

Jan Witowski, Mateusz Sitkowski, Mateusz K. Hołda,  
Michał Pędziwiatr and Marek Piotrowski

## 10 Hospital management

### 10.1 Hybrid rooms

The rapid development of minimally invasive techniques, as well as imaging systems with the possibility of image fusion from various devices, and the possibilities of integrating and managing medical devices have made the traditional operating room concept find its complement in the form we call *hybrid room*. It is therefore an operating room where treatments are performed in the form of a hybrid (combination): minimally invasive procedures (e.g., coronary vessel diagnostics—coronary angiography and angioplasty treatment) with the possibility of performing full surgical procedures (including cardiosurgical procedures). The concept of a hybrid room is quite ambiguous; there are no detailed requirements or guidelines regarding its equipment. It is assumed, however, that such a room must be equipped with a device enabling blood vessel imaging such as an angiograph (one- or two-plane). Quite often, the concept of hybrid type rooms is also used when there is a large diagnostic device (e.g., MRI or CT scanner) in the operating room. These and other devices (such as endoscopic imaging systems, intraoperative microscopes, and ultrasound scanners) should be able to interact and communicate with one another, for example, by means of data exchange or by overlapping (merging) images. The combination of many techniques significantly improves diagnostic quality, increases the precision and effectiveness of treatments, and makes treatments shorter and less invasive. The large accumulation of equipment, however, means that rooms of this type need special methods of equipment planning and device placement, or even the way of moving and communicating between the staff of various specialties (surgeons, anesthesiologists, consultants of selected fields, and nursing and technical staff). A hybrid room is therefore a specific place where ergonomics and regulations from many fields of medical engineering should be taken into account (e.g., radiological protection, medical gases, ionizing radiation, electromagnetic field, complicated laminar airflow supply systems, and other climatic conditions). Among other devices, in addition to the aforementioned equipment, the hybrid room usually includes the following: a surgical lamp (usually a dual head with the ability to record and transmit audio and video signals); a set of (anesthesiological and surgical) power columns equipped with medical gas outlets, power sockets, fasteners, apparatus for general anesthesia, and vital signs monitoring; resuscitation and anesthetic equipment (defibrillator, suction pump, respirator, and set of infusion pumps); electrosurgery system (available in many forms, e.g., as a classic electrosurgical knife, jet surgery knife, plasma knife, ultrasonic knife, or using other technology); cardiology equipment (counterpulsation controller, turbine hemopump, extracorporeal

circulation pump, autotransfusion device, and blood coagulation monitor); and a set of surgical instruments and other small equipment (e.g., infusion fluid heaters, patient heaters, functional furniture, tool tables, and containers). For the efficient and safe management of such a technology-saturated zone, the operating room management systems discussed below are being used more and more often. It should be anticipated that the concept of hybrid rooms, which for many years has usually belonged to cardiac disciplines, will quickly evolve toward other specialties that use advanced intraoperative imaging techniques. Hybrid rooms closely cooperate with or are even created as an integral part of the integrated room systems described below. Because of the accumulation of equipment and installations for the correct and safe operation of the hybrid room, it is necessary to properly organize its work allowing free movement of both equipment and medical personnel without restrictions in access to the patient. To optimize the costs, however, it is advisable that the hybrid rooms can also function as standard operating rooms, which can be achieved, for example, by appropriate selection of equipment allowing its easy rotation. In the future, one can expect the development of hybrid rooms technology in the direction of large-area rooms where even several treatment and diagnostic devices will be grouped, e.g., a tomograph, an angiography (or a hybrid of both), or various versions of MRI devices. It will be a natural development in the direction that became the determinant of this technology at the beginning of its implementation, that is, especially the constant increasing of the diagnostic and treatment potential within the operating room, which significantly increases the effectiveness of the procedure, reduces the number of additional procedures that should be performed outside the operating room, and accelerates the ability of the operating team for quick intervention.

## 10.2 Integrated rooms

The increasing amount of medical equipment within operating rooms means that integration systems are becoming an increasingly common standard especially in the operating blocks of several or a dozen or so rooms. The operating room integration system in the basic version usually has such functions as control from a touch All-in-One computer installed on the power column or another place indicated by the user, graphical and text control interface, video module for preview, control, recording and playback of recorded images from several connected sources, an audio module for capturing, recording of sound reproduction, and a module for controlling medical devices operating in the operating room (e.g., lamps, columns, electrosurgical systems, tables, etc.), which should be a modular structure element allowing expansion for subsequently introduced devices. The integration system should also have or be ready to be expanded with the control of infrastructure elements such as a medical gas module and electric power lines within operating rooms or devices securing climate parameters required by medical equipment suppliers and ensuring adequate

work comfort for users and a patient. The application controlling the system should have an intuitive graphical control interface that provides control of all system functions, the function of assigning an operated patient to a specific surgical operator, including the possibility of individual system configuration depending on the needs and selected functions. The system control can be done on touch and conventional devices. Typically, it is implemented by a set of devices in the following configuration: a touch screen panel installed in an operating room on an additional arm on the power column or in another place convenient to control with a resolution in min full HD class, built-in high-capacity hard disk, integrated graphics module, min 8GB RAM memory, a set of USB, RJ-45, HDMI, DPx1, line-out or other types of signal inputs, and other controls like the keyboard and mouse connected via a USB port with protection rating of min IP65.

