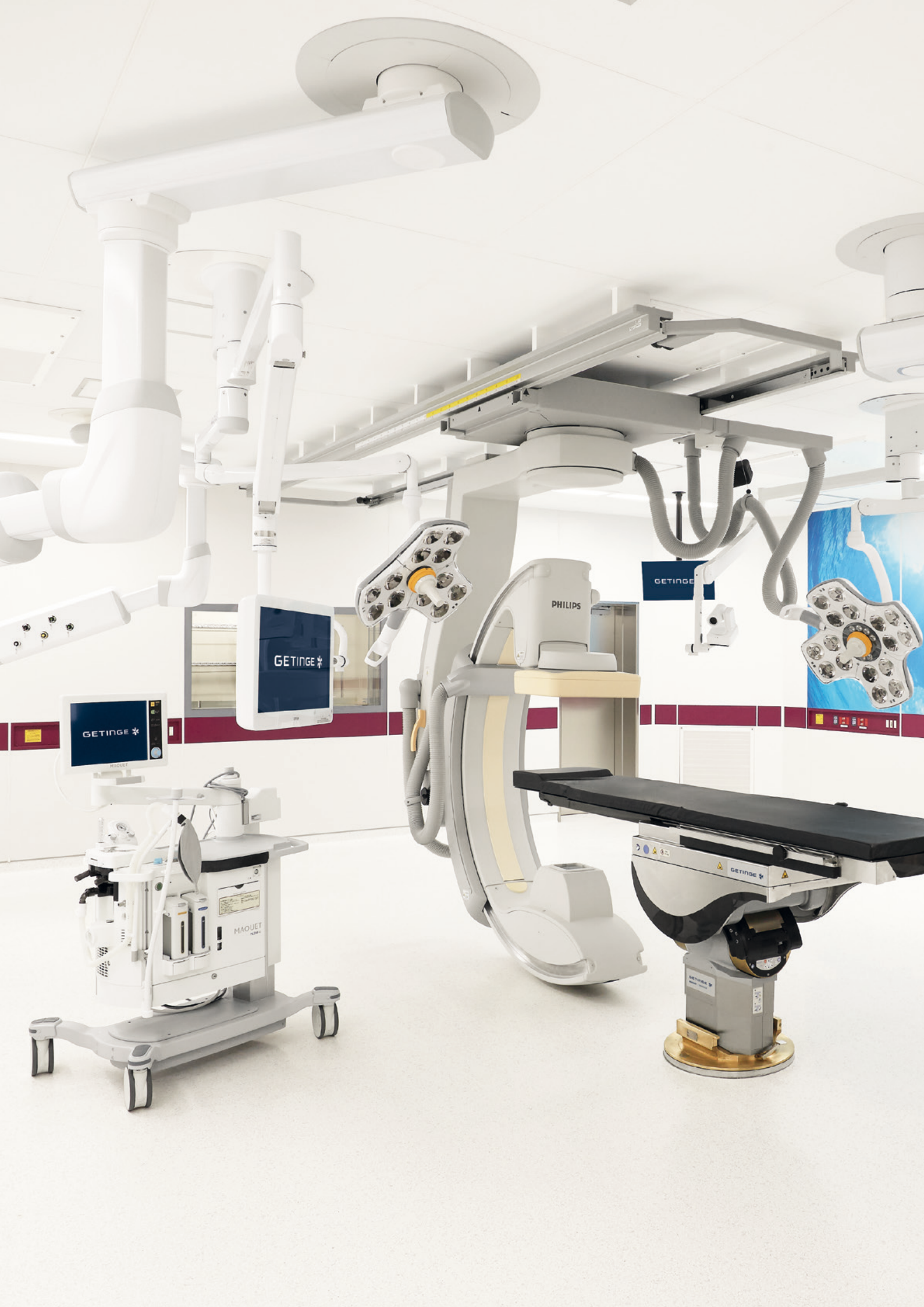
WHITE PAPER

Road map to the Hybrid suite

Optimizing the Planning Process

for Designing and Commissioning the Single-Discipline, Multidisciplinary and Multi-Modality Hybrid OR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The evolution of the Hybrid suite

The clinical and workflow advantages of image-guided surgery within an interdisciplinary Hybrid OR environment have been well established over the course of the past 20 years.

The initial Hybrid ORs added intraoperative CT and MRI functionality to the surgical suite. As the hybrid concept continued to evolve, vascular, cardiovascular, and cardiac procedures were conducted, merging the functionality of a classical cath lab containing an angiography system with a traditional cardiac-focused OR incorporating a surgical table in a sterile environment.

Over time, the frequency and complexity of minimally invasive surgeries continued to increase. Once limited to vascular, cardio and neuronavigation procedures, today's Hybrid OR is increasingly scheduled for multidisciplinary use across a growing list of specialties including neuro-surgery, orthopedics, traumatology, thoracic surgery, oncology and urology.

