumonia and to work with selected laboratories that can carry out the direct sequencing of the new coronavirus, waiting for a full development of a RT-PCR (*Reverse Transcriptase - Polymerase Chain Reaction*) test to uniquely identify sequences of viral nucleic acids.

At that moment, still no evidence of human-to-human transmission was proved, but the rapid and continuous expansion inside and outside Wuhan city, together with the first nosocomial infections of healthcare professionals working with SARS-CoV-2-positive patients, would have driven to a different conclusion [3].

In a few weeks from the outbreak origin, new cases had been reported in Japan, Korea, Thailand, USA and in multiple Chinese regions, including more than 130 deaths by the end of January (Figure 1) [4].

Figure 1 – Main steps in the starting phase of the infection (source: Avetta)

Because of the extension and seriousness of such an outbreak, the state of **international public health emergency** was declared by the WHO on 30th January 2020, and the first 2 cases of SARS-CoV-2 infections were reported in Italy the next day [5]. A few days later, on 11th February 2020, WHO defined ***COVID-19*** as the name for the new coronavirus disease.

In late February, the number of new infections reported from outside China proved to be superior to the new cases inside, showing that the epidemic was clearly moving towards the evolution in a global pandemic [6]. On 7th March 2020, the threshold of 100.000 infections, of which 3500 deaths, was globally broken down and the state of **global pandemic** was officially declared by the WHO on 11th March 2020. Europe had become the pandemic epicentre, reporting more infected and deceased than the rest of the world combined, China excluded.

On 19th March, the number of confirmed infections passed 200.000: after taking over 3 months to exceed 100.000 cases, less than 2 weeks have been necessary to duplicate the infections; only 8 more days have been necessary to surpass 500.000 cases globally, of which more than 23.000 deaths. By the 4th April 2020, worldwide cases overcame 1 million, with over 50.000 deaths [7].

European situation continued to worsen until mid-April, after which it saw a steading and then improvement in the number and severity of infections, thanks to the prompt

interventions introduced in February and March 2020. The pandemic epicenter shifted to the Americas, whose underestimation of the infections and late response to the pandemic led the continent to experience a continuous increase in infections and deaths, with about 120.000-150.000 daily contagions and 3.000-5.000 daily deaths in mid-late August 2020; a similar trend, but with lower entity, was followed in South-East Asia. Western Pacific proved to be most virtuous region in the control of the pandemic, while the African continent reported a quite low number of infections and deaths, probably underestimated due to the limited economic and organizational resources invested in the contagion tracking.

Therefore, the global growth rate of infections continued to increase exponentially during the whole spring and summer seasons, while deaths reached a stationary level of about 4.000-7.000 daily cases since mid-April to late August 2020 (Figure 2, Figure 3) [8].

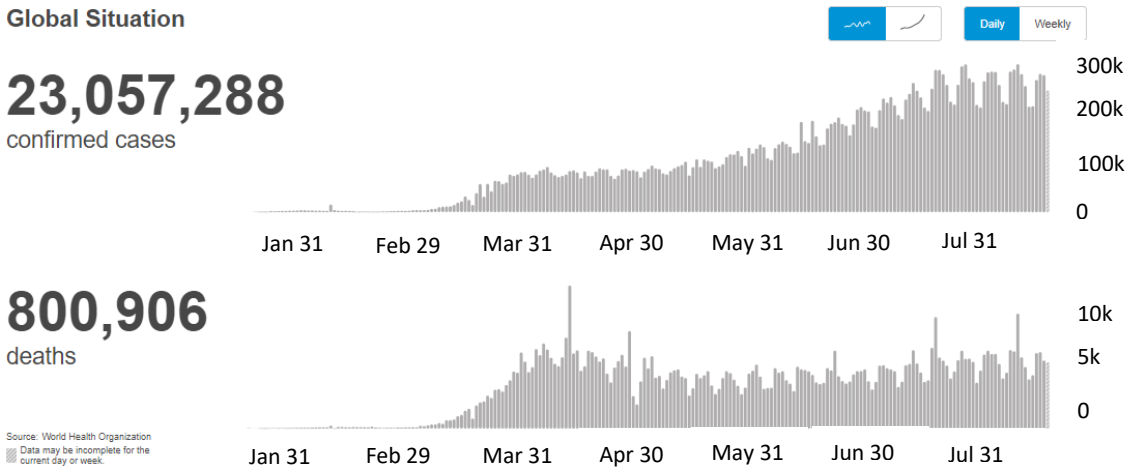


Figure 2 – Global daily infections and deaths (23rd August 2020) (source: WHO)

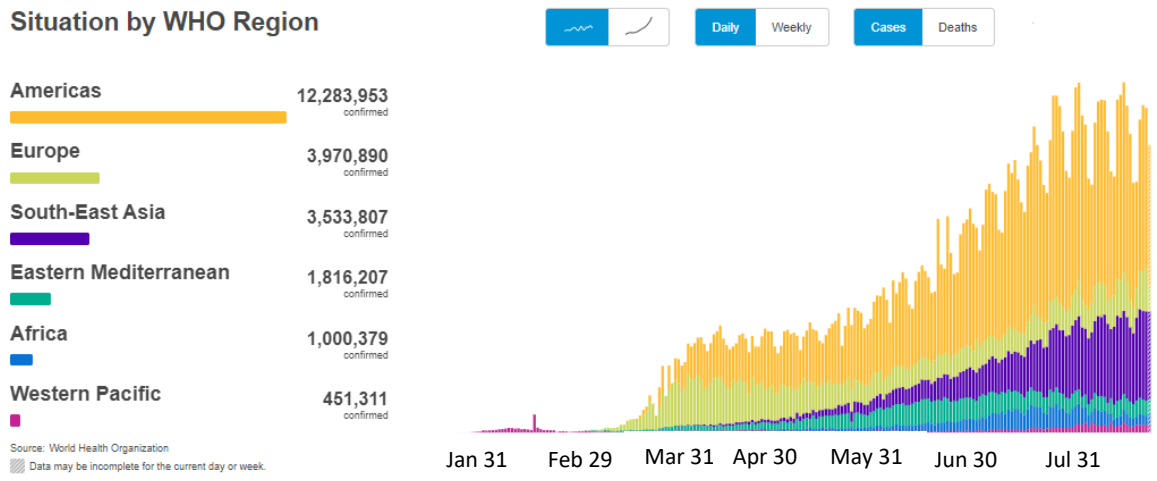


Figure 3 – Global daily infections by WHO region (23rd August 2020) (source: WHO)

The trend of infections and deaths has followed different paths in different countries, with some of which having already overcome the peak and others not, depending on several elements such as the speed of response to the epidemic, the efficacy of quarantine measures and other safety rules implemented, the density and size of population and the capacity of healthcare systems.

Possible second waves of infections are forecast by some experts for the next autumn and winter season. Whether COVID-19 will come to an end or will become an endemic illness is still unclear, and a fundamental role will be played by the discovery and global distribution of an effective vaccine against SARS-CoV-2.

1.2 Italian condition

On 31st January 2020, together with the declaration of **health state emergency** by the Italian Council of Minister, Italy reported the first 2 cases of COVID-19 in people who had travel history from Wuhan, while on 21st February the first cases in people who had not returned from China were highlighted in the Lodi area. In the next days, several restriction measures were introduced to contain the infections: a first Decree Law on 23rd February 2020 set the prohibition of access and exit in the municipalities where outbreaks were present, together with the suspension of demonstrations and events; subsequently, the Prime Minister Decree of 11th March 2020 defined the closing of all commercial activities of non-primary necessity and introduced a ban on travel, except for work or health reasons.

The exponential growth of the contagion continued until reaching its top on 21st March, with 6.557 new diseases (Figure 4): to that day, Italy has accounted for 42.681 infections of which 4825 deaths. Thanks to the adoption of containment measures, the number of infections and deaths started to decrease, together with the consequent reduction of hospitalizations in health facilities.

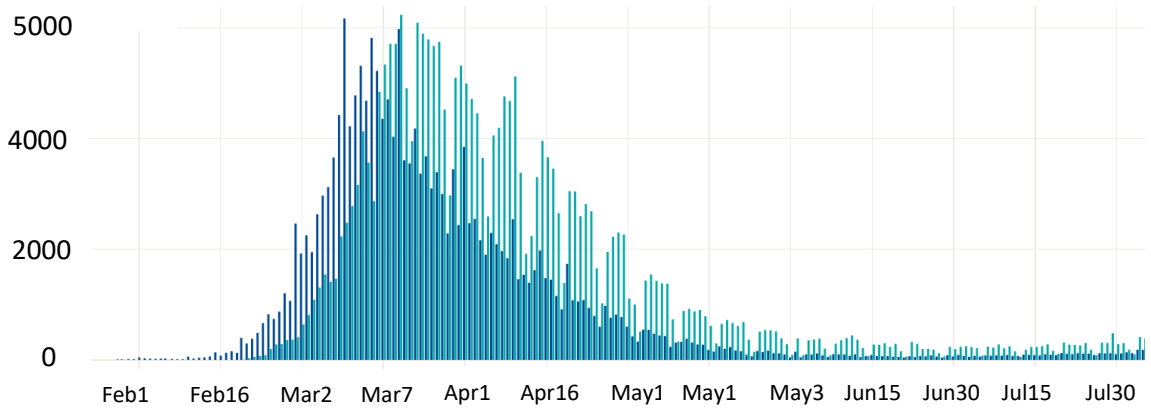


Figure 4 – Epidemic curve in Italy by diagnosis (green) and symptom start (blue) (source: ISS)

The **Lombardy Region** was the most affected by the pandemic, as the area with the highest percentage of deaths (49.1%) followed by Emilia Romagna (12.5%), Piedmont (9.1%) and Veneto (5.8%). This determined a higher pressure on the National Health Service, especially in public northern healthcare facilities. In response, new COVID-19-dedicated structures were activated and a special plan for intensive care units was developed by Italian regions, increasing the number of total ICU beds, available even after the emergency period, from about 5.400 to almost 7.800 [9]. To a lesser extent than Northern Italy, also the Southern was affected by the contagion, requiring anyhow particular attention due to its lower capacity to cope with the healthcare emergency, given the weaker quality and size of medical assistance.

Emergency management measures

In Italy, the monitoring of COVID-19 cases is carried out through two daily data streams:

- the flow of aggregate data sent by Regions with the support of the Civil Protection and, from 25th June 2020, with the further support of ISS (*Istituto Superiore di Sanità*), to collect timely information on the total number of positive tests, deaths, hospitalizations and intensive care admissions in every Province of Italy;
- the flow of individual data sent by the Regions to the ISS, which also includes demographic data, comorbidities, clinical status and its evolution over time, for a more accurate analysis.

Since the first case of SARS-CoV-2 local transmission was confirmed, the EMS (*Emergency Medical System*) in Lombardy Region represented the first response for handling suspected symptomatic patients, for adopting containment measures, and for

addressing population concerns. The EMS of the metropolitan area of Milan instituted a COVID-19 Response Team with the goal of tackling the viral outbreak without burdening ordinary EMS activity (Figure 5).

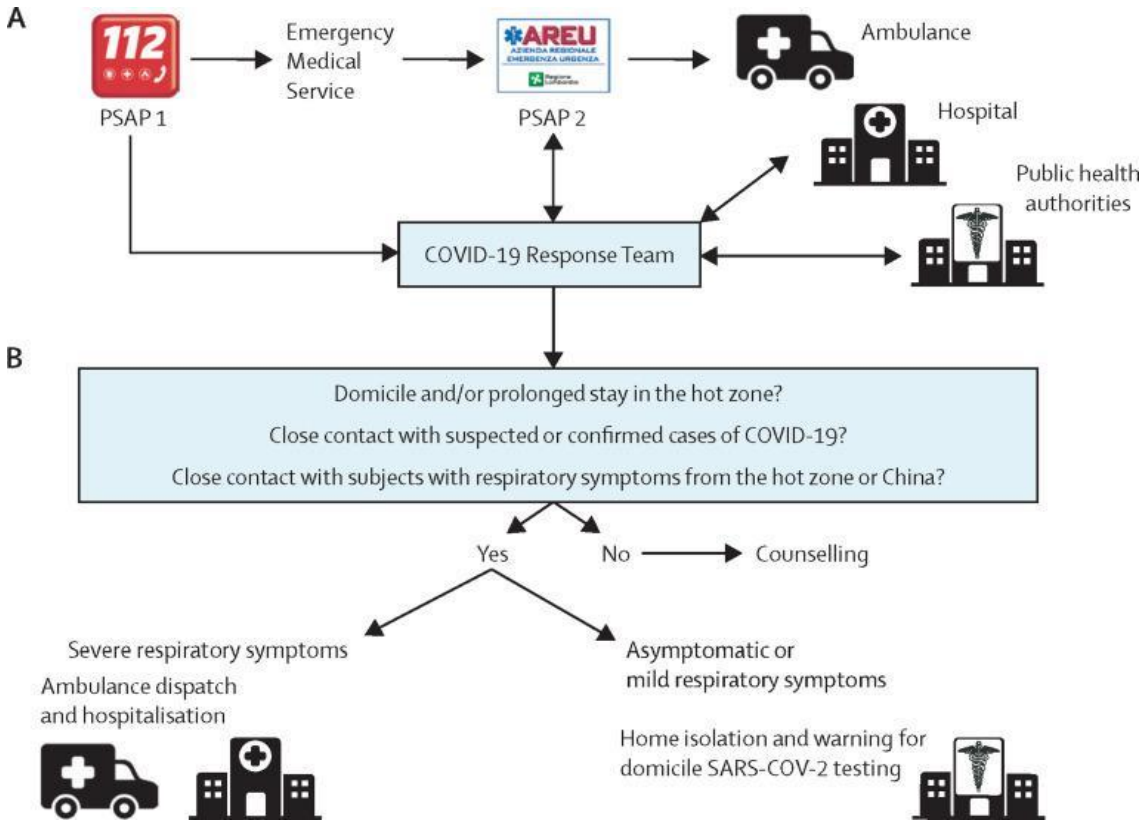


Figure 5 – Emergency Medical System of Milan for COVID-19 (source: The Lancet)

The COVID-19 Response Team collaborated with regional medical authorities to design a procedural algorithm for the detection of suspected cases of COVID-19, which allowed to handle patients flow to hospitals and to address issues about the overcrowding of emergency departments, managing the need for patients transfer to other specialised facilities. The algorithm is constantly updated to meet regional directives about critical zones extensions and modalities for SARS-CoV-2 testing. Lombardy responded to the lack of beds for COVID-19 patients by sending non-COVID-19 patients needing intensive care to hospitals outside the region. The population also actively participated in multiple fundraisers to support hospitals and institutions, thanks to which it was possible to create new beds in intensive care and to reorganize the hospitals with the machinery required [10].

Another measure adopted by the government since 1st June 2020 was the *Immuni* app, an innovative technological support which allows to trace the contacts that may have exposed a person to the risk of contagion.

1.3 COVID-19

Characteristics

Coronaviruses are viruses that originate and circulate among animals, with some of them also known to infect humans. The primary mode of human-to-human transmission is the inhalation of respiratory droplets generated by breathing, sneezing, coughing, or the hand-mediated transfer of the virus from contaminated fomites to mouth, nose or eyes. Also, the transmission through aerosols is being considered but it is still unclear.

SARS-CoV-2 can survive on different surfaces from several hours up to a few days. However, the amount of viable virus declines over time and may not always be present in sufficient quantity to cause the illness. The infectious period may begin 1-2 days before symptoms appear and the current estimates, as of September 2020, suggest a median incubation period for COVID-19 of 5-6 days, ranging from 2 to 14 days. It is estimated that the 25% of reported cases have been hospitalised, of which the 14% required ICU and/or respiratory support [11].

In order to respond to an infectious outbreak, organizations and nations need information about the power of the virus and the spread ability: the *basic reproduction number* (R_0) defines the average number of people who will catch the disease from a single infected person, in a population that has never seen the disease before. If R_0 is greater than 1, the infection will probably keep spreading, while if it is lower than 1, the outbreak will likely peter out. The ECDC (*European Centre for Disease Prevention and Control*) reports the mean basic reproductive number for COVID-19 at 3.28, with a median of 2.79. When outbreak control interventions are in place and the population cannot be considered as fully susceptible, the *effective reproductive number* (R_e) assesses the transmission potential at a given time.

Medical information

In Italy, based on ISS (*Istituto Superiore di Sanità*) data as of 22nd July 2020, the average age of deceased patients is 80 years, while the distribution of sex among the cases is 57.6% of men against 42.4% of women. Elderly people and those with underlying health conditions (e.g. hypertension, diabetes, cardiovascular diseases, chronic respiratory diseases and cancer) are considered to be more at risk of developing severe symptoms: in fact, among the

deceased in Italy only 3.9% had no previous pathologies, 13.9% had one previous pathology, 20.4% had two pathologies and 61.8% had three pathologies prior to hospitalization [11].

Symptoms of COVID-19 vary in severity from having no symptoms at all (being asymptomatic) to having fever, cough, sore throat, general weakness and fatigue and muscular pain; in the most severe cases, severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock can all potentially lead to death. Reports show that clinical deterioration can occur rapidly, often during the second week of disease. Recently, *anosmia* – the loss of smell sense – and, in some cases, the loss of taste sense have been reported as further symptoms. COVID-19 infections usually show mild and flu-like symptoms, which are rather common and need to be distinguished from similar symptoms caused by common cold viruses and from allergic symptoms. It is good to bear in mind that the definitive diagnosis of COVID-19 is not clinical, but through laboratory testing of a sample from the nose or mouth. The following table (Table 1) presents a comparison of the most common symptoms of all three conditions according to their reported frequency [11].

Table 1 – Comparison of symptoms: common cold, hay fever and COVID-19

Illness	Common cold	Hay fever (pollen allergy)	COVID-19
Fever	Sometimes, usually < 38.5°C (±)	No	Yes, maybe high grade (+++)
Cough	Sometimes (+)	Sometimes (±)	Yes, persistent dry cough (+++)
Runny / stuffy nose	Yes (++)	Yes (+++)	Sometimes (±)
Sneezing	Yes (++)	Yes (+++)	Sometimes (±)
Headache	Yes (+)	Yes (+)	Yes (+++)
Myalgia	No	No	Yes (++)
Anosmia	Sometimes (±)	Sometimes (±)	Sometimes (±)
Conjunctivitis	Sometimes, depends on the virus (±)	Yes (+++)	Yes (++)
Skin rash	No	Yes (++)	No
Fatigue	Sometimes (±)	Sometimes (±)	Yes (+++)
Difficult breathing	No	Sometimes, esp. if allergic asthma (±)	Yes, in moderate to severe cases (about 20% of infections) (++)
N/V/D (Nausea / vomiting / diarrhea)	No	No	Sometimes (±)
Relieved by antihistamines	Antihistamines are included in OTC cold medications	Yes (+++)	No

Case definition and laboratory testing

WHO introduces different case definitions of COVID-19 depending on patient's symptoms, travel history and laboratory test result:

- suspected case:
    - a patient with severe acute respiratory illness (fever, cough, and requiring admission to hospital), AND with no other etiology that fully explains the clinical presentation AND a history of travel to or residence in China during the 14 days prior to symptom onset;
    - a patient with any acute respiratory illness AND at least one of the following conditions during the 14 days prior to symptom onset: contact with a confirmed or probable case of SARS-CoV-2 infection, or worked in or attended a healthcare facility where patients with confirmed or probable acute respiratory disease patients were being treated;
- probable case is a suspect case for whom testing for SARS-CoV-2 is inconclusive or a suspect case for whom testing could not be performed for any reason;
- confirmed case is a person with laboratory confirmation of SARS-CoV-2 infection, irrespective of clinical signs and symptoms.

WHO requests that national authorities report probable and confirmed cases within 24 hours from the identification. Suspected cases should be screened with NAAT (*Nucleic Acid Amplification Tests*), such as RT-PCR (*Reverse Transcriptase – Polymerase Chain Reaction*). Also, serological test could be a solution to validate the immunologic response to the given viral pathogen. This would require the analysis of paired serum samples, from acute and convalescent phases of each case [12].

Routine confirmation of COVID-19 cases is based on the detection of unique sequences of virus RNA by NAAT, such as real-time RT-PCR, with confirmation by nucleic acid sequencing when necessary. To consider a case as laboratory-confirmed by NAAT, in an area with no known circulation of SARS-CoV-2, one of the following conditions needs to be met:

- a positive NAAT result for at least two different targets on SARS-CoV-2 genome, of which at least one target is preferably specific for SARS-CoV-2 using a validated assay;

- a positive NAAT result for the presence of a Betacoronavirus, and SARS-CoV-2 further identified by sequencing partial or whole genome of the virus as long as the sequence target is larger or different from the amplicon probed in the given NAAT.

When there are discordant results, the patient should be resampled and, if appropriate, sequencing of the virus from the original specimen or of an amplicon generated from an appropriate NAAT assay, different from that initially used, should be obtained.
In areas where SARS-CoV-2 is widely spread, a simpler algorithm might be adopted: for example, the screening by RT-PCR of a single discriminatory target can be considered sufficient. In general, all test results should be immediately reported to national authorities.

Prevention

As the virus enters the body via eyes, nose or mouth, touching the face with unwashed hands must be avoided. Washing hands with soap and water for at least 20 seconds, or cleaning hands thoroughly with alcohol-based solutions, gels or tissues is recommended in all settings. It is also recommended to stay one metre or more away from infected and symptomatic people, to reduce the risk of infection through respiratory droplets.

Physical distancing aims to reduce physical contact between potentially infected people and healthy people, or between population groups with high rates of transmission and others with low or no level of transmission. Internet- and phone-based communications are therefore key tools for ensuring a successful physical distancing strategy, which must be adopted in particular by and from people having suggestive respiratory symptoms and belonging to a high-risk group (i.e. aged 70 years or more, or in underlying health condition).

Treatments

In severe and critically ill patients, different drugs are being tried to target the virus, but their use needs to be more carefully assessed in large-scale and multicentric RCTs. The EMA (*European Medicines Agency*) is interacting with developers of potential treatments and vaccines to enable the development of promising medicines, also by making use of real-world data to monitor safety and effectiveness of treatments used in COVID-19 patients. Several pharmaceutical products have undergone clinical trials to evaluate their safety and efficacy as potential treatments, including the following authorized treatments at September 2020:

- *Remdesivir* is a 'viral RNA polymerase inhibitor' (a drug that interferes with the production of viral genetic material, preventing the virus from multiplying) given by infusion into vein. It has been authorised for marketing in the European Union under the name *Veklury*, since 3rd July 2020, for the treatment of COVID-19 in adults and adolescents over 12 years with pneumonia who require supplemental oxygen;
- *Dexamethasone* is a corticosteroid with anti-inflammatory and immunosuppressant effects, authorised at national level in the EU and used in a wide range of conditions (rheumatic problems, skin diseases, severe allergies, asthma and chronic obstructive lung disease). As there is no evidence of benefits for patients not requiring oxygen, the US NIH (*National Institutes of Health*) recommends the administration of dexamethasone for COVID-19 patients who are either mechanically ventilated or require supplemental oxygen.

Other treatments described below are still under investigation and have not yet shown sufficient results for authorization [11]:

- *Chloroquine* and *Hydroxychloroquine* are currently authorised at national level as treatments against malaria and certain autoimmune diseases such as rheumatoid arthritis;
- *Lopinavir / Ritonavir* is currently authorised as an anti-HIV medicine;
- non-steroidal anti-inflammatory drugs, whose receptor is used by SARS-CoV-2 to enter the target cells;
- ACE-inhibitors and angiotensin receptor blockers, used for the treatment of hypertension, heart failure or renal disease;
- convalescent plasma: plasma with antibodies from recovered COVID-19 patients.

No vaccine is currently available, but several pharmaceutical companies and research laboratories are working on possible candidates. However, vaccine development timelines are difficult to predict and, based on past experience, it might take at least until the beginning of 2021 before a vaccine against COVID-19 is ready for approval and available in sufficient quantities to enable its widespread use.

2. ASST FBF-SACCO and Clinical Engineering

2.1 ASST history and organizational chart

ASST history

The ASST FBF-SACCO (*Azienda Socio-Sanitaria Territoriale Fatebenefratelli-Sacco*) is a set of public hospitals and healthcare facilities based in Milan, Lombardy Region, Italy. Established on 1st January 2016, on the basis of the organizational changes in public health introduced by the regional law 23/2005 ("Evoluzione del Servizio SocioSanitario Lombardo"), it is composed by 4 Hospitals Centers and 26 Territorial Offices [13]:

- ***Luigi Sacco* Hospital – University center**: born as a center for tuberculosis treatment in 1931, it was early known as a sanatorium for patients affected by long-term illnesses (*Sanatorio di Vialba*) and carries the name of Dr. Luigi Sacco, Italian pioneer of smallpox vaccination. It is classified as 1st level polyfunctional provincial hospital since 1968 and as University pole from 1974, hosting different bachelor's and master's degrees in medical specialties from the University of Milan. Finally, in 1994 it is recognized as a national high-specialty hospital;
- ***Fatebenefratelli e Oftalmico* Hospital**: founded as a convalescence hospital at the end of the XVI century by the *Fatebenefratelli* religious congregation. After becoming a secular institution, it was aggregated with *Ciceri* Hospital (or *Fatebenesorelle*) in 1925 and 50 years later with *Oftalmico* Hospital. In 1995, *Fatebenefratelli e Oftalmico* Hospital gets recognized as a national high-specialty hospital;
- ***Macedonio Melloni* Hospital**: born in 1912 and established in 1950s as a maternity hospital. It was transformed in 1917 into an obstetric-gynecological center and then merged with the *Fatebenefratelli e Oftalmico* Hospital (1998). Its main focuses concern the assistance in obstetrics, gynecology, neonatal pathology and intensive care;
- ***Vittore Buzzi* Children's Hospital**: originated in 1897 as a children hospital, it was later expanded into a full hospital thanks to the generous donations of Vittore Buzzi. It represents a reference for maternal and child specialist care in medical and psychological fields, both pre- and post-natal, and hosts the school of Fetal Maternal Medicine from the University of Milan;

- **26 Territorial Offices** based in Milan's different city halls (no. 1 – 2 – 3 – 4 – 8) (Figure 6).

Figure 6 – Hospital centers of ASST FBF-SACCO (source: ASST FBF-SACCO)

ASST FBF-SACCO represents one of Italy's best realities in different medical specialties (including urology, cardiology, clinical pharmacology, biomedical research) and the Italian vanguard in the field of infectious diseases, together with Spallanzani Hospital in Rome. Chosen as references in the fight against COVID-19, Sacco and Spallanzani are the only two hospitals in Italy to have a laboratory facility with the highest-certified pathogen-protection level: the BSL-4 (*biosafety level 4*). Sacco Hospital laboratory is responsible for the diagnostic activity of microbiology of the ASST and it is qualified as a national reference for response to bioterrorism and infectious diseases emergencies [14]. The laboratory operates in collaboration with several Italian universities and on national level with the Health Minister and Civil Protection for health-emergency plans. Several projects are carried out with European and international lenders and partners, including *European Commission*, *United Nations* and *Global Health Security Initiative*.

ASST Organizational chart

The organizational structure of the ASST is subdivided in multiple sections [13]:

- Management Departments:
    - General Director: the highest position, to which are subjected 3 other directors:
        - Health Director: main responsible for the Hospital Centers;
        - Social-Health Director: main responsible for the Territorial Offices;
        - Administrative Director: responsible for the Administrative Dep.;
- Functional Departments: staffs of the previous Management Departments;
- Hospital Centers and Territorial Offices: composed by several Simple Departmental Operating Units, which represent and organize the medical activities.

  Each Functional Dep. and Simple Dep. Op. Units are in turn made up of several
    - Complex Operating Units (U.O.C. – *Unità Operativa Complessa*);
    - Simple Operating Units (U.O.S. – *Unità Operativa Semplice*);

    which carry out disparate activities, ranging from prevention, flow management, risk control and pharmacies, to informative systems, clinical engineering and medical direction of each facility.

In particular, the Clinical Engineering in ASST FBF-SACCO operates in the functional department of the Health Direction as decisional support and technical services for biomedical equipment. It is identified as a U.O.C. and includes the U.O.S. '*Management of biomedical equipment maintenance*'.

2.2 Clinical engineering

Biomedical Engineering is the discipline that uses engineering methodologies and technologies in various fields of application of Medicine and Biology. This discipline applies both in the design and construction phase of diagnosis, therapy and rehabilitation devices and equipment, and in the management of the technologies in the hospital and health care sector, to ensure their efficiency and full safety of use for patients and operators.

Clinical Engineering is the area of Biomedical Engineering which deals with the application of knowledge and methods of Engineering in order to improve the quality of the health service, in relation to the management of Medical Devices and technologies, as well as to

the development of hospital information systems and telemedicine networks. Therefore, the Clinical Engineer is the professional who, both within a public or private healthcare organization and through service companies or professional activities, participates in health care by ensuring safe, appropriate and economics of technologies and Medical Devices used in social and health services [15].

Development and national reality

Around 1960, the administrations of US hospitals observed an increase in the costs of both insurance policies and reimbursements for damage to patients, due to the ungoverned introduction of increasingly complex biomedical technologies. Hospitals hired the engineers who designed the equipment and it was at this historic moment that these engineers assume the title of clinical engineers. Also in Europe, the appearance of clinical engineers dates back to the 70s. In 1990 the time was ripe for the organization of the first Italian conference on 'Clinical Engineering' which took place in Bolzano and from which it arose, in 1993, the birth of the AIIC (*Italian Association of Clinical Engineers*). Clinical Engineers overcame the initial role of guarantors of the safe and appropriate use of biomedical technologies, becoming for healthcare companies the main points of reference for the management of the equipment life cycle.

At the moment in Italy, each region has its own autonomous healthcare reality and this entails a different regional organization also in the field of clinical engineering. Despite the SIC (*Servizio di Ingegneria Clinica*) is a defined structure in companies, the figure of the clinical engineer still seems to be represented as an academic definition in Italy. Clinical Engineers are in fact identified for the functions performed, but in the national health system it is not a recognized professional figure. Only in recent years the various governments, and most of the regions, demonstrated on several occasions the need to establish SIC in every Italian healthcare facility, in perfect analogy to what has been happening for years in the countries of Northern Europe and United States.

In Italy, the number of clinical engineers enrolled in AIIC has risen to 1716 in 2018. These are equally distributed geographically between the North (37%), the Center (30%) and the South (33%) and by area of activity, between engineers engaged in hospital area (53%) and those operating in the service area (47%) (Figure 7) [16].

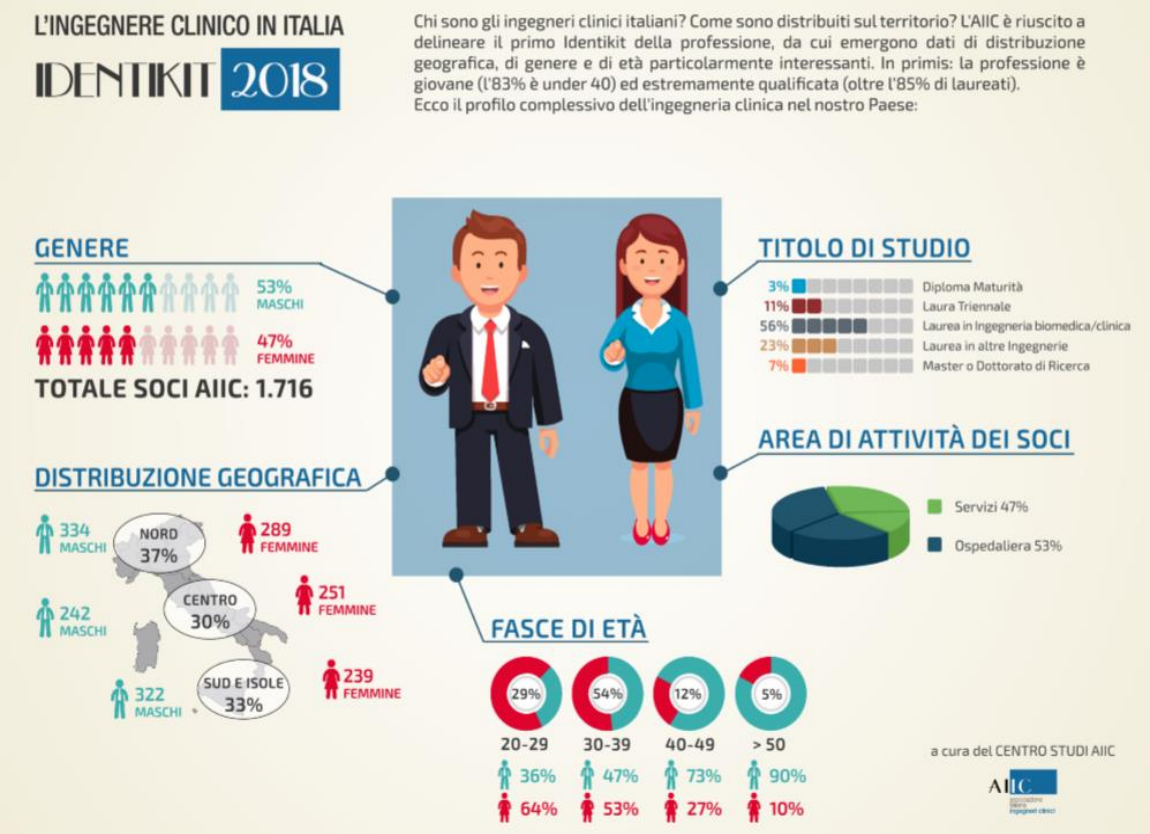


Figure 7 – Clinical engineers in Italy (source: AIIC)

Organizational models for the Clinical Engineering Service (SIC)

Currently it is possible to identify three different organizational models for the Clinical Engineering Services (*Servizio Ingegneria Clinica*):

- internal SIC: it provides for the performance of all activities by employees of the healthcare facility, consisting of a staff of clinical engineers and biomedical technicians. This solution, implemented from the 70s-80s, allows prompt intervention and control of maintenance activities;
- external SIC: it provides that the entire technical assistance of the technologies is entrusted to a single interlocutor external to the company, the so-called Global Service companies.
- mixed SIC: the control is entrusted to internal clinical engineers and the maintenance activity is entrusted to specialized third-party companies: this is the formula that has become more established in Italian hospitals since the 90s.