In the case of operating blocks consisting of a larger number of rooms, each of them is an integrated unit but has communication with others through technical cabinets (the so-called rack). Thus, it is possible to redirect the captured data, images, and films to any of the monitors inside the room, and to other rooms, conference rooms, doctors' offices, etc. In addition to elements permanently connected with the infrastructure (like surgical lamps or power columns), devices that can be integrated within the management system include, among others, X-ray machines, surgical microscopes, anesthetic and life-monitoring devices, navigational systems, and surgical robots. In addition to device control and the ability to transmit audio-video data, these systems may have or cooperate with external digital systems for managing medical data that are also used for recording, archiving, and processing of images and video sequences from recorded surgical procedures. Events are recorded on digital media, e.g., CDs, DVDs, memory cards, and other devices connected via USB ports. These images can then be viewed on external computers and dedicated media players or directly in the system. The system allows saving photos and video images, and it also allows adding descriptions, analyses, and interpretations with the possibility of editing and later access. Systems integrating the management of medical devices within the operating rooms also evolve toward other areas, e.g., as management systems for endoscopy laboratories. In this case, in addition to the standard functions of medical instrument management, the tracking process is important, which is the system for tracking endoscopes, which reduces the risk of infections and is a tool for decision-making support in the event of occurrence of such an event (determining who and when was in contact the instrument, who and in what moment carried out individual processes). This type of information can be in fact generated automatically, thanks to an access system that recognizes equipment and service at every stage (washing, drying, storage, and dispensing of equipment). In the case of large amount of equipment, the introduction of an automated control system minimizes the effect of human errors and constitutes a significant contribution to the documentation of the entire surgical process, increasing the probability of its safe conduct.

## 10.3 Surgical robotics

More and more commonly used surgical robots, despite the differences in their design, specific to each manufacturer, have several common elements, which can include the following:

- operator console
- robotic instrument arms with auxiliary elements, e.g., endoscopic camera
- high-resolution video system
- a set of reusable surgical instruments (forceps, blades, handles, etc.)

The robotic instrument arms of the robotic system can be integrated into the main unit as well as a set of interchangeable and independent arms in which surgical instruments or endoscopic devices are placed. In the case of a modular system, the operator determines how many arms will be active during the current treatment.

The operator console should provide vibration reduction to minimize natural hand shake and accidental movements, and to scale instrument motion proportional to the operator's movements. It should take into account the individual parameters of the operator (body structure, movement mechanics, and ergonomic position during the procedure), faithfully reproduce the tactile sensations, recognize and eliminate accidental movements, and control various system elements such as instruments or camera. Depending on the design of the robot, the control levers mimic the actual movements of the operator's hands (i.e., movement of the operator's hand to the right causes the instrument to move to the right, and movement of the operator's hand to the left causes the instrument to move to the left), enabling the surgeon to control the instruments and the endoscopic camera inside the patient's body, or offer a solution in which the console handles transmit the movement of the operator's hand to the movement of the active instrument in a manner corresponding to the natural movements of laparoscopic instruments during the surgery and react to the touch and pressure of the instrument tip on the tissue even outside the operator's field of view so as to minimize the risk of damage (perforation) during the procedure. Simultaneous control of visualization and surgical instruments can be aided by eye tracking functions that are used to adjust the field of view (zoom in, zoom out), and by moving the endoscope, it is possible to assign instruments to the most appropriate robot arms.

The design of the console should make it possible to obtain a comfortable, ergonomic position during the procedure performed by adjusting the console position to the operator's body structure. The operator, sitting comfortably behind the console, should be able to issue instructions for devices connected to the robot's individual arms using drivers on the console. In addition to a typical desktop that contains the control levers and control buttons for adjusting the operating parameters, power buttons, or emergency switch, an important control element is the footswitch panel. It is placed at the base of the surgical console, acting as an interface enabling the performance of various surgical operations (camera control, coupling of main

controllers, arm switching, and control of electrosurgical devices). There is also a solution in which the footswitch panel located on the basis of a surgical console allows configuring a set of foot controllers controlling various functions of devices in the operating set and includes a foot switch controlling the system's safety system enabling stopping (freezing the position of instruments) at any moment of the treatment to improve the position of the operator's hand or in the event of the need to perform other activities related to the safety of the procedure. The control panel, e.g., in the form of a touch screen, should enable a selection of various system functions (including camera/endoscope settings, advanced video parameter adjustments, display preferences, audio settings, account management, record management, and preferences regarding system control parameters). In systems with independent modules, in which each arm is equipped with a movable base allowing any arm location, each base includes its own touch panel. It controls the arm setting and the emergency switch, and it also has a communication interface with the central system unit and base-stabilizing system in the place of its setting and interlocking. The advanced system function adjustments, including account management, operator login to the system, and preferences regarding system control parameters, can be controlled using the keyboard on the operator console.

The system should allow changing the patient's position during a procedure performed using a standard operating table. This also applies to laparoscopic procedures—its construction should ensure that in an emergency the instruments will be easily removable from the patient's body and the patient should be able to safely change position (without the need to disassemble the robot arms operating the patient). The instruments used should be reusable instruments with the possibility of sterilization (there are also reusable solutions with a limited number of applications after which the instrument cannot be used, which is explained by the quality of treatments and prevention of nosocomial infections). In each of these solutions, however, it should be possible to sterilize in line with commonly available sterilization technique standards. This also affects the economy of the system used, especially in the long-term profitability and amortization analysis in relation to operating costs.

The control of the instrument arms and the camera arm can be done by synchronizing several elements such as adjusting joints, integrated instrument arms, camera arm, and electrically assisted or relying on the cooperation of several robotic arms located independently around the operating table, each of which can operate a surgical instrument or a camera depending on the configuration chosen by the operator. To increase the freedom of the system, the arms may have telescopic elements for adjusting the height and the range of the arm. Joints are then used to set the arms on a surgical platform to establish a central point, or a solution is also possible in which the arm joints enable the desired setting of the instrument or the instrument relative to the camera, and the button on each arm allows determining the "central" point for each selected instrument.