This trend is expected to continue as room functionality further expands to accommodate multi-modality pre-operative, intraoperative and postoperative advanced imaging techniques (angiography, MRI, CT).

In the future, it's widely acknowledged that the separation of diagnostics and surgery will become the exception rather than the rule.

Asking the right questions

As hospital administrators look to create a customized Hybrid OR solution tailored to their institution's specific clinical, operational, and financial needs, it's imperative they address each of the following questions to help ensure a future-proof implementation that achieves their short- and long-term goals.

- How much planning and installation time is required to commission a new Hybrid OR?
- Who should manage the project?
- Who should be assigned to the project team?
- Who among potential industry partners can help ensure an efficient and smooth project implementation?
- Which disciplines will be practised in the Hybrid OR?
- What types of OR table configurations will be required?
- What is the anticipated impact of room design on future workflows and collaboration?
- How will hygiene and sterility be ensured during surgery?

Defining the value for providers and patients

In today's healthcare environment, clinicians, managers, and administrators are being held more accountable for their patients' safety and quality of care than ever before.

This increased scrutiny is not solely initiated by regulatory agencies and private accrediting organizations – but by a well-informed public that has greater access to hospital performance data to make informed decisions about where to seek treatment.

As a result, decision-makers are constantly challenged to manage the clinical, operational, and financial risks that impact their institutions' ability to sustain life and improve the quality of life for their patients.

The addition of Hybrid OR capabilities enables new and more efficient treatment options that result in shorter patient stays and optimized workflows that benefit from the significant reduction of patient transport between surgery and radiology.

The value to patients includes:

- Potential to speed diagnosis and therapy
- Access to minimally invasive techniques that support the goal of faster recovery times
- Likelihood of shorter procedures and eventual elimination of corrective surgeries that could reduce the amount of anesthetic and X-ray exposure
- Real-time availability of high-quality imaging that helps surgeons preserve as much healthy tissue as possible

The value to hospitals includes:

- Closer collaboration among specialists throughout the treatment chain, especially between radiologists and surgeons
- Diagnostic advantages that create an environment to advance new and innovative therapeutic techniques
- Expansion of reputation-enhancing medical services
- Potential to reduce the length of procedures that would permit more procedures per day
- Application of cost-effective multidisciplinary use of strategic resources
- Ability to leverage clinical advantages of advanced imaging quality and reduction of radiation
- Flexibility to focus on increasing the number of patient-preferred minimally-invasive procedures
- Capabilities that show promise in reducing the length of patient stays that can often result in increased patient satisfaction and revenue generation
- Ability to meet increasing workforce expectations to attract and retain top talent

Setting expectations for project completion

For Hybrid OR project planning and scheduling purposes, available industry data serves as a valuable guideline for each phase of the project timeline:

Phase 1

Analysis and evaluation
3 to 6 months

- Clinical needs and workflows
- Building-related aspects
- Imaging modalities
- OR table system
- Hygienic and safety considerations
- Usability and ergonomics

Phase 2

Budgeting and planning
6 to 12 months

- Budget evaluation
- Interface analysis
- Equipment planning

Phase 3

Installation and commissioning
6 to 12 months

- Installation
- Commissioning
- User / application training

Determining stakeholder involvement – who should be included

The complexity and duration of Hybrid OR planning and implementation require the timely free flow of information among all relevant stakeholders in each phase of the project to achieve the desired outcome.

- Project managers
- Architects and technical planners
- Hygiene professionals
- Surgeons
- Radiologists
- Anesthesiologists
- Head nurses
- Experienced industry partners
- IT specialists

Phase 1 stakeholders plus financial or purchase department managers

Phase 1 stakeholders plus application specialists (trainers)

Phase 1 considerations

– analysis and evaluation

Traditional OR planning processes and capital equipment purchasing decisions that are well understood and routinely implemented by hospital administrators don't always apply when it comes to designing and commissioning the image-guided and OR integration-enhanced surgical suite.

The interrelationship of surgical and imaging equipment dictates that the performance of any Hybrid OR will be limited by the effectiveness of its weakest link. Each critical decision point between initial planning and commissioning has the potential to maximize or limit the long-term potential of the suite to enhance patient outcomes and throughput.

A single mistake early in the planning process can have serious consequences in subsequent project phases that can require costly remediation and missed project deadlines. Many potential issues can be avoided by having clearly stated written objectives that guide the planning process and prevent the need for mid-course corrections. The relative placement of the OR table and imaging system with the room's ceiling supply unit and surgical lighting is of particular concern. Often, one or more components can get in the way of each other or hinder workflow.

That's why clinicians play an important role early in the planning process when project objectives are being set. The plan should anticipate utilization of the Hybrid OR over the following three to five years to accommodate evolving surgical workflows, imaging technologies, and increased patient volumes.