In order to make the right choice for the organizational model, it is essential to evaluate the qualification of the internal technical and administrative staff, the polycentricity of the healthcare facility, the quantity of devices present in the facility and the technological level of the same as well as the availability and distance of services offered by manufacturers, suppliers and external firms.

Competences areas

The Clinical Engineering Services are responsible for carrying out the following functions and activities:

- Planning of Technologies investments: the Clinical Engineer contributes to the renewal choices of the technological park, planning the replacement of Medical Devices and equipment by evaluating: technology obsolescence, workloads, compliance with technical standards, safety for patients and operators and existence of innovative technologies that can improve clinical performance;
- Health Technology Assessment (HTA): HTA is a scientific approach that allows an hospital to evaluate the impact that a technology could have in each context and to determine the priority of the interventions;
- Health Risk Management: Health Risk Management is defined as the set of strategic activities that serve to prevent accidents (adverse events). The risks treated in the health sector are clinical risks, financial risks, strategic risks, legal risks and any other risk relating to the safety of workers, patients and the management of human resources;
- Health information technology: almost all diagnosis and treatment activities are now supported by software that manage data, with potential repercussions on patient safety. HIT (*Health Information Technology*) indicates the design, development, creation, use and maintenance of information systems to support healthcare;
- Health technology management: the management of biomedical technologies includes all aspects of the life cycle of an equipment within a healthcare facility, starting from investment planning, through the purchase process, up to the technical operational management and final disposal. Analyzing this activity in detail, it is possible to find different stages of the process.

Health Technology Management

The World Health Organization schematizes the Health Technology Management Lifecycle (Figure 8), that includes research / development / production / marketing phases, purchase processes and operational management.

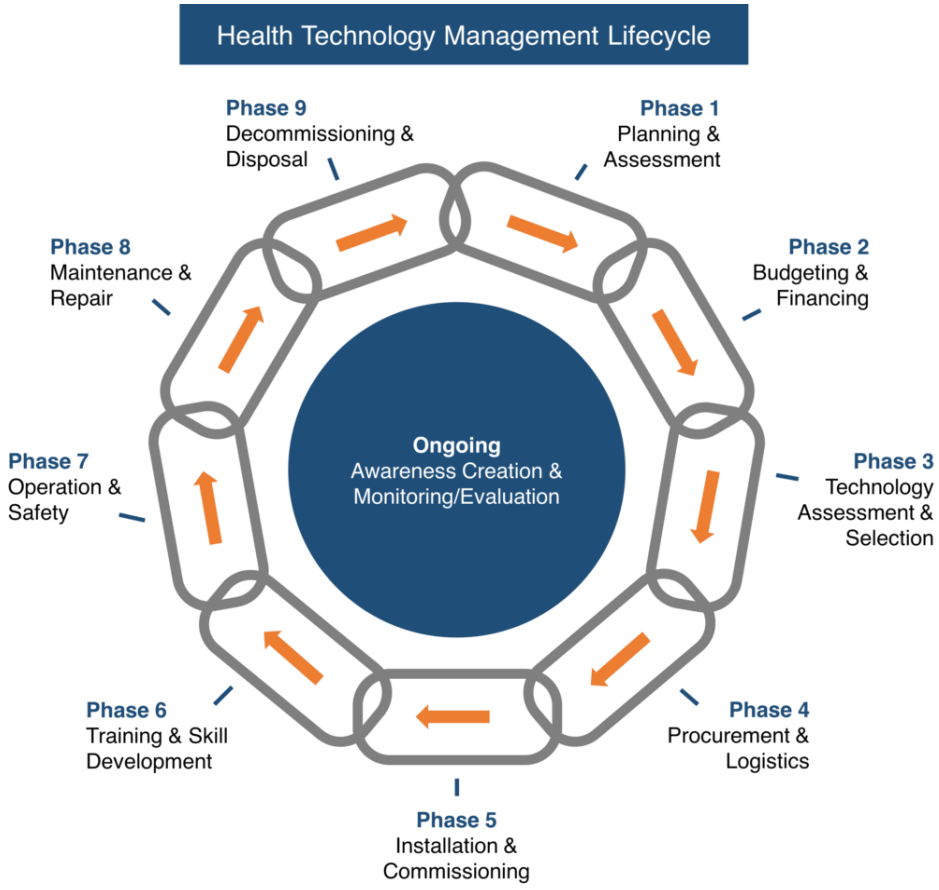


Figure 8 – Health Technology Management Lifecycle (source: WHO)

In particular, the activities of the Health Technology Management where the Clinical Engineer is involved are mainly placed from Phase 6 on:

a) testing: this activity considers all those verification operations to which an electromedical equipment is subjected upon arrival at the hospital;
b) corrective maintenance: the Clinical Engineer coordinates all activities aimed at bringing the device back to normal operating conditions;
c) preventive maintenance: preventive maintenance means the set of maintenance activities performed at pre-established intervals and according to predefined criteria. For each appliance, the maintenance program must comply with both the current

regulations (constantly evolving) and the maintenance indications defined by the manufacturer as per the user manual;

d) functional checks: functional checks are used to ensure that, during clinical operation, electromedical equipment is always safe and efficient in performance;
e) electrical safety check: it is essential to ensure that each equipment used in the health sector, before being effective, is safe, especially from an electrical point of view. This level of safety must be guaranteed for the entire life of use of each electromedical equipment;
f) contract management: one of the main tasks of the Clinical Engineer is the control of maintenance activities on medical equipment entrusted to external companies through one or more contracts;
g) disposal: the Clinical Engineer carries out an analysis of the technical and maintenance information aimed at determining the state of safety, quality and functioning of the equipment and then a costs and benefits assessment collaborating with other professional figures [15].

ASST FBF-SACCO – SIC

As declared in the corporate organizational plan of the hospital (PAO) , the Service of Clinical Engineering of ASST FBF-SACCO has been established in 2002 and operates according to a certified quality system (ISO 9001 standard), fulfilling both decision support functions (staff functions for the Strategic Management), and more operational functions (acceptance of equipment, maintenance, controls) which are in any case part of the overall technology management process.

The U.O.C. of Clinical Engineering is placed in the staff of the Health Department (*Direzione Sanitaria*) [17]. To date, the Clinical Engineering staff is composed by an UOC engineer director, an UOC engineer manager, an UOC administrative and two technicians.

The tasks and activities of the UOC, in collaboration with the competent offices, are [18]:

- management and maintenance of biomedical equipment;
- technical advice for purchases;
- drafting of equipment replacement plans;
- risk management;
- training activities.

U.O.C. activities of management and maintenance of electromedical equipment are supported by a Global Service company, representing an example of a mixed type SIC organization.

MATERIALS AND METHODS

3. Medical Devices and Regulations

3.1 Medical Devices

According to the Directive 93/42/CEE, implemented in Italy by the Legislative Decree (D.Lgs.) no. 46 of 24th February 1997, the term *Medical Device* is related to *any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [19].

Since the 1990s, the use of an increasing number of equipment and Medical Devices for diagnosis, therapy and rehabilitation and the lack of tools for their correct management has made clear the need to define specific classifications for these products (Figure 9).

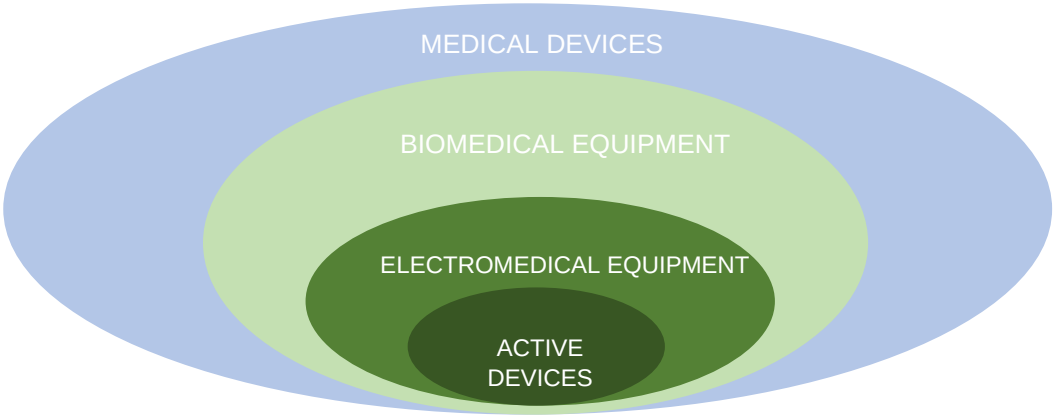


Figure 9 – Classification of Medical Devices

Biomedical equipment

The CIVAB (*Center for Information and Evaluation of Biomedical Equipment*) of Trieste, on behalf of the Ministry of Health (1990) defined the biomedical technologies as: *the set of products and Medical Devices that pertain to the health sector with the exception of drugs; biomedical equipment constitutes a subset of this sector, with reference only to instrumentation* [20].

Electromedical equipment

The definition of electromedical equipment is provided by the standard CEI 62-5 (or by the equivalent EN 60601-1): *electrical appliance equipped with an applied part that transfers energy to or from the patient, or detects this transfer of energy to the or from the patient and that is:*

a) equipped with no more than one connection to a particular network supply;
b) provided by its manufacturer to be employed:
1) in the diagnosis, treatment or monitoring of a patient; or
2) to compensate, alleviate a disease, injuries or impairments.

Active implantable Medical Devices

Active Medical Devices are all those devices that require some form of energy to function, other than that generated directly by the human body or gravity, and which act by converting this energy. They are intended to be implanted entirely or partially, through surgery or medical intervention, in the human body [21].

3.1.1 Classification of Medical Devices

Medical Devices are grouped, according to their complexity and potential risk for the patient, in four classes (I, IIa, IIb, III) by consulting the rules contained in Annex IX of the D.Lgs. no. 46 of 24th February 1997. The classification depends on the intended use indicated by the manufacturer, taking into account three main aspects:

- invasiveness: *non-invasive* devices are those that do not penetrate any part of the body, either through an orifice or through the skin; *invasive devices*, are those intended to penetrate even partially into the body, through an orifice or body surface;

- dependence on an energy source: if dependent on an energy source, the device is known as *active device*;
- duration of contact with patient's body: devices can be intended for *temporary use* if the expected continuous duration is less than 60 minutes; *short-term use* if the expected continuous duration does not exceed 30 days; *long-term use* if the duration lasts more than 30 days.

Therefore, the four classes can be briefly summarized as:

- Class I: low-risk and non-invasive devices (wound dressing, stethoscopes, latex gloves, wheelchairs, medical glasses, …);
- Class IIa: medium-risk and short-term invasive devices (tracheal tubes, lancets, electrocardiograph, …);
- Class IIb: high-risk and often long-term surgically invasive (intraocular lenses, surgical lasers, …);
- Class III: highest-risk, long-term and directly body-interacting devices, such as active implantable devices (heart valves, vascular stents, artificial organs, …).

The decree indicates rules for the classification of biomedical devices in the belonging classes. As an example, Rule 7 refers to short-term and invasive devices (Figure 10).

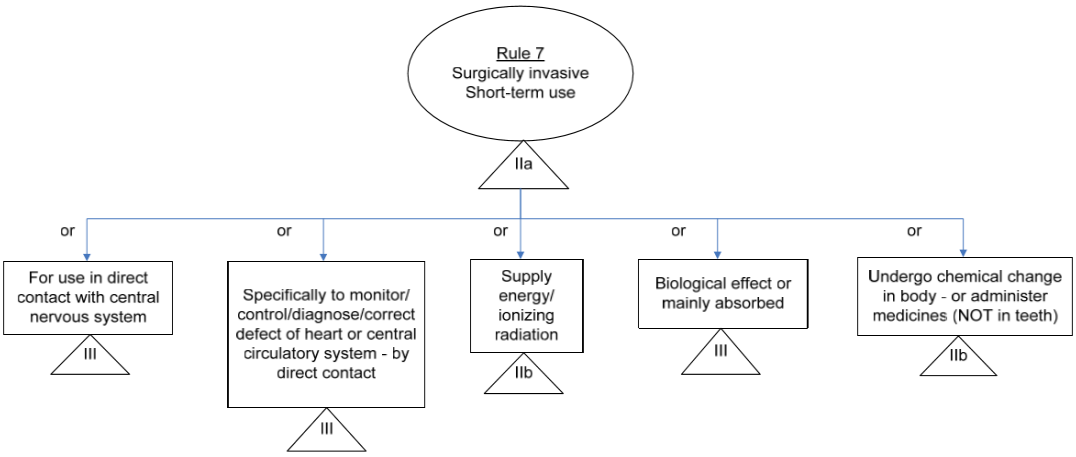


Figure 10 – Classification Rule 7 (source: European Commission)

Classificazione Nazionale dei Dispositivi – CND

The Single Commission on Medical Devices (CUD - *Commissione Unica sui Dispositivi medici*) was established by the article no. 57 of 2003 Finance Law (Law 289/2002), with the task of classifying all products in specific classes and subclasses. With the Ministerial Decree of 22nd September 2005, CUD defined the first version of the National Classification of Medical Devices (CND - *Classificazione Nazionale dei Dispositivi*). It represents the Italian classification that groups Medical Devices into homogeneous categories of products intended to perform a similar therapeutic diagnostic intervention. As an example, the class identified by the letter Z groups together sanitary equipment and their main components (Figure 11) [22].

RAMO CND	DESCRIZIONE RAMO CND	LIV	TERMINALE
Z11	**STRUMENTAZIONE PER BIOIMMAGINI E RADIOTERAPIA**	**2**	**N**
Z1104	**STRUMENTAZIONE PER ECOGRAFIA**	**3**	**N**
Z110401	**ECOTOMOGRAFI**	**4**	**N**
Z11040101	ECOTOMOGRAFI INTERNISTICI	5	S
Z11040102	ECOTOMOGRAFI PER USO CARDIOLOGICO	5	S
Z11040103	ECOTOMOGRAFI PORTATILI	5	S
Z11040104	ECOTOMOGRAFI MULTIDISCIPLINARI (INTERNISTICI E CARDIOLOGICI, ECC.)	5	S

Figure 11 – Example of CND structure (category Z) (source: Ministero della Salute)

Particular attention was paid to the alignment of the CND with the terminologies and classifications existing in the sector at an international level, in particular to the GMDN (*Global Nomenclature of Medical Devices*), a nomenclator that uses lexical items – with synonyms, explanations and the corresponding alphanumeric codes – to uniquely identify a product. Indeed, the CND has an increasing role as a reference for the identification of Medical Devices in the European Community.

3.2 Regulations for the marketing of Medical Devices

3.2.1 European Legislation

The distribution of Medical Devices (MDs) must satisfy several European directives and Italian legislative acts. In particular, EU directives are transposed by Italian legislation, which regulates separately three categories of Medical Devices:

- Directive 90/385/CEE: transposed by Italian D.Lgs. 507/92, regulating active implantable MDs;
- Directive 93/42/CEE: transposed by Italian D.Lgs. 46/97, regarding generic MDs;
- Directive 98/79/CE: transposed by Italian D.Lgs. 332/2000, about in-vitro diagnostic MDs.

European regulatory framework for Medical Devices is under constant monitoring and updating, and is now being standardized by the new:

- European Regulation 2017/745 for Medical Devices (MDR);
- European Regulation 2017/746 for in-vitro diagnostic Medical Devices (IVDR).

A transitory period of 3 years for MDR and 5 years for IVDR had been predisposed to lead to their full application (26th May 2020 for MDR – postponed by 1 year in 2021; 26th May 2022 for IMDR). These new Regulations aim to improve patient safety and to create a sustainable and innovation-directed legislative framework, that will substitute the actual early directives in force for more than 25 years [23].

From the Directive 93/42/CEE to the new MDR

Published in 1993, the Directive 93/42/CEE has been transposed by the Italian D.Lgs. no. 46 in 1997 and made compulsory one year later with the D.Lgs. no. 95. Furthermore, with the update of February 2007 it has been made necessary for each MD to be registered in the 'inventory' of the Ministry of Health. The Directive harmonizes previous national legislations on MDs and allows their use in all EU countries.

Its aims are to ensure a strong protection for safety and health of patients and operators, good functioning of European market and guarantee correct results from the intended use of each device. MDs are classified in different classes and categories, depending on the intended use and riskiness, for which different conformity assessment procedures are disposed [24]. The legislation sets health and security requirements to which MDs must comply with: if so, devices are granted with a **CE marking** and can be employed in all EU. CE marking has to be affixed, if possible, in a visible, readable and indelible way on the device or on its sterile wrap, together with its code number. In conclusion, can enter the market the devices that:

- satisfy the essential requirements for what concerns projection, fabrication and materials used;

- have been subjected to an approval process by a Notified Body (except for Class I devices);
- carry the CE-marking, followed by the identification number of the Notified Body that has certificated the production (except for Class I devices).

Multiple integrations have been implemented in the past years to improve and update the legislation, that will be however substituted in May 2020 (postponed by 1 year in 2021), together with the Directive 90/385, by the new European Regulation 2017/745 for Medical Devices (MDR). Such new legislation, under the new form of *Regulations* instead of *Directives*, will be directly applied at national level without needing law transpositions, preventing European States from adopting norms on MDs in different ways.
Aims of the new legislation are to:

- update and harmonize across Europe the transpositions of current norms;
- update the rules regulating the marketing of MDs and their accessories;
- introduce new rules on how evaluations on equipments are performed in the EU;
- improve patient safety by introducing stricter processes for conformity assessment, to prevent unsafe devices from ending up on the market and strengthening post-market surveillance by competent EU authorities.

Moreover, the regulation tightens the dispositions about Notified Bodies of each country, which now have to meet the same standards in all EU and must perform conformity assessments through professional staff, employing a larger number of doctors or clinical experts and to ensure rotation of the main auditors for surveillance audits.
Finally, the Regulation harmonizes the traceability system of MDs and their producers, introducing the UDI (*unique device identification*) code. Besides manufacturers' responsibility, also healthcare professionals are encouraged to report suspect malfunctioning or adverse events at national level with appropriate formats. Finally, a centralized database, the EUDAMED (*European Databank on Medical Devices*), has been developed to provide information on MDs available in the EU [25].

3.2.2 Technical standards and CE marking

Technical standards

A manufacturer of MDs, in order to prove the compliance of its products with the essential requirements of safety and standardization provided by the European Directives, can apply existing technical standards belonging to one of different categories (Figure 12):

- International standards (ISO), regulated by the *International Organization for Standardization – ISO* or by the *International Electrotechnical Commission - IEC*;
- European standards (EN), regulated by the *European Committee for Standardization – CEN*;
- National standards (UNI), regulated in Italy by the *Ente Italiano di Normazione – UNI*.

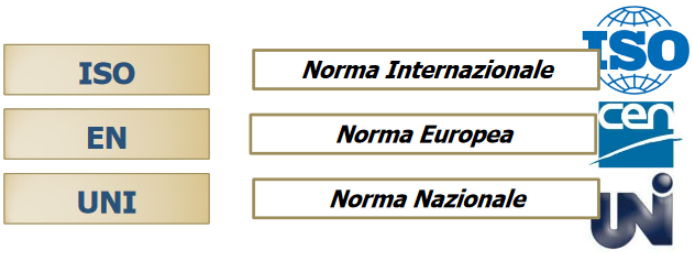


Figure 12 – Technical standards (source: AIIGM)

These different norms reflect the actual scientific knowledge regarding the specific scope of application, and their enforcement by the manufacturer is voluntary and non-retroactive, as the emanation of a new and stricter technical standard does not imply the replacement of an equipment built according to the previous norm [26].

Technical norms are usually known as *horizontal* when applied to a broad range of Medical Devices, and *vertical* when they describe specifications referred to individual devices model. Moreover, technical standards become *harmonized* when adopted at European level by the CEN, and they usually represent the adoption in the EU community of international ISO standards. Such harmonized norms are particularly important in the field of MDs, as they ensure compliance to the essential requirements for CE marking of individual devices, and guarantee the correct performance, interoperability and quality, protecting the safety of workers, consumers and environment.

To obtain a certification standard and to prove the compliance with CE-marking, it is necessary that the manufacturer predisposes a complete project to be approved by a Notified Body and made available to the competent authorities (i.e. the Ministry of Health) of each EU country in which the device will be commercialized. All the information related to project, production, and packaging must be collected in the Technical File (TF - *Fascicolo Tecnico*). Such document also constitutes a contractual obligation: it cannot be modified only at manufacturer's will, but every modification must be submitted for a new approval by the Notified Body to become effective. Several indications must be reported in the TF, including: general description of documentation and device, its intended use and class, applicable standards, requirements followed during the process of design, raw materials and components used, processing procedures, sterilization processes, risks analysis and clinical evaluation, methods for packaging, storage and transport.

The main set of technical norms concerning safety, performance and management of Medical Devices is given by the following standards:

- ISO 14971: application of risk management to Medical Devices;
- ISO 13485: quality management systems for Medical Devices;
- IEC 60601: safety and essential performance of electromedical equipment;
- IEC 62304: software for medical devices and software lifecycle process;
- IEC 62366: application of usability engineering to Medical Devices.

ISO 14971

The international standard ISO 14971, implemented and harmonized in Europe by the EN ISO 14971, specifies a process for the risk management of Medical Devices, including softwares and in vitro diagnostics, in order to identify the hazards associated with a Medical Device, to estimate and control these risk (e.g. related to biocompatibility, data and system security, electricity and radiation, usability) during its manufacturing and its whole life cycle [27]. The process of risk management consist in the following steps:

1) identify risks and dangerous situations associated to a Medical Device which may harm patients or healthcare workers;
2) estimate the probability that each risk may occur and evaluate the extent of the possible consequences;

3) develop and implement safeguard measures, inside the device or during the manufacturing process, to control such risks;
4) review and monitor the whole risk management process to assess its efficacy [28].

ISO 13485

The international standard ISO 13485, implemented and harmonized in Europe by the EN ISO 13485, certifies a Quality Management System for manufactures of MDs (generic, active implantable and in-vitro diagnostic MDs); in particular, the standard emphasizes the activity of risk analysis linked to every process. Therefore, the manufacturer should clearly structure all the production processes, defining what / when / where / how to be made, from who, with which material and equipment, under which control, measure and registration. Moreover, a defined plan of research and development must be drawn and validated with clinical and performance assessments [29].

IEC 60601

The IEC 60601, implemented and harmonized in Europe by the EN 60601, is fundamental for manufacturers of electromedical equipment and applies within the scopes of security, essential performance and electromagnetic compatibility. It represents a family of more than 70 sub-standards, including:

- IEC 60601-1: regards basic security and essential performance of all electromedical equipment and implies compelling qualifications of risk analysis. It serves to guarantee that no kind of failure could imply an unacceptable risk for patients and users, in condition of normal use and first fault, and requires that all parts that may come in contact with the patient must be evaluated and categorized as 'applied parts'. Further sub-norms (*collateral norms*) indicate the specific application: examples are the 60601-1-2 (electromagnetic compatibility) and the 60601-1-8 (alarm systems);
- IEC 60601-2: outlines requirements for specific groups of products. Further sub-norms (*particular norms*) indicate the specific categories of devices: examples are 60601-2-4 (defibrillators and monitors) and 60601-2-5 (ultrasound therapy equipment) [30].

  Noteworthy in our application is the IEC 60601-2-12 ('*Particular requirements for the safety of lung ventilators – Critical care ventilators*'), which pointed out indications on pulmonary ventilators. Such devices are fundamental for patients in

intensive care units (ICUs), as about half of them is partially to fully assisted with ventilatory support. This particular standard set the minimum requirements that should be satisfied by each ventilator for critical care, and it has been withdrawn and substituted by the new ISO 80601-2-12:2020 [31].

Independently by the articulation of the sub-norms, the IEC EN 60601 requires the classification of devices depending on:

- protection against electric shock: several tests are required to verify the electric security;
- protection against the dangerous entrance of water or dust;
- method of sterilization, as indicated in the conditions of use;
- possibility of use in environment at high oxygen concentration;
- operating mode (continuous or intermittent) [26].

Moreover, the manufacturers must estimate the probability of risks arising in their products in conformity to the standard ISO 14971. Such estimations can be contested in each different market of destination [32].

CE marking

CE marking allows the commerce and commissioning in Italy and EU of Medical Devices. It can be released, with a special procedure, by authorized bodies designated from competent authorities of each European State. The manufacturer can contact any designated body in Italy or in another EU State to present the required documentation and obtain the conformity assessment. The charged Office - together with the Ministry of Economic Development, representatives of European Commission and of other EU States - will evaluate the presence of requirements needed by law. According to the D.Lgs. 46/97, the obtainment of CE marking is composed by three steps:

1) device classification: the first action to be performed by the manufacturer, in order to identify the class of the device (I, IIa, IIb, III) and to adopt the respective marking procedures;
2) compliance with essential requirements: the device and its whole production system must satisfy safety and efficacy requirements such that the use of the tool in question does not compromise patient's clinical situation and security, neither that of users and third parties, when used in the predisposed situations and modalities. Eventual

risks must be of acceptable entity, considered the benefits brought to the patients and in any case indicative of a high level of protection and security.

The list of essential requirements is divided in two parts: the first concerns general requirements, dedicated to the intrinsic device security; the second, further differentiated in 7 groups, regards all the design and construction aspects. The higher the riskiness of the device, the higher the security requirements that must be proved.

3) device marking: depending on the device classification, different modalities are defined (Figure 13):

    a. Class I: the manufacturer can obtain CE marking after writing a *declaration of conformity* to the essential requirements, and then enters the market. This is the easiest way to obtain CE marking, and with this document the manufacturer guarantees that its MDs satisfy the European Directives, without the intervention of a Notified Body. An exception regards sterilization and measuring functions, for which peculiar processes are needed: the mere declaration is not sufficient, and further procedures must be dispatched and subjected to the exam of a Notified Body;
    b. Class IIa: the manufacturer must ask the Notified Body for the approval of its production structures and/or its product;
    c. Class IIb: the manufacturer must ask the Notified Body for the approval of its production structures and/or its product, with further guarantees and controls;
    d. Class III: the manufacturer must ask the Notified Body for the approval of its production structures and/or its product, with further and stricter guarantees and controls regarding design and project of the device.

Further clarifications are needed for systems and kits regarding the operating field, composed by several MDs that may be assembled together. If all the devices are CE-marked, then the kit does not require a global CE marking; anyhow, a declaration by the manufacturer attesting the correct compatibility of the individual products is needed. If not all the devices are CE-marked, then the kit becomes a new device in its own right and subjected to a regular procedure for the obtainment of the CE marking [33].

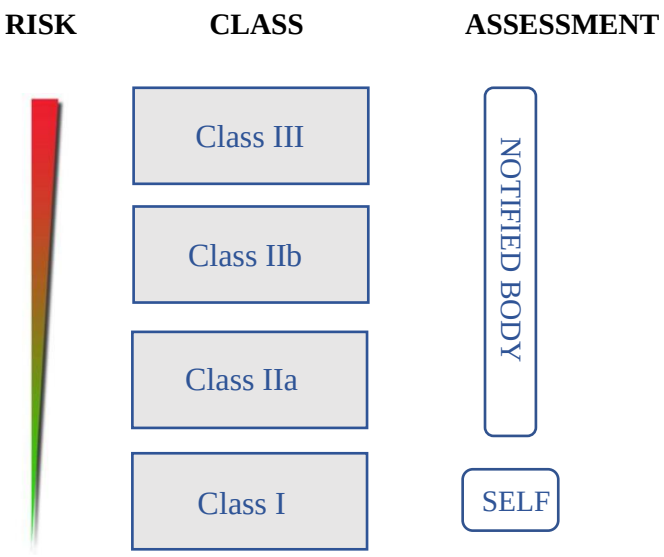


Figure 13 – Medical Device classification by risk and assessment

3.3 Accreditation requirements for biomedical equipment in healthcare structures

The D.P.R. (*Decreto del Presidente della Repubblica*) no. 37 of 14th January 1997, on the basis of the previous D.Lgs. 502/92, has defined the minimum structural, technological and organizational requirements required for the exercise of health activities by public and private structures. Over the past twenty years, all Regions and Autonomous Provinces have implemented the D.P.R. 37/97 with different levels of customization: some aspects of biomedical equipment are often very different from region to region, without objectively identifying a specific regional planning that motivates this diversity .

The Health Pact 2010-2012 has promoted the development of an agreement aimed to revising the accreditation legislation and remuneration for healthcare services at national level. In particular, there is a need to favour an accreditation model for health and social-health structures, shared between the public and the private sector, which is as uniform as possible throughout the national territory [35]. The goal of this model is to ensure the proper functioning of all biomedical equipment in use within the healthcare company.

Considering that the requirements related to technologies are elements in constant evolution, the AIIC (*Associazione Italiana Ingegneri Clinici*) has set itself the objective of providing univocal indications at national level for the accreditation requirements and keeping them constantly updated over time. On the basis of the indications contained in the ‘Disciplinary

for the revision of the accreditation legislation' defined in the context of the State-Regions Agreement of 20th December 2012, AIIC has drawn the general references valid for the accreditation process of a specific area of Medical Devices: the biomedical equipment. Therefore, formalized procedures are defined regarding [36]:

- organization of responsibilities for all activities related to the management and maintenance of biomedical equipment;
- dynamic inventory management;
- maintenance and electrical safety checks of biomedical equipment;
- methods of acceptance and testing of biomedical equipment;
- the methods of disuse of biomedical equipment;
- methods of carrying out company training programs that include periods of training of the personnel involved in the use, maintenance and disposal of biomedical equipment aimed at verifying knowledge by the user staff;
- risk management;
- Health Technology Assessment.

4. Healthcare structures requirements

The D.Lgs. no. 46 of 24th February 1997 determines the minimum structural, technological and organizational requirements for public and private structures to carry out health activities. In particular, the decree empowers the individual regions to regulate the methods for ascertaining and verifying compliance with the minimum requirements. All the principal structures must possess the requisites envisaged by current laws on:

- microclimatic conditions
- gas distribution systems
- electrical safety and electrical continuity
- seismic protection
- fire protection
- acoustic protection
- accident prevention safety
- hygiene in the workplace
- protection of ionizing radiation
- elimination of architectural barriers
- waste disposal
- explosive materials [37].

For details regarding the individual aspects, refer to the applicable regional, local or international standards. In particular, with the DGR (*Deliberazione della Giunta Regionale*) of 6th August 1998, the requirements and indicators for the accreditation of healthcare structures in the regional area were established. Subsequently, with regional law no. 23 of 11th August 2015, a more specific standardization of the regional health and socio-sanitary organization was introduced, highlighting the institution of territorial socio-sanitary companies (ASST – *Aziende Socio Sanitarie Territoriali*). Also in this case, the reference requirements have been defined.

4.1 Electrical system

The main standard referred to the regulation of electrical systems is the **CEI 64-8**, sub-articulated in different chapters.