All control functions are supported by an electric drive—it allows docking and/or changing the position of the surgical platform. In the case of an integrated system, the electric drive interface includes a steering column, a throttle valve, a throttle opening switch, and displacement switches, while a solution, where each arm of the surgical platform is equipped with a movable platform enabling free positioning of the arms relative to the operated patient depending on the type of procedure performed. The electric drive of each platform enables the precise positioning of the arm and stabilization/locking it at the place of installation.

The robotic system works with a high-quality video system to process and transmit video information during the procedure, the elements of which are as follows: system core, light source, stereoscopic camera head, camera control system (connected to the camera via a single cable, controlling acquisition and processing of camera image), endoscope, video system trolley—central set for processing and displaying images, touch screen (for setting system parameters and viewing the image of the operating field), and fixtures for CO<sub>2</sub> tank. In addition, it should be possible for the system to be integrated with existing video systems adopted and used by the hospital for visualization during surgeries. It is also important to equip the system with a simulator for learning and to assess the operator's manual efficiency.

Apart from robots of a general surgery nature, robots dedicated to specific medical specialties are also becoming more and more common applications. One of the examples can be a neurosurgical robot designed for surgery within the head and spine areas. They allow performing procedures such as neuronavigation, biopsy, SEEG, DBS, or neuroendoscopic procedures. The robotic arm supported by a mobile trolley, which is also used to integrate the control and computing platform, is coordinated by means of hydraulic cylinders, providing several degrees of freedom of movement in space, including linear motion. The basic elements of the robot for this purpose are as follows:

- articulated arm for rigid attachment of the work handle and controlling neurosurgical instruments in accordance with the operation plan
- computer system for surgical planning, navigation, and stereotaxy, enabling the import of CT and MRI images, as well as enabling the design and saving of patient folders containing planned trajectories, markers, and other operational areas
- mechanical probe to locate anatomical structures during neuronavigation and a set of instrument adapters to adapt surgical instruments of various shapes and sizes
- optical distance sensor for the noncontact location of anatomical structures, for automatic registration without markers and hands-free navigation;
- calibration tools for manual recording of X-ray images in 2D
- mechanical holder for precise mechanical steering of the neurosurgical endoscope during chamber procedures and adapter for adapting a specific endoscope model, positioned by the robotic arm in accordance with the preoperative plan

- numerous modules of specialized software used, among others, for manually registering the patient's position using skin markers, matching automatic registration without markers; for merging multiple sets of patient data, enabling the manual setting of several multimodal images (CT or MRI) using anatomical landmarks; for surgical planning in functional neurosurgery, enabling the setting of images the patient; for endoscopic neurosurgery, enabling specific surgical planning, neuronavigation, and robotic manipulation of an endoscope, which enables determination of safety zones for each trajectory and advanced modes of manipulation of the endoscope using automatic movements.

An example of another specialized surgical robot is a system designed for ENT. This type of system not only must work in a straight line but also must apply to flexible surgery, i.e., in such specialties as head and neck surgery (through transoral approach) and in colorectal surgery (through transanal access), as well as in gynecology, thoracic surgery, and percutaneous general surgery. Systems can also be used for treatments in subsequent surgical specialties, including urological procedures. Treatments in all of the mentioned specialties are performed by the same robotic system, and only disposable tips and instruments are adapted to the requirements of a given specialty.

Systems of this type are developed in areas inaccessible in a straight line, like large intestine or airways, and thanks to the construction with a flexible arm allowing both visualization and conducting surgical procedures in the anatomical areas invisible and inaccessible in a straight line through the natural openings of the body, access is possible to areas with complex access routes in a virtually noninvasive manner.

Systems of this type have or cooperate with optical navigation systems, which plan an examination based on diagnostic tests (e.g., CT). They allow, among others, for planning the procedure through the outline with an indicator of the anatomical structures of the head with the sound effect signaling the correctness of the process and other activities such as calibration of any number of surgical instruments, application of multiple-use markers, automatic recording of surgical procedures with a built-in camera, an interface allowing easy adjustment of the procedure to the needs of the user in terms of instrument and treatment profile, the possibility of spatial 3D rotation and reconstruction, automatic zoom of operated structures, and image processing by adjusting parameters such as brightness, contrast, zoom, rotation, mirroring, and even a view from the perspective of the introduced instrument within structures. The specific type of navigation cooperating with robotic systems is intraoperative radio navigation. It is a gamma ray detector on the boom with an arm that can be controlled (e.g., by means of an electromagnetic system), and its operation is based on a scintillation lens made of CsI (Na) and photomultiplier sensitive to changes in position. Imaging of isotope-saturated areas takes place in real time on monitors, which means that the removed change is immediately visible on the

screens without having to rescan the area. A wide spectrum of markers should cooperate with the device, which allows the detection of many areas (e.g., sentinel lymph node, head and neck tumors, thyroid and parathyroid tumors, breast tumors, prostate tumors, endocrinology tumors, or other deep tumors). The auxiliary elements of such a system are lasers with positioning function and external gamma radiation probes for open and laparoscopic surgery displaying the results of measurements directly on the surgical radionavigation screen.

In the case of endoscopic procedures, robotic systems can be in the form of automatic optics positioners. Robotic optics positioner is a system in the form of an arm, fastened to the table rail in any place with the possibility of remote control without the help of an assistant. Communication with the device can be done by voice activation, and additional control is carried out using a sterilizable joystick. The system should be able to change the position of the “trocar point” at any time during the procedure and provide a large range of motion that allows a full 360° view with the inclination of the endoscope as much as possible. This type of system can be mounted to the operating table or have a mobile stand for transporting and storing the arm.