Establishing clinical requirements and workflow preferences

An effective Hybrid OR should reflect each hospital's specific utilization strategy, clinical preferences, and operational requirements. Clinicians and administrators must have a clear idea how diagnostics and surgery will positively impact outcomes for their hospital and patients. This requires intensive discussions among radiologists and surgeons whose combined expertise help enable advanced image-guided surgical techniques and treatment options.

Important considerations over the next three to five years include:

- Which specialties will use the Hybrid OR, and what others could be added later?
- What types of surgeries typically will be performed?
- Which modalities of imaging equipment will be required based on current and anticipated room utilization for intraoperative planning, guidance, and check-up?
- Whose expertise should be called to help establish an image-guided environment that effectively merges imaging and surgical requirements?
- How will the goal of improving patient outcomes be measured?
- What will be the impact on current workflows and collaboration?
- How can well-established effective processes be preserved in the Hybrid OR?
- How will imaging equipment be made accessible for routine examinations while not utilized for surgery, to further leverage the investment?

Hybrid OR
implementation matrix

	Single-discipline, single-modality	Multi-discipline, single-modality	Multi-discipline, multi-modality
Typical implementations	• Angiography for cardio and vascular use (TAVI, EVAR, TEVAR, HCR, CABG) • Angiography for urology (laparoscopic partial nephrectomy) • Angiography for orthopedics (treatment of complicated fractures) • CT for oncology (iVATS lung tumor resection, needle guidance for liver tumor ablation) • MRI for neurosurgery in combination with a stereotactic or navigation room (brain tumor surgery, deep brain stimulation)	• Combining disciplines sharing a modality	• Angiography / CT (traumatology, tumors affecting bone structures, spinal fusion, stroke treatment) • Angiography / CT / MRI (tumor ablation incl. needle guidance and ablation monitoring, polytrauma)
Considerations	• Large volume of procedures justifies dedicated use • MRI and CT should also be accessible for examinations	• Ideal for smaller hospitals where total volume of cases (case mix) supports investment • Helps private hospitals attract surgeons across diverse specialties interested in advanced intraoperative imaging capabilities • MRI and CT should also be accessible for examinations	• Ideal for smaller hospitals where total volume of cases (case mix) supports investment • Helps private hospitals attract surgeons across diverse specialties interested in advanced intraoperative imaging capabilities • MRI and CT should also be accessible for examinations

Minimizing the impact on current infrastructure

A majority of Hybrid OR projects are initiated within the hospital's existing structural footprint. As a result, architectural and engineering requirements must be balanced with current clinical needs to help ensure minimal disruption to existing surgical workflows throughout the duration of the project.

The complexity and interrelationship of these issues strongly suggest the need to assign a single individual to continually scrutinize building- and equipment-related decisions to ensure total compatibility among these interfaces (e.g., air conditioning system and building power supply).

- How much space is available for the Hybrid suite? Is the allocation of space sufficient for the amount of space that is required?
- How many rooms and how much additional space will be required adjacent to the Hybrid suite (storage, scrub, etc.)?
- How will the selected imaging equipment impact space utilization?
- Are the ceiling height and supporting structures sufficient to accommodate all of the equipment?
- Is the air conditioning system well integrated and capable of meeting any applicable laminar air flow or HEPA filtration standards?
- Have all standards-based hygiene-related requirements been accounted for (national and international)?

Comparing the functionality of available imaging systems

As the core component that helps distinguish the Hybrid OR from a traditional surgical suite, each type of imaging system offers a distinct set of diagnostic advantages.

Data acquired by different imaging modalities also can be merged, enabling the use of high resolution overlays to achieve better orientation and guidance while working with low-dose fluoroscopy.

An increasing number of Hybrid ORs incorporate multiple imaging system modalities to enhance the quantity and quality of diagnostic data. This helps clarify and improve treatment options while keeping the patient securely positioned under anesthesia throughout each step of the image-based procedure – planning, guidance, and final check-up. Imaging device(s) should be selected early in the planning process, given their subsequent impact on room / building design and hygiene strategies.

Angiography systems

Traditionally associated with real-time 2D X-rays taken during surgery. Angio systems also enable fluoroscopy in real time – typically for catheter-based applications. 3D scans are generally limited by the detector size, and are valuable in confirming the correct placement of screws in orthopedic cases and providing guidance in needle placement for tumor ablation. The evolution of 3D and 4D (real-time 3D) functionality of these C-arms now enables new and enhanced ways of examining and treating patients.