Local for medical use

As stated in the **CEI 64-8/7** standard, a room for medical use is *a room intended for diagnostic, therapeutic, surgical, surveillance or patient rehabilitation purposes (including aesthetic treatments).* For the subdivision of premises for medical use it is essential to analyse the electromedical equipment (defined in Chapter 3.1) in use and define its applied part. The APPLIED PART is *a part of the appliance that in normal use:*

- *necessarily comes into physical contact with the patient so that the device can perform its function; or*
- *can be brought into contact with the patient; or*
- *needs to be touched by the patient.* [38]

From this consideration, groups of rooms for medical use are therefore defined (Figure 14):

- Group 0: medical room in which electromedical devices with applied parts are not used (i.e. medical clinic where electromedical devices are not used or where devices without applied parts are used);
- Group 1: medical premises where the applied parts are intended for external use or invasive use within any part of the body, except for the heart area (i.e. patient room or other environment for medical use);
- Group 2: local for medical use in which the applied parts are intended for use in applications such as intracardiac interventions, surgical operations, or where the patient is subjected to vital treatments during which the lack of power supply can be life-threatening (i.e. surgical room or intensive care area).

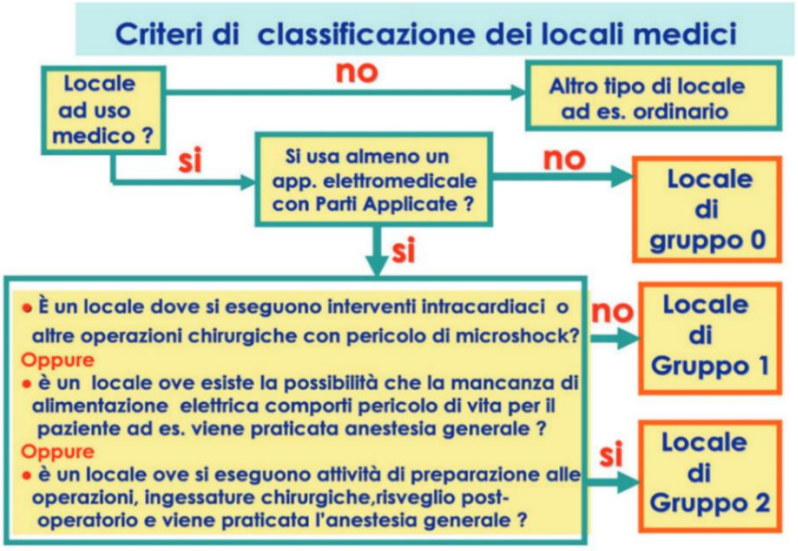


Figure 14 – Classification of medical premises (source: Albiqual)

The patient area inside a local for medical use is defined as *any volume in which a patient with applied parts can come into intentional or unintentional contact with other electromedical devices or electromedical systems or with foreign bodies or with other people in contact with these elements* [39]. For this reason, design measures are defined considering the right spacing of the patient within the room (Figure 15).

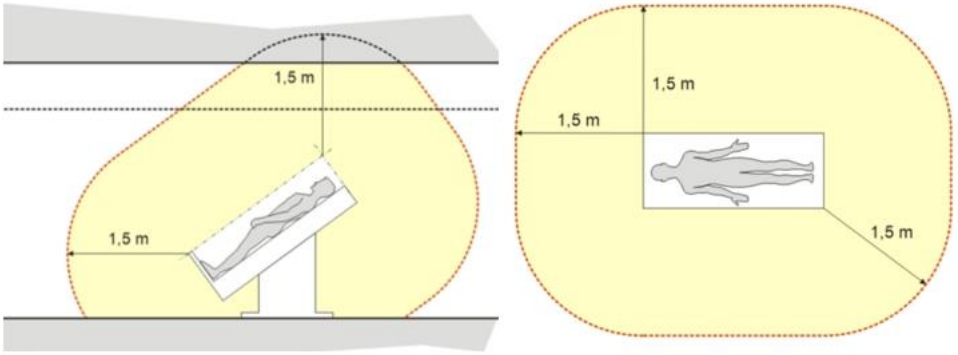


Figure 15 – Patient area measures (Source: CEI 64-8)

The patient area must be determined during the design phase by identifying a priori the possible positions and movements taken by the patient with electrical parts applied. In some cases, it can coincide with the entire room. The classification of premises for medical use and the identification of the patient area must be done by medical personnel or in agreement with the health organization, indicating which medical treatments should be carried out within that room.

Protection system

In medical rooms it is necessary to ensure the safety of patients, who are particularly vulnerable when subjected to the application of electromedical equipment. Safety is achieved with provisions on electrical systems, on the basis of requirements linked to the particular activities carried out in the premises as indicated in the **CEI 64-8/710** standard.

In spite of the high internal insulation impedance, a small current called leakage current flows from each device and disperses towards the ground, the housing and the patient (Figure 16). The most significant risk in the case of electromedical equipment is electrical discharge, as there may be deliberate contact between the live parts and the patient and / or the user.

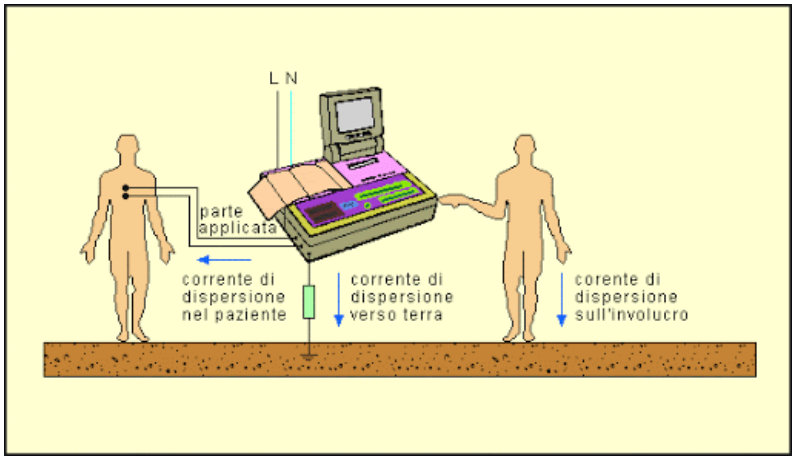


Figure 16 – Leakage currents in electromedical devices (source: Elektro)

Direct electrical contact is defined as contact between people and active parties. The protection from direct contact in medical premises is treated in the article CEI 64-8/710.412. In general, protection can be:

- total: by isolating the active parts or by means of enclosures or barriers;
- partial: through obstacles or by distancing.

Indirect electrical contact is defined as contact with a part of the system that is normally not in voltage, which has accidentally taken on a dangerous electrical voltage due to failure of the main insulation. Indirect contact can cause the patient electrical risks classifiable as microshock and macroshock (Figure 17), dangerous events that can produce ventricular fibrillation.

Macroshock occurs when there is a passage of current in the person due to the contact between a live part, which is accidentally on voltage, and a part of the human body. The current flows through the body affecting a large section, while only a small part flows through the heart, implying a minimal risk of ventricular fibrillation.

The risks increase when the patient is subjected to medical surgical procedures that involve cardiac catheterization or the application of probes or electrodes near the heart. This represents the case of *microshock* as the current, largely passing through the heart, introduces a disturbance to the electrophysiological balance of cardiac activity which makes the probability of a ventricular fibrillation very high.

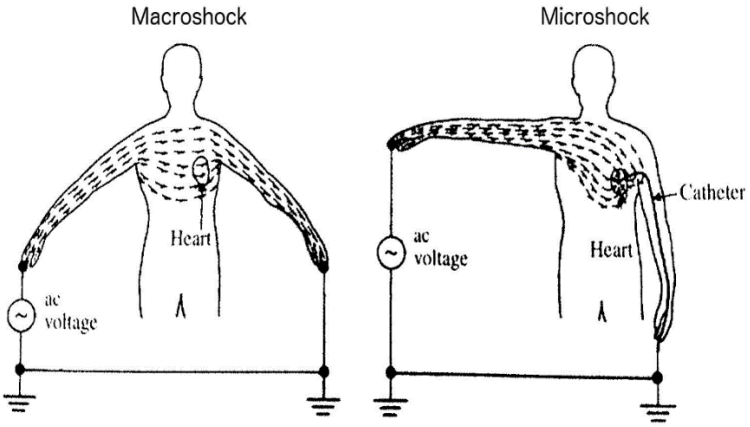


Figure 17 – Micro and macroshock (Source: F.J. Weibell)

Protection against indirect contact depends on the classification of rooms for medical use (Group 0, 1 or 2). In **Group 0** premises, special requirements are not necessary and the general dispositions of standard CEI 64-8 are applied; protection against indirect contact in **Group 1** and **2** medical rooms can be achieved with one of the following methods [40]:

- protection by automatic interruption of the circuit;
- protection by extra-low safety and protection voltage (SELV and PELV);
- protection by using Class II components or with equivalent insulation;
- protection by electrical separation;
- protection by IT-medical system.

Based on the degree of protection against direct and indirect contact, the medical electrical equipment is divided into (Figure 18):

- type B appliances: appliance with applied part with reduced leakage current, having an adequate degree of protection against direct and indirect contacts with particular regard to the allowable leakage currents (max 100 μA) and the reliability of the grounding connection (if existing);
- type BF appliances: type B appliance with a floating applied part (type F) and insulated from the ground, of greater safety than type B;
- type CF appliances: Class I or II device, or device equipped with an internal electrical source, having a high degree of protection against direct and indirect contacts with particular regard to the permissible leakage currents (max 10 μa), and having a type F applied part insulated from the ground with maximum safety guarantees (greater than the BF).

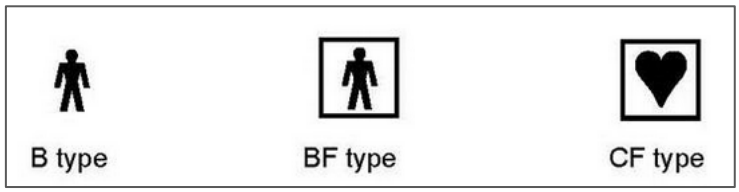


Figure 18 – Medical electrical equipment symbols (CEI 64-8)

Safety power supply

The safety power supply guarantees the supply of electricity to privileged users in the event of a lack of ordinary power supply [40].

The distribution system must be designed and installed to facilitate automatic switching between the main power supply and the safety power source. In medical rooms, in relation to their classification and the activities being carried out in, **continuity classes 0.5**, **15** and **>15** are required for safety power supplies:

- **Class 0.5** (short interruptions): switching period $0.15 \leq T \leq 0.5$ s. Used when the ordinary power supply voltage in the main distribution panel drops, in one or more conductors, by more than 12% of the nominal value for a time ≥ 3 seconds, for lighting fixtures of the operating tables (operating lights) and for electromedical devices that require safety power supply within 0.5 seconds (equipment of vital importance for the patient);
- **Class 15** (medium interruptions): switching period $0.5 \leq T \leq 15$ s. Used when the ordinary power supply voltage in the main distribution panel drops, in one or more conductors, by more than 12% of the nominal value for a time ≥ 3 seconds, for emergency lighting electrical appliances intended to supply medical gases, lifts, ventilation systems for fume extraction, call systems, detection, alarm and fire extinguishing systems;
- **Class >15** (long interruptions): switching period $T > 15$ s. Used when the ordinary supply voltage in the main distribution panel drops, in one or more conductors, by more than 12% of the nominal value for a time ≥ 3 seconds, for electrical components other than those that require power supply of Class 0.5 or 15, useful for keeping hospital services in operation (e.g. sterilization, waste disposal, heating, air conditioning, ventilation, refrigerators, cooking appliances, etc.). The minimum duration must be established by the designer in agreement with the client.

An example of classification of premises for medical use is shown in Table 2 [41].

Table 2 – Classification of premises for medical use

Locali ad uso medico	Gruppo			Classe alimentazione di emergenza	
	0	1	2	T≤ 0,5	0,5<T≤ 15
01. Sala per massaggi	X	X			X(5)
02. Camere di degenza		X			X
03. Sala parto		X		X(1)	X
04. Sala ECG, EEG, EHG, EMG		X			X
05. Sala per endoscopie		X(2)		X(1)	X
06. Ambulatori	X	X(2)			X(5)
07. Sala per urologia		X(2)			X
08. Sala radiodiagnostica e radioterapia		X			X
09. Sala per idroterapia		X			X
10. Sala per fisioterapia		X			X
11. Sala per anestesia			X	X(1)	X
12. Sala per chirurgia			X	X(1)	X
13. Sala di preparazione alle operazioni		X	X(3)	X(1)	X
14. Sala per ingessature chirurgiche		X	X(3)	X(1)	X
15. Sala di risveglio postoperatorio		X	X(4)	X(1)	X
16. Sala applicazione cateteri cardiaci			X	X(1)	X
17. Sala per cure intensive			X	X(1)	X
18. Sala esami angiografici, emodinamici			X	X(1)	X
19. Sala per emodialisi		X			X
20. Sala per risonanza magnetica (MRI)		X			X
21. Sala per medicina nucleare		X			X
22. Sala prematuri			X	X(1)	X

(1) Apparecchi di illuminazione e apparecchi elettromedicali che richiedono alimentazione entro 0,5 s o meno
(2) Se non è una sala per operazioni chirurgiche
(3) Se viene praticata anestesia generale
(4) Se ospita pazienti nella fase di risveglio da anestesia generale
(5) Solo per locali di gruppo 1

Electrical system checks

The verification of an electrical system connected to the network can be carried out with reference to the **CEI 64-8/6** standard, which provides the requirements for the initial and periodical checks of any electrical system:

- the initial verification is used to determine the compliance of the system with the current state of the art, in order to issue the declaration of conformity, to check the conformity of the installation to the project and to identify any defects in the system;
- the periodic checks are aimed at determining the persistence over time of the functionality and safety requirements of the system and its equipment. Periodic checks are useful to confirm that the system is not damaged or deteriorated, in order to improve safety and to identify any system defects that have not been highlighted with the previous checks.

The outcome of any type of verification is recorded and is kept available to the supervisory authority (example of a check list – Figure 19).

DOCUMENTI TECNICI

	Requisito richiesto:	SI	NO	N.A.
	a supporto del servizio di manutenzione e ai fini delle verifiche sono presenti documenti di disposizione topografica dell'impianto elettrico, unitamente a rapporti, disegni, schemi e relative modifiche e istruzioni per l'esercizio e la manutenzione? *NORMA CEI 64-8/7 art. 710.514.5 – GUIDA CEI 02*	☐	☐	☐
	esiste un quadro di distribuzione nell'edificio destinato alla distribuzione principale dell'energia elettrica a tutto l'edificio (quadro generale) o ad una sua parte consistente, dove è misurato l'abbassamento di tensione (12%) al quale va riferito il funzionamento dei servizi di sicurezza? *NORMA CEI 64-8/7 art.710.562.1.2*	☐	☐	☐
	il sistema di distribuzione è progettato ed installato in modo da facilitare la commutazione automatica tra la rete di alimentazione principale e la sorgente di alimentazione di sicurezza? *NORMA CEI 64-8/7 art. 710.313.1*	☐	☐	☐
	le protezioni sono selettive rispetto ai dispositivi di protezione a monte? *NORMA CEI 64-8/7 art. 710.53.1*	☐	☐	☐

Figure 19 – Check list example

According to CEI 64-8/6, the frequency of the periodic verification of a plant must be determined considering the type of plant and components, its use and operation, the frequency and quality of maintenance and the external influences to which the plant is subject.

4.2 Medical gases distribution system

Medical gases are gases used with medical purposes such as treatment, anaesthesia and for driving medical tools and devices. Depending on their destination of use, they are subjected to a different regulatory framework, being recognized as:

- medicinal gases if the action mechanism is pharmacological (e.g. O_2, N_2O, medicinal air and mixtures), firstly regulated by D.Lgs. 219/2006 on medical drugs;
- Medical Devices if the action mechanism is physic-mechanical (e.g. CO_2, N_2, N_2O, Ar), for driving tools and used in spirometry, cryotherapy and cryopreservation; subjected to Directive 93/42/CEE and the respective D.Lgs. 46/97 [42];

Italian and European Pharmacopoeia (Ph. Eur. or F.U.) set the limits for impurity concentration and testing methods for each of the medical gases, that are *oxygen, nitrous oxide, carbon dioxide, nitrogen, medicinal air and synthetic medicinal air, nitrogen monoxide, helium, argon* and mixtures of these gases. Examples of impurity limits can be identified as follows [ppm = parts-per-million] (Table 3) [43]:

Table 3 – Examples of limits of impurity concentrations in medical gases

Impurity ↓	Oxygen	Oxygen 93%	Nitrous oxide	Nitrogen	Medicinal air
CO_2	≤ 300 ppm	≤ 300 ppm	≤ 300 ppm	≤ 300 ppm	≤ 500 ppm
CO	≤ 5 ppm	≤ 5 ppm	≤ 5 ppm	≤ 5 ppm	≤ 5 ppm
H_2O	≤ 67 ppm	≤ 67 ppm	≤ 67 ppm	≤ 67 ppm	≤ 67 ppm
NO, NO_2		≤ 2 ppm	≤ 2 ppm		≤ 2 ppm
SO_2		≤ 1 ppm			≤ 1 ppm
Oil		≤ 0.1 mg/m^3			≤ 0.1 mg/m^3

Distribution system

Medicinal gases can be prepared in two main modalities, as:

1) industrial products: according to the D.Lgs. 219/2006, industrial medical drugs must be approved for commerce by AIFA (*Agenzia Italiana del Farmaco*), with the exception of drugs requested and urged by doctors who agree to use that particular medicine on specific patients under their direct responsibility;
2) hospital pharmacy products: these products do not require marketing authorization by AIFA [42]. Medicinal air is usually produced in hospitals by compression and purification of ambient air, or by mixing of F.U. oxygen and F.U. nitrogen in defined percentage (where F.U. represents the quality standards required by the European Pharmacopoeia).

Stationary plants represent the optimal solution for the distribution of medical gases, in terms of safety and economy, compared to mobile solutions, avoiding the storage of cylinders inside health departments.

Distribution system of medical gases in healthcare facility deals with three main functions:

- distribution of medical gases through special terminals in hospital premises;
- vacuum suction network (*vacuum line*);
- aspiration of anaesthetic gases in operating room and similar.

A centralized system is mainly constituted by a distribution center, a control system, a distribution network and terminal units (Figure 20).

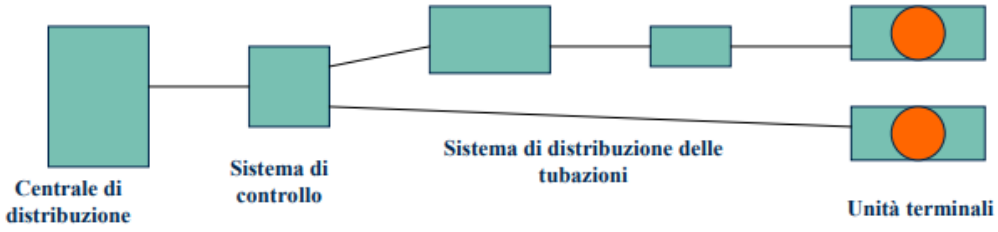


Figure 20 – Centralized system scheme (source: ASST Pavia)

Different strategies can be adopted for its realization, such as a *ring structure* (Figure 21) or for the distribution network – connected to distribution centers ( ) at opposite points – or a *star structure* (Figure 22) with a unique distribution center [44]. Shut-off valves ( ) guarantee the interruption of gas supply in each branch and compartment of the network in case of necessity, ensuring the continuity of gas provision in other rooms or premises not affected by the emergency.

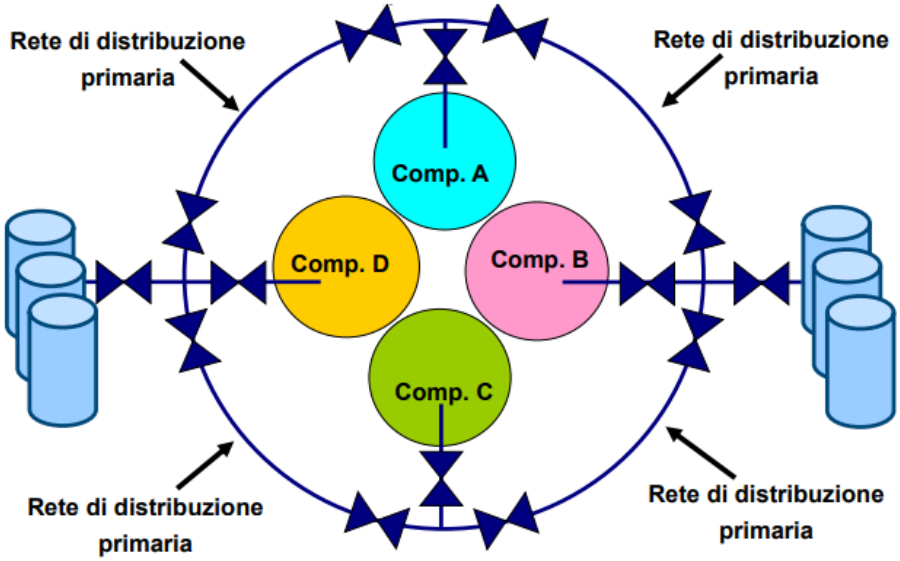


Figure 21 – Medical gas distribution system (ring structure) (source: AIIGM)

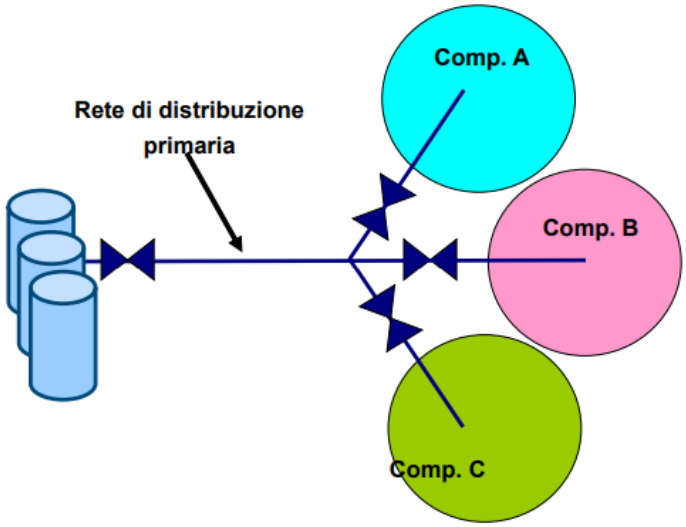


Figure 22 – *Medical gas distribution system (star structure) (source: AIIGM)*

The distribution center is the place where medical gases are stored, in the form of cylinders grouped in special rooms or liquefied gas contained in cryogenic containers. The distribution center feeds the distribution network, usually composed by a series of copper pipes or other oxygen-compatible materials, which provides the delivery of gas to the points of use through a decompression system [45]. Two main modalities of distribution (Figure 23), which act differently on the pressure regulation, can be adopted:

1) single-stage distribution: pressure reduction down to 3.5-4 bar occurs through a single regulator located after the distribution center;
2) double-stage distribution: pressure reduction occurs firstly after the distribution center down to 8-9 bar, secondly to 3.5-4 bar by a reducer placed before the terminals of use [44]. It represents the preferred method due to its significant benefits of use.

1 = distribution center, 2 = distribution network, 3 = terminal units, 4 = monitoring system; 5 = single-stage pressure reduction system, 6 = double-stage pressure reduction system

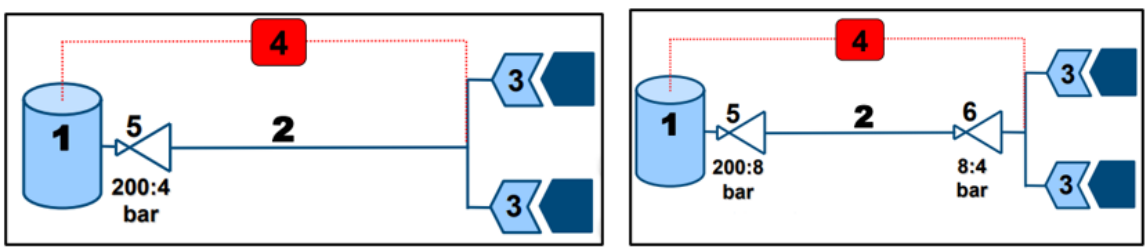


Figure 23 – Single-stage (left) and double-stage distribution (right) (source: AIIGM);

Different advantages and disadvantages derive from the adoption of each system (Table 4) [45]:

Table 4 – PROS and CONS of single and double-stage distribution

	PROS	CONS
Single-stage	• Lower failure risks; • Lower manutention costs.	• Different design and sizing of ducts, depending on their ramifications, to obtain the fixed pressure at terminals; • Difficulties in case of future modifications.
Double-stage	• Better pressure stability at terminals of use; • Possibility to differentiate pressure values if needed; • Ease of extension and modification of the network.	• High costs for pressure regulators.

Distribution network for medical gases must be used exclusively for all that concerns patient care (providing breathing air, anaesthetic gas evacuation, test of medical equipment, hyperbaric chambers, …) and not for external uses (workshop, painting, sterilization, …), and must be protect from physical damages, for example due to the moving of equipment. Therefore, a distribution system for medical gases must ensure the product quality at the point of use, the continuity of supply even in exceptionally critical situations and the safety of patients, users and third parts. Such plant networks, like biomedical equipment, are considered Medical Devices and therefore subjected to CE marking according to the Directive 93/42/CEE.

Regulations for the medical gases distribution system

All parts of the system are regulated by strict requirements. For what concerns gas storage, deposits must be set up only on the ground floor, not above nor below other rooms, and minimum distances are requested for stationary tanks, based on the Ministry of the Interior Circular no. 99 of 15th October 1964. For example, oxygen tanks must be 15m far from hospitals, gas or combustible material deposits and public entertainment places; 5m far from premises and 3m from traffic routes and pedestrian crossing. Moreover, cylinders must be stored at repair from sunrays and excessive temperatures, far from moving machinery and/or dangerous situations [45].

An example of standard regarding gas storage is the **UNI EN 1089-3**, which provides an identification system for cylinders of medical gases with color codes placed on their spinner,

while the bodies remain white. In general, the color identifies not the gas itself but the risk associated with it; specific colors exist only for the principal gases (Table 5).

Table 5 – Principal gases colors and risks associated

Risk Associated	Gas
Toxic and/or corrosive	Oxygen
Inflammable	Nitrogen
Oxidant	Carbon dioxide
Inert	Nitrous oxide

Anyhow, to identify the gas it is essential to refer to the labels and the cylinders themselves, which are characterized by univocal valves for each type of gas to prevent their involuntary exchange.

As of the medical gases distribution, several norms have been applied in the previous decades, now substituted by the following harmonized standards that cover a larger scope:

UNI EN ISO 7396-1 – *Medical gas pipeline systems - Pipeline systems for compressed medical gases and vacuum*: introduced with the Directive 47/2007/CE, as update of 93/42/CEE, it has been enforced in Italy since 21st March 2010 and certifies distribution systems for medical gases and vacuum line. It sets the minimum requirements related to their design, fabrication, installation-test-performance, traceability, manutention and lifetime. Guidelines for the extension or modification of existing distribution systems are also provided, including that power systems or sources, with the aim to ensure:

- non-interchangeability between different terminal, tubes and units of different pipeline systems;
- correct installation and functioning of the system, cleanliness of components, use of appropriate materials;
- continuous monitoring of gases supply and functioning of alarm systems;
- continuous supply of gases at given quality, pressure and flows;
- definition of possible causes of malfunctioning (such as missed supply), potential deriving danger situations and risk control measures to be adopted [46].

The standard also introduces technological requirements, including the installation of three power sources for each gas and vacuum line (primary, secondary, backup - with the exception of nitrogen and air for instrumentation) and a dedicated power input for maintenance. The installation of clinical and operating emergency alarms, to alert healthcare and technical personnel, is also required [47].

Therefore, the manufacturer of distribution systems, to prove the compliance with the previous requirements of the standard, must provide the following documentation:

- instructions for use, diagrams of electrical systems and technical installation drawings, schematic representation of the typical power supply systems and distribution systems, guidelines for the location and storage of containers and tanks for cryogenic and non-cryogenic fluids;
- example of procedures for testing and implementation, non-interchangeability, manutention and post-installation checks plans, checklist for risk management;
- release of the Operations Management Document (DGO – *Documento di Gestione Operativa*): document in which are reported in detail the main operational requirements of the system, with procedures and nominatives of the staff authorized and responsible of different activities regarding the system (executive responsible, technical responsible, authorized person, …) [48];
- additional reference standards for specific equipment, such as terminal units for distribution and evacuation (EN ISO 9170-1, UNI 9507), medical supply units (ISO 11197), low pressure hoses for medical gases (ISO 5359); anaesthetic and respiratory equipment (ISO 15001) [47].

UNI EN ISO 7396-2 – *Medical gas pipeline systems - Anaesthetic gas scavenging disposal systems*: similarly to the previous, it certifies evacuation systems of anaesthetics gas, specifying requirements for preventing interconnections with the medical gas distribution systems and vacuum line [47].

All these standards refer to UNI EN ISO 14971 (*Medical devices — Application of risk management to Medical Devices*), for what concerns risks analysis.

4.3 Hydraulic system

Hydraulic system in healthcare facilities deals with drinking, sanitary and industrial uses. A typical network for water distribution sees two main collectors departing from the water station: the *service collector* for the industrial uses (thermal power plant and secondary heath systems, fire-fighting systems, laundry, production of chilled water and cooling of generating sets); the *utility collector* for kitchen, toilets, hot water production and special services (laboratories, pharmacy, sterilization).

Cold water distribution is regulated by pressure reducers placed after the water station, while sanitary hot water is regulated by heat exchangers after the thermal power plant and by expansion vessels before the terminals of use. Several uprights branch off from the collectors and go up to the buildings, with backflow valves to prevent water refluxes. They detect pressure variations and maintain pressure in the water distribution network around 2.5 bar, while pressure reducers prevent from exceeding 5 – 5.5 bar. It follows that water emergency in hospitals is potentially critic, because of the difficulty to have backup systems able to guarantee adequate flows.

Water quality

Water quality is established by the European Directive 98/83/EC (transposed in Italy with the D.Lgs. 31/2001) and its revisions, such as the latest Directive 2015/1787. Several parameters are taken in consideration for water assessment, including chemical-physical and microbiological parameters which strongly affect the conservation of metal conduits:

- CO_2 content: carbon dioxide dissolved in water increases its acidity and therefore its corrosive effect;
- O_2 content: oxygen dissolved in water increases its oxidant effect, damaging the pipes both internally and externally;
- $CaCO_3$ content: calcium carbonate is the main component of limestone, whose deposits must be prevented; its content is strictly related to water hardness.

For each parameter and unwanted microorganism, the Directive defines the frequency of the analysis and criteria for risk assessment. One of the fundamental protection systems regards the *Legionella Pneumophila*, bacteria which tends to develop in still and warm waters (32-45°C) - infesting pipe terminals, tanks and low-use sections of water network - and responsible for bacterial pneumonia. Several ministerial documents have regulated the

adoption of measures against Legionellosis in previous years, now reunited into the '*Guidelines for prevention and control of legionellosis*' (State-Regions Conference, 7th May 2015). Each healthcare facility must develop an annual risk analysis considering environmental and structural characteristics, hosted and assisted population, health services provided and the epidemiological precedents: on the basis of this assessment, it is possible to identify different risk categories in which to classify the departments and the consequent security measures. Methods for contamination prevention and control for the hydraulic system can be summarized in two main categories:

- short-term measures include decalcification in acid solution and substitution of discontinuity elements (worn joints, tap joints, flexible hoses, …);
- long-term measures include water microfiltration at the point of use, thermic treatments (thermal shock and thermal disinfection), UV irradiation, chlorination (shock and continuous hyperchlorination), disinfection with chlorine dioxide, ozonation, copper-silver ionization, disinfection with hydrogen peroxide and silver ions [49]. Disinfection with chlorine dioxide is the most used method in hospitals.

Regulations for the hydraulic system

To prove compliance with the Directive, manufacturers of hydraulic systems must guarantee their components with several standards, which aim to make available the water supply in each sampling point at the design temperature and pressure, to prevent the pipelines from being damaged by corrosion and to prevent the worsening of the quality of drinking water.

Some of the main technical standards regarding hydraulic system are the following:

UNI EN 806 - *Specifications for installations inside buildings conveying water for human consumption*: divided in 5 sub-norms which define generality (Part 1), design (Part 2), simplified method for pipes dimensioning (Part 3), installation (Part 4), use and manutention (Part 5). The standard regulates the water flow rate for each sampling point: known the sum of the flow rates among all the utilities connected to the desired system, it is possible to evaluate the whole project flow, which cannot exceed 9 l/s for standard hydraulic implants. Depending on the material used for the piping and on the desired flow, it is possible to determine the diameter of each section of pipe on the basis of coefficients present in special tables [50].