Surgical robotics also develops outside of the traditional operating rooms, an example of which is a cyberknife. It is a device located in radiotherapy laboratories, dedicated to noninvasive radiosurgery with the possibility of irradiation from many directions using a robotic arm with many degrees of freedom. The apparatus enables irradiation with the OMSCMRT method (image-monitored stereotactic and cybernetic microradiotherapy), where the radiation source are photons with the energy of 6 MeV. Thanks to its construction, the system allows irradiation in any plane without the need to move the patient, keeping the position of the therapeutic table unchanged. In this way, it is possible to apply the therapy with multiple isocenters and one isocenter, and the total error of determining the location of the tumor is reduced to a tenth of a millimeter. Because of the size and weight of the device and its components, the apparatus must have an anticollision system preventing the patient from touching the moving parts of the system. Movements of the robotic arm are closely correlated with the patient position control system using a minimum of two images taken at different angles to obtain spatial information. The position control system is integrated with the therapeutic device with respect to the possibility of automatically changing the position of the patient or changing the position of the apparatus during the irradiation procedure in case of finding a change in the position of the tumor. Therefore, it is possible to take pictures during the irradiation procedure without having to interrupt it, and the control of the location of tumors does not require the use of markers and eliminates artifacts of tumor movements caused by respiratory movements. This in turn requires another integration within the entire system, namely, with the therapeutic table. The integration enables the correction of the location of the patient relative to the radiation source, determined based on the performed position control, which allows the patient to be automatically positioned in the correct



position to conduct therapy and automatic table movements performed without the operator entering the therapeutic room. This is also ensured by the extensive movement of the board—vertical, transversal, longitudinal, and revolutions—around the long axis of the table, around the axis perpendicular to the long axis of the table and its twisting. In addition to the typical mechanics and automation of movements of all components, an integral part of the robotic radiotherapy system must be a treatment planning system. It should provide the following elements: fusion of images from various imaging devices (CT/NMR/PET in the DICOM version 3.0 and DICOM RT format); planning 3D dose distributions, including nonuniform density; contouring of anatomical structures and areas for treatment; calculation and optimization of dose distribution; viewing and editing of treatment plans (dose schedules, DVH); the possibility of contouring on cross, frontal, sagittal, and oblique sections; the possibility of calculating dose distributions; and various optimization methods, including one in which the objective function includes the optimization of the total number of monitor units.

Other areas of interest for the development of robotics are the areas where the preparation of cytotoxic drugs takes place. Because they are classified as dangerous, carcinogenic, teratogenic, and mutagenic drugs, their preparation takes place in the premises of hospital pharmacies, which require special preparation and control. Efforts to effectively reduce the exposure of people working on their production led to the emergence of production and use of a system referred to as a robot for the production of cytostatics. The system prepares substances using a robotic arm, and the individual stages of preparation are controlled by sensors and elements of the video system. The system consists of the main unit, in which preparation, production, storage, dispensing of the finished drug, and waste securing take place, as well as a computer control system together with a set of devices for air treatment (pipes, ventilation, fans, HEPA H14 class filters, roof panels, etc.). The robotic part is equipped with a gripper cooperating with a dispensing device suitable for syringes of various sizes, a bar code reader for incoming products and an automatic, rotating magazine. Because of the specifics of the products, the system should have a number of monitoring and control elements, e.g., a syringe location system, a multistage filtration system, a UVC lamp system to prevent the growth of bacteria, and temperature, pressure, and airflow monitoring devices. The system is able to perform chemotherapeutic drug preparations through the implementation of many automated procedures, e.g.,

- collecting from the magazine for all materials needed for production;
- positioning the material in dedicated containers;
- material recognition and verification;
- automatic dosing, aspiration of the drug or its excess, introduction into the final packaging;
- automatic collection of waste, including closing, sealing, and storage;
- positioning and dispensing of preparations.

Irrespective of the robotization of the production procedures themselves, the system should have software for managing both semifinished products and ready-made drugs, cooperating with the pharmacy management system as a whole.

## 10.4 Patient verification systems

As the elements supporting the operation of this type of devices as well as the entire oncological therapy process, patient verification systems can be applied to control and identify the patient, for example, using a hand blood vessel scanner. The system can use, as a reference image, elements of the patient's body contours imported in the DICOM RT format as well as an image of the patient's surface collected by the system during the previous positioning or during positioning on a computer tomograph. Its construction is based on a three-dimensional imaging system in the visible light of the patient's body surface for the purpose of positioning and verification of the patient's position in real time using a set of high-sensitivity cameras observing the patient's body along its entire length and allows

- graphic displaying (visualization) of mismatch areas with an indication of the direction of the suggested correction of the body position of the patient;
- defining several areas of observation and verification in the field of camera system imaging;
- functions of automatic sending of an alarm signal in the case of motion detection outside the defined tolerance range;
- detection of patient's respiratory movements based on observation of the patient's body surface in a noninvasive and noncontact manner, without the need to use any additional accessories such as markers, belts, etc.,
- the ability to generate automatic reports at every stage of planning and performing therapy.

In addition to checking and verifying the patient, it is possible to use the system for the automatic control of parameters of radiotherapy treatments. A specialized dosimetry system offers for this purpose the possibility of automatic control of radiotherapy treatment parameters in real time, registering information about each segment of the applied beam. Constant and automatic control includes the shape, size, and position of the beam as well as the radiation dose. All these parameters are tracked with very high spatial resolution and sensitivity and compared with the treatment plan recorded in the DICOM RT system.

After automatically importing the patient's treatment plan, the parameters of the expected beam for each segment are automatically calculated, and after it is completed, the system is ready to analyze the course of the irradiation process. During the procedure, the analysis results are displayed in the form of tables and graphs on the control monitor.

If the dose received by the patient, i.e., its shape, size, or location in space in any segment, exceeds the margin set by the therapist, the system immediately alerts it through a sound signal, which allows the therapist to stop the irradiation immediately. All these activities are fully automatic and do not require any interference from the therapist. The system indicates an area incompatible with the planned one, i.e., whether the problem related to the shape of the field of irradiation, its size, or the dose rate that was delivered to the patient. This information can also be very helpful for the accelerator service. In the case of failures, they indicate the place where the problem occurred, which can greatly speed up the removal of the fault.