CT (computed tomography)

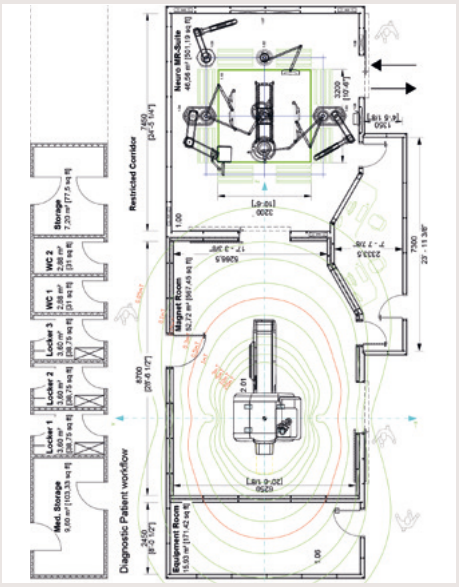
Often are used to provide an extremely fast overview of the patient's condition in trauma cases. CT scans furnish high-resolution details of hard structures (bones) in addition to the vascular system when used with contrast media. Typical uses include full-body scans in traumatology; fractures; bleeding or occlusions in vessels; and for the initial detection of tumors. CT scans also are playing an increasing role in intraoperative documentation and preoperative treatment planning.

MRI (magnetic resonance imaging)

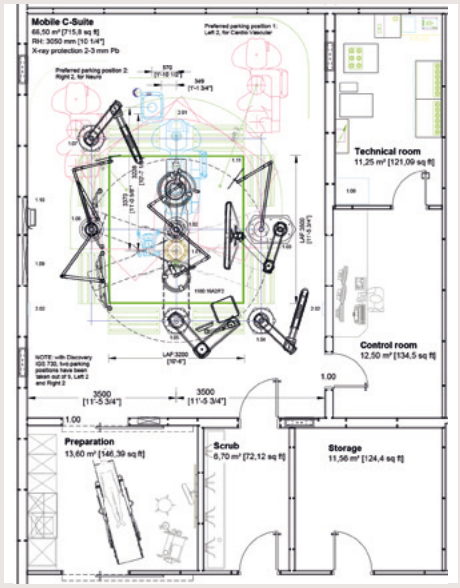
Designed to provide superior visualization of soft tissues such as organs, nerves, and cartilaginous structures at the cellular level. Also detects areas of inflammation. MRI, coupled with CT, optimizes real-time diagnostics enabling faster decisions which also can involve angio. MRI equipment requires careful planning to ensure effective integration into the surgical environment.