The EN 806 also defined the temperature limits for both collectors of the distribution network (Table 6):

Table 6 – Temperature limits for water network

Water network type	Temperature limit [°C]
Cold water	≤ 25°C
Hot water	≥ 60°C

UNI 9182 - *Hot and cold water supply and distribution installations - Design, installation and testing*: the standard set the technical aspects and parameters related to the dimensioning of piping for drinking water systems, for hot water production, storage and distribution, application of non-drinking water and overall specifications for system installation and testing. This standard applies to both new systems and existing installations to be modified. The determination of the project flow rate and pipe dimensioning follows a similar method to that of UNI EN 806:

1) indication of the flow rate for each section, both for cold and hot water;
2) sum of the flow rates of all sections to determine the whole project flow rate;
3) determination of the minimum diameter of piping;
4) calculation of the pressure drops along the pipe and check their compatibility with the available pressure;
5) for hot water distribution, evaluation of its delivery time for the most disadvantaged terminal, to verify the eventual need for a recirculation system. As indicated by the norm, hot water must be guaranteed at the given pressure and flow within 30s.

UNI EN 15975 - *Security of drinking water supply - Guidelines for risk and crisis management*: this EU standard defines the good practices of management of drinking water supply systems in case of emergency events, from preparatory phases to follow-up measures. Several other norms regulate each specific component of the distribution system, valves and pumping units and sanitary appliances connected to the network.

In similar modalities, other norms define the requirements for water discharge systems (UNI EN 12056, UNI EN 274, UNI EN 12201, …).

4.4 HVAC *(Heating, Ventilation and Air Conditioning*) system

Thermal energy in hospital facilities is usually managed by a centralized system, composed by several elements: a heat generator (boiler) produces thermal energy to be conveyed to a heat transfer fluid, which is sent towards the users through a primary heat distribution network. By means of heat exchangers, several secondary heath distribution systems are connected to the primary network and distribute the heat to the network terminals.
Boiler functioning requires electricity, fuel and water. It follows that hydraulic and electric systems are clearly related to that of heating, whose working continuity must be guaranteed in these 3 aspects:

- fuel continuity is ensured by ambivalence of boilers (methane/gasoline), and gasoline reserves that allow several days of functioning are maintained;
- electric energy continuity is ensured by the presence of different generating sets;
- if water supply fails, it becomes necessary to turn off the boilers, because of the huge amount of water needed.

Water required by HVAC system must also satisfy technical standards, including the **UNI 8065** - *Water treatment in winter and summer air conditioning systems, for production of domestic hot water and solar thermal systems*: it specifies the chemical-physical water characteristics used in conditioning systems and in the production of sanitary hot water, in order to optimize yield, safety and duration of the system and minimize energetic consumption. The norm also indicates specifications for the rehabilitation of existing plants (for example with problem of corrosion, fouling and biological growth), their overall management and manutention [51].

Environmental-related parameters

In hospital premises several sanitary activities take place, which suppose the presence of patients and healthcare workers with different environmental well-being needs. It is therefore necessary to understand the setting of environmental-related parameters that can contribute to the well-being, such as temperature (T), speed, purity and relative humidity of air (φ), generally included in the following ranges (Table 7):

Table 7 – Environmental parameters

Season	Temperature	Relative humidity
Winter	19,5°C < T < 24°C	25% < φ < 85%
Summer	21°C < T < 27 °C	20% < φ < 75%

In particular, the D.P.R. of 14th January 1997 defines requirements for specific premises in healthcare facilities (Table 8) [52]:

Table 8 – Requirements for specific premises

Parameter	Operating room	Delivery and birth room	Resuscitation / Intensive care	Day surgery	Pharmacy and sanitary material	Sterilization/ Disinfection service	Mortuary
Summer temperature	20-24 °C	20-24 °C	20-24 °C	20-24 °C	20-26 °C	20-27 °C	< 18 °C
Winter temperature	20-24 °C	20-24 °C	20-24 °C	20-24 °C	20-26 °C	20-27 °C	< 18 °C
Relative humidity	40-60 %	30-60 %	40-60 %	40-60 %	50% ± 5%	40-60 %	60% ± 5%
Air exchanges	15 v/h	6 v/h	6 v/h	15 v/h	2 v/h	15 v/h	15 v/h
Air filtering	99,97 %	n.d.	n.d.	99,97 %	Medium efficiency	n.d.	n.d.

These regulations depend on the different air conditioning systems, which can be identified as:

- ventilation system: it realizes the air exchange, by entering pure air (as much as possible by filtration) in the premise and ejecting the stale old air;
- thermoventilation system: it produces pre-heated air, that realizes both fan and heat function;
- humidification system: it increases the relative humidity of air by means of special batteries that spray water into the air itself;
- complete air conditioning system (HVAC system): it realizes all the previous functions simultaneously, besides cooling and dehumidification, thanks to a ventilation system which set the specific air parameters in the environment. These are today the most diffuse systems, allowing a total control of environmental condition.

Regulations for air quality

Air quality depends not only on the physical variables like temperature and humidity, but also on variables indicating air contamination:

- *corpusculate*: constituted by dust, micro-drops and fumes;
- *sterility*: linked to the presence of microorganisms, especially bacteria, that are transported by the corpusculate (of which they represent a minor part). These two factors represent therefore a unique problem;
- *foreign gases*: extraneous substances to the normal composition of the ambient air. In medical field, they can be represented by medical gases and anaesthetic agents.

Therefore, a fundamental task of air conditioning systems is to guarantee the emission of air as pure as possible, obtainable through filtering operations. Depending on their filtration efficiency, defined as

$$E_{f\%} = \left[1 - \frac{C_o}{C_i}\right] * 100$$

(Co = particles outgoing concentration, Ci = particles incoming concentration), filters can be generally classified as follows:

- pre-filters: inlet filter to the ventilation system;
- intermediate filters;
- EPA filters (*Efficient Particulate Air filter*);
- absolute HEPA filters (*High Efficiency Particulate Air*): they retain up to 99.999% of particles with a diameter up to 0.3 microns;
- absolute ULPA filters (*Ultra Low Penetration Air*): they retain up to 99.9999999% of particles with a diameter up to 0.12 microns.

Absolute filters, especially HEPA filters, are today the most used in medical practice. They are composed by a cellulose sheet, folded several times on itself to increase the filtering surface, and must be placed as far downstream as possible in the filtration system (i.e. close to users) to prevent air from deteriorating again in the ducts [52].

Different norms set criteria to classify filters depending on their efficiency, such as:

ISO 16890 – *Air filter for general ventilation*: it establishes an efficiency classification system based on PM (*particulate matter*): the norm identifies 4 classification groups in term

of ePMx (*PM efficiency*), depending on the capacity of retaining particulate of various sizes (PM10, PM2,5 and PM1). For being classified into a certain ePM group, the filter must retain at least the 50% of particulate of the given size [53] (Table 9).

Table 9 – ISO 16890 filtration classes

Classi di filtrazione	Requisiti			Valore di classe nel report
	ePM1min	ePM2,5min	ePM10	
ISO Coarse	-	-	<50%	Efficienza in massa iniziale
ISO ePM10	-	-	≥50%	ePM10
ISO ePM2,5		≥50%	-	ePM2,5
ISO ePM1	≥50%	-	-	ePM1

The norm is divided in 4 sub-norms and also defines test procedures and requirements for marking the filters.

It must be noticed that the standard ISO 16890 is suitable for applications in general ventilation, therefore its classifications do not substitute that of high-efficacy filters (EPA, HEPA and ULPA, defined by the following norm) .

UNI EN 1822-1 – *High efficiency air filters (EPA, HEPA and ULPA - Part 1: Classification, performance testing, marking)*: this standard applies to high efficiency air filters for ventilation and air conditioning systems in pharmaceutical and clean-room applications. It determines procedures for assessing filtration efficiency by particle counting method through an aerosol test, allowing a standardized filter classification based on their local and integral efficiency [54]. Consequently, the norm classifies filters in 3 groups: Group E (EPA filter), Group H (HEPA filter), Group U (ULPA filter) (Figure 24) [55].

Filter Group Filter Class	Integral value		Local value [a] [b]	
	Efficiency (%)	Penetration (%)	Efficiency (%)	Penetration (%)
E 10	≥ 85	≤ 15	---[c]	---[c]
E 11	≥ 95	≤ 5	---[c]	---[c]
E 12	≥ 99,5	≤ 0,5	---[c]	---[c]
H 13	≥ 99,95	≤ 0,05	≥ 99,75	≤ 0,25
H 14	≥ 99,995	≤ 0,005	≥ 99,975	≤ 0,025
U 15	≥ 99,999 5	≤ 0,000 5	≥ 99,997 5	≤ 0,002 5
U 16	≥ 99,999 95	≤ 0,000 05	≥ 99,999 75	≤ 0,000 25
U 17	≥ 99,999 995	≤ 0,000 005	≥ 99,999 9	≤ 0,000 1

[a] See 7.5.2 and EN 1822-4.

[b] Local penetration values lower than those given in the table may be agreed between supplier and purchaser.

[c] Group E filters (Classes E10, E11 and E12) cannot and shall not be leak tested for classification purposes.

Figure 24 – Classification of high efficiency air filters (UNI EN 1822-1)

4.5 Data system

With the deepening of hospital information building, medical data generated by the HIS (*Hospital Information System*) has grown at an unprecedented rate, which means the starting era of Big Data in the healthcare sector. The characteristics of health data, if used in a timely and appropriate way, can bring enormous benefits in the form of cost savings, better quality of healthcare and better productivity.

However, the complex and interdisciplinary nature of medical data has highlighted the limitations of traditional data access analysis, archiving, distribution and data sharing capabilities. New efficient technologies, such as cloud computing, data mining and semantic web technologies, are becoming necessary to obtain, use and share the wealth of information and knowledge underlying these medical Big Data. [56].

It is necessary to clarify that a software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a Medical Device, is considered a Medical Device; standalone software for general purposes when used in a healthcare setting is not a Medical Device [57]. However, some standalone softwares may break down into a significant number of user applications; such softwares may be intended to cover many needs, including:

- collect and maintain administrative patient details;
- keep on file the medical history of the patient;
- invoicing and other accounting functions;

- provide a link to the social security system for reimbursement;
- provide a link to drug prescription systems;
- provide expert system assistance for medical decision making (e.g. radiotherapy dose planner). [58]

The regulation **IEC 80001-1** defines the fundamental rules for the coexistence of Medical Devices and computer networks. The risks of IT networks incorporating Medical Devices are therefore assessed, defining the roles and responsibilities inside the hospital.

HIS

The HIS (*Hospital Information System*) is a comprehensive and integrated information system designed to manage the administrative, financial and clinical aspects of a hospital. Components of a HIS consist of two or more of the following systems [59]:

- Picture Archiving Communication System (PACS**)** is a medical imaging technology which provides economical storage and convenient access to images from multiple modalities. The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine);
- Radiology Information System (RIS) is an information system used to create, store and manage radiological data and images of patients;
- Clinical Information System (CIS) is a system designed for collecting, storing, manipulating and making available clinical information during the healthcare delivery process. In the critical care environment, CIS can network several computer systems, such as pathology and radiology, drawing information from all these systems into an electronic patient record;
- electronic patient record systems are intended to store and transfer electronic patient records, which contains health events and summary documents generated by the various actors of the healthcare system [60].

Supervision system

The increasingly efficient, coordinated control and management of all these systems requires the presence of a large number of sensors and regulation systems, which would not be possible to manage individually. In addition to reading, collecting, recording and displaying parameters, these systems allow to control trends over time, adjust remotely actuators and

control systems in order to meet different needs, ensuring at the same time the continuity of service, comfort conditions, energy and economic efficiency.

A remote management and remote-control system can be divided into three main sections (Figure 25):

1. measurement and implementation system: mainly composed of measurement sensors and actuation systems;
2. transmission system: includes the data transmission line from the sensor to the data acquisition system, which can be wired or wireless;
3. supervision and control system: composed by a data control unit with the relative management software, which can be managed by the user in charge of reading the parameters detected and/or programmed to generate and send periodic reports. Alarms for reporting anomalies are also included in the system.

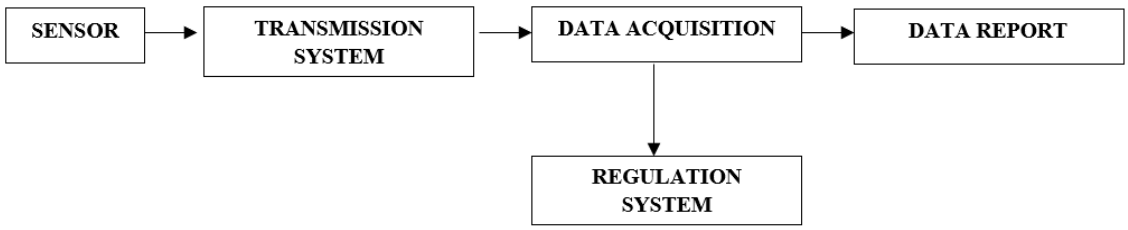


Figure 25 – Remote management and remote-control system

Supervisory Control And Data Acquisition (SCADA)

SCADA systems are management structures in charge of supervision, control and data acquisition. Each SCADA, in its generality, fits within an architecture that provides:

- one or more interconnected computers to which the supervisory functions and, in particular, the man-machine interface are entrusted;
- a series of peripheral units that interface directly with the process through sensors and actuators;
- a communication network, characterized by a multiplicity of transmission media and communication protocols, capable of ensuring the correct exchange of information between the supervision computer and peripheral units.

By SCADA software is meant the integrated development environment which provides all the useful tools for creating SCADA applications intended to run on the supervision computers, in order to carry out the characteristic functions of the SCADA systems [61].

4.6 Automation system

The automation of technological systems within the hospital is leading to a structural and informative change in healthcare, aimed at the future realization of the *Hospital 4.0*. One of the characterizing aspects of the automation in a hospital is the use of Domotics: the science that deals with the study of technologies aimed at improving the quality of life in home and, more generally, in anthropized environments. It could make significant progresses in the reduction of energy waste and in the improvement of the quality of life in the rooms, in particular for non-self-sufficient patients through a continuous interface between patient parameters and medical personnel.

In order to structure a hospital system by following the rules related to domotics, the following standards are to be taken into consideration:

- **CEI 64/8 (V3)**: it defines the standards of buildings and electrical systems according to the degree of automation;
- **EN 15232**: European standards that gives a method of classification by degree of energy efficiency and therefore energy saving.

The concept of *Hospital 4.0* is new way of conceiving the hospital structure, that will no longer be intended just as a "building", but as a series of processes and technologies capable of delivering healthcare even from a distance. ICT (*Information and communication technologies*) will play a central role in the creation of the new model of Hospital 4.0: different devices and sensors will be able to communicate through a dense network of wireless communications capable of providing healthcare.

In order to achieve these goals, the hospital system needs to consider the growth and developments of artificial intelligence and robotics within healthcare.

Artificial intelligence (AI) and Robotics

AI is a discipline that is concerned with the development of theoretical models, their implementation in software and supporting hardware systems, which lead the computer to "simulate" or to have behaviour comparable, to a certain extent, to human intelligence. In

the healthcare sector, *IBM Watson* and *Google Cloud Healthcare app* are the reference softwares in the world of AI. The softwares are able to processes data from patients' electronic medical records to support the best and most appropriate clinical decisions [62].

Moreover, robots are a rapidly growing part of the modern health care landscape. They have been introduced for different tasks such as: carrying out surgical interventions, performing initial diagnostic checks without requiring a doctor or nurse and to avoid contact between patient and healthcare worker in conditions of infectious risk.

Several benefits are carried by the introduction of robots in healthcare, including:

- provide assistance or comfort to patients or visitor;
- eliminate human error in delicate, high-risk procedures;
- reduce the time required for surgeries;
- improve patient recovery time;
- shorten hospital stays;
- create targeted and personalized treatments.

One of the first significant attempts to bring robotics in compliance with the legislative context is represented by the Resolution of the European Parliament of 16th February 2017. It indicates three specific areas, in the health sector, to which particular attention should be paid: robots used for assistance, medical robots and reparative and improvement interventions of the human body. In particular, it underlines the importance of establishing robot ethics committees with appropriate staff who have the task of examining and helping solve complex and unusual ethical problems concerning the care and treatment of patients [63].

5. Intensive Care Unit (ICU)

The Intensive Care Unit is a hospital ward reserved for people in life-threatening health conditions, where one of the vital functions (respiration, blood circulation, neurological activity) is currently insufficient to maintain life [64]. Therefore, hospitalization in ICU ensures highly specialized clinical support, not available in other departments, which integrates the appropriate medical knowledge, specific nursing assistance and modern instrumentation, electronics and IT resources. Once vital functions are restored and stabilized, the ICU patient is transferred to different departments for the continuation of the necessary treatments. However, a patient may still not be able to continue his stay in an ordinary ward: hence the need to have intermediate intensity structures (Sub-Intensive Therapies) where patients are still monitored 24 hours per day, but with less invasive supports than in ICUs.

ICU design is aimed at maximizing healing capacity of the environment – by improving patient's physiological parameters, reducing medical errors and patient length of stay – and should initially follow a *performance-oriented* approach, identifying the function and needs to be accomplished, rather than a *prescriptive-oriented* guide, which in example quantifies the minimum square footage for room. Another analysis that should be carried on firstly, together with the development of a requirements program, is an Infection Control Risk Assessment, in order to evaluate the risk of infection for both construction and use phases of the room. The configuration of an ICU should therefore follow its function, from common requirements to subspecialty necessities: for what concerns infection control, peculiar additions must be included, such as isolation facilities, several hygiene stations, upgrade of mechanical ventilation systems, dedicated methods of disposal for human waste and antimicrobial materials.

During the design process, staff from multiple sectors must be included:

1) hospital administrators to evaluate finance and budgets;
2) clinical team: physicians, nurses, pharmacists and others;
3) design team: architects, engineers and technology planners;
4) other hospital representatives for food, environmental services and others [65].

5.1 ICU structural requirements

In ICU, patient rooms represent only a part of the spaces necessary for the care of critically ill patients, as a large amount of accessory spaces is necessary to allow the regular performance of the functions of the unit. According to the D.P.R. of 14th January 1997, premises and spaces for ICUs must be related to the type and volume of the activities provided, and must satisfy the presence of the following minimum requirements (Figure 26):

- filter area for patients
- filter area for staff
- hospital stays
- room for infected patients with a dedicated filter area
- room for doctors
- work room for nurses
- toilets for staff
- storage for clean material and health aids
- deposit for dirty material.

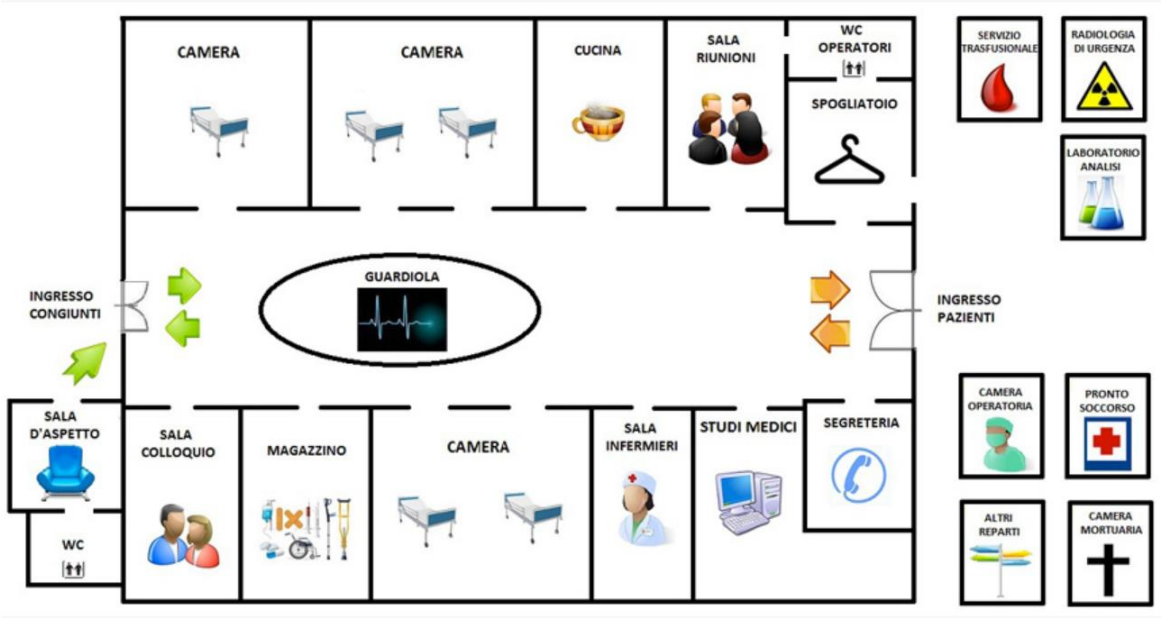
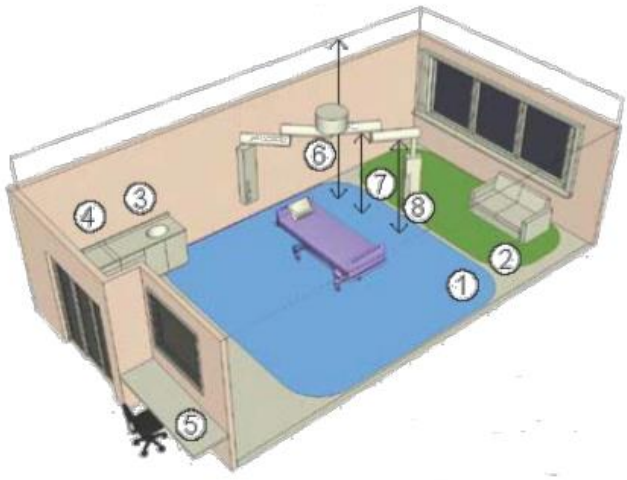


Figure 26 – ICU schema (source: Intensiva)

According to the design of the facility, the ICU is generally located near the emergency room and the operating block. A service entrance is provided for relatives, while the main entrance allows patients and staff to access ICU together with other structures essential for critical care, such as the laboratory, the transfusion centre or the emergency radiology.

Real-time data from all patient rooms (e.g. waveforms, vital parameters and alarms from physiological patient monitors) are provided and visible to a central Monitoring Center. It must contain all the tools to support clinical decisions, including a secure web access with multi-patient view, a display of all electromedical devices interfaced to each bedside, HL7 data export to clinical computer systems and the technology to access to hospital applications (PACS, LIS, Digistat, etc.). The Monitoring Center must also display and store patient data and allow remote secure viewing from any hospital PC [66].

ICUs can be structured for single or multiple hospitalizations (usually from 6 to 12 beds), for economic and efficiency reasons. Typical single-patient rooms share the following characteristics [67]:



1 Patient Zone
2 Family Zone
3 Hygiene Zone
4 Clinical Zone
5 Charting Sub-station
6 Ceiling Height (2.7 – 3.3 m)
7 Clearance (2.4 – 3 m)
8 Clearance (2.1 – 2.7 m)

Figure 27 – Single-patient ICU scheme (source: European Healthcare Design Congress)

Multiple-patient ICUs are similarly structured, with several patient zones inside the same room. Four main areas can be identified in an ICU:

- *Patient Care Zone*: represented by patient room and adjacent areas;
- *Clinical Support Zone*: refers to functions concerning patient care;
- *Unit Support Zone*: consists of areas related to material and device management, administration and staff support activities;
- *Family Support Zone*: zone for relatives and visitors. It is not always present inside the patient room, depending on the number of hospitalizations and on the type of patient recovered (i.e. ICUs for infectious patients cannot contemplate a family zone near the patient himself).

Patient Care Zone

Patient Care Zone represents the areas where direct care is performed, and its design must therefore consider the necessary space to carry out the required activities.

A clear floor area must be defined around patient bed, with dimensions that must allow services to be brought to the bedside, such as portable imaging devices and examination equipment. Optimal distances are recommended to be not less than 1.2m from bed head and foot, not less than 1.8 from each side of the bed.

Medical gases and electrical outlets are necessary to provide the patient with the necessary therapies, therefore a medical supply unit must be chosen between different existing categories (*headwall*, *column* or *boom* systems), on the basis of layout and size of the room. Electronic documentation of each patient must be visualized and updated: a wireless system and/or data ports for computer terminals must be provided, and a computer-controlled system is necessary to dispense the medications needed.

Medication storage must be dimensioned to include peculiar articles - like intravenous bags, large syringes and others – and small refrigerators should also be included in patient room to reduce staff travel for medication. Separate storage is needed for clean and used medical equipment, and different containers are necessary for trash, waste products and hazardous wastes, such as syringes and needles. Finally, of particular importance is the control of infections: fluid disposal, hand washing facilities, alcohol gel dispensers must be provided, and the eventual room setting at negative pressure for infectious patient can prevent the external diffusion of pathogen [65].

Clinical Support Zone

Clinical support functions regard all the actions concerning diagnosis and treatment of patients. Being the ICU staff exposed to several hazardous fluids, an emergency eyewash station must be provided.

Usually, a centralized monitoring is available to control patient's physiologic parameters, possibly accommodated with unique alarms to alert personnel of dangerous situations or malfunctioning of devices. Moreover, ICUs may need to send physiological data to specialist in remote locations, inside or outside the hospital: video observation, communication links and all the necessary stuff to allow an external reporting must be provided in the room.

Pharmaceutical delivery processes are also to be evaluated in ICU design, to guarantee a 24/7 availability of supplies. A dedicated workstation should be included, and pneumatic

tubes represent a diffused solution to transport medicines to and from the main hospital pharmacy. Medication rooms must provide medication storage, dispensing machines for patient-specific substances and computer access to electronic patient records.
ICUs must also have a 24/7 access to laboratory services, that can be provided by central or secondary hospital laboratories, to which pneumatic tubes can send specimens. If specific exams are frequent in the unit, considerations for implementing specific analysers in the ICU can be included in its design.
Imaging services should be immediately accessible, and storage for portable imaging devices could therefore be planned. Similar considerations can apply to ventilators and other respiratory devices [65].

5.2 ICU technological requirements

5.2.1 ICU Medical Devices

The D.P.R. of 14th January 1997 defined the minimum technological requirements related to the ICUs, which must include:

- *automatic ventilator*
- *defibrillator*
- *vital signs monitor*
- *technical bed*
- *anaesthesia unit* with gas evacuation system
- *endoscopic column* for bronchoaspiration
- *operating light*
- *wall diaphanoscope*
- *refrigerators* for drugs and blood products.

All ICU Medical Devices follow a maintenance procedure that can be carried out directly by the hospital or, in cases of collaboration with external companies, delegated to Global Service companies. In particular, different types of maintenance are highlighted:

- preventive maintenance is carried out at predetermined regular intervals in accordance with prescribed criteria. Routine interventions include the check of operating parameters, calibrations, replacement of spare parts and parts subject to wear and, in case of non-compliant equipment, the reconditioning of the

device. If during the preventive maintenance a malfunction of the equipment is found, the type of failure is reported and the machine must be stopped;

- corrective maintenance is performed following the detection of a failure and aimed at restoring an activity to the state in which it performs a requested function [68].

Safety, essential performance and electromagnetic compatibility of medical electrical equipment and systems are covered by the UNI CEI EN 60601 family of standards, whose "Part 1" (EN 60601-1) concerns the basic safety and essential performance for all medical electrical equipment and "Part 2" (EN 60601-2) covers requirements for specific product groups. The Italian equivalent standard is the CEI 62 and its subnorms (e.g. CEI 62-20 for lung ventilators).

Another aspect common to almost all ICU electromedical devices is the ability to interconnect each other via software and their capability of data transmission, on the basis of the EU regulation 679/2016 (*General Data Protection Regulation*), which sets the rules for the management and monitoring of patient personal data in the ICT area. Therefore, cybersecurity protection is needed to address wireless communication risks, and manufacturers can include encryption systems, advanced network connectivity, compliance with specific information processing standards and security patch updates.

Besides the mandatory Medical Devices listed above, a set of further instrumentation can be considered essential for the practices within the ICUs: *infusion pumps, manual ventilator, dyalisis machine, radiographic imaging devices, ultrasound scanner, emergency trolley and other support instrumentation*. For both mandatory and additional equipment, a description of their functioning, components and main technical standards is provided below.

Automatic ventilator

Lung ventilation (or artificial ventilation or mechanical ventilation) replaces or supports the activity of the inspiratory muscles by ensuring an adequate volume of gas in the lungs. They incorporate highly customizable ventilation methods that carefully control the volume and pressure of gas delivered per breath and the composition of the inspired gas. Mechanical ventilation is performed for relatively short periods in operating theatres and for longer periods of time in ICUs, but it is also performed in specialist ward areas and in patient's home under specific monitoring.

There are different types of pulmonary ventilators depending on the pathologies treated and the patient's clinical condition:

- negative pressure ventilator: represents the first generation of mechanical lung ventilators (*steel lungs*). A depression is generated inside the cistern that wraps the patient by means of a bellows, then the thoracic case expands, generating a depression inside patient's airways and, due to pressure difference, the ambient air enters the airways and lungs. The interruption of the bellows function, with the return to the starting position, allows the passive emptying of the lung. However, the abdomen is also contained in the tank and consequently expanded during the bellows action, creating a blood seizure that reduces the venous return to the right heart, which represents a particularly dangerous situation;
- positive pressure ventilator: positive pressure ventilation is the direct and forced delivery of air and oxygen to the lungs, bypassing normal physiological breathing. This allows an easier patient access than an iron lung, but it has the potential to cause damage to the delicate lung tissue. Positive pressure lung assistance can be delivered in two ways: by NIV (*non-invasive ventilation*) through an adherent face or a nasal mask, or more commonly by IV (*invasive ventilation*) through a tube positioned in the larynx or trachea.

NON-INVASIVE VENTILATION (NIV)

NIV is an effective therapeutic strategy for the treatment of respiratory failure without having to resort to tracheostomy. Two main modalities can be identified:

1. **CPAP** (*Continuous Positive Airway Pressure*) is a ventilation mode that consists in maintaining a constant positive pressure inside the respiratory tract, both in inspiratory and expiratory phases (Figure 28) [69];

Figure 28 – Pulmonary pressure trend in patients with CPAP (source: Rossoemergenza)

2. **BIPAP** (*Biphasic Positive Airway Pressure*) is a ventilation mode characterized by the biphasic application of continuous positive airway pressure (IPAP and EPAP - *Inspiratory* and *Expiratory Positive Airway Pressure*) (Figure 29). Two different pressure levels are set, functioning as two different CPAP levels that alternate rhythmically, while the patient breathes spontaneously. Four commands are therefore essential: a low-pressure level (P_{low}), a high-pressure level (P_{high}), the duration of P_{low} ($T_{P_{low}}$) and the duration of P_{high} ($T_{P_{high}}$). [69]

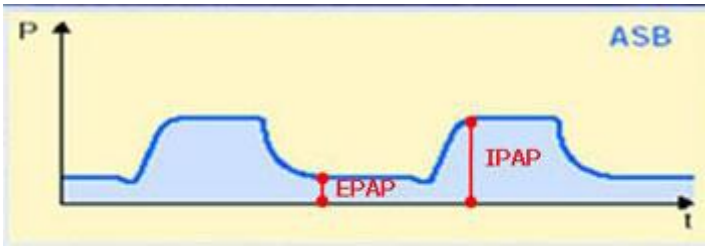


Figure 29 – Pulmonary pressure trend in patients with BIPAP (source: Rossoemergenza)

INVASIVE VENTILATION (IV)

Invasive ventilation allows the patient to breathe with the help of a ventilator connected directly to the tracheal path through a connecting tube, which depends on the introduction site (tracheal, nasotracheal or tracheostomy tube). The positive pressure pulmonary ventilators used in IV are composed by the following essential components (Figure 30):

- oxygen and air deliver: all ventilators are able to provide a mixed percentage of oxygen and air, known as the FiO_2 (*inspired oxygen fraction*);
- Respiratory Rate (RR): the set respiratory rate may be increased or decreased to enable the elimination or retention of arterial CO_2 (*carbon dioxide*);
- volume and pressure-controlled ventilation: positive pressure ventilation can be delivered to the lungs using a volume-controlled ventilation or a pressure-controlled ventilation, which represents the preferred mode used in ICUs;
- Positive End-Expiratory Pressure (PEEP) and continuous positive airway pressure: normal physiological breathing prevents the lungs from collapsing completely at the end of the exhalation, since the epiglottis closes the airways, leaving a residual volume of air in the lungs. This is not possible if the larynx is permanently open,

given the presence of an endotracheal tube: PEEP ensures that a certain amount of pressure remains in the lungs throughout the entire ventilatory cycle.