The verification of the delivered dose to the patient is the final stage of quality control of patients irradiation with external beams. In addition to controlling the patient's position, aimed at ensuring geometric compliance of the therapy with the treatment plan, it is one of the most important steps in quality control.

The advantages of this type of systems are as follows:

- a. They enable the verification of the compliance of exposures with the treatment plan in real time (additionally, there is a possibility of interrupting irradiation in case of incorrect realization of the exposure).
- b. They are characterized by very high sensitivity in detecting discrepancies between the actual state and the planned state (the ionization chamber is a very sensitive and reliable radiation detector).
- c. They are characterized by a wide range of use of the device (it can be used to carry out quality control tests of therapeutic devices to verify treatment plans before its start, etc.).

## 10.5 Management systems for surgical instruments

At least the partial robotization of procedures is also taking place in other areas of hospitals. An example may be the management systems for surgical instruments and the circulation of other material subject to sterilization within a central sterilizer and operating block. Its basic functional features usually include the following:

- Observation of current sterilizers, washer–disinfectors, other devices by direct connection with device controllers in real time
- Monitoring the work of washers–disinfectors, autoclaves in a continuous manner—displaying the device status, monitoring errors and information in standby mode and during operation
- Registration of disinfectant and autoclave washer processes and archiving of these parameters
- Registration of all washer errors—disinfectors and autoclaves
- Documentation of receipt of material for the Central Sterilization Department, external release documentation using barcode scanners

- Documentation of the instrument treatment process within the Central Sterilization Department with the assignment of activities to the personnel performing it physically using barcode scanners
- Storage of all information about individual instruments, kits, packaging materials, personnel, devices, and processes carried out on them in a single database on the server
- Possibility of automatic searching of batches by the system after defining parameters such as date and time, machine name, program name, batch status, and batch number
- Identification with access codes to the appropriate levels of competence for the staff operating the system together with the possibility of logging into the system using a barcode scanner
- Identification of packages based on the serial number assigned
- Possibility of documentation of instrument repair processes within the Central Sterilization Department and external services, documentation of issuing instruments for repair and their return, performed using barcode scanners
- Possibility of interactive packaging of the set by the user, using the on-screen packing list, verification of each type of an instrument, modification of the quantitative composition including the actual number of instruments
- The possibility of graphical presentation and storage of process flow charts carried out in washers, disinfectors, and sterilizers
- Possibility to create cost statements divided into groups depending on the size of the package
- Printing the table of contents of the set on laser printers
- Enabling tracking of the path of a set or instrument within the Central Sterilization Unit and to the patient and back
- Ensure the elimination of issuing of nonsterilized items to the recipient, and issue to the wrong recipient
- Possibility to modify and enter new data on instruments, kits, packaging, and recipients, regardless of activities performed on other computer stations
- Creating own queries/rules in the system, aimed at confirming compliance with specific procedures in the Central Sterilization Department by working personnel, to which the answers are registered in the system and after verification (the system should allow further work or block it)

Systems that manage the circulation of instruments should be consistent with the instrument marking system, e.g., with the Data Matrix code or a comparable or matrix two-dimensional bar code (2D bar code), consisting of black and white fields (modules) placed within the boundaries of the so-called search pattern, in a way that allows the full identification of the instruments in each set and the ability to scan each instrument in the set. In each individual Data Matrix or equivalent code, the encoded information can be placed, e.g., a unique instrument/container number and

the ability to use the code for synchronization with IT systems and work organization within the Operational Block and Central Sterilization Department (e.g., composition of surgical instrument sets, circulation within OB/CSD, planning the regeneration and replacement of instruments in sets).

## 10.6 Intensive medical care area management system

To efficiently manage the entire processes taking place within the hospital, solutions dedicated to particular areas are also created and implemented. An example of advanced software that provides a clinical data repository that stores clinical data is the intensive medical care area management system. It is software designed to collect, store, manipulate, and provide clinical information relevant to the process of providing health care. It should provide users with a broad spectrum of tools to acquire, manipulate, use, and display relevant information to help make accurate, timely, and evidence-based clinical decisions. This type of system creates a complete electronic record of the patient's treatment in the intensive care unit by

- the ability to fully configure the user interface of the system from the level of the administrator application, consisting in the ability to add or hide and remove any functionality, button, and any other element available in the software;
- creating charts of patient's clinical data with division into individual tables presented in separate views and collecting all physiological data from medical devices (presentation in graphical and numerical form).

The system should support processes as part of admission to the ward through the following:

- Review of the complete patient record (including displaying all trends and curves) from previous patient admissions
- Assignment of the bed to the patient
- Documentation of patient's belongings
- Documentation of patient demographics data
- Preliminary assessment of the patient
- Setting physiological goals
- Documentation of patient's home medicines
- Evaluation of patient results
- Documentation of the patient's condition upon arrival, e.g., drains
- Pain assessment
- Laboratory orders

The system should also support processes during ICU stay through the following:

- Current drug management
- Preparation and application of drug doses

- Documentation of care tasks administered to the patient
- Graphic documentation and electronic supervision of the wound healing process
- Adaptation of ventilation
- Monitoring instructions for nursing staff
- Supervision of the balance of liquids based on the interface with automatic calculation of fluid balances
- Daily medical assessments
- Periodic nursing assessments
- Pain assessment
- Documentation of clinical events and incidents
- Documentation of family visits and information provided.