Planning examples – imaging systems

Single-modality setup:
MRI with connected neuronavigation OR

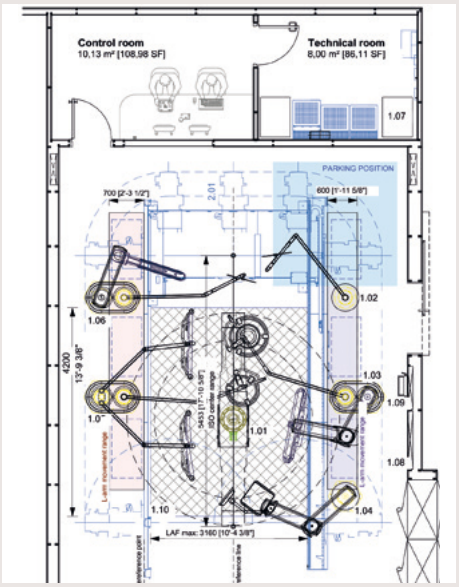


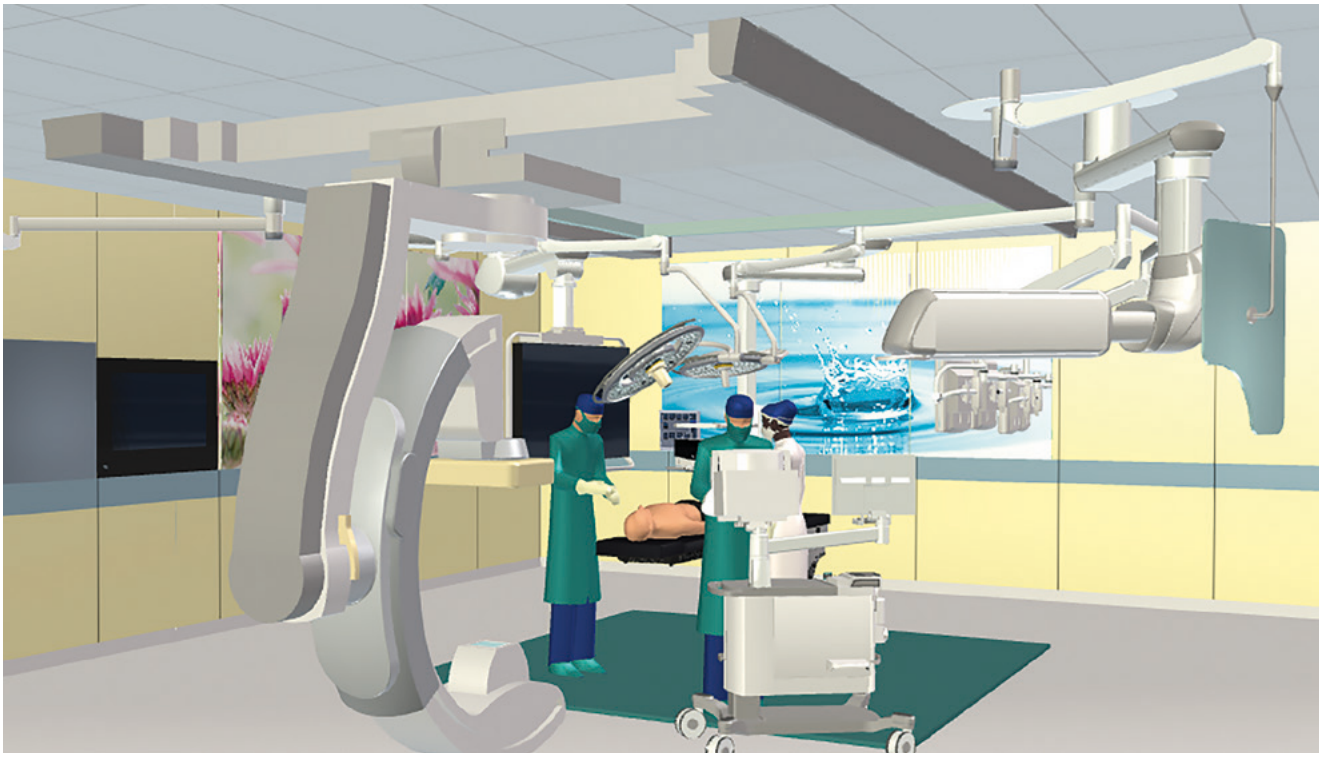
Single-modality setup:
Floor-mounted angiography system



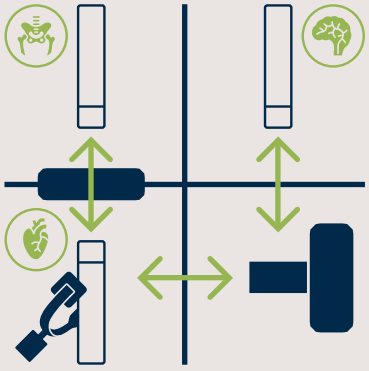
Planning examples – imaging systems

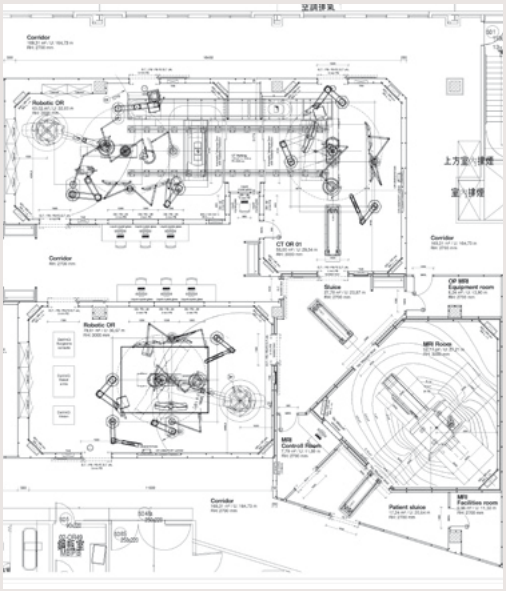
Single-modality setup:
Ceiling-mounted angiography system