- monitoring and alarms: all modern ventilators have the possibility to view the general settings on a visible screen, while a series of alarms are activated when the set parameters are violated or if a disconnection occurs in the circuit;
- humidification: in patients with an endotracheal tube, conditioning of respiratory gases is unable to occur. Therefore, it is essential that the gas is clean, warm and humidified when mechanical ventilation is provided invasively or non-invasively. All mechanical ventilation circuits contain a respiratory filter that prevent pathogens or foreign material from entering the patient's body, with an external heating and humidification system usually added to the ventilator circuit. For prolonged mechanical ventilation, this is achieved by passing the ventilator gas through an external heated water bath chamber (wet circuit). To avoid the accumulation of water vapor in the ventilator tube, the inspiratory circuit tube usually incorporates a heater wire over its entire length [70].

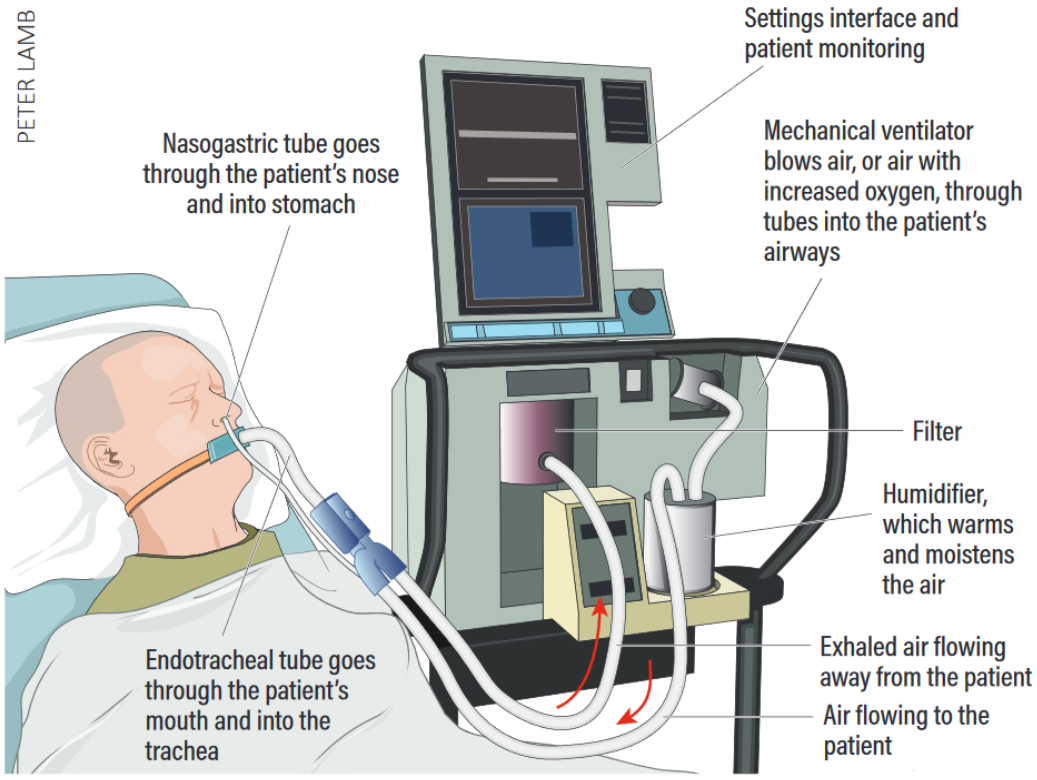


Figure 30 – Mechanical ventilator in ICU (source: Nursing Standard)

The ventilator performance is based on the ventilation capacity of the machine, the different ventilation modalities and the ability to promptly compensate for any physiological

variations. For safety, an alarm system is capable of reporting vital signs at given accuracy intervals and making subsequent changes to the settings.

Ventilators are classified according to their invasiveness: invasive lung ventilators belong to the Class IIb of Medical Devices, while non-invasive ventilators belong to Class IIa. Regarding the minimum requirements for anaesthesia and lung ventilation instrumentation, reference is made to EN ISO 5356 and EN ISO 7376 standards, and to CEI EN 60601-2-12 (CEI 62-20) for preventive and corrective maintenance. Annually, it is recommended to remove and replace the pneumatic kits with and without compressor, the O_2 sensor and the internal and external batteries. Furthermore, it is necessary to check the transducers for each sensor, calibrate and confirm the operation of the ventilator with optimal parameters, calibrate the touch screen and the CO_2 detection [71]. During periodic maintenance, functional tests verify that:

- the airway pressure increases during the inspiratory phase;
- the airway pressure limit intervenes;
- the change in the set value of the oxygen concentration (O2%) corresponds;
- as the ventilation parameters change, the ventilator behavior is corresponding;
- trigger operation is effective;
- the set values of volume and respiratory rate are displayed correctly and the pressure, volume and flow curves are in accordance with the monitored parameters;
- the alarms intervene correctly.

Defibrillator

Defibrillators are life-saving devices that apply an electrical discharge to establish a physiological heart rhythm in patients who have ventricular fibrillation or another shockable rhythm (Figure 31). Defibrillators typically have three basic operating modes: external defibrillation, internal defibrillation and synchronized cardioversion. An integrated ECG monitor is used to check the rhythm and the effectiveness of the treatment. Many defibrillators can be equipped with optional monitoring features, such as SpO_2 (*pulse oximetry*), temperature, $ETCO_2$ (*end-of-tide carbon dioxide*) and NIBP (*non-invasive blood pressure*). The defibrillator charges with a large capacitor and an audible and visible indicator informs the operator when the capacitor is charged and the device is ready [72]..

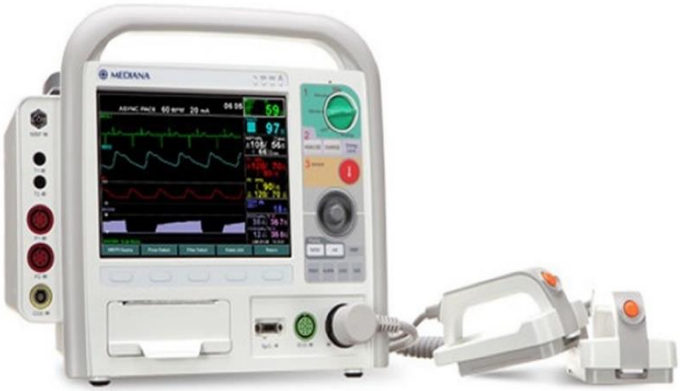


Figure 31 – Defibrillator (source: SEDA S.p.A)

According to the classification rules of Directive 93/42, the defibrillator is a Class IIb Medical Device. IEC 60601-2-4 (CEI 62-13) sets preventive and corrective maintenance aspects for defibrillators: functional checks regards the recharging times, the measurement of the discharged energy, the evaluation of batteries life, the evaluation of the charge before automatic disarming, the measurement of synchronization times, the verification of the acquisition and recognition of the ECG signal (plates, electrodes, cables) and the verification of set alarms.

Infusion pumps

Infusion pumps are necessary to the intravenous delivery of medications, fluids, nutrition and blood products to patients with specified accuracy (± 5%) over a given range of flow rates and time intervals. *Volumetric* infusion pumps allow the administration from a medication sack at a flow rate usually between 0.1 – 1200 mL/hr, while *syringe* infusion pumps can deliver inferior volume (≤ 60 mL) at lower rate (0.5-10 mL/hr) [73].

The main components of an infusion pump are the following:

- pump: realizes the intravenous infusion, through consumable administration sets;
- administration set: consumables that provide the fluid administration from the medication sack or syringe into the patient intravenous catheter;
- pole: support for one or more infusion pumps and hanger of the medication sack;
- softwares:
    - DERS (*Dose Error Reduction System*): software that sets medication safety limits based on its drug library, minimizing manual administration errors;

  - drug library: system that allows the configuration and updating of drug libraries;
  - quality analytics: software that collects and elaborates data from the infusion pumps (e.g. time and date of each event), deriving analysis of DERS usage to identify possible improvements in clinical practice or in the softwares themselves. Usually, quality analytics also provide a report of infusion pumps data in the facility;
  - maintenance and service: software for performance analysis, device calibration and updating;
- pump server: system that eases the integration of the infusion pump with the hospital information system, allowing data exchange with electronic health records. It is also responsible for drug library updates distribution and for the storage of infusion-related data;
- pump alarms: warn the healthcare staff of infusion conditions that could represent an harm to the patient, by pressure detection, optical sensors or ultrasonic transducers.

Figure 32 – Volumetric (left) and syringe (right) infusion pumps (source: ECRI)

The mechanical performance has remained quite stable and mature in recent years, and technology features are the principal aspects taken in consideration for infusion pumps evaluation, including the infusion modalities, the gravity-flow protection, the dose error reduction system (DERS), fault and operational alarm system and wireless connectivity. The

assessment of pump flow rate continuity across the whole operational range, in particular on the lowest flow rate setting, is fundamental to verify its security and performance, together with the definition of pumping pressure, especially in worst-case or emergency scenarios. Other features concerning pump safety regard the configurability of drug library software, clarity and visibility of DERS alarms [74].

Infusion pumps are usually classified as Medical Devices belonging to Class IIb. Besides the use of consumables administration sets after each use, the ordinary weekly or monthly maintenance of infusion pumps concerns the update of drug library and its correct distribution, performance verification and calibration of the pump. Functional testing can be executed through the review of data analytics or with the use of an infusion analyser, an autonomous device which verifies that the pump flow is coherent with the value that appears on the pump display. Annual operations mainly regard the change of pump battery (usually after around 2 years or differently, as indicated by the producer) and the eventual license renewal for softwares.

Infusion pumps safety and performance are regulated by the standard CEI EN 60601-2-24 (CEI 62-99), which requires the accuracy performance of infusion at set time intervals (*observation windows*) in the second hour and in the final hour of infusion, while the first working hour is generally considered as 'warm up' time. *Trumpet curves* describe the maximum percentage deviations, both positive and negative ($E_p(max)$, $E_p(min)$) from the expected flow rate, and the overall percentage error (A) of the set flow rate in fully operational conditions (Figure 33); generally, an acceptable accuracy value (A) is considered around ± 3% [75].

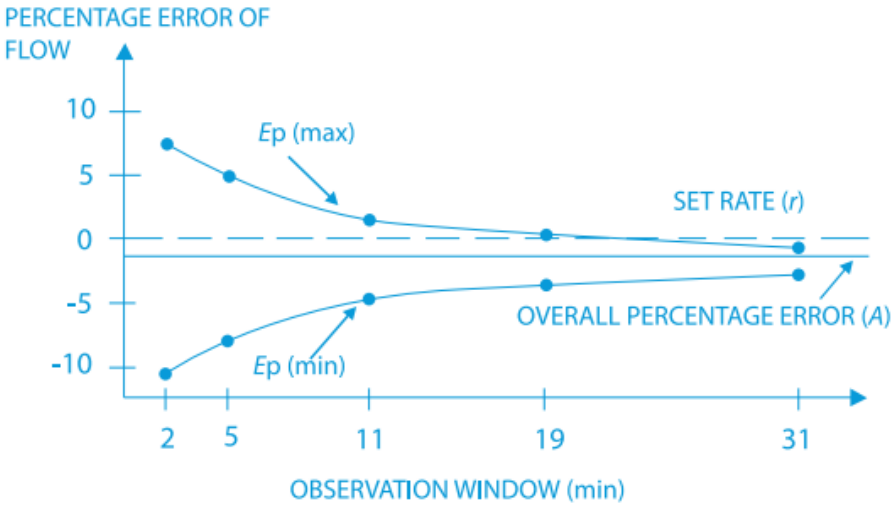


Figure 33 – Trumpet curve (source: Rigel Medical)

Vital signs monitor

Physiological monitoring provides real-time measurements of patient parameters and some non-real-time information, such as trending and alarm review data. Each monitor is connected to the central monitoring center, that allows the simultaneous observation of all hospitalized patients. In addition, there is also the possibility of having portable monitors to facilitate the transition from intensive care to other hospital blocks so that the patient can be monitored continuously without suspending the measurements.

Physiological monitoring uses a conventional format rooted in anesthesiology to present physiological variables: a SSSI (*single sensor-single-indicator*) approach, which provides a single indicator for each individual sensor connected to the patient [76]. Physiological parameters currently displayed on ICU monitors include (Figure 34):

- blood pressure, acquired by an arterial catheter and an external cuff;
- saturation of oxygen in the blood, acquired by a pulse oximeter;
- heart rate and respiratory rate, acquired from external transducers and electrocardiogram waveform;
- central venous pressure, right atrial pressure, pulmonary artery (PA) pressure, cardiac output and other parameters calculated by hemodynamic monitoring using a PA catheter;
- temperature.

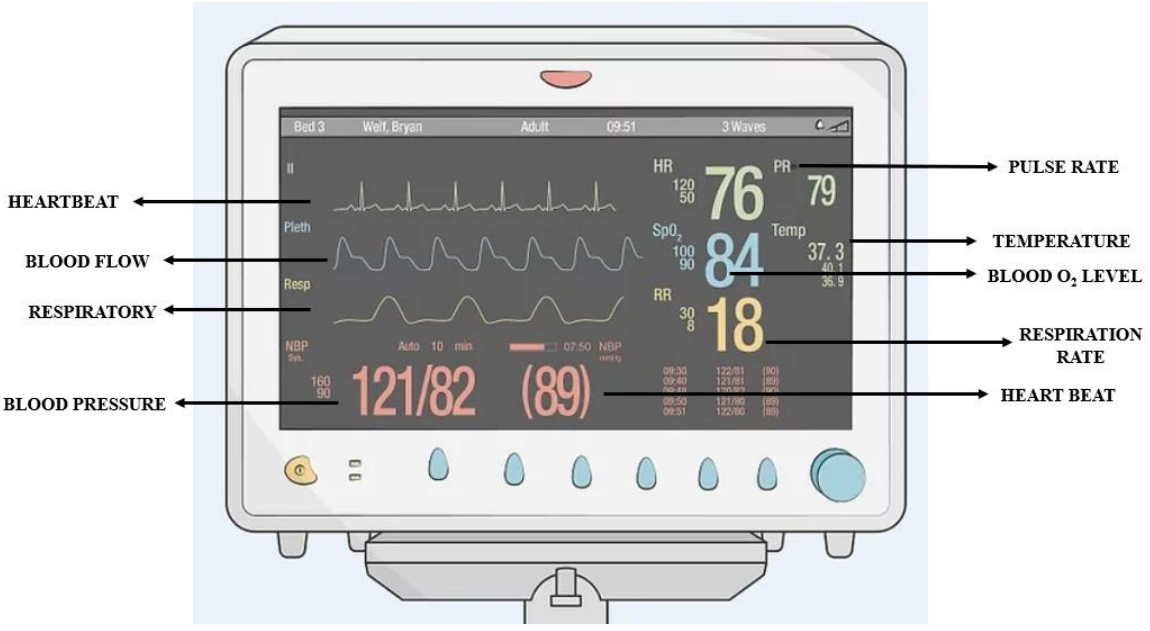


Figure 34 – Vital signs monitor (source: Frank A. Drews)

One of the main features of monitors is to emit sounds (alarms) and to illuminate with different colours related to measurements or to any other acquisition of state descriptors, indicating a significant deviation from a normal state: this is used to warn operators that an action may be required.

The monitors must therefore have the ability to support the personalization of the patient-related monitoring with the associated alarms, without decreasing the security of the acquired data, but facilitating the acquisition and setting by the clinical operator.

Multiparameter monitors belong to Class IIa of Medical Devices. The reference standards for this type of technology are the UNI CEI EN 50518 for the management of alarm monitoring and reception centers, and the CEI EN 60601-2-27 (CEI 62-71) and CEI EN 60601-2-30 (CEI 62-74) for safety indications about corrective maintenance [77]. The main functional checks, carried out using a patient simulator, are the following: calibration of SpO_2 measurement, calibration of the heart rate measurement, electrocardiographic monitoring control (linearity, offset, noise immunity), non-invasive systolic / diastolic pressure calibration and the correct operation of the alarms that can be set.

Hospital technical bed

Electric beds allow the motorized adjustment of height and position of the bed without needing manual force. Different designs are specific for medical sub-specialties like critical care, paediatrics, bariatric patients and others. In particular, critical care beds require the presence of bed alarms and additional positioning options, to minimize patient moving and ease his repositioning by the healthcare staff, while air anti-decubitus mattress auto-regulates its inflation in different areas, on the basis of the support pressure exerted by the patient. Additional features include integrated scales, bed alarms, removable headboards and footboards, motorized system for transport and x-ray compatibility (Figure 35).

Technology changes are mainly related to bed-devices connectivity and smart features, to work together with specialized supports and to deliver patient-specific treatments. The main components of hospital electric beds are the following:

- bed frame: typically divided in three or four sections to allow several patient positionings (*Fowler* and *Trendelenburg* positions, *hyperextension*, *cardiac chair*, …);

- bed motors: permit to regulate the height and the different sections of the bed, and additionally help its transportation;
- patient controls: allow the patient to adjust height and positioning of bed different sections, besides to call medical staff for assistance;
- caregiver controls: special controls for patient lockout and for particular bed positions;
- alarms and status system: include indicators for siderail condition, bed height and section positionings, brakes activation and others.

Figure 35 – ICU bed (source: Malvestio)

The main performances to be analysed are the prevention of pressure ulcers with anti-decubitus mattresses, the maximum safe working load, patient-repositioning and bed-exiting assists, adjustable bed position and regulations (together with their capacity to provide efficacy as pulmonary therapy) and interoperability capacities (e.g. data exchange with EMR). The principal safety characteristics concern the brake effectiveness, a tip-over prevention system, the presence of patient bed-exit alarms and of an emergency release switch for CPR (*Cardio-Pulmonary Resuscitation*) maneuver, battery characteristics (including the availability of a backup and charging time) and cybersecurity features [78].

Hospital beds are classified as Medical Devices of Class I, but can integrate components belonging to different classes (i.e. anti-decubitus mattress can belong to Class IIa), and a suitable reference standard for safety and essential performance is the UNI CEI EN 60601-2-52 (CEI 62-95). An easy ordinary maintenance is required: before each use, it is recommended to verify the functioning of wheels and brakes, the integrity of side bars,

wirings and electrical outlets, while lubrification and check of moving parts is suggested monthly. Control of batteries and motors should happen annually [79].

Anaesthesia Unit

Anaesthesia can be local, to inhibit sensitivity at peripheral levels, or general, which is used in conjunction with surgical operations. In intensive care, if surgical operations are not necessary, sedation of the patient is sufficient. Sedation allows the patient to face intensive care procedures as intubation, to control anxiety and to facilitate patient-ventilator synchrony; moreover, thanks to the use of sedatives, the demand for oxygen is less, the response to stress (tachycardia and hypertension) is better modulated, and a better pain management ensues. The level of sedation that is required varies from moderate to profound, depending on the conditions of patients and the type of treatment they are subjected to [80].

In the event that surgical procedures are necessary, and the patient has to be fully anesthetized, an anaesthesia machine is required. The basic function of the anaesthesia machine is therefore to prepare a mixture consisting of precise and controlled quantities of gas to be blown to the patient. The screens on the machine allow a constant monitoring of all the parameters of interest and to check both the effectiveness of the anaesthesia and the patient's well-being. For example, during controlled mechanical ventilation with tracheal intubation, patient ventilation is monitored by the following systems:

- a spirometer, with sensor placed on the expiratory line to measure the volumes expired by the patient;
- a capnometer, to determine the end expiratory CO_2 value.

Both appliances must be equipped with alarms, audible and visual, of the maximum and minimum value [81]. For anaesthesia machines it is necessary to follow the indications of the CEI EN 60601-2-13 (CEI 62-21) and to ensure preventive maintenance usually every 6 months, regarding various components of the equipment such as the respiratory tubes, the flexible arm for the manual respiratory balloon, the patient membrane, the flow sensors, the exchange tubes and other elements [82].

Endoscopic column

Endoscopic column allows the visual analysis and the eventual suction of secretions present inside bronchial tracts, thanks to an aspiration source and a tube inserted into patient’s

respiratory airways. Its aims are to increase respiratory ventilation and tissue oxygenation, decrease respiratory frequency, maintain the respiratory tracts clear and to prevent the increasing of infection due to the stagnation of secretions [83].

Bronchoscopy system (Figure 36) is usually composed by:

- flexible bronchoscope: it has controllable bending segments at the tip and captures images or videos to be displayed on a monitor, and can incorporate suction channels and ultrasounds that allow to perform biopsies and other procedures;
- light source: it illuminates the respiratory tracts and can be external to the bronchoscope, connected to a guide channel, or integrated into the device. Typically LED;
- video and information processing system: it records processes images and videos, optimize their quality and send them to the display;
- display: it shows patient data, images and videos, status of the device, … [84].

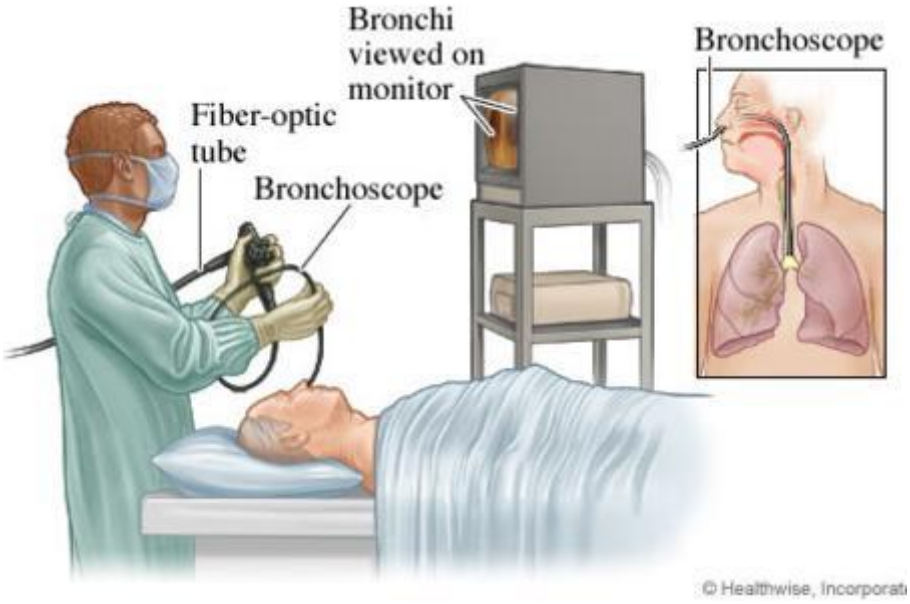


Figure 36 – Bronchoscopy system (source: Waterbury Pulmonary Associates)

Both reusable and disposable bronchoscopes are available, but in recent years single-use models started to substitute reusable ones because of the risks of cross-contamination, especially in an infectious disease context as COVID-19.

In case of excessive production of bronchial secretions that can occlude the respiratory tracts, a transbronchial needle aspiration can be performed: after inserting the bronchoscope and reaching the desired location, the physician enters a needle through the channel guide of the

device, then penetrates the desired bronchus or trachea wall and suction is applied to the needle, which is finally removed. The amount of negative pressure (or vacuum) sets the pressure gradient that will be responsible for extracting secretions, that will move from an higher pressure area (bronchus, at atmospheric pressure) to a lower pressure area (suction needle). The negative pressure for nasotracheal and endotracheal procedures is recommended to be between 60 and 150 mmHg [85].

A suction system (Figure 37) can be structured as follows:

- central vacuum source: composed by at least two vacuum pumps in parallel, each able to maintain the minimum vacuum level necessary. It must be connected to the hospital emergency electrical system or power supply, and it is usually located outside the ICU rooms, in which non-interchangeable vacuum inlets are present. Alternatively, portable suction source can be integrated in a mobile unit which carries a pump, a gauge and a collection container, and can be powered by electricity or compressed air;
- vacuum regulator: the vacuum source creates an amount of negative pressure higher than that usually required for clinical procedures, then controlled by a vacuum regulator which sets the maximum value of suction to be applied on patients (0 – 200 mmHg). The regulator is able to provide continuous or intermittent suction, or both;
- trap bottle and filter: they prevent liquids or secretions to flow into the vacuum system from the collection container, in case of overflow or malfunctioning. Filter is a potential source of obstruction and contamination, and it is therefore subjected to frequent inspection and replacement;
- collection container: case, usually disposable, in which aspirated material is stored and measured;
- suction catheter: several typologies and dimensions of catheters can be used, depending on the clinical needs.
- tubes: connect the different parts of the system.

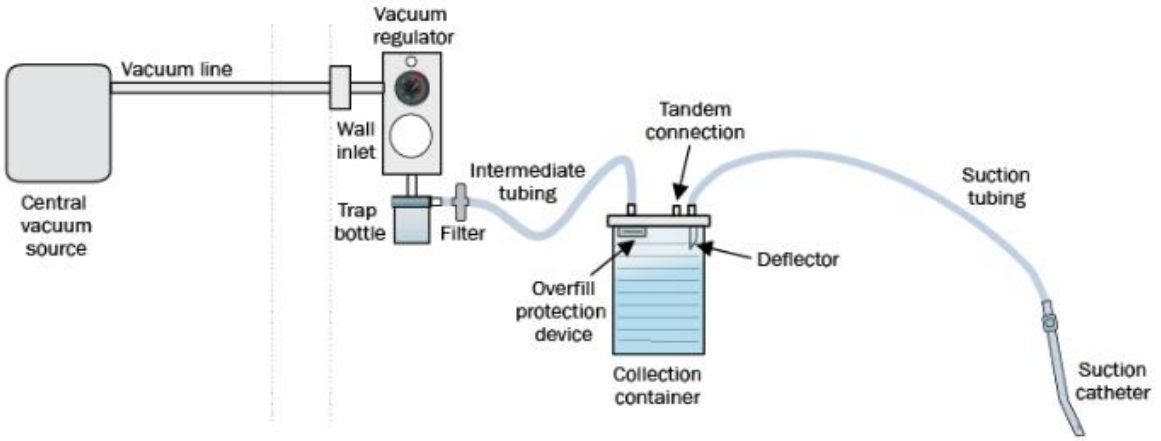


Figure 37 – Suction system components (source: ECRI)

The main safety aspects to be considered regard complications that may arise from the procedure (e.g. infection, laryngospasm or bronchospasm, bronchial haemorrhage, ..), the heating of scope tip during light activation – which may contribute to patient burns – and the risk of contamination in case of reusable instruments, while performance mostly concerns the video quality of the device (resolution, contrast, noise, …) [86].

Bronchoscopy and suction systems are usually classified as Class IIa Medical Devices, or rarely as Class IIb. Endoscopic column requires significant ordinary maintenance, which includes the periodic inspection and testing of all components, the replacing of filters and aspiration elements, and routine decontamination of the instruments. In particular, specific guidelines should be followed for disinfection and sterilization of reusable bronchoscopes, to prevent the onset of infections due to the cross-transmission of microorganisms between patients and to prevent the occurrence of false positives samples that may arise from the contamination of biological materal. An example of standard that applies for the sterilization of Medical Devices is the UNI EN 556-1, while safety and essential performance of endoscopic equipment are regulated by the CEI EN 60601-2-18 (CEI 62-82).

Manual ventilator – AMBU

The AMBU (*Auxiliary Manual Breathing Unit*) is a self-expanding plastic balloon used in ICU to manually ventilate a sedated patient or to support ventilatory activity in a patient in cardio-circulatory arrest. The AMBU connects to its ends with two one-way valves: the proximal valve has a 15 mm universal fitting which is used to connect it to different devices for the management of the airways; in the distal part of the balloon, an attachment is provided for the reservoir and for the connection with an oxygen source. The function of the one-way

valves is to avoid the inhaling of the exhaled air (re-breathing phenomenon). For this reason, while one valve conveys air to the patient, the other allows air to enter inside the balloon.

If the patient is supported by an invasive ventilation, it is necessary to connect an HME filter (*Heat and Moisture Exchanger filter*) before connecting the self-expanding balloon to the unit; it is also recommended the use of a corrugated tube. Otherwise, in case of non-invasive ventilation, the procedure can be performed by using the face mask which, covering patient's nose and mouth, allows the insufflation of air inside the lung tree (Figure 38).

Figure 38 – Manual ventilation with AMBU device (source: nurse24)

Once the AMBU is connected to the patient, the operator compresses the balloon, generating inside it a higher pressure than atmospheric, which produces an air flow that opens the proximal one-way valve and closes the distal one, directing this flow towards the patient. Once the balloon is released, the negative pressure creates the reverse effect on the valves, closing the proximal one and opening the distal one, thus allowing the balloon to fill again. Particular attention during this manoeuvre must be given to the volume to be insufflated and to the pressure used.

Eventually, self-expanding balloons can be connected to an oxygen cylinder or tank, allowing different oxygenation methods related to different FiO_2 percentage delivery to the patient:

- ambient air: in this case the balloon is not connected to any oxygenation system. The delivered FiO_2 is therefore 21%, that is the percentage of oxygen in ambient air;

- oxygen source at 12-15 l/min: by connecting an oxygen source, ambient air is mixed with this medical gas, allowing to reach an FiO_2 level of 50-60%;
- oxygen source at 12-15 l/min and reservoir: thanks to the presence of the reservoir, filled exclusively with O_2, the delivered FiO_2 is 90-100%.

As regards the special requirements for manual resuscitators, reference is made to the UNI EN ISO 10651-4 standard. The AMBU is classified as a Class IIa Medical Device, for whose maintenance it is generally recommended to use checking and cleaning methods suitable for the individual parts. In particular, the main procedures performed are the disassembly of the resuscitator and its accessories, the cleaning, disinfection and/or sterilization of the parts, their drying and cooling, reassembly and final testing [87].

Dialysis machine

AKI (*Acute kidney injury*) affects up to 60% of ICU patients and is associated with mortality rates between 15 and 60%. Up to 2/3 of patients with AKI require RRT (*renal replacement therapy*), whose objectives are the removal of solute and water, the correction of electrolyte anomalies and the normalization of acid-base disturbances. This result is obtained by diffusion or convection, which is respectively referred to as hemodialysis or hemofiltration [88]:

- hemofiltration involves the pumping of blood through an extracorporeal system which incorporates a semi-permeable membrane. The hydrostatic pressure created on the blood side of the filter guides the plasma water through the filter;
- hemodialysis, on the other hand, involves the pumping of the blood through an extracorporeal system that incorporates a dialyzer. In the dialyzer, the blood is separated from a crystalloid solution (dialysed) by a semi-permeable membrane. The solutes move across the membrane along their concentration gradient from one compartment to another;
- hemodiafiltration is a combination of filtration and dialysis: it has the advantages of both techniques, but to a lesser extent than when the individual techniques are used alone [89].

In critical care, dialysis is provided as IHD (*Intermittent HemoDialysis*), delivered for a few hours every day or every 2/3 days, or as CRRT (*Continuous Renal Replacement Therapy*), delivered continuously 24-hours. Currently, the preferred therapy in intensive care for

critically ill patients is made up of continuous techniques (CRRT), as the large amount of liquid removed during hemodialysis is not always tolerated by critically ill patients. Through this technique, liquid and waste products are removed slowly, at a rate similar to the natural kidney and is more tolerated by patients with blood pressure problems (Figure 39).

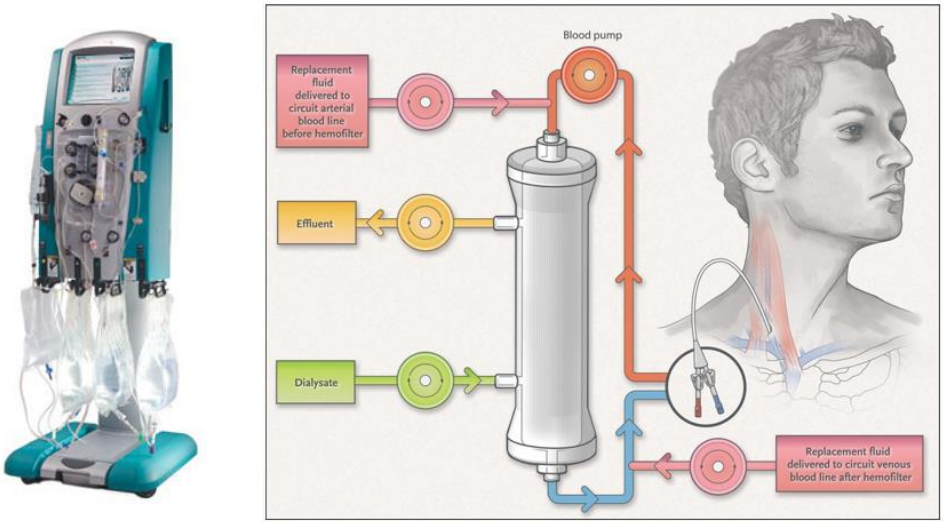


Figure 39 – Dialysis machine and its working principle (source: Chrysochoou G et al.)