The system should accept (store temporarily) and display DICOM files and provide support for the DICOM standard for archiving, displaying, downloading, and uploading DICOM files. In terms of registration and monitoring the patient, it should enable

- the ability to preregister the patient by filling out the patient identification number, automatically importing personal, clinical, and demographic data from existing records;
- the automatic generation of the ID so that the patient can be assigned to the bed and the data could begin to flow into the patient file;
- the possibility of assigning the patient to the bed on the graphic panel of the ward, reflecting the layout of the room and beds;
- searching for patients by searching for keywords or by means of advanced queries, such as a reference to a specific time interval or a care team. The search should be carried out according to any combination of different elements: patient's name, account number, MR number, date of admission, date of discharge, patient status, transport, ward, care team, bed's number, bed group, bed status.

Personnel should be able to document, analyze, and update diagnoses, problems, interventions, and results of the patient in the primary areas of care: cardiovascular, respiratory, neurological, urological, excretory, temperature, coherence, digestion, skin, mobility, communication, and pain. The system should enable grouping of patients according to selected criteria (e.g., cardiac patients) regardless of place or ward. Choosing a patient from the list should automatically display the full patient chart with a panoramic view of information obtained and presented on a regular basis, such as HR, blood pressure, temperature, reminders, events, planned, and administered medications and other relevant information. A report from any clinically relevant information can be generated and delivered to the admitting unit, such as admission, essential findings, diagnoses, procedures, medicines, and condition during the transfer. The user interface should display spreadsheets presenting graphical and tabular parameter data over time, which are captured by various sources. Data can automatically fill charts using physiological monitors and other medical

devices as well as clinical interfaces, such as laboratory and microbiology. Data points can be manually entered or calculated data, such as scoring calculations, and are also displayed in diagrams. Physicians can confirm any data obtained from physiological devices (manually entered values should always be automatically checked). Clinicians can add annotations to any data point, mark it as an error, or mark it with a warning if needed. Each of them has a clear indication on the diagram so that clinicians do not have to seek irregularities. Authorized users can also view parameters for various systems, including respiratory, neurological, temperature, pain, and others, in one tab, allowing an overview of individual patient systems without having to switch to separate views for each of them. Patient's vital parameters are collected from devices automatically and on a regular basis. It is easy to link the patient's vital signs with other patient data, as they are displayed simultaneously over time. Physicians can access and fill any form available in the entire system from a central location without having to look for a chart or button that opens it. They can also view all saved forms, both signed and unsigned, with data for the patient. The system provides a full cycle of treatment and drug management: treatment planning, ordering, reviewing the pharmacy, preparation and administration, reviewing treatment, and reviewing and customizing the order. The system provides easy access to all information necessary to confirm the correctness, for example, administration of any drug because the carer is obliged to check the right patient, the right medicine, the right dose, the right time, and the right route. Nurses or pharmacists can register the preparation of medication doses for the patient. A single dose or multiple doses can be marked as being prepared at once for the patient. Physicians can also mark doses for many patients, just as they were prepared at once. Nurses may perform various activities at doses of defined duration, depending on the dosage status, e.g., they may also undo the validation of a dose that has been incorrectly labeled as being administered. Physicians can order exact doses in exact amounts and at exact times, even for specialist therapies that do not comply with the standard protocol. The system may also recommend replacing the drug and an alternative treatment plan based on hospital policy and support irregular dosing schedules, such as varying doses per day. The system should be equipped with tools to support the doctor's decision, by tracking changes in the patient's condition and deviations from clinical or administrative protocols. The system should inform the doctor about it to cause action by sending on-screen notifications, e-mails about required actions, such as initiating or terminating treatment, activating care protocols, performing tests, or adopting recommended security measures. The system records the event, the conditions that triggered the event, the history of comments, and the validation of each triggered event, and it may inform doctors to consider changing the patient's medicine to a cheaper but equally effective replacement. The system must automatically collect patient monitoring data from cardiac monitors and automatically collect ventilation data from respirators, infusion data from pumps and data from anesthetic machines, data from anesthetic gas analyzers, data from critical parameter analyzers, and other life support devices

(graphical and numerical data presentation). On this basis, the system should generate patient reports. Reports can be automatically generated by the end user from the application level after a specific event or according to the schedule (e.g., daily print). The solution must enable the development of a mobile application that fully synchronizes with the software to support nursing documentation, observations, vital signs, drug administration, and task lists for many patients and should guarantee integration with the hospital HIS system together with the delivery and support of necessary operating systems and database systems for the proper functioning of the system.

## 10.7 Medical device management systems

IT systems supporting medical device management are usually integrated: open ERP systems with functionality, including, among others, management of medical devices; their locations, inspections, contracts, and service calls; and their implementation, including human resources, investment planning, and analysis of the status and value of assets. To improve management procedures, they should provide, among others, functions such as the following:

- User administration (various levels of authorization)
- Management of current failures, periodic inspections, and purchase of spare parts
- Management of already concluded contracts (including lease, lending, purchases, bundled, and test agreements) and cooperation with the contract register system through the ability to attach scans of contracts
- Management of contract features of devices that are required by the payer of medical services
- Editable database of contractors (contact details: companies, individuals, and competence areas)
- Determining the location by linking to inventory systems and the ability to use the data contained therein
- Full functionality of the system available through a web browser (availability of the version for tablet and smartphone)
- Use of the identification data of the equipment already owned by the user—for example, inventory number, bar code, name, model, serial number, year of manufacture, manufacturer, supplier, location, cost center, date of acceptance, last review (with the type of review), last software update, next scheduled review, last repair, warranty period, guarantor, status (deleted, for deletion, in current operation, temporarily decommissioned), type of ownership of the apparatus (lending agreement, ownership, lease, test), service (authorized, alternative, own), and responsible/user (contact details to these people)
- Information on assigning the apparatus to the contract (or multiple contracts) with payers together with the possibility of exporting such data, informing other SU departments about the device being commissioned/decommissioned