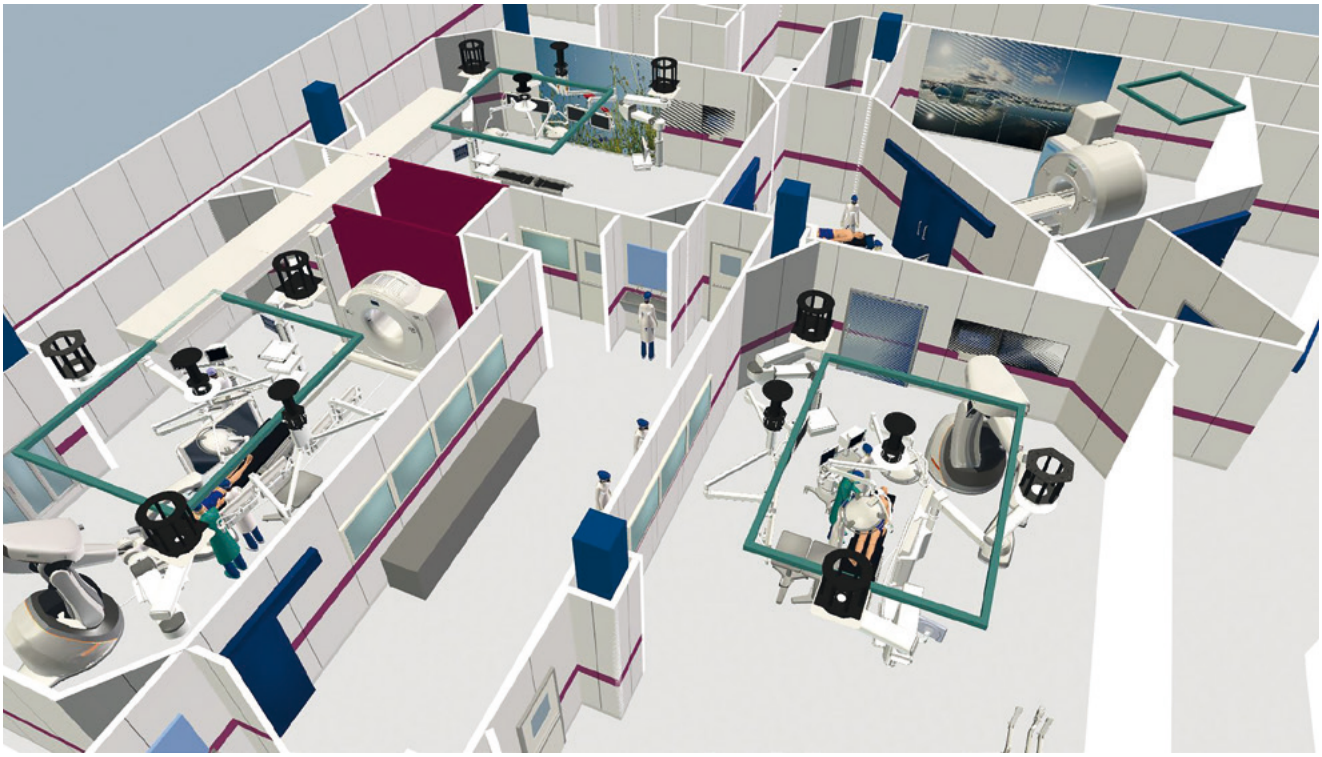




Multi-modality setup:
Angiography, sliding gantry CT and MRI







Evaluating surgical table requirements

for image-guided surgeries

For most hospitals, Hybrid OR utilization will continue to change over time, especially as the frequency and complexity of minimally invasive procedures increase over a wider range of specialties.

For this reason, many hospitals specify that surgical tables destined for the Hybrid OR incorporate two or more interchangeable carbon fiber and universal table tops that can be quickly configured to accommodate a wide range of surgical disciplines and procedures. This becomes necessary to keep the Hybrid OR fully scheduled and profitable even when only a portion of their current workflow is dedicated to image-guided interventions.

At the same time, tables are expected to be seamlessly synchronized with leading imaging systems to eliminate any integration issues that could compromise imaging or table performance.

It's important to stress that mobile OR tables cannot be used because precise positioning and alignment between the table and imaging system is extremely difficult, if not impossible, to achieve. Some imaging robots even require that the OR table be installed on an exact reference point, as movements are aligned via software.

Additionally, fixed-column surgical tables eliminate the potential for collisions while giving surgeons superior concurrent access to the imaging device and patient.

Imaging OR table with radiolucent single-piece table top

Imaging OR table with segmented table top and radiolucent back plate

For surgeons, safe, ergonomic, and flexible patient positioning throughout the entire procedure is of paramount importance, given the range and complexity of surgeries that will be performed in the Hybrid OR. Additional considerations include:

- Ensuring effective hygiene and sterility
- Reducing downtime between procedures
- Providing effective radio-translucency in all areas of interest
- Accommodating a wide range of patient weights
- Permitting the safe and rapid transport / transfer of patients within the OR environment (OR table to MRI) as well as in and out of the surgical suite with either no or minimal need for repositioning

In many cases, fixed-column tables with specially designed table tops make it possible to have a risk-reducing single patient transfer from initial admittance in the ER through the Hybrid or traditional OR and ICU.

Imaging OR table in low position for ergonomic spine access

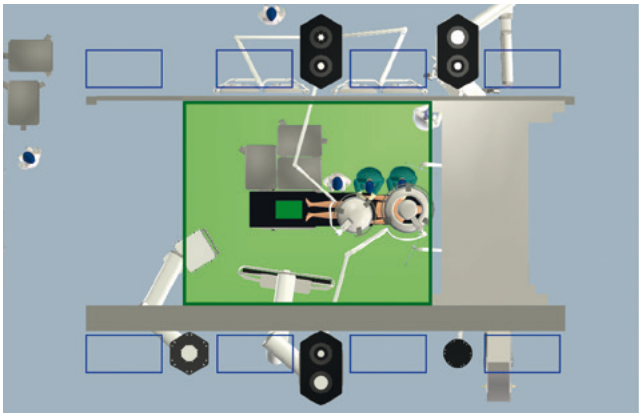
Patient transfer to MRI, CT or for intrahospital transport from emergency department or to ICU

Ensuring effective hygiene and safety

By design, the Hybrid OR must physically accommodate a diverse array of equipment as well as an expanded number of staff members who must work in close collaboration to meet all surgical, imaging, and OR integration requirements in a completely safe and hygienic environment.