The dialysis machine is classified as a Class IIb Medical Device according to its invasiveness and high-risk, and the CEI EN 60601-2-16 (CEI 62-98) represents the reference standard for safety and preventive and corrective maintenance related to dialysis Medical Devices.

Wall diaphanoscope

Wall diaphanoscope is a luminous screen for the display of different types of radiographic images. It consists of a cold light and of a frosted opaque panel that makes the lightning uniform; artificial light can disturb the correct image reading, that is usually practiced in dim light rooms or with special masks or glasses (Figure 40).

Being a low-risk and non-interacting device with patient's body, wall diaphanoscope is classified as a Medical Device of Class I. Wall diaphanoscope does not require specific maintenance, except from removing dust and fingerprints that may filter the emission of light, inducing erroneous artefacts on the screen. An example of standards that applies to wall diaphanoscopes are the CEI EN 61010-1 and the IEC 62471 for photobiological safety of lamp systems [90].

Figure 40 – Wall diaphanoscope (source: Cablas)

Radiographic imaging devices

In a context of pulmonary diseases like COVID-19, thoracic imaging technologies such as CXR (*Chest Radiography*) and CT (*Computed Tomography*) are fundamental tools to help diagnose and manage the infection, in particular for patients with moderate-to-severe symptoms and in case of worsening of the illness.

The use of both CXR and CT strongly depends upon clinical team decision and public health directives of different countries. CXR seems insensitive in early stages of COVID-19 infection [91], while CT is a more sensitive technology to detect parenchymal lung disease and its progression, being a technique that produces a series of cross-sectional digital body images from which a dedicated software creates a 3D model of the body sector. However, the higher radiation exposure during CT exams, together with the possibility of use of portable radiographic system, can favour the CXR use. CT is not a device present in ICU rooms, but it is part of the imaging technologies that may be required and accessible to the ICU wall diaphanoscope by the healthcare staff.

Radiographic scans can be performed in dedicated rooms or with portable units, that could be used to perform imaging exams at the point of care, especially in case of contraindicated patient transportation as for ICU patients. Mobile radiographic units (Figure 41) are composed by a wheeled cart which transport:

- batteries: provide power for device movement, x-ray emission and workstation functioning;
- x-ray generator and tube: provide power for the generation and emission of x-rays at a given energy [kV], intensity [mA] and duration [ms];
- wireless mobile detector: to be positioned posteriorly to the patient, it acquires the x-ray beam and generates the grey-based radiographic image on the basis of x-rays attenuation through patient's body. The image is automatically sent to computer workstation;
- computer workstation: provides tools for setting exam parameters and for acquiring, reviewing and sending images to an archive (PACS);
- networking system: device for acquiring worklist from a central informative system (RIS) and sending images to the PACS.

Figure 41 – Mobile radiography unit (left) and detector (right) (source: Carestream)

The main aspects related to the performance are the battery capacity, which should allow to perform several exams without the need to be charged, and the power rating of the x-ray or generator, which must be sufficient to obtain an adequate-quality image. High generation power also allows shorter exposure, which can represent an advantage in case of requiring patient movement that may degrade the image quality and the heat and cooling capacity of the x-ray tube. Safety concerns the exposure to excessive radiation dose, possible physical injuries that may arise from malfunctioning in the mobile unit, and the risk of unauthorized access to personal information contained in the device [92].

Considered as high-risk and body-interacting devices, x-rays technologies are classified as Class IIb Medical Devices. Ordinary maintenance concerns the opening and cleaning of the x-ray tube to inspect the components of the circuit and the mechanical, electrical and safety testing to ensure the correct functioning of warning lamps, interlocks and sensors. After reassembling the tube, an overall performance testing ensures the proper quality of the images and of the x-ray emission dose; if not, a further alignment of tube and detector is performed. Finally, the battery replacement of cart, x-ray tube and detector takes place every one or two years [93]. Different standards apply for the security and essential performance of radiographic devices, including the CEI EN 60601-2-54 (CEI 62-154) and the CEI EN 60601-2-44 (CEI 62-110).

Ultrasound scanner

Ultrasound diagnostic uses sound waves at high frequency, whose returning echoes create video-images of the body structure. Recent technology improvements include features that help detect diseases, expand image-guidance capabilities and advanced imaging modes (elastography, contrast-enhanced imaging, 4D imaging). These cart-based scanners (Figure 42) share similar physical characteristics with x-ray mobile systems, and include:

- console: contains a PC that manage the ultrasound generator, receiver and processing system;
- user interface and display: controls to set the exam and adjust image quality, to be viewed on the display;
- transducer: converts the electrical signals into high-frequency sound waves, which are transmitted to the patient and reflect his internal tissues. The reflections return back to the transducer, which re-convert them into electrical signals that are processed and displayed in various grey shades;
- internal storage and networking system: archiving and transmission of acquired data.

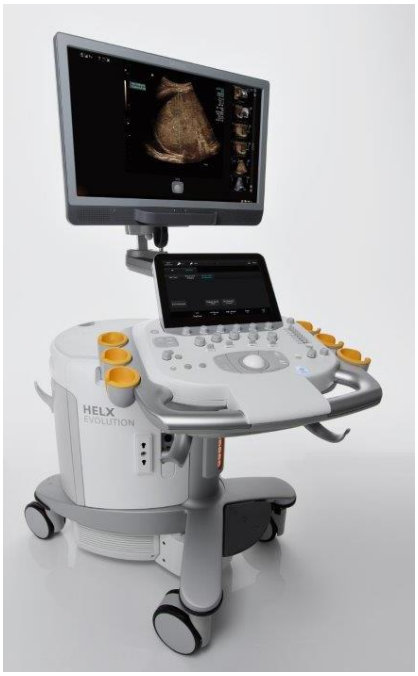


Figure 42 – Ultrasound scanner (source: ECRI)

Safety mainly regards the ergonomic features that can prevent work-related musculoskeletal injuries arising from the continuous movement and rotation of the transducer [94].

Ultrasound scanners can be classified as Class IIa Medical Devices. Routine maintenance is similar to that of other mobile imaging technologies, and ranges from the annual electric safety check, filter cleaning and substitution, to the overall functioning and image quality control, the substitution of batteries and the periodical software updates. Cleaning and disinfection treatments are required after each use for peripheral units (transducers) that are in contact with patients. Reference standard for security and essential performance of ultrasound scanners for diagnostic and monitoring is the CEI 60601-2-37 (CEI 62-124).

Emergency trolley

The emergency trolley represents an essential device in all hospitals and in all departments for prompt intervention in case of emergency situations in which there is danger for the patient's life. The emergency trolley must contain a defibrillator, an external pacemaker and the ventilatory assistance material. In particular, the defibrillator is a device that sends a high voltage electrical discharge to the heart of a patient affected by sudden cardiac arrest. To intervene instead on bradycardia events, an external pacemaker can allow cardiac stimulation by supplying an impulse of electric current through the catheter of the electrode to the cardiac surface.

Finally, it is necessary to have everything necessary for the patient respiratory assistance,

including therefore the AMBU, oxygen and all the tools necessary to access the airways, and transport ventilators, which are mainly used during the moving of patients from one area of a hospital to another or between hospitals. Transport ventilators are relatively small and lightweight and can be hand carried if necessary; they could also be used as backup ventilators for ICUs [95].

The emergency trolley must be placed in a specifically identified room. Once the minimum requirements are guaranteed, each hospital has the responsibility of defining a set of machinery, Medical Devices and tools necessary for each trolley in each ward. Periodical checks are documented through specific forms which must be kept in the cart file and must be compiled after each use.

Surgical light

LED surgical lights provide medical staff with high-quality illumination and are preferred over halogen bulbs light because of their higher efficiency, longer life (12-15 years for the light source) and lower heat production. They can be ceiling- or wall-mounted, with one or more lights, additional support arms for supporting monitor or other devices needed by the healthcare staff. The majority of surgical lights are divided in cluster of angled LEDs, design that allows to path the light in such a way to eliminate or strongly reduce shadows.

LED surgical lights (Figure 43) are composed by three main elements:

- light head: provides the illumination;
- controls: can be located near the top of the head light, on a separate arm or on a wall mount;
- optional video camera: can be integrated in surgical light head or can be installed in the aftermath.

Figure 43 – Surgical light (source: USA Medical Surgical)

Surgical light safety mostly concerns its correct installation more than the device itself, while performance regards the capability of reducing shadows, the available illuminance levels, size and depth of light field and the range of rotation of the instrument [96].
Surgical light is low-risk and non-invasive device, and is therefore classified as a Class I Medical Device, rarely as a Class IIa. Considered the simple working principle and the fact that LEDs would ideally last as long as the device itself, surgical lights require easy ordinary maintenance: electric safety checks, integrity verifications, disinfection of handpieces and the removing of dust and fingerprints that may alter the emission of light are the main actions to be routinely performed. The substitution of LEDs would be eventually necessary in case of their malfunctioning. The reference standard that applies to surgical lights safety is the CEI 60601-2-41, together with the IEC 62471 for photobiological safety of lamps.

Other ICU support instrumentation

Laryngoscope is an endoscopic equipment that allows to visualize the glottis (the space between vocal cords) and to introduce the endotracheal tube, in case patient intubation is required. It is composed by two main parts: a handle and a blade with light (usually LED or optic fiber), to be introduced into the mouth to inspect glottis and larynx. Different blades dimensions, types (disposable or reusable) and shapes (straight or curved) can be chosen.
Laryngoscopes are regulated by the standards ISO 7376 and IEC 60601-1 for basic safety, and generally classified as Class IIa Medical Devices.

Medicinal refrigerator are designed to store drugs, blood products, testing reagents and biological material. Different ranges of temperature can be set by means of microprocessor control and several safety functions are usually implemented, including malfunctioning and

temperature alarms, power-on delay system and safety door lock to prevent unauthorized access. The refrigerating system ensures the inner temperature consistency and uniformity across the whole device, and a dedicated software registers the temperatures data.
Medicinal refrigerators are not classified as Medical Devices, except for that dedicated to the conservation of blood products of biological fluids to be infused, which are classified as Class IIa Medical Devices.

Electrocardiograph is the medical instrument necessary for the execution of the ECG (*electrocardiogram*). The track generally has a characteristic pattern which varies in the presence of problems or anomalies. The electrocardiograph is a device equipped with a recording voltmeter and electric wires, which connect the device to the patient by means of electrodes applied to the skin. Finally, a monitor allows the graphical view of the track [97]. The electrocardiograph is classified as a Class IIa Medical Device and regulated by the IEC 60601-2-25 standard. During periodic maintenance, electrical checks are carried out to check the leakage currents to patient, frame and earth, and the dielectric power. Furthermore, the state of the electrodes and the battery is checked periodically. [98]

Automatic external massager are devices that allow the mechanical execution of external chest compressions once positioned on the patient. International guidelines (AHA / ERC 2015) that define some parameters to be respected, as the frequency of compressions (100-120 per min), the depth (5-6 cm), the alternation between compressions and ventilations (2 ventilations every 30 compressions). The compact dimensions, the low weight and the simplicity of positioning on the patient allow to use this massager easily in all situations and gives the possibility to save energy and to concentrate completely on the patient. The automatic massagers are classified as Class IIb Medical Devices.

5.2.2 ICU implant systems

As defined by the Italian D.P.R. of 14th January 1997, definite ambiental characteristics must be ensured in ICUs:

- winter and summer indoor temperature: 20-24°C;
- winter and summer relative humidity: 40-60%;
- air changes/hour (external air without recirculation): 6 v/h.

Moreover, the following systems are mandatory:

- medical gas distribution system;
- medical gas exhaustion signal system;
- fire detection system.

Being the ICU classified as a Group 2 medical room by the CEI 64-8, specific requirements for the electrical system must be satisfied to comply with the technical norm. Finally, the communication lines in ICUs plays a role of great importance, and suggested criteria are to be followed also in this area.

ICU HVAC system

HVAC (*Heating, Ventilation and Air Conditioning*) system must ensure an ICU indoor temperature of 20-24°C, at relative humidity of 40-60%, and guarantee an air exchange rate of at least 6 volumes/h. High-efficiency absolute air filtering (99,95%) can also be required, both on incoming and outcoming air, and realized with HEPA or ULPA filters. A further optimal requirement is to guarantee areas with adjustable positive or negative pressure (+10 or -10 Pa than atmospheric pressure, depending on the presence of an immunosuppressed or infectious patient, respectively).

Ambiental characteristics are set and controlled by a centralized informatic system (SCADA), which regulates the HVAC system, in particular its AHUs (*Air Handling Units*), within which the external air is treated and carried through the pipelines into the ICU. AHUs can be located near the ICU department or farther in a centralized area, with different implications on the dimensioning of the system: the first solution implies a shorter air path, a shorter extension of the pipelines and a more calibrated air treatment, but generally produces a stricter range of air flow and power; the centralized solution allows to concentrate AHUs in a unique area, but the distribution network increases in dimension and complexity. ICU-dedicated AHUs are preferred in case of planimetric organization of the rooms [99] (Figure 44).

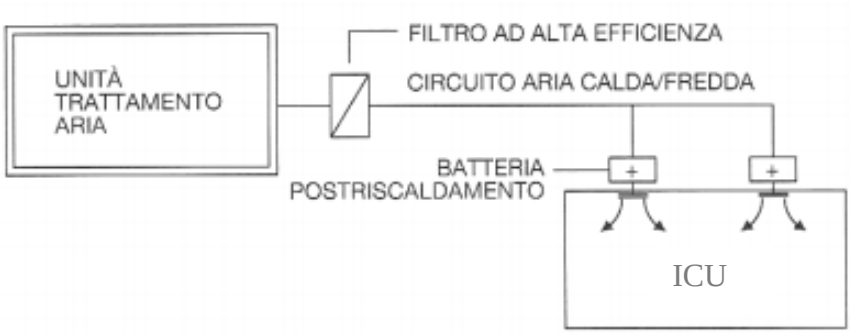


Figure 44 – From AHU to ICU (source: Università di Napoli)

ICU medical gas distribution

Each pipeline, from the start in the distribution network until the final point of use, must deliver medical gas with respect of nominal values and maximum variations of pressure established by the UNI EN ISO 7396-1 (with small changes eventually required by regional or national laws) (Table 10, Table 11):

Table 10 – Pressure ranges for medical gases (UNI EN ISO 7396-1)

Medical gas	Ranges of nominal pressure [kPa]
Air or nitrogen for driving surgical tools	800^{+200}_{-100}
Other compressed medical gases	400^{+100}_{-0}
Vacuum	≤ 60

Table 11 – Maximum pressure variations allowed at the outlets (UNI EN ISO 7396-1)

Pipeline system	Pressure variation	Test flowrate
Air or nitrogen for driving surgical tools	$-15\ \%$	$350\ l/min$
Other compressed medical gases	$-10\ \%$	$40\ l/min$
Vacuum	$+15\ kPa$	$25\ l/min$

Moreover, different flow rate values must be ensured for medical gases and vacuum line: at least 20 l/min for oxygen or other medical gases and about 40 l/min for vacuum in each outlet, when all outlets are operating [100].

Single-stage or double-stage distribution (as described in Chapter 4.2) set the indicated pressure at the points of use, that are located in dedicated medical supply units (or utility

distribution system). Different types of medical supply unit, considered as Medical Device of Class IIb, can be adopted in an ICU room:

- *headwall (or flat) configuration*: this system is installed on the wall above the head of the bed or hanging from the ceiling. It allows an easy arrangement of terminal outlets to satisfy patient needs, but can be problematic during a crisis situation by compelling the healthcare staff to step over a set of tubes and lines (Figure 45);

Figure 45 – Medical supply unit (headwall configuration) (source: Sostel)

- *column configuration*: array of terminal outlets on a stationary vertical column, which can be fixed and hanging from the ceiling or attached to both floor and ceiling (Figure 46):

Figure 46 – Medical supply unit (column configuration) (source: LM Medical Division)

- *boom configuration*: it consists of one or multiple movable articulated arms that offer optimal flexibility and accessibility to the bed placement, resulting advantageous in case of patient crisis. This configuration also allows the montage of several

accessories, such as shelves and brackets, to change devices position (monitors, PCs, intravenous pumps, …) (Figure 47).

Figure 47 – Medical supply unit (boom configuration) (source: Dräger)

Such medical utility distribution systems contain terminal outlets for medical gases, vacuum line, data and electricity, all accessible from each bedside and organized to provide the correct space and disposition for several procedures to be carried out on the patient (e.g. the oxygen outlet must be easily accessible for intubation processes) [101].

Design specifications for medical supply units, including minimum distances to be respected between outlets (e.g. at least 20cm between electric and medical gas terminal units), are defined by the UNI EN ISO 11197. Terminal units for medical gases are designed according to several technical norms (such as UNI 9507 and UNI EN ISO 9170-1), that set unique dimensioning, connections and labels for each gas outlet to prevent incorrect connections (Figure 48):

Figure 48 – Labels of medical gases outlets (UNI 9507) (source: MD S.r.l.)

In case of excessive or reduced pressure, visual and audible alarms connected to dedicated ICU pressure gauges are automatically activated; further alarms are included in the whole control system of the distribution, which informs about the eventual exhaustion of medical gases and other clinical or operating issues (Figure 49):

Category	Operator response	Indicator colour	Visual signal	Auditory signal
Emergency clinical alarm	Immediate response to deal with a hazardous situation	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8	Complying with IEC 60601-1-8 [a]
Emergency operating alarm	Immediate response to deal with a hazardous situation	Red	Flashing [b]	Yes
Operating alarm	Prompt response to a hazardous situation	Yellow	Flashing [b]	Optional
Information signal	Awareness of normal status	Not red Not yellow	Constant	No

[a] If a pattern of more than two tones or frequencies is used.

[b] Visual flashing frequencies for operating alarms and emergency operating alarms should be between 0,4 Hz and 2,8 Hz with a duty cycle between 20 % and 60 %.

Figure 49 – Alarm categories and signal characteristics (UNI 7396-1)

To regulate the supply pressure of medical gases, flowmeters are connected to the terminal units of the distribution system. After passing through the flowmeter - which can be mechanical (a reel moves up and down depending on the gas flow) or electronic (with sensors and LCD display) - the gases pass through a vaporizer, if required, and then it is administered to the patients by means of required device (e.g. CPAP or BPAP masks, helmets and others).

ICU Electrical system

The minimum requirements regarding the electrical outlets of the intensive care unit declare that for each bed-place must be provided a minimum of 16 electrical outlets divided into 4 groups and a button for "request for urgent help", while in each hospitalization area must be

provided at least one electrical interlocked type socket for the radiological devices. It is also recommended to have an output for high current absorption equipment.

The electrical system of the ICU follows the safety standards related to Group 2 medical rooms [39]. In particular, the Group 2 characteristics necessary in every ICU room are:

1. **equipotential node** to which are connected: the masses (protective conductors), extraneous masses and any metal shields (against interference, in isolation transformers, etc.);
2. adoption of the **IT-M system**: isolation transformer for medical use and permanent control device of the isolation;
3. adoption, in circuits not powered by IT-M transformer, of **differential switches exclusively of type A or B**;
4. **safety power supply (UPS)**: it guarantees adequate continuity for essential users and lights intervention times.

1. Equipotential node

The function of the equipotential node is to galvanically interconnect all the masses and foreign masses present or that can enter the patient area. In this way, if a ground fault occurs, all the masses are at the same potential and the patient, possibly in contact with two or more masses, is not subject to dangerous currents (Figure 50). The conductors that connect the extraneous masses to the equipotential node are called equipotential conductors (EQS) and must have a section of not less than 6 mm^2.

For Group 2 rooms, the resistance presented by the conductor and by the connections between the equipotential node and a mass or a foreign mass must not be greater than 0.2 Ω. In presence of sub-nodes, the resistance limit of 0.2 Ω refers to the resistance of the overall connection, also including the resistance of the sub-node [102].

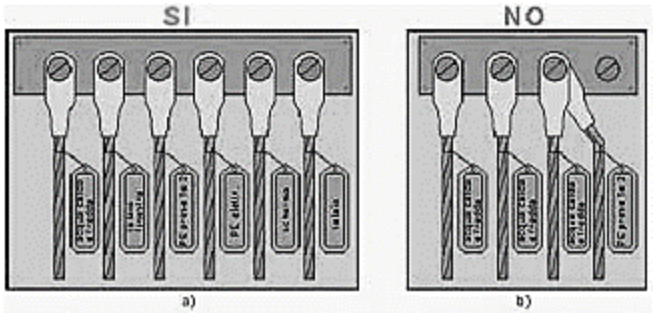


Figure 50 – Equipotential node configuration (source: ABB)

2. IT-M system

The IT-M system consists of a medical isolation transformer and a permanent control device of the insulation resistance to the ground (Figure 51). With the isolation transformer, two essential functions are obtained: guaranteeing the continuity of operation in case of a ground fault and reducing the voltage to which the patient may be subjected. Since a second ground fault would be equivalent to a short-circuit, with the consequent intervention of protections and a high danger for the patient, it is necessary to associate the isolation transformer with a device capable of detecting the decay of the insulation and signaling the first fault to the ground [102]. For this reason, in Group 2 medical rooms with risk of micro-shock, the standard prescribes the use, together with the equipotential node, of the IT-M system for all circuits that supply:

- electro-Medical Devices located less than 2.5 m from the walking surface, or which can enter the patient area;
- plug sockets (with the exclusion of those that power devices with a power greater than 5 kVA and radiological devices).

Therefore, the IT-M system allows to limit ground fault currents by limiting contact voltages, reducing leakage currents and ensuring continuity of service in the event of the first ground fault of a device.

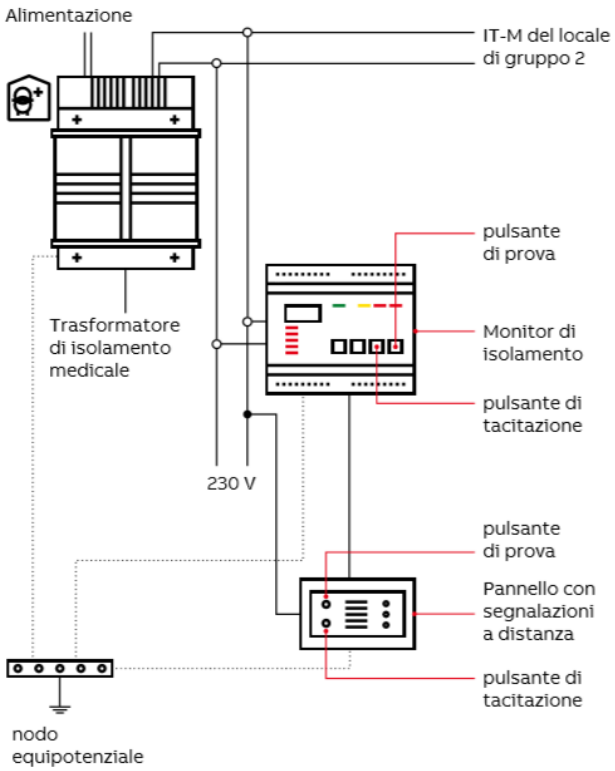


Figure 51 – IT-M system (source: ABB)

3. Differential switches

The differential switch is a protective device that determines the automatic interruption of the power supply if it detects the passage of a current to earth higher than a given threshold. In Group 2 medical rooms, all circuits not powered by an IT-M system must be protected by differential switches with Idn (*Nominal differential current*) ≤ 30mA.

Some utilizers, such as UPS, personal computers, printers and electromedical equipment incorporate electronic circuits that give rise, in the event of a ground fault, to currents able to compromise the operation of normal AC type differential devices placed to protect the power supply circuits.

One of the most important parameters is the class of the differential, related to its ability to detect certain waveforms of currents. Hence the obligation for Group 1 and Group 2 room to use only type A differentials, capable of intervening even with pulsating unidirectional fault currents, or type B differentials, capable of intervening even with pulsating and continuous unidirectional fault currents (Table 12).In the case of power supply via three-phase UPS, the product standard requires that protection is obtained by means of type B differential switches. [102]

Table 12 – Differential switches (source: ABB)

Symbol	Type	Application	Description
	AC	Ordinary rooms with TN and TT system	It works only for alternate differential currents, applied instantaneously or slowly increasing
	A	Group 1 rooms. For Group 2 rooms, only for lighting, radiological sockets and non-IT-M devices	It works for alternate differential currents and pulsating unidirectional currents, applied instantaneously or slowly increasing
	A	Group 1 rooms. For Group 2 rooms, only for lighting, radiological sockets and non-IT-M devices	It works for alternate differential currents, pulsating unidirectional currents and direct-current components, applied instantaneously or slowly increasing

4. Safety power supply

The UPS operates as an energy reserve in the event of a blackout. Thanks to the immediate intervention time, it is able to guarantee continuity and safety in public environments and in all those cases in which the continuity of power is fundamental: the use of emergency power sources is always required for premises classified as Group 1 and 2. In particular, for ICUs, all lighting and electromedical devices with life support function require class ≤ 0.5 safety feeding (automatic feeding available in a time greater than 0.15 s but not exceeding 0.5). For other electromedical devices the safety class could be greater than 0.5, but not exceeding 15s. [103]

Communication lines

The recommended indications for ICU communication lines prescribe the presence of 2 external telephone lines for every 8 beds, an emergency line with pass-through selection and an adequate number of internal lines. Furthermore, an intercom system must connect each hospitalization, the medical offices and the kitchen with the control center, while a system of intercoms between inpatients and any external corridor is necessary for communication between patient and visitors. It is also required the presence of an acoustic and visual alarm capable of being activated by every hospital stay and detected by the control center. Finally, if the arrangement of the inpatients does not allow direct viewing of the patient, the installation of a closed circuit TV system with light amplification and control monitor in the surveillance center is needed [100].

RESULTS

6. New ICU measures in COVID-19 emergency

A variable percentage between 5% and 15% of COVID-19 patients needing hospitalization presents clinical conditions that require admission to intensive care, with the need for ventilatory care, often due to severe bilateral interstitial pneumonia. ICU beds capacity represented one of the main problems encountered by healthcare systems, as many hospitals have been unable to meet the demand. This is also due to the fact that, if in a normal condition a patient is hospitalized in ICU for an average of 14-16 days, in a COVID-19 condition the stay can reach 30 days [104].

Before the beginning of the crisis, according to the SISTAN (*National Statistical Manual*), in Italy there were 5090 beds in total between public and private structures, but the lack of resources in relation to the national population was already evident. In a short time, the number of beds required has grown enormously to deal with the COVID-19 emergency: in mid-April, Italy reached a total number of 9500 ICU beds, of which 7800 will be maintained even after the emergency condition, leading to a permanent 50% increase in the capacity of Italian intensive care.

The pandemic has involved several countries around the world, but the different healthcare systems and resources have led to a different response from hospitals. Indeed, as Figure 52 shows, the number of ICU beds per 100,000 people varies by country, resulting in different resources available to tackle the pandemic.

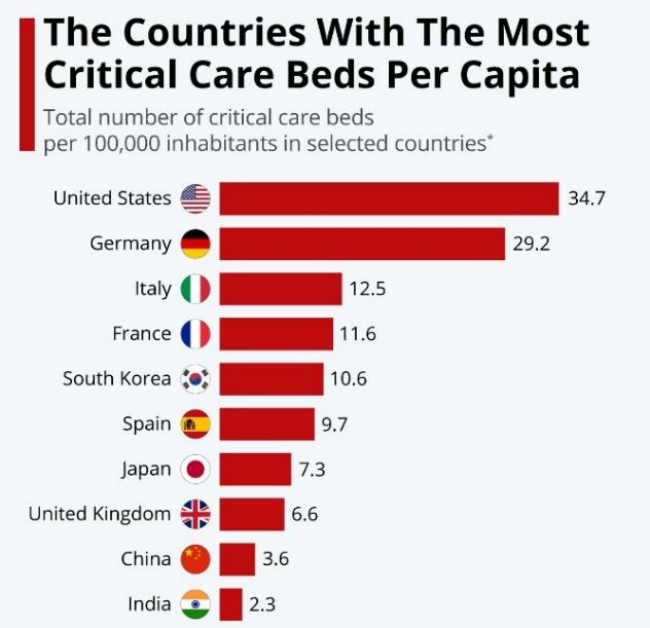


Figure 52 – Critical beds per 100.000 inhabitants in selected countries (source: Statista)

COVID-19 ICU entry criteria

As already mentioned, hypoxia is one of the main symptoms of COVID-19, but the clinical presentation can vary from mild respiratory symptoms to severe pneumonia with critic prognosis. SIAARTI guidelines (*Italian Society of Anesthesia Analgesia Intensive Care and Intensive Care*) determine a classification and a protocol to divide patients according to the degree of respiratory insufficiency, in order to differentiate clinical pathways (Figure 53).

In evaluating the functional capacity and therefore the exchange of lung gas, the first fundamental parameters to be considered are the percentage of oxygen in the blood (SpO_2 - O_2 saturation) and the RR (*respiratory rate*). The second step, in case of altered parameters, is to treat patients with an high concentration oxygen therapy (10-15 l/m), which should determine a FiO_2 (*oxygen fraction*) in inspired air > 50%: patients are distinguished in responsive and non-responsive to the therapy. In case of non-responsive patient, mechanical ventilation (NIV) must be started and a continuous monitoring of blood gases is performed, through which the *alveolar respiration index* ($PaPO_2$ / FiO_2 – the ratio between the arterial partial pressure of O_2 in the blood, $PaPO_2$, and the oxygen fraction in inspired air with external support, FiO_2) is evaluated. This value is normally about 450 mmHg, but in cases of severe respiratory insufficiency it can drop to about 200 mmHg, determining the need to intervene with patient intubation [105].

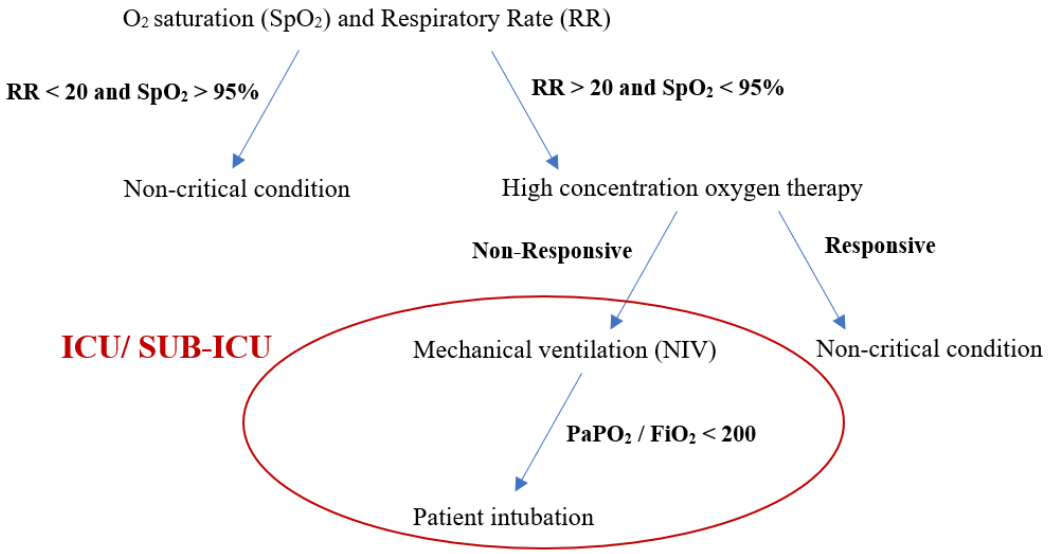


Figure 53 – COVID-19 clinical pathway schema

However, it remains a choice of the hospital and doctors to decide how to hospitalize the patient during the path of diagnosis and clinical procedure. For example, some hospitals have preferred to divide patients who needed only mechanical ventilation from those who needed intubation, as there is no single guideline for this type of choice.

Another test that can be performed to determine the degree of pulmonary impairment is the HRCT (*High Resolution Computer Tomography*), through which it is possible to calculate the percentage of pulmonary parenchyma involvement in each of the five main pulmonary districts (upper, right and left lobes, middle lobe and lower right and left lobes), related to the extent of the disease (Figure 54). The recognition of the most peculiar features of COVID-19 pneumonia (bilateral emery glass opacities and segmental consolidation areas) is fundamental for the early identification of the disease, as they could detect early false negatives.