- Creating and modifying the classification of devices, technical cards/passports for devices
- The possibility of attaching documents in the .pdf, .jpg, and .bmp format, such as operating manuals, certificates, technical statements (stored on the server, outside the program database, according to a specific scheme also available from the intranet level—without using the application)
- The option of attaching the nameplate as well as the device itself to each device (keeping on the server, outside the database)
- Possibility of attaching links to documents located outside the database on the server, e.g., to the register of contracts
- The ability to filter data by any features, the ability to write filtering schemes (e.g., by cost centers, classification)
- Dedicated application/applet (also mobile) for reporting failures, the need for inspections, etc.
- Possibility of defining users who can submit applications (without limitation as to the amount of software licenses)
- Personal identification: a user with his/her unique ID and password to verify the source of the request, each application registered in the system, the ability to create user groups. Each user with access to strictly defined resources (medical devices) defined on the basis of their affiliation to the selected location
- Defining the minimum registration requirements, e.g., each application must contain at least the following data set: name, type of device, inventory number or another number confirming the possibility of its operation within the unit, location and its availability, cost center, person reporting/responsible person, type of failure, description of failure, telephone, e-mail.
- Automatic sending of a unique notification number, the ability to indicate by the user of the devices only and exclusively from the lists to which the user has permission, e.g., devices assigned to his/her location

To cumulate and organize the stream of information, the system should provide information flow to ensure the continuity of the case and its monitoring at every stage. An exemplary scheme for submitting and maintaining a service case may be the following:

- On the basis of the notification, a task is automatically created, which the administrative person transfers to the own (internal) service or starts the service order procedure (it is also possible to set an automatic redirection)
- Service staff performs tasks based on electronic information; upon completion, they prepare a registered note/report
- Completion of the task is confirmed by the superior of the internal service (it should be possible to issue tasks related to the already executed order, e.g., purchase of parts, additional measurements, or redirect the case to be carried out outside)

- For external orders, the ability to generate, modify, and send price queries to companies from the database and entered manually (additional option to generate a query with a request for a diagnosis valuation)
- Generating orders based on sent offers or based on the information entered
- The ability to generate purchase orders for spare parts for the internal service carried out by own operations
- The possibility of printing a request for proposal and an order adapted to the user's procedures
- Registration of individual stages of the case
- The possibility to take notes to the case
- Circulation of documents regarding the order along with the approvals and comments of the superiors adjusted to the aforementioned hospital procedures
- Automatic report “from review/failure report to completion of effective actions” assigned to the internal service engineer
- Assessment of the service after completion of the intervention
- Registration of the invoice along with costs and connection with the order to verify the legitimacy of costs:
  1. costs of the case—invoice number, date, overall amount, unit amount, the net amount for individual VAT rates
  2. the possibility of breaking the invoice into components, including, at least, the cost of repair, travel, parts
  3. building the history of orders and costs for individual devices from the database.

The task of the system should also be the archiving of orders and the possibility of their analysis and interpretation. To this end, the system should ensure

- archiving and processing of repair information, e.g., costs of repair, costs of used parts and other components affecting the overall cost of repair, and date of completion;
- generating order history along with relevant data: date, contractor, type, and value of materials used;
- the possibility of communication and realization of applications for smartphones/tablets (e.g., preview of orders for a given working group, taking over of orders, execution of orders, adding notes, bar code scanning, entering data on the progress of the case—for authorized users);
- purchase and spare parts registration function purchased and installed directly by technicians/engineers, i.e., the database, in addition to the history of inspections and services, should also include the history of the purchase of spare parts with the assignment of a directly purchased part of the device to which it was purchased;
- alert regarding spare parts held in stock to avoid redundancy of orders;
- creating requests for proposal, offers or orders, or invoices allowing for automatic reading of data from the previous document;

- the possibility of granting varying degrees of authority for selected users, coordinators, and supervisors (e.g., order preview, data entry, and correction, decision making);
- building own templates and sample documents, modification of existing templates during the processing leading to the selection of the contractor, e.g., by the possibility of using more arguments and criteria (not only the price but also other criteria, e.g., qualitative, warranty, technical, economic, related to a contract) to a management decision and with a suitable place for selection argumentation, comments, etc. (documents in electronic form, conducting polemics of negotiation in electronic form, additionally a printout option);
- the possibility of full access to the program by own technical staff, including the ability to generate a direct response to the user, a comment on the status of the repair, waiting time, no possibility of repair, the ability to close orders after completed online work (the required number of licenses in accordance with the number of employees executing orders, the possibility of direct contact with software on the device (smartphone, tablet);
- automatic generation by the system of confirmation of the service performed or information about further use of the device;
- creating technical opinions and deletion opinions, together with the possibility of sending opinions directly to the user and other units of the hospital;
- the registration of invoices, the possibility of accepting electronic invoices and the introduction of processed invoices (scans, other electronic forms), and the ability to easily verify orders versus invoice for cost control;
- creating schedules of medical device reviews according to the given algorithm, e.g., for individual departments, groups of equipment, broken down by time units, and/or costs or according to individual user criteria, informing on the possible aggregation of interventions;
- creating a register of inspections made, including information about the planned date of the next review (the possibility of automatic or individual introduction of deadlines);
- the possibility of marking the type of device review: internal inspection, inspection performed by the external service, and warranty review;
- the ability to define the inspection cycles, in particular, year, half year, quarter, two years, own periods;
- inspection calendars: information about upcoming, exceeding deadlines, completed, canceled, unperformed/unfinished, ended with a negative opinion;
- creating a history of inspections (postwarranty and warranty): in the inspection calendar for all devices covered by the plan, for individual devices, for individual cost centers;
- verifications of appointments and reminder functions:
  - a. automatic generation by the program: a reminder, e.g., of the 20th of each month about the devices requiring technical inspection in the following month