Room design and equipment selection have a significant impact on the clinical staff's ability to prevent contamination and the risk of infections while ensuring sterility throughout each and every surgical workflow. At the same time, effective planning should minimize unnecessary staff movement while creating strict protocols to eliminate excessive traffic (e. g., students) that could compromise hygiene. Key imperatives include:

- Keeping the floor clear of obstacles by suspending as many components as possible from the ceiling
- Implementing proper air conditioning and air flow concepts
- Orchestrating workflow that accounts for patient, staff, movable equipment, and sterile goods
- Minimizing patient repositioning and enabling safe and rapid transfers along the treatment path
- Establishing room management strategies that support effective workflows
- Labeling the floor to help each staff member identify the sterile area around the table



Sterile working area around the imaging OR table

Floor marking indicating the sterile working area

Enhancing usability and ergonomics

The need to accommodate a diverse set of clinicians (e. g., radiologists and surgeons) and the unique requirements of multiple specialties in a single setup necessitates a Phase 1 emphasis on usability and ergonomic factors.

Equipment placement must be flexible enough to accommodate the increased number of people in the OR and their need for an unimpeded view of real-time or stored imaging data without compromising workflow efficiencies. Cardiac procedures often require a dedicated work space for a perfusionist and a heart-lung machine.

Neurosurgery often requires the help of microscopes and navigation systems. The anesthetist may need additional flexibility in positioning. The planning team is better equipped to determine the most advantageous placement of ceiling supply units, OR lights, and the OR integration system by answering these questions:

- What are the unique needs for each distinct function in the OR?
- What type of equipment needs to be readily accessible to each staff member?
- What kinds of images need to be displayed and who needs comfortable visual access to them?
- How will staff be able to effectively operate or monitor multiple devices simultaneously with minimal training?
- How can the room be designed to support effective collaboration among clinicians and support staff?

Envisioning proposed room layouts in three dimensions

The diverse group of stakeholders who participate early in the planning process are typically challenged to envision the relationship of the Hybrid OR's footprint to the installed array of equipment that enables image-guided, interventional, and traditional surgical procedures.

Today, available vendor-specific software generates life-like 3D renderings of the proposed room design populated with staff and equipment selections that provide an accurate visualization to support ongoing decision-making throughout the planning process. 3D software support is especially helpful early in the evaluation stage to help visualize avoidable conflicts (collisions) and workflow optimization opportunities while verifying that proper hygienic measures have been incorporated into the proposed room design.

Phase 2 considerations

– budgeting and planning

Many hospitals have the ability to access historical financial data to guide their calculations for funding a traditional OR. Administrators can expect to spend an additional 70% to 90% of those costs to design and commission a Hybrid OR that incorporates imaging equipment, integration software, and high-resolution monitors.

These calculations also reflect the additional initial planning time that's required to ensure that all systems and platforms coexist in harmony to avoid costly remediation prior to commissioning. Budgets should also take into account all safety, hygienic, usability, and ergonomic considerations outlined in Phase 1.

It has been found that a number of hospitals allocate a large portion of the cost differential associated with the imaging system to multiple cost centers, given the Hybrid OR's flexibility to schedule non-surgical radiology examinations. Budget approvals for a Hybrid OR have increasingly been justified on this basis as well as on the shared-use aspect of the room among multiple disciplines.

Orchestrating multiple interfaces

The Hybrid suite can be viewed as a composition of diverse components that need to seamlessly work as a singular functional unit to ensure smooth workflows and clinical success.

Complicating the issue is the need to accommodate a wide range of patient positioning across multiple surgical disciplines that impacts the placement of the surgical table, imaging system, lights, ceiling service units, and monitors. Equipment can be rendered useless for specific procedures and surgeon preferences if collisions occur that prevent the required or desired positioning of these critical components.

Planners are tasked with the responsibility to ensure the Hybrid OR quickly adapts to the needs and preferences of each surgical discipline. Unnecessary complexity reduces usability. Understanding the relationship among people, equipment and information flow is vital to help planners create a safe and ergonomic environment, regardless of what type of surgery is being performed.

Sequencing the planning process

Interactions among multiple installed systems and components in the Hybrid OR require a systematic approach to planning that organizes decision-making in a logical step-by-step manner.