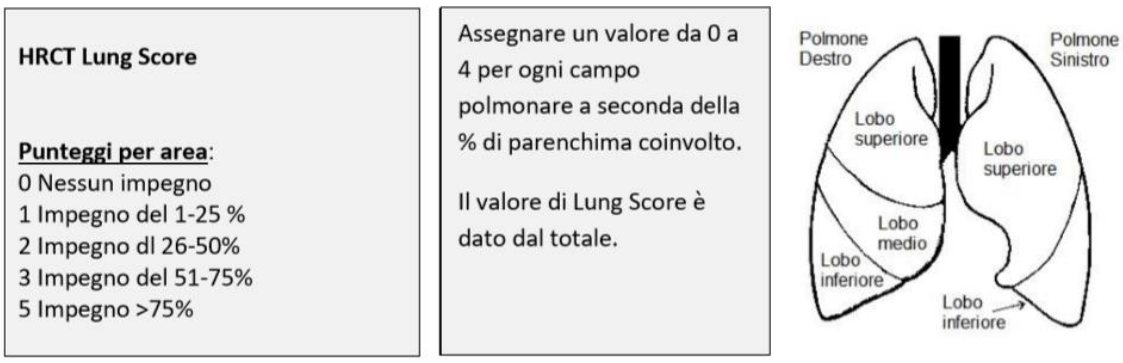


Figure 54 – HRCT Lung Score (source: Società Italiana Medicina d'Emergenza e Urgenza)

In a context of infectious diseases such as COVID-19, special measures must be implemented to minimize the danger and optimize treatment. This implies necessary changes to the structural, implant and technological ICU requirements that can lead to an efficient and effective hospital organization: some points for the functional modification of the normal hospital context are highlighted in these paragraphs and summarized in '*COVID-19 Structural modifications*' table (Table 13), '*COVID-19 HVAC setting*' table (Table 14), '*COVID-19 Medical gases setting'* table (Table 15), '*COVID-19 Medical Devices recommendations'* table (Table 16) and '*COVID-19 Cleaning and Disinfection measures'* (Table 20).

6.1 COVID-19 ICU structural and technological modifications

Structural modifications

Clinical care pathways and the flow of patients must be clearly separated, from the initial suspected diagnosis to eventual hospitalization of the infected from non-infected patients. Depending on the availability of hospital premises, COVID-19-dedicated wards should be detached from that non-COVID-19, and cohort stays should be generally preferred over single stays (also in ICUs), in order to optimize the use of healthcare resources and to minimize the use of PPE from workers. To meet the greater need for hospitalizations in emergency situations, the number of ICUs beds should be increased; new and dedicated ICU wards must be created if the increase in beds is insufficient.
Peculiar attention must be paid on the definition of entry paths into each dirty area (dressing) and even more on exit paths (undressing and decontamination). For the latter, if possible, two adjacent rooms are preferred: one to get rid of all the dirty disposables and one to sanitize and inert the virus (in particular on hands).

Physical barriers, such as transparent plastic panels, should be installed wherever there is a possible personal interaction, to prevent the spreading of the infection through sneezing and coughing [106].

Table 13 summarizes the main structural changes between the standard ICU and the COVID-19 ICU.

Table 13 – COVID-19 Structural modifications

STRUCTURAL MODIFICATIONS	STANDARD ICU	COVID-19 ICU
CLINICAL PATHWAYS AND PATIENTS FLOW	Separation firstly based on clinical necessities	Separation firstly based on pathology (COVID-19 vs. non-COVID-19)
WARDS	Union of patients with different pathologies within the same ward	Separation of COVID-19-dedicated from non-COVID-19-dedicated wards
HOSPITAL STAYS	Cohort or single stays	Preference for cohort over single stays
INCREASING HOSPITALIZATIONS	Increase the number of beds is typically enough	Increase the number of beds and create new COVID-19-dedicated ICU wards
ICU ENTRY AND EXIT PATHS	Always defined with strict safety measures	
PHYSICAL BARRIERS	Typically unnecessary	Necessary
FIXTURES CLOSURE	Sealed and hermetic closures	

HVAC system setting

ICUs for infectious patients should ideally be realized with the criteria of AIIRs (*Airborne Infection Isolation Rooms*):

- creation of negative pressure inside the isolation room;
- installation of a filter unit on the air extraction site (portable or fixed);
- air ducting to the outside;
- adequate control of temperature, humidity and air exchange rate;
- ensuring the sealing of the room and the hermetic closure of the fixtures.

Maintaining the isolation room at negative pressure (between -2.5 ÷ -10 Pa than atmospheric pressure) prevents the infection from exiting the chamber, in particular during aerosol-generating procedures such as patient intubation, non-invasive ventilation, bronchoscopy and others. To realize negative pressure, it is necessary that the volume of outgoing contaminated air is greater than the volume of incoming clean air, both regulated by centralized control of the air valves. Moreover, the outgoing air must undergo microfiltration

and decontamination before being expelled outside the premises and never recirculated for the ICU air exchange (Figure 55).

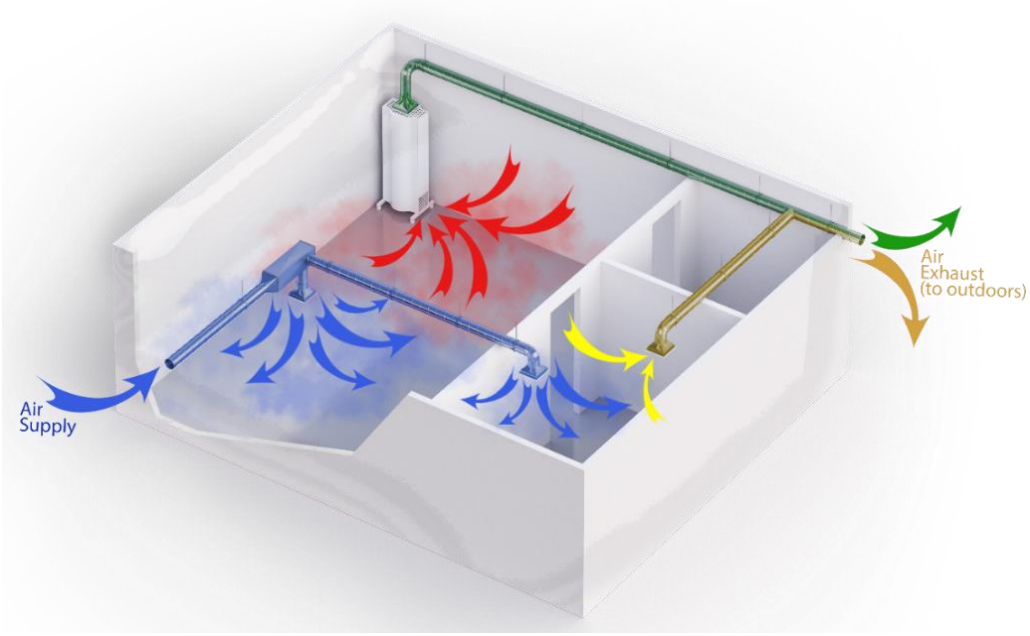


Figure 55 – Air exchange system scheme (source: Genano)

To control the effective negative pressure in the ICU, an electronic system operates on ventilators and shutters by varying the incoming or outcoming air flows on the basis of a pressure transmitter that measures the pressure difference between ICU and adjacent rooms [107].

If possible, UVGI units (*UltraViolet Germicidal Irradiation*) should be installed as supplements to HEPA filters into air ducts and increasing the number of air recirculation volumes from the minimum 6 v/h up to 12 v/h or more is suggested by the CDC for infectious diseases. After patient discharge, the room must undergo a sterilization cycle (with closed ventilation system) through special nebulized substances that effectively neutralize pathogenic organisms and their spores.

The following table (Table 14) shows the major changes regarding the HVAC setting in a COVID-19 ICU.

Table 14 – COVID-19 HVAC setting

HVAC SYSTEM SETTING	STANDARD ICU	COVID-19 ICU
AIR EXCHANGE RATE	≥ 6 v/h	≥ 12 v/h
AIR FILTRATION AND DECONTAMINATION	HEPA / ULPA filters	HEPA / ULPA filters + UVGI units
PATIENT ROOM PRESSURE	Positive / atmospheric / negative	Negative (-2.5 ÷ -10 Pa than atmospheric pressure)
OUTGOING AIR	Air ducting to the outside	

Medical gases distribution system setting

In a situation of increased ICU hospitalizations and high necessity of ventilation support, particular stress is posed on the medical gases distribution system. Flow rate capacities must be therefore verified, considering the adequate oxygen supply required: AIIC suggests at least 40 l/min for each patient (ideally 60 – 70 l/min), in non-invasive ventilation.

The capacity of each section of the implant, therefore including the ICUs branches, is determined by the number of outlets (m) and the flow required at each outlet (Q_i): to guarantee the adequate gas supply to each patient, the flow rates at the outlets must be lower or equal to the whole flow at the second-stage reducer of the distribution network (Q_{DN}) [108]:

$$\sum_{i=1}^{m} Q_i \leq Q_{DN}$$

Therefore, considering a higher number of outlets required (m) due to the increase in hospitalizations and a greater flow rate for each patient (Q_i) can represent a solution to verify the capacity of the medical gases distribution system in emergency situations. If the necessary requests are not satisfied, the entry of additional patients cannot be granted or, conversely, interventions on the dimensioning of the system (e.g. sizing of gases pipes) must be carried out.

Several solutions can be adopted for the connection of medical gases terminal units and the final delivery system, depending on the availability of Medical Devices:

- socket splitters can guarantee the supply of medical gases from one terminal unit to two patients, dividing the gas flow into two single flowmeters and then into separated tubes (Figure 56). Each flowmeter can therefore adjust the flow rate for the respective patient;

Figure 56 – Socket splitters (source: Rosiglioni Impianti)

- dual flowmeters can directly be connected to the single terminal unit without the need of splitters, dividing the gas flow for two patients and allowing their separate flow rate regulation (Figure 57). Dual flowmeters or splitters represent an optimal solution to double the number of patients assisted, coping with the scarcity of outlets due to the increased number of beds. In order to guarantee the adequate flow to each patient, high-capacity supply must be provided at the outlet, superior to the sum of both flow rates (up to 120 – 180 l/min at the socket);

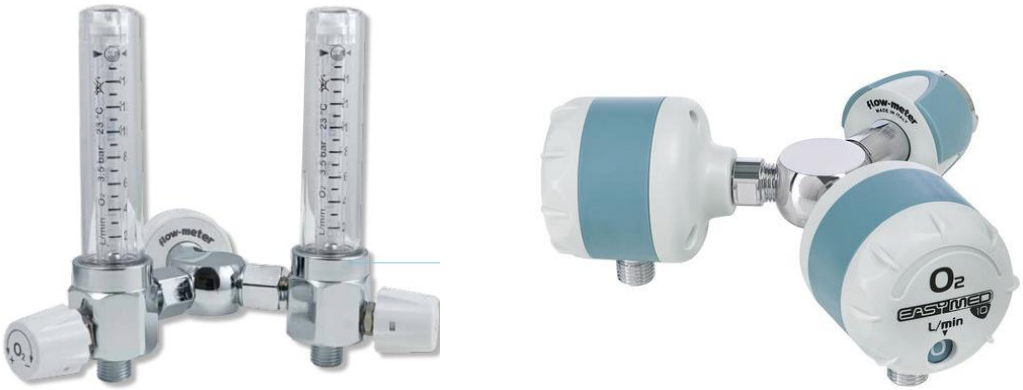


Figure 57 – Dual flowmeters (source: flow-meter™)

- y-junction: contrary to socket splitters and dual flowmeters, y-junctions allow the merging of two separate gas flows, to provide the patient with extra oxygen and/or medical air if needed or if the distribution system cannot guarantee the desired flow rate at each outlet. Furthermore, in exceptional situations in which single flowmeters

cannot be available, the flows outgoing from a dual flowmeter can be merged to reach the desired single flow. Instead of connecting the terminal units, y-junctions directly connect gas tubes (Figure 58).

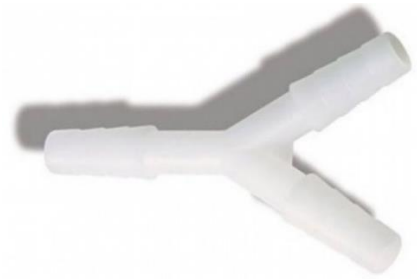


Figure 58 – Y-junction (source: Vygon)

As the terminal outlets, also flowmeters and splitters are regulated by analogue standards (e.g. UNI 9507) and characterized by fixed connection for each type of gas.

Also in the connection to patient mask, different methodologies can be applied: a single tube for the delivery of oxygen or air, or a mix of oxygen and air in a y-junction, can be plugged into the main airway of the mask; alternatively, oxygen can be connected to the main airway and the air tube to a secondary mask channel (Figure 59) [109].

Figure 59 – Methodologies for patient mask connection (source: Vygon)

The following table (Table 15) summarizes the possible changes concerning medical gases setting during the COVID-19 emergency, compared to the standard condition.

Table 15 – COVID-19 medical gases setting

MEDICAL GASES SYSTEM SETTING	STANDARD ICU	COVID-19 ICU
OUTLETS FLOW RATE CAPACITY	At least 20 l/min per patient	At least 40 l/min per patient (ideally 60-70 l/min)
OUTLET CONNECTIONS	Outlet connection to single patient	Use of splitters or dual flowmeters to guarantee supply to all patients
DISTRIBUTION NETWORK CAPACITY	Distribution network capacity determined in design phase	Verification of distribution network capacity when increasing: - the number of patients and outlets - the flow requested at each outlet

Medical Devices recommendations

During the emergency, the need to have the highest possible number of critical care hospitalizations has led to definition of Medical Devices criteria that differ from the standards set by D.P.R. of 14th January 1997 for ICUs. Therefore, ICUs in emergency situation must include the following essential equipment [110]:

1. bed
2. high flow ventilator
3. at least 4 infusion pumps.

Particular attention in cases of COVID-19 is placed on pulmonary ventilation systems, due to the respiratory debilitation of the disease. Companies must provide additional filters, valves or disposable materials to hospitals; in addition, the respiratory system filter must be mechanical with HEPA quality and the daily filter replacement is required. All monitoring accessories (ECG cables, SpO_2 sensors, blood pressure cuffs, temperature probes) are required to be used for a single patient and must be disposed immediately after use.

In cases of non-invasive ventilation, the use of an helmet (Figure 60) is preferred over a mask, as a safer interface thanks to the maximal reduction of aerosolization; otherwise, if a face mask is used, the single-circuit system is preferred over the double and it must be equipped with an integrated expiratory valve and an antimicrobial filter. In cases of invasive ventilation, closed-circuit endotracheal aspirations are used and the replacement of the circuit are foreseen up to a maximum of one week of consecutive use. [111]

Figure 60 – Helmet for non-invasive ventilation (source: Harol)

In order to reduce the probability of contagion of other patients or operators and the infection of clean areas, patient movements outside the ICU must be minimized, also by trying to replace static instrumental examinations (CT) with portable equipment inside the ICU. This has led to a greater use of portable x-rays and ultrasound systems, thanks to their structural simplicity and the diagnostic capacity for an initial evaluation. In cases where the existing equipment is not sufficient and the purchase of new devices cannot be immediate, emergency instruments (e.g. non-ICU ventilators from other departments) can help alongside the standard ones.

Finally, a maintenance scheduled with higher frequency than the standard condition reduces the probability of assistance during the use, preventing further complications in presence of an infectious disease. In case of technical intervention, it is preferred to perform the repair inside the patient room by operators equipped with all the necessary PPE; however, if this would not be possible, the equipment is previously decontaminated and then transported to the laboratory. It is also possible to use a protective film for parts of the equipment that do not require direct contact with the patient (body, cables, various accessories) to reduce the contaminated components. [112]

When the transportation of patients within the same hospital or between two different health facilities is necessary, the use of a **high bio-containment stretcher** is envisaged. In order to guarantee the protection of operators against exposure to potentially infectious agents, the high bio-containment stretcher is characterized by the addition of an overlapping space to create an area with a containment atmosphere (Figure 61). The high bio-containment stretcher is characterized by four basic elements:

- metal frame supporting the structure;

- transparent PVC casing;
- aluminium transport stretcher;
- power supply set, featuring four batteries that power the ventilation and HEPA filtration system.

The healthcare workers can assist the patient from the outside of the PVC casing, through the presence of lateral sleeves that allow any therapeutic manoeuvre. Safety is guaranteed by the HEPA filtration system, the possibility of setting negative or positive pressure gradient and the suitable concentration of O_2 and CO_2 for maintaining the correct vital functions of the transported patient.

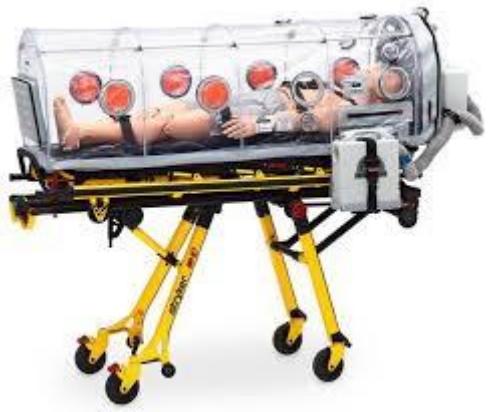


Figure 61 – High bio-containment stretcher

Given the difficulty of finding PPE, the use of video surveillance systems could reduce their use. In absence of a remote monitoring system, the framing must also resume multi-parameter monitors so that healthcare professionals can monitor patients without being physically exposed to the risks of infection. If patients remain isolated in hospital for weeks, a possible solution could be to equip patients with tablets to allow video-callings with staff or relatives.

Finally, an aspect that has gained visibility through this health emergency, and that will probably be implemented in the future, is the possibility of using robots within the wards to carry out simple actions normally performed by clinicians, in order to greatly reduce the risk of infection due to repeated visits.

A summary of the recommendations regarding Medical Devices during the COVID-19 emergency is represented by the Table 16.

Table 16 – COVID-19 Medical Devices recommendations

MEDICAL DEVICES RECOMMENDATIONS	STANDARD ICU	COVID-19 ICU
ICU MINIMUM EQUIPMENT	Complex set of instrumentation and devices	At least: bed, intensive care ventilator, 4 infusion pumps
MONITORING OF PARAMETERS	No limitation of contact with patients, allowing a continuous and physical monitoring	• Limitation of contact with patients to cases of absolute necessity • Continuous monitoring is carried out by robots or video surveillance
MAINTENANCE	Follow manufacturer's guidelines	
		Increase preventive maintenance
PLACE OF MAINTENANCE	Preventive maintenance performed both on site and in the laboratory	
		Preference for on-site disinfection before laboratory maintenance; if not possible, on-site with adequate protection
VENTILATOR	Follow manufacturer's guidelines	
		Preference for disposable valves and filters for daily substitution
NON-INVASIVE VENTILATION	Oronasal masks or helmets	Preference for the use of helmets
INVASIVE VENTILATION	Open or closed-circuit endotracheal aspiration	Only closed-circuit endotracheal aspiration
DIAGNOSTIC TESTS	Static or movable instrumental examinations	
		Preference for movable devices whenever possible for use at patient bed
MEDICAL DEVICES ACCESSORIES	No specific requirements	Preference for disposable accessories

6.2 COVID-19 Cleaning and disinfection

Cleaning and disinfection processes, based on quantity and specificity of the pathogens, aim to inactivate all the microorganisms populating surfaces and materials that may be cause of infection during all the steps of patient care. The most recent evidence shows that the environmental stability of SARS-CoV-2 is very similar to that of SARS-CoV (both viruses

have an average aerosol half-life of 2.7 hours) and MERS-CoV. In general, human coronaviruses can remain viable and maintain the infectious capacity on inanimate surfaces at room temperature for a period ranging from 2 hours to 9 days, depending on different parameters such as the type of vector, residual humidity, temperature, presence of organic material, initial viral concentration and the nature of the surface on which the virus settles. SARS-CoV-2 has proven to be resistant up to 4 hours on copper surfaces, up to 24 hours on cardboard and up to 2-3 days on plastic, but remains highly susceptible to environmental changes: the virus could decay from 1 day (at 30°C and 80% relative humidity) up to 3 days (at 20°C and 40% relative humidity). In addition, SARS-CoV-2 is extremely stable in a wide range of pH values (pH 3-10) at room temperature (Table 17).

Table 17 – Coronaviruses characteristics

CORONAVIRUSES	
Resistance (type of surface)	**Time**
Copper	4 h
Cardborad	24 h
Plastic	2-3 days
Avaragae aerosol half-time	2.7 h
pH stability	3-10
Highly susceptible to	High temperature and high humidity

A dedicated area, not usable for other purposes, is designated for environmental cleaning services and another for preparation, storage and reprocessing of reusable cleaning equipment and supplies. A further separate area should be available for the reprocessing of biomedical equipment only. All individuals in charge of environmental cleaning, laundry and dealing with soiled bedding, towels and clothes from patients with COVID-19 infection should wear appropriate PPE, including heavy-duty gloves, a mask, eye protection (goggles or a face shield), a long-sleeved gown, and boots or closed shoes. Hand hygiene must be performed after exposure to blood or body fluids and after removing PPE and soiled PPE should be put in a sealed bag for later safe laundering [113].

Surface disinfection

Firstly, existing recommendations about cleaning and disinfection procedures for health-care facilities must be followed consistently and correctly. Many disinfectants are active against enveloped viruses, such as SARS-CoV-2, including common hospital disinfectants. Currently, the most recommended methods are:

- 70% ethyl alcohol to disinfect small surface areas and reusable dedicated equipment (e.g. thermometers);
- sodium hypochlorite at 0.1% (1000 ppm) for disinfecting surfaces and 0.5% (5000 ppm) for disinfection of blood or bodily fluids spills;
- hydrogen peroxide at 0.5%.

The efficacy of all disinfectants is affected, to different degrees, by organic material. Thus, it is essential to clean surfaces with detergent and water before applying a disinfectant, whose concentration and exposure time are critical parameters for its efficacy. Mechanized systems for the sanitization of large surfaces are avoided because they produce aerosols or disperse dust; it is preferable to avoid also dry sweeping, spraying on surfaces or dusting, preferring instead all wet methods. Therefore, electronic devices such as tablets, touch screens, keyboards and remote controls should be cleaned and disinfected with pre-impregnated wipes or cloths soaked in 70% ethyl alcohol-based products. To increase the degree of safety, it is also possible to consider the use of sanitizable envelopes for these devices.

Frequency of cleaning and disinfection of the premises within the hospital must also be increased: Table 18 from WHO describes frequency and measures required for cleaning and disinfection of different COVID-19 areas [114].

Table 18 – Cleaning and disinfection recommendations

Patient area	Frequency [a]	Additional guidance
Screening/triage area	At least twice daily	• Focus on high-touch surfaces, then floors (last)
Inpatient rooms / cohort – occupied	At least twice daily, preferably three times daily, in particular for high-touch surfaces	• Focus on high-touch surfaces, starting with shared/common surfaces, then move to each patient bed; use new cloth for each bed if possible; then floors (last)
Inpatient rooms – unoccupied (terminal cleaning)	Upon discharge/transfer	• Low-touch surfaces, high-touch surfaces, floors (in that order); waste and linens removed, bed thoroughly cleaned and disinfected
Outpatient / ambulatory care rooms	After each patient visit (in particular for high-touch surfaces) and at least once daily terminal clean	• High-touch surfaces to be disinfected after each patient visit • Once daily low-touch surfaces, high-touch surfaces, floors (in that order); waste and linens removed, examination bed thoroughly cleaned and disinfected
Hallways / corridors	At least twice daily [b]	• High-touch surfaces including railings and equipment in hallways, then floors (last)
Patient bathrooms/ toilets	Private patient room toilet: at least twice daily Shared toilets: at least three times daily	• High-touch surfaces, including door handles, light switches, counters, faucets, then sink bowls, then toilets and finally floor (in that order) • Avoid sharing toilets between staff and patients

[a] Environmental surfaces should also be cleaned and disinfected whenever visibly soiled or if contaminated by a body fluid (e.g., blood); [b] Frequency can be once a day if hallways are not frequently used.

In particular, patient areas must be adequately ventilated for at least 1 hour by natural aeration or by the mechanical ventilation system, before proceeding with the remediation.

Laundry

Specific indications must be followed for the laundry process to avoid contamination [114]:

- soiled linen should be placed in clearly labelled and leak-proof bags or containers, after carefully removing any solid excrement and putting it in a covered bucket to be disposed of in a toilet or latrine;
- after machine washing with hot water (90°C) and laundry detergent, laundry can then be dried according to routine procedures;
- the drum should then be emptied, and the linens soaked in 0.05% chlorine for approximately 30 minutes;
- finally, the laundry should be rinsed with clean water and the linens allowed to dry fully, if possible in sunlight.

Excreta found on surfaces or floor should be carefully removed with towels and immediately disposed of safely in a toilet or latrine. If the towels are single use, they should be treated as infectious waste; if they are reusable, they should be treated as soiled linens. The area should then be cleaned and disinfected following published guidance on cleaning and disinfection procedures for spilled body fluids.

Medical Devices disinfection

Medical Devices can be divided between *disposable* and *reusable* devices: disposable devices are dismantled after use, while reusable devices follow different disinfection and sterilization standards according to their classification, based on the risk for infection that may derive from their use. Equipment for patient care can be categorized as critical, semicritical and noncritical:

- critical items involve a high infection risk if contaminated with microorganisms. This category includes equipment to be inserted in body cavities, such as cardiac and urinary catheters and ultrasound probes. Most of these devices should be disposable or sterilized with steam, if possible. Heath-sensitive equipment can be processed with ethylene oxide, hydrogen peroxide gas plasma or other suitable chemical sterilants;
- semicritical items are those in contact with mucous membranes or non-intact skin. Respiratory and anaesthesia equipment, endoscopes and laryngoscopes blades are examples of semicritical devices. These items require high-level disinfection, but not strictly sterilization, as they should be free from every microorganism but not rigorously from all bacterial spores. Glutaraldehyde, hydrogen peroxide, peracetic acid and sodium hypochlorite are reliable chemical disinfectants;
- noncritical items are those in contact with undamaged skin and not with mucous membranes, therefore do not require strict sterilization. Most of noncritical reusable items, such as bedrails, can be treated in the place of use, without needing to be transported in dedicated areas. Several EPA (*Environmental Protection Agency*) registered disinfectants are suitable [115].

Particular attention must be put on respiratory equipment, that should receive high-level disinfection after cleaning. The standard process is composed as follows:

1. wash the item with soap and clean water;
2. rinse the item completely with clean water;
3. disinfect the item to inactivate the remaining pathogens, by chemical or physical methods (e.g. with steam or pasteurization);
    a. If a chemical method is used, rinse the equipment with sterile or clean water;
4. dry the item;
5. store the dried item in closed packages [116].

As previously described, ethyl alcohol (70%), sodium hypochlorite (at 0.1% for surfaces and 0.5% for bodily fluids spills) and hydrogen peroxide (0.5%) with chlorine addition can be indicated as reliable for the processing of MDs in case of COVID-19. Device materials are also to be considered to choose the most appropriate disinfectant and calculate the necessary insulation times following the previous Table 17.

Disposal of infectious wastes

All healthcare wastes produced during patient care, including those contaminated with SARS-CoV-2, is considered to be infectious and should be collected safely in clearly marked lined containers and sharpsafe boxes. Hospital wastes are usually classified before disinfection and should be treated, preferably on-site, and then safely disposed.

As the volume of infectious wastes increases during an infectious outbreak such as COVID-19, especially for the greater use of PPE, the capacity to handle and treat healthcare wastes must be increased. Latrines or holding tanks should be designed considering potential sudden increases in cases, and there should be a regular schedule for their emptying based on the wastewater volumes generated. Therefore, factors such as the amount of waste, costs, maintenance and types of waste, etc. should be considered when selecting appropriate disinfection technologies in a certain hospital. For example, the incineration technology could be adopted when the amount of wastes is large and the investment is bearable by the hospital; if the hospital is smaller and the investment is limited, chemical disinfection and high temperature steam disinfection are preferred [112]. Table 19 shows the main disinfection technologies for hospital wastes with their advantages and disadvantages.

Table 19 – Disposal technologies for infectious waste

DISINFECTION TECHNOLOGY	ADVANTAGES	DISADVANTAGES
Pyrolysis vaporization incinerator	Complete destruction of toxic and hazardous components	High investment costs and strict demand for heat value of wastes
Rotary kiln incinerator	High incineration efficiency with wide range of applications and good adaptability	High dust content in the exhaust, high air demand, high investment and maintenance costs and low investment recovery
Plasma incinerator	High energy efficiency with no intermediate products	High requirement of technical personnel and high costs
Chemical disinfection	Rapid action, stable performance and broad sterilization spectrum	Residual disinfectants after the procedure
Microwave disinfection	Energy saving, low action temperature, slow heat loss, rapid action, light damage and low environmental pollution with no residues or toxic wastes	Relative narrow disinfection spectrum and complex impact factors of disinfection
High temperature steam disinfection	Low investment and operation costs, simple operation management and low secondary pollution	Weak odor control

The following table (Table 20) recaps all the major changes in the area of cleaning and disinfection.

Table 20 – Cleaning and disinfection procedures

CLEANING AND DISINFECTION	STANDARD ICU	COVID-19 ICU
PLACE	Not strictly defined area	Creation of dedicated area
DISINFECTION	Ordinary procedure for devices and periodic procedure for spaces	Ordinary procedure for both devices and spaces
PERSONNEL	Qualified staff with protective measures	Qualified staff with definite PPE (heavy-duty gloves, mask, eye protection, long-sleeved gown, closed shoes)
SURFACE		
DISINFECTION TECHNOLOGY	Many disinfectants are available	
		Preference for ethyl alcohol (70%), sodium hypochlorite (at 0.1% for surfaces and 0.5% for bodily fluids spills) and hydrogen peroxide (0.5%)

EQUIPMENT	Dry or wet equipment	Preference for wet equipment
METHODS	Use of manual and mechanized systems	Avoid mechanized systems (dry sweeping, spraying or dusting)
FREQUENCY	From 1 to 3 times a day according to the necessity	At least 2/3 times a day or more for surfaces with high contact frequency and for areas dedicated to dressing / undressing of PPE
LAUNDRY		
SOILED LINEN	Different protocols, depending on whether the patient is infected or not	Same protocol for each patient: remove any solid excrement, put it in a covered bucket and place it in clearly labelled bags or containers
MEDICAL DEVICES		
DISINFECTION CLASSIFICATION	Disposable or reusable devices: disposables are dismantled, reusables follow the risk classification instructions (*critical, semicritical, non-critical*)	
		• Preference for disposable over reusable devices • Increase device disinfection (after each use)
DISPOSAL OF INFECTIOUS WASTES		
LATRINES OR HOLDING TANKS	Designed according to the standard waste volumes of the facility	Designed considering a sudden waste increase and provide a more frequent emptying schedule
DISINFECTION TECHNOLOGY	Choose the most appropriate technology according to the type of structure	
		Epidemy factors (e.g. amount of waste, facility response) could change the most appropriate technology

No-touch disinfection technologies, independent from the presence of operators, can represent a supplement method to normal cleaning and disinfection processes: the main ones are based on the use of electromagnetic waves (i.e. UV rays) and ozone. These technologies have great disinfectant powers against pathogens, but in case of SARS-CoV-2, ozone technology is not recommended by the Ministry of Health. UV technology has gained importance due to its effectiveness against viruses: its main benefit is that, at the right wavelengths and with an appropriate exposure time, UV energy can disrupt the DNA or RNA of microorganisms that are exposed to the light, preventing them from replicating. On

the other hand, UV technology is not yet CE-certified and the recommendations in this field may change in the future as research in this sector is constantly evolving [117].

6.3 Emergency purchases, donations and testing of Medical Devices

Speeding up the purchasing of Medical Devices, to cope with the increased request and necessity, is another critical aspect during a health emergency. Urgency acquisition procedures are authorized by specific legislative decrees and outlawed in derogation of the regular public contracts Code (D.Lgs. 50/2016) by delegated implementing bodies (i.e. ARIA S.p.A in Lombardy Region or Consip S.p.A at national level). Furthermore, an increase in the public procurement auction base was carried out during the COVID-19 emergency: between a threshold of 40.000 - 150.000 € it is possible to rely directly on specific companies for goods and services, without setting up a public tender [118]. Public procedures are then awarded according to the criterion of the lowest price, without prejudice to the compliance with the required specifications by the offered devices [119]. Health authorities, such as the Civil Protection Department, are therefore authorized to purchase and distribute to healthcare facilities the needed Medical Devices, in faster timings than usually required.

Regulatory problems

Due to the sharp increase in the requests of Medical Devices, several problems have been faced regarding both purchased and donated equipment from foreign countries:

- user interface in foreign languages (e.g. Russian or Chinese);
- lack of the user manual in community language, which represents a legal obligation;
- lack of the CE marking in devices not originally intended for the EU market, the consequent lack of registration in the Italian Directory of the Ministry of Health and therefore the absence of a conformity declaration to essential health and safety requirements requested by the Directive 93/42/CEE.