- b. the ability to generate inspection orders for all the devices indicated by the system
  - c. information about exceeded deadlines
- creating within the database a simple search system of devices using ionizing radiation and magnetic field;
- the ability to specify a functional calendar for handling specialist tests of the above-mentioned devices: date of the last test, test result (in the case of negative tests creating noncompliance form (the possibility of circulation of the form along the path proxy–radiological protection inspector–unit manager–department of medical equipment–proxy)—connection with the function of reporting device failures (minimizing documentation);
- the evaluation of the number of devices owned by various criteria: type, model, producer, location, and cost center;
- apparatus replacement value reports for all devices, groups, locations, cost centers, etc.;
- the registration of device operation time and/or device activity;
- the analysis of the technical condition of devices based on
  - a. dates of purchase
  - b. number of operation hours
  - c. numbers of tests
  - d. number and cost of failure and calculation of availability time
- the cost analysis of consumables for individual devices, price change in time, comparison to the competition;
- the introduction of data regarding service contracts/specialist tests—assigning to the contracts the list of devices, duration of the contract, contractors;
- a statement of the operating costs of a given device and for a given group of devices;
- cost statements broken down into cost centers, individual departments, the hospital as a whole: breakdown of costs for failures and inspections, breakdown of costs by places of use, and breakdown of costs by cost centers;
- other cost statements, e.g., related to service contractors, purchase and/or use period, source of purchase (own funds, external financing sources, lent apparatuses, etc.), comparison of service costs for different contractors, at different periods, for different users, comparing the costs of spare parts themselves the same kind;
- cocreating investment and repair plans—generating proposals for a purchase plan based on, among others, the degree of device wear, age, exceeding the profitability ratio of further repairs, the number of available (already owned) devices of the same type and their location, and other set values;
- estimation and evaluation reports of contractors based on, e.g., delays, prices, quality of services, response time: notification—a repair performed and/or completed;
- all reporting in both graphical and numerical form, the ability to generate trend reports;

- importing/exporting data to already functioning programs (financial and accounting, warehouse), the ability to independently modify the structure and content of reports, and the ability to import/export/process numerical data at least in .xls .csv, pdf formats;
- the possibility of cooperation or extension with a module cooperating with RFID systems for the location of devices;
- the automatic preparation of documentation for the receipt of equipment in accordance with the procurement procedure (creation of delivery and acceptance protocols and noncompliance protocols);
- the certification of the service or rejecting damaged/receiving the repaired equipment through the mechanism of the signature on the tablet in the form of graphic notation (or other solution eliminating receipts, confirmations, and other paper documents).

## 10.8 Radio- and brachytherapy management systems

Examples of management systems that are intended for specialized service of selected facilities are also systems for managing radio- and brachytherapy. The functionality of the software used to manage radiotherapy should provide such activities as

- patient movement management in the radiotherapy, chemotherapy, diagnostics, and surgery units, preparing schedules, and dates of visits;
- identification of patients by means of ID number, photo, and/or bar codes;
- the possibility of introducing external examination results by scanning documents;
- management of clinical trials and automatic adjustment of patients to clinical trials conducted;
- creating procedures for patient management, including chemotherapy, radiotherapy, and surgery;
- remote access to patient data on mobile devices;
- management of the patient portal, enabling conducting surveys, checking dates of visits;
- data exchange between the management system and the irradiation systems in radiotherapy.

Each such system should have its own hardware base based on a central data exchange server providing data exchange with external devices in the DICOM standard, data exchange about patients with HIS hospital system in the HL7 protocol, and automatic backup and data archiving tools. For direct work with the system, the following tools are used: direct management systems in radiotherapy, chemotherapy, diagnostics, and surgery units; control stations in therapeutic devices (min 2 for each irradiating device) and in the rooms of diagnostic equipment (min 1 station for each

device); medical stations with medical monitors in consultation rooms; a review station with a projector and preview monitors in the consulting room; management stations in treatment planning rooms and additional devices such as scanners for medical records; bar code readers (for each management position and at each diagnostic and therapeutic devices); or barcode printers for each management station.

In turn, the 3D treatment planning system for brachytherapy is a system that allows manual and automatic preparation of contours for target and critical areas when planning brachytherapy treatment. It is a tool for the preparation of plans and 3D distribution enabling planning for stationary photon and electron beams, dose calculations, and presentation of results in the form of dose-volume histograms. In addition, it should provide the following features:

- Automatic and manual application of various series of images: CT, NMR, and PET
- Exchange of image data with external devices in the DICOM standard
- Exchange of data on patients with an HIS hospital system in the HL7 protocol
- Automatic backup and data archiving tools
- Transfer of the treatment plan of the offered planning system directly to the HDR camera via a computer network
- Import of teleradiotherapeutic 3D treatment plans from other treatment planning systems to offered DICOM RT brachytherapy planning stations
- Summing of teletherapeutic plans (imported in the DICOM RT standard from other 3D treatment planning systems) with brachytherapy plans made on the brachytherapy planning stations offered
- The possibility of planning brachytherapy based on 2D images from a radiotherapy simulator or C-Arm X-ray apparatus
- Planning 3D brachytherapy based on CT images from a computer tomograph and using NMR images
- 3D fusion of CT and NMR images and overlapping of two different sets of images (e.g., CT and NMR)
- Presentation of 3D absorbed dose schedules and presentation of 2D absorbed dose schedules in any plane
- 3D display of the patient along with the contoured structures, reconstructed applicators and CT images
- Manual or automatic reconstruction of catheters
- User selection of the average electron density for inhomogeneity correction (to remove the contrast of the material or image artifact)
- Optimization of the dose distribution by means of graphic mouse modeling of the 3D isodose shape and functions to optimize the location of the source based on the set dose values in the 3D structures of the patient

Computer equipment for the offered 3D brachytherapy planning software, as well as any other system, should be offered and operated in a configuration compatible with the requirements of the manufacturer of the offered system.