Evaluate choice of wall systems – traditional stick-built versus the flexibility of modular construction that can reduce the time and cost of change orders prior to commissioning as well as for future room modifications and technology upgrades

Select preferred imaging system(s) (angio, CT, MRI) and ancillary equipment based on intended room use

Allocate room furniture; determine workflow patterns between primary suite and adjacent rooms

Select a Hybrid OR surgical table with multiple interchangeable universal and carbon fiber table tops to accommodate a wide range of patient positioning requirements and the ergonomic-influenced comfort of the surgical team

Size and integrate the air conditioning system to ensure effective laminar flow and sterile working conditions under all circumstances

Select all ceiling-mounted equipment (surgical lights, ceiling supply units) and determine proper positioning to ensure effective interactivity among all devices

Choose and position ambient room lighting and placement of controls

Evaluate available integration systems to simplify and ensure effective image handling inside the OR; centralize documentation; enable communication with people outside of the room; and control equipment functions

Select anesthesia system

Determine need for additional equipment (ultrasound, heart-lung machine, injector, robotics, microscopes, navigation system) based on room utilization

Formulate integration strategy with the hospital's IT infrastructure

Managing project risks

The inherent complexity of the Hybrid OR introduces a level of project management risk that can only be mitigated by the participation and interactions of knowledgeable stakeholders and consultants. Common issues include workflow interruptions; missing software and hardware interfaces; patient positioning challenges; and collisions due to misaligned equipment installation. Hospitals that have successfully implemented their first Hybrid ORs have taken the following steps to avoid these potential problems:

- Involve experienced consultants to help ensure there are no oversights in the planning process
- Team with solution providers rather than equipment-focused vendors to better manage interface-related issues among various systems and platforms in planning, installation, and service that can delay project completion or limit its usability.
- Visualize the Hybrid OR utilizing available 3D tools that facilitate discussions among stakeholders while helping identify potential problems that otherwise would not be readily apparent to members of the planning team


Discovery

Phase 3 considerations
– installation and commissioning

The duration of any Hybrid OR project strongly suggests the need to have continuity of involvement by stakeholders who participated in Phase 1 and Phase 2 and were intimately involved in making the upfront planning decisions. At this point in the process, successful installation relies heavily on confirming the room configuration, equipment specifications, and exact placement of all Hybrid OR technology.

Scrutinizing drawings and equipment configurations

Detailed 3D visualization and DWG drawings should be completed for the new Hybrid OR and cross-checked and approved by each equipment supplier to help avoid unanticipated installation issues. Special attention should be paid to the placement and number of outlets for gas, power and data.

In traditional stick-built construction, last-minute alterations can result in expensive change orders and the need to replace large sections of lead-lined sheetrock. For this reason, many hospitals have gravitated to modular stainless steel wall panels that facilitate any required modifications without impacting installation scheduling.

Meeting project deadlines

Limiting the number of suppliers involved in supplying equipment and technology has shown to minimize the potential for experiencing connectivity and installation issues that delay commissioning.

Regardless of the number of suppliers, a mandatory installation schedule is key to ensuring that everyone and everything is on site when required to speed commissioning. In addition, in-depth discussion should take place between project leaders and suppliers to establish best practices in determining the optimal sequence of installation steps and areas of concern where collaboration is required among multiple vendors and specialists to successfully interface hardware and software.

Creating an effective training regimen

Even if most workflows will be maintained, the nature of image-guided surgery and OR integration introduces new elements into the surgical team's daily interactions that can result in a degree of unwelcome uncertainty immediately following go-live.

An ample training plan can reduce adaptation time, increase staff confidence, satisfy regulatory requirements, and meet internal performance standards. Considerations include:

- What is the makeup of the surgical team whose members will be working in the new Hybrid suite (e.g., factor in a learning curve for radiologists and other surgical staff members who have been accustomed to a traditional examination table instead of an interchangeable table top)?
- What are the assigned tasks for each individual – especially support staff?
- How will collaboration differ in the new setup?
- What new equipment will require special user training?
- What kind of application training is required – especially where there is interactivity between systems (OR table, imaging equipment)?
- How will the training program be documented?

It is also recommended that key users are identified to facilitate knowledge transfer to all current and future staff members.

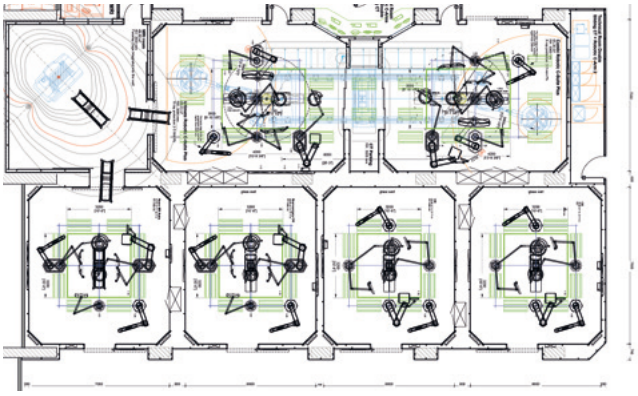
Key learnings and conclusions