Such defaults also regarded high-quality devices from reliable manufacturers, in possession of regular certifications issued by non-European bodies, but simply not intended to be implemented by the EU-market. Further problems were faced in the development of open-source projects and do-it-yourself devices, such as diving masks transformed into assisted ventilation devices: these solutions represented an innovative step for research, but the

absence of normative regulation and the presence of voluntary and non-CE certifications have limited their safe use [120].

In absence of a defined normative, the only circumstance to justify the commissioning of electromedical equipment that is not up to standard is the identification of the '*state of necessity*': the use of MDs not totally compliant with law requirements as the only possibility for vital patient care. The identification of abnormalities, such as the aforementioned absence of CE marking or presence of incomplete information, implies the device to be marked as 'reserve' and its use is promoted only under the given state of necessity. Therefore, ceased the emergency, it must be put out of service. The decision to declare the state of necessity, and therefore to determine the use of such MDs, is up only to the healthcare personnel. Afterwards, the testing activities assess the status of the device in relation to safety and performance and its eventual commissioning [121].

The emanation of legal measures to face the crisis have not always covered all the real-cases applications that occurred, and situations of non-compliance of electromedical equipment have continued to exist. On 26th April 2020, the Ministry of Health formalized the possibility of use of Medical Devices without the CE marking, imported from non-EU markets, after a sanitary check of the competent office (USMAF - *Ufficio di Sanità Marittima, Aerea e di Frontiera*) on the basis of compliance with technical standards or alternative solutions which must meet the essential health and safety requirements. However, the communication lacked in several aspects, including:

- the connection between the technical norms (or the alternative solutions) and the essential health and safety requirements in a non-CE-marked device;
- the testing methods and commissioning of the device in emergency situation.

In regular situations, the process for the acceptance of a device is composed by two phases:

1) verification of CE marking and accompanying documentation (including technical standards applied by the manufacturer);
2) evaluations and technical tests to be implemented according to the EN 62353, and eventual indications by the manufacturer for the commissioning.

The positive outcome of both phases consents the commissioning of the device. Therefore, the actual legislative framework does not allow the commissioning of non-CE-marked devices, because of the non-compliance with phase 1 [122].

Interassociative proposal

To cope with the situation described, a system of emergency derogations has been proposed by several Italian Associations (AIIC – *Associazione Italiana Ingegneri Clinici*, AIIGM – *Associazione Italiana Impianti Gas Medicali*, ANTAB – *Associazione Nazionale Tecnici Apparecchiature Biomediche*, ANTEV – *Associazione Nazionale Tecnici Verificatori*) [123]. In absence of further ministerial guidances, this interassociative proposal could be the solution to be considered. Two main phases can be identified for the commissioning of devices:

1) equipment verification procedures: standard or emergency protocols are defined to verify the equipment eligibility to the commissioning;
2) equipment certifications evaluation: depending on the certifications possessed by the equipment, the previous standard or emergency protocols are applied.

1. EQUIPMENT VERIFICATION PROCEDURES

STANDARD VERIFICATION

The standard verification consists of a set of indications given by the following standard and equipment-specific recommendations:

- EN 62353
- manufacturer indications
- interassociative guidelines (AIIC, AIIGM, ANTEV, ANTAB) for the specific equipment.

If the outcome of the verification is positive, the asset could then be put into service. Otherwise, it is necessary to evaluate the possibility to resolve the non-conformities: in positive case, another standard verification would highlight whether with the new measures the device can be eligible for commissioning; if not, the device is decommissioned (Figure 62).

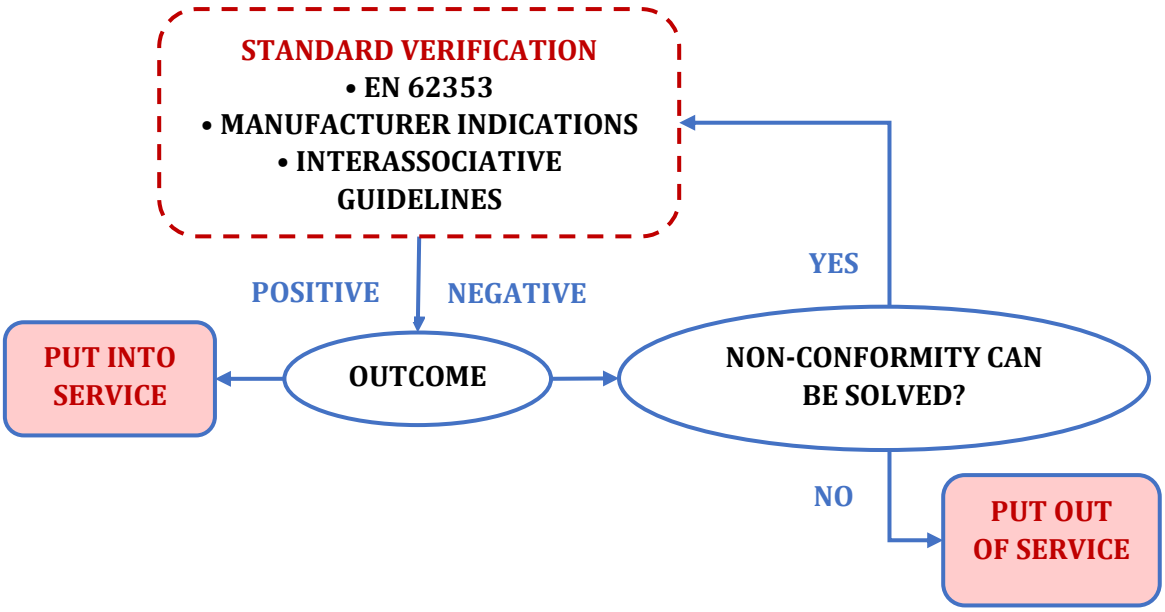


Figure 62 – Standard verification process

EMERGENCY VERIFICATION

The emergency procedure consists in the equipment evaluation by the medical personnel. It is therefore assessed that the device meets minimum requirements (e.g. those defined by the MHRA – *Medicines & Healthcare products Regulatory Agency*, the MdS – *Ministry of Health* or the European Community), that no other equipment is available, that the patient can have benefits compared to alternative treatments and that there is a validation signed by a clinician. If the device does not respond positively to such clinical requirements, the good cannot be put into service; otherwise, the previous **standard verification** is implemented for commissioning evaluation. In case that a laboratory technical verification is required, an urgency validation procedure by a Notified Body precede the **standard verification** (Figure 63).

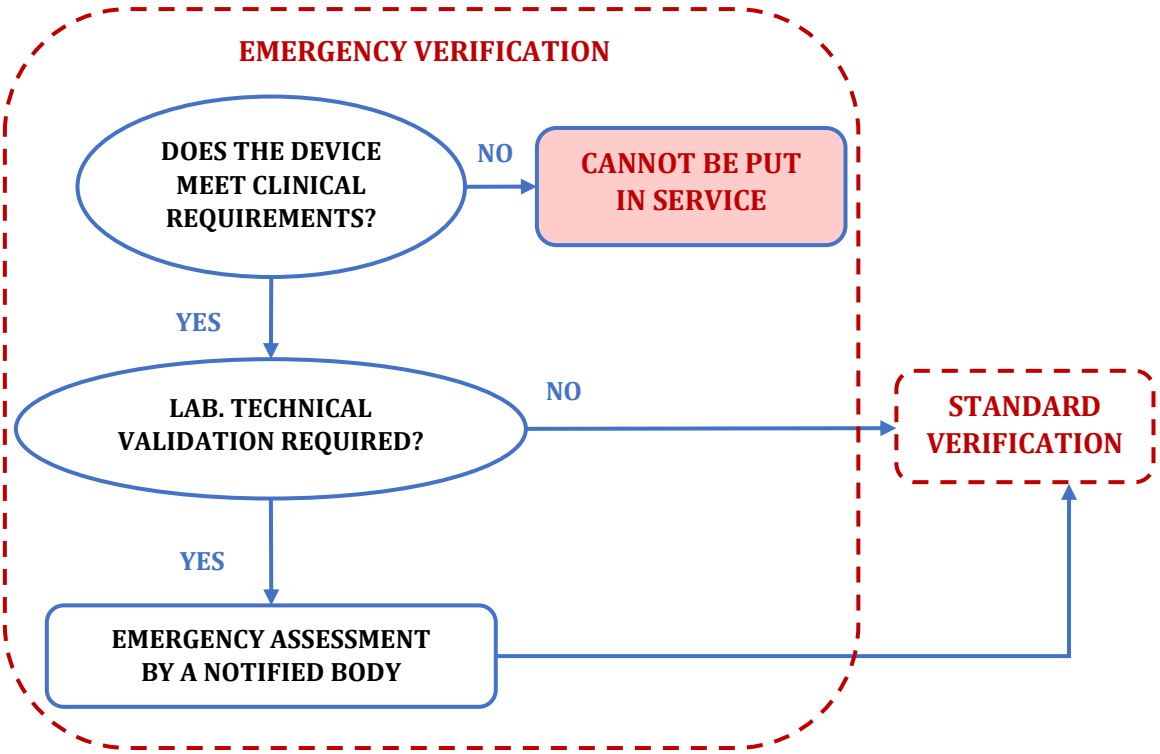


Figure 63 – Emergency verification process

2. EQUIPMENT CERTIFICATIONS EVALUATION

The first step is to consider whether the device has CE certification (Figure 64). If so, it is checked the presence of the equipment notification to the MdS (*Ministero della Salute*) and therefore the registration in the MdS database; if the CE certification is not present, a specific research is conducted to evaluate the available evidence, eventual international registrations in non-EU governmental agencies (FDA, GOST, MHLW, etc.), the user manual and the label check.

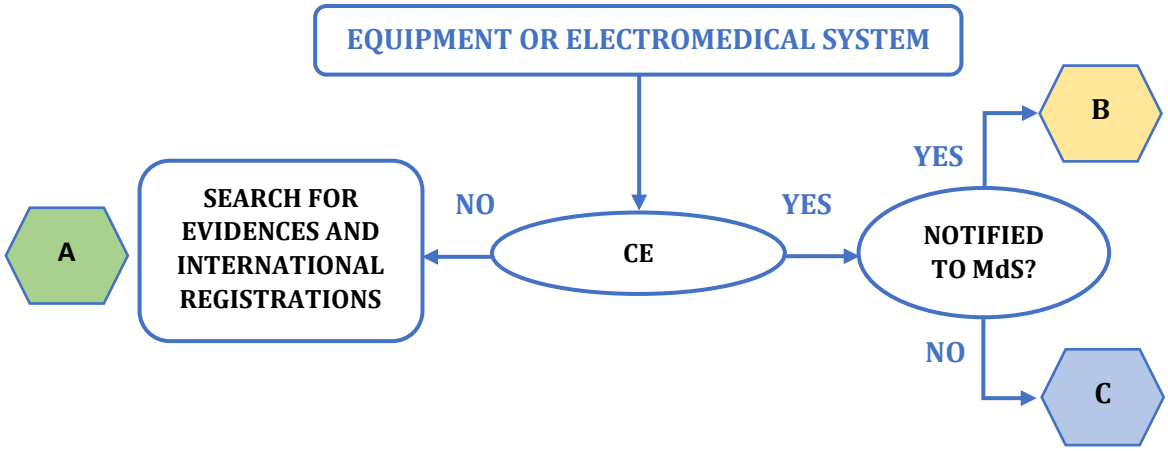


Figure 64 – Equipment certifications evaluation

Depending on the certification possessed, different verification protocols are applied:

A. When the equipment or electromedical system is not CE-marked but is registered with a governmental authority and reflects the same technical standards as the CE marking, the **standard verification** is carried out. Otherwise, if the registration with a governmental authority is absent or the technical standards applied do not reflect that of the CE marking, the **emergency verification** evaluates the possibility of commissioning the device (Figure 65).

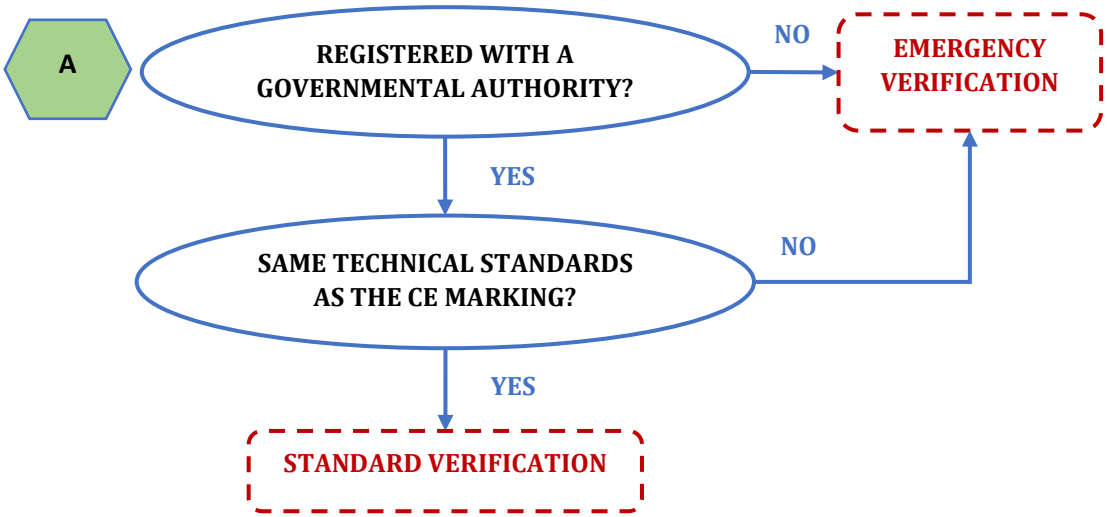


Figure 65 – Verification process: case A

B. If the asset is already CE-certified and has already been notified to the MdS, it is verified that it is not out of use and that there are no changes in its intended use. If both conditions are satisfied, the **standard verification** is carried out. Otherwise, if the device is proposed for a non-intended use or is an attempt to use an asset that is already out of use, the **emergency verification** is implemented (Figure 66).

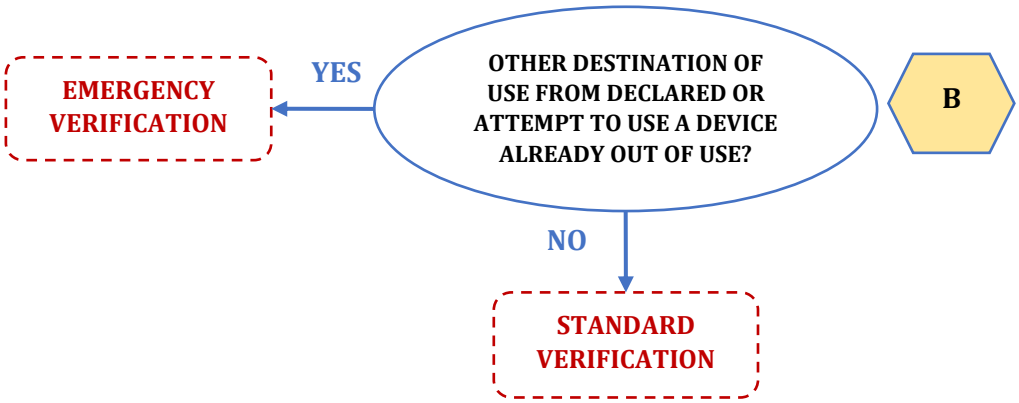


Figure 66 – Verification process: case B

C. If the good is CE-certified, but has not yet been notified to the MdS, all available evidence is analyzed (CE certificate verification, applied technical standards and consultation of the Notified Body): in case of reliable CE certification, the **standard verification** is carried out; otherwise, if the CE certification is unreliable, the asset cannot be commissioned and a report must be sent to the Competent Authority. In exceptional situation, the healthcare facility can request the implementation of the **emergency verification** (Figure 67).

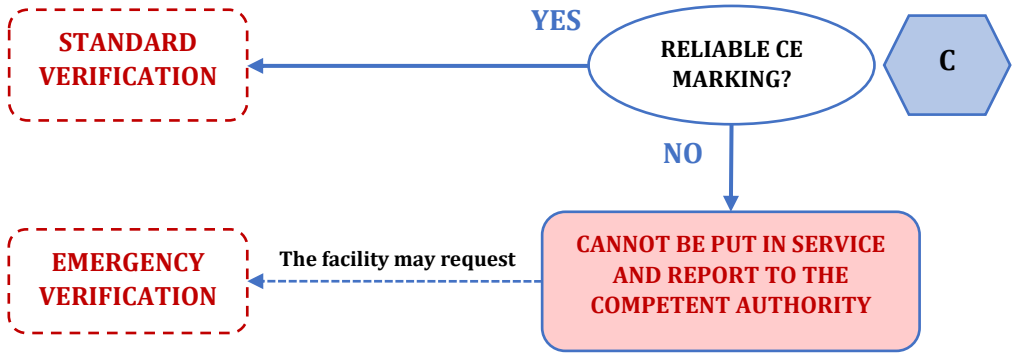


Figure 67 – Verification process: case C

Finally, the following flowchart (Figure 68) summarizes the **verification processes** that cover the whole set of described situations:

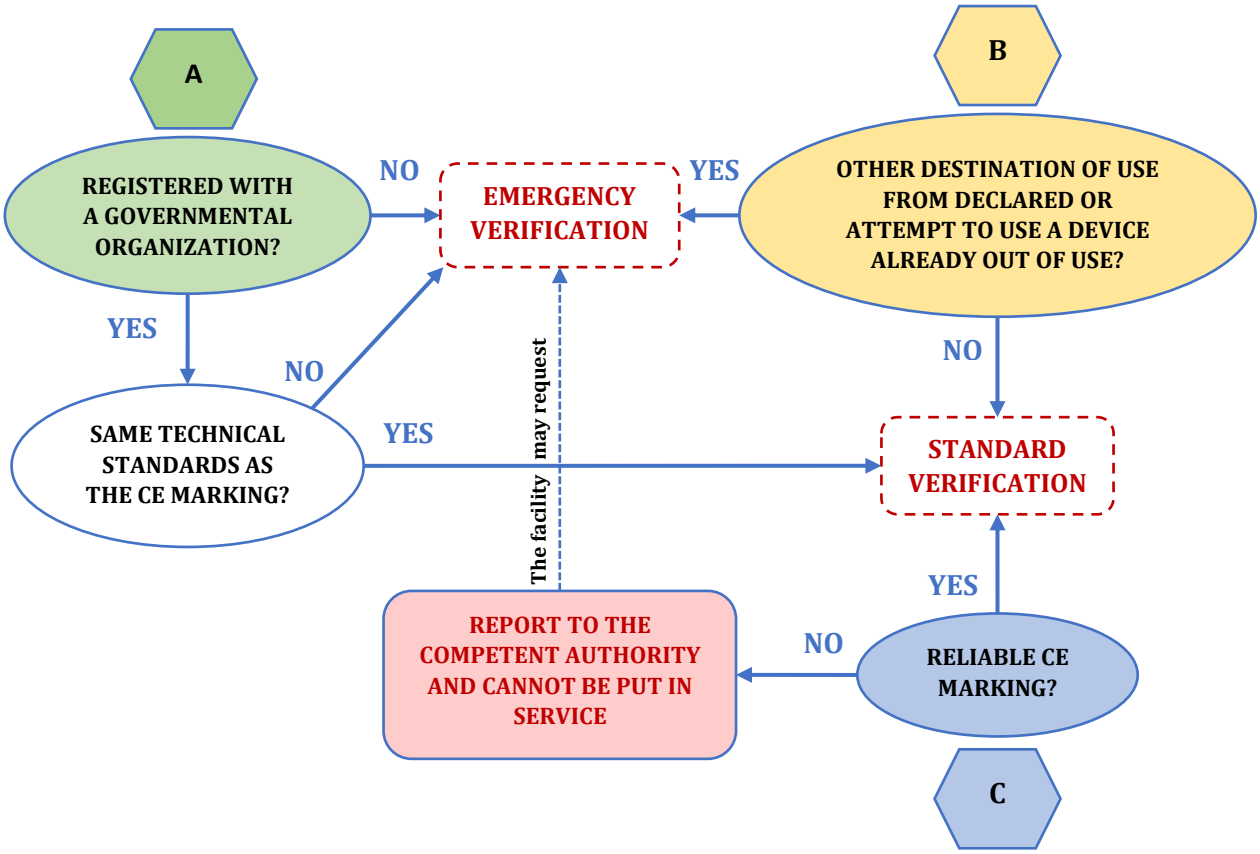


Figure 68 – Complete verification protocol

DISCUSSION AND CONCLUSION

7. COVID-19 ICU Reorganizational Protocol

Since its inception, COVID-19 emergency has placed particular stress on healthcare facilities, which have proven unprepared in many cases. Especially during the initial phases of the epidemic, the unpreparedness regarding the management of patient flows and the lack of medical equipment increased the difficulty in optimizing patient care.

In order to deal with an emergency of COVID-19 or similar infectious diseases, it is necessary to underline the differences between standard and emergency conditions, understanding the organizational changes that may be needed to face an extraordinary situation by optimizing resources and timing. Therefore, our following scheme (Figure 69) could represent a possible solution to deal with the structural and technological modifications required inside a healthcare facility to face a large-scale infectious emergency.

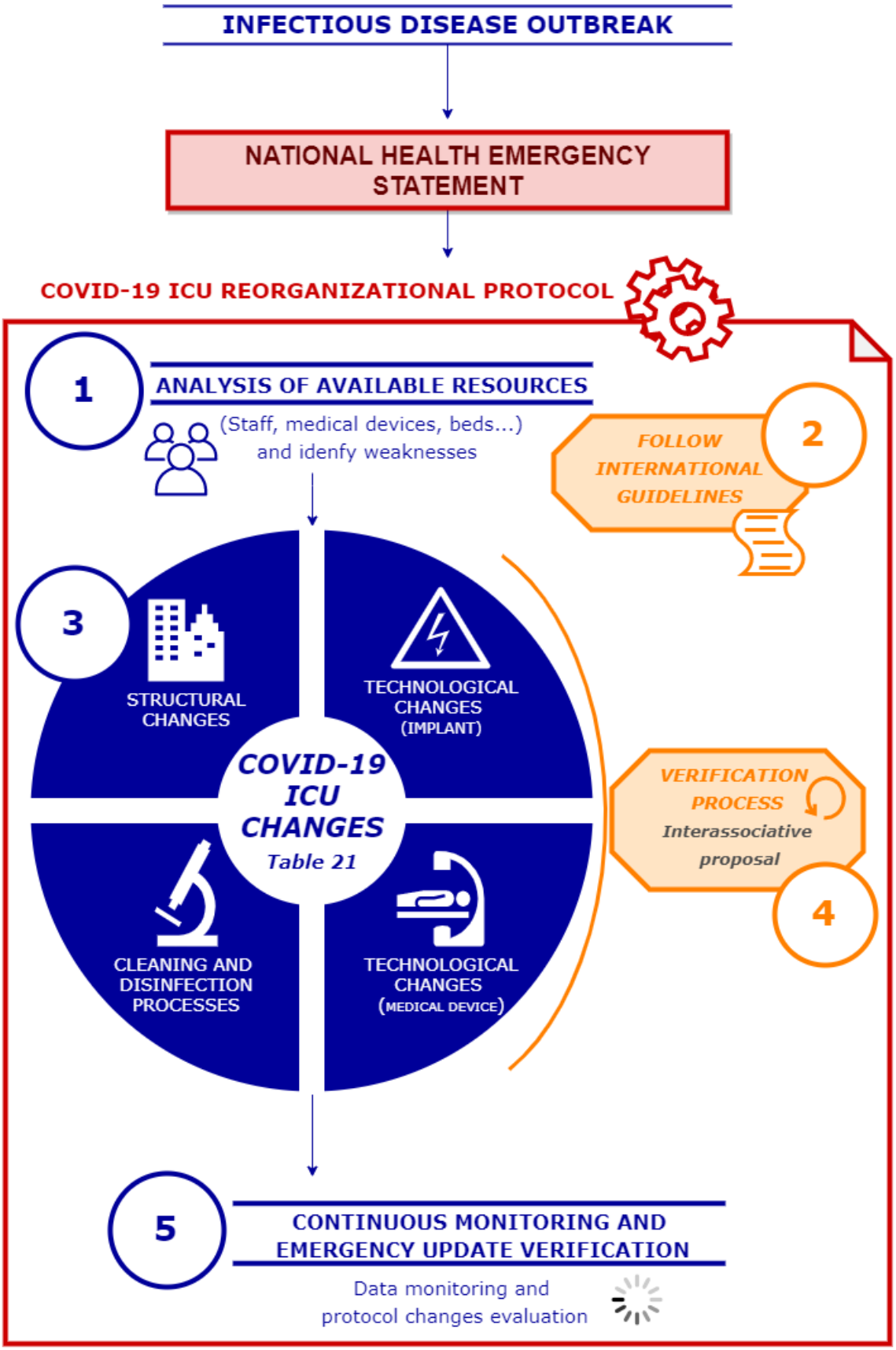


Figure 69 – COVID-19 ICU Reorganizational Protocol

The process starts when an **infectious disease outbreak** is identified and followed by a **national health emergency statement**: this condition becomes the starting point to follow the ***COVID-19 ICU Reorganizational Protocol***, so that a healthcare clinic can respond quickly with efficient solutions. Therefore, the facility implements the following steps:

1. A detailed **analysis of the available resources** of the structure is necessary to respond to local clinical requests. In particular, it is essential to identify:

    - the number of current patients, the hospitalization capacity and the intensive care beds of the structure;
    - the available equipment for each bed;
    - the workforce of the staff and their qualification:
    - the presence of free spaces which can be occupied in case of necessity.

    In order to prepare the structure for an emergency situation, at the end of the analysis it is essential to define which are the strengths and weaknesses to act on.

2. The structure must **follow international guidelines** issued by institutional bodies for any internal action or change. For COVID-19 emergency, recommendations were issued and continuously updated by entities such as the Ministry of Health (*Ministero della Salute*), WHO (*World Health Organization*), ECDC (*European Centre for Disease Prevention and Control*), ISS (*Istituto Superiore di Sanità*), AIIC (*Associazione Italiana Ingegneri Clinici*).

3. After evaluating the overall condition and the available guidelines, a series of changes could be necessary for the structure to optimally deal with the emergency. These can be divided into **structural changes**, **technological changes for Medical Devices** and **implant systems** and specific **cleaning and disinfection** procedures within the different departments: 4 main tables (Table 14, 15, 16, 20), available in Chapter 6 and summarized in Table 21, can detail this analysis.

Table 21 – COVID-19 Requirements changes

STRUCTURAL MODIFICATIONS	STANDARD ICU	COVID-19 ICU
CLINICAL PATHWAYS AND PATIENTS FLOW	Separation firstly based on clinical necessities	Separation firstly based on pathology (COVID-19 vs. non-COVID-19)
WARDS	Union of patients with different pathologies within the same ward	Separation of COVID-19-dedicated from non-COVID-19-dedicated wards
HOSPITAL STAYS	Cohort or single stays	Preference for cohort over single stays
INCREASING HOSPITALIZATIONS	Increase the number of beds is typically enough	Increase the number of beds and create new COVID-19-dedicated ICU wards
ICU ENTRY AND EXIT PATHS	Always defined with strict safety measures	
PHYSICAL BARRIERS	Typically unnecessary	Necessary
FIXTURES CLOSURE	Sealed and hermetic closures	

HVAC SYSTEM SETTING	STANDARD ICU	COVID-19 ICU
AIR EXCHANGE RATE	≥ 6 v/h	≥ 12 v/h
AIR FILTRATION AND DECONTAMINATION	HEPA / ULPA filters	HEPA / ULPA filters + UVGI units
PATIENT ROOM PRESSURE	Positive / atmospheric / negative	Negative (-2.5 ÷ -10 Pa than atmospheric pressure)
OUTGOING AIR	Air ducting to the outside	

MEDICAL GASES SYSTEM SETTING	STANDARD ICU	COVID-19 ICU
OUTLETS FLOW RATE CAPACITY	At least 20 l/min per patient	At least 40 l/min per patient (ideally 60-70 l/min)

OUTLET CONNECTIONS	Outlet connection to single patient	Use of splitters or dual flowmeters to guarantee supply to all patients
DISTRIBUTION NETWORK CAPACITY	Distribution network capacity determined in design phase	Verification of distribution network capacity when increasing: - the number of patients and outlets - the flux requested at each outlet

MEDICAL DEVICES RECOMMENDATIONS	**STANDARD ICU**	**COVID-19 ICU**
ICU MINIMUM EQUIPMENT	Complex set of instrumentation and devices	At least: bed, intensive care ventilator, 4 infusion pumps
MONITORING OF PARAMETERS	No limitation of contact with patients, allowing a continuous and physical monitoring	• Limitation of contact with patients to cases of absolute necessity • Continuous monitoring is carried out by robots or video surveillance
MAINTENANCE	Follow manufacturer's guidelines	
		Increase preventive maintenance
PLACE OF MAINTENANCE	Preventive maintenance performed both on site and in the laboratory	
		Preference for on-site disinfection before laboratory maintenance; if not possible, on-site with adequate protection
VENTILATOR	Follow manufacturer's guidelines	
		Preference for disposable valves and filters for daily substitution
NON-INVASIVE VENTILATION	Oronasal masks or helmets	Preference for the use of helmets
INVASIVE VENTILATION	Open or closed-circuit endotracheal aspiration	Only closed-circuit endotracheal aspiration
DIAGNOSTIC TESTS	Static or movable instrumental examinations	
		Preference for movable devices whenever possible for use at patient bed
MEDICAL DEVICES ACCESSORIES	No specific requirements	Preference for disposable accessories

CLEANING AND DISINFECTION	STANDARD ICU	COVID-19 ICU
PLACE	Not strictly defined area	Creation of dedicated area
DISINFECTION	Ordinary procedure for devices and periodic procedure for spaces	Ordinary procedure for both devices and spaces
PERSONNEL	Qualified staff with protective measures	Qualified staff with definite PPE (heavy-duty gloves, mask, eye protection, long-sleeved gown, closed shoes)
SURFACE		
DISINFECTION TECHNOLOGY	Many disinfectants are available	
		Preference for ethyl alcohol (70%), sodium hypochlorite (at 0.1% for surfaces and 0.5% for bodily fluids spills) and hydrogen peroxide (0.5%)
EQUIPMENT	Dry or wet equipment	Preference for wet equipment
METHODS	Use of manual and mechanized systems	Avoid mechanized systems (dry sweeping, spraying or dusting)
FREQUENCY	From 1 to 3 times a day according to the necessity	At least 2/3 times a day or more for surfaces with high contact frequency and for areas dedicated to dressing / undressing of PPE
LAUNDRY		
SOILED LINEN	Different protocols, depending on whether the patient is infected or not	Same protocol for each patient: remove any solid excrement, put it in a covered bucket and place it in clearly labelled bags or containers
MEDICAL DEVICES		
DISINFECTION CLASSIFICATION	Disposable or reusable devices: disposables are dismantled, reusables follow the risk classification instructions (*critical, semicritical, non-critical*)	
		• Preference for disposable over reusable devices • Increase device disinfection (after each use)
DISPOSAL OF INFECTIOUS WASTES		
LATRINES OR HOLDING TANKS	Designed according to the standard waste volumes of the facility	Designed considering a sudden waste increase and provide a more frequent emptying schedule

DISINFECTION TECHNOLOGY	Choose the most appropriate technology according to the type of structure	
		Epidemy factors (e.g. amount of waste, facility response) could change the most appropriate technology

However, it is up to the individual healthcare facilities to adapt the indications according to their needs.

4. The conditions of commissioning and acceptance of the equipment can vary in case of emergency. For this reason, it is necessary to take into consideration a guideline capable of solving any specific conditions: we identify as a reference the **Interassociative Proposal** of AIIC, ANTEV, ANTAB, AIIGM, described in Chapter 6.3 (Figure 68).

5. Finally, once the emergency protocol has been implemented, a continuous monitoring and constant updating on the trend of the infections and ministerial indications are required. Furthermore, new changes to the emergency protocol could be implemented based on the needs found and the clinical data collected during the implementation period.

Different procedures and guidelines were analysed in order to select all those changes and suggestions, from March 2020 to September 2020, which have been useful and effective in clinical practice. This protocol is made with the aim of limiting the spreading of an eventual second wave of COVID-19 infections within hospitals and optimizing patient care, as an adjuvant to the D.G.R. 3264 (*Delibera di Giunta Regionale*) for the reorganization plan of Lombardy Region hospital network. The given indications could also be applied to any other territory and for other infectious pandemics, always considering the specific information related to the given virus, essential for the correct implementation of the procedures.

In conclusion, it is necessary that the protocol is used only after having thoroughly analysed updates and results present in literature at the time of application. Possible new procedures are still under development and several results may be available later, thus determining possible changes to our results.

Figures

Tables

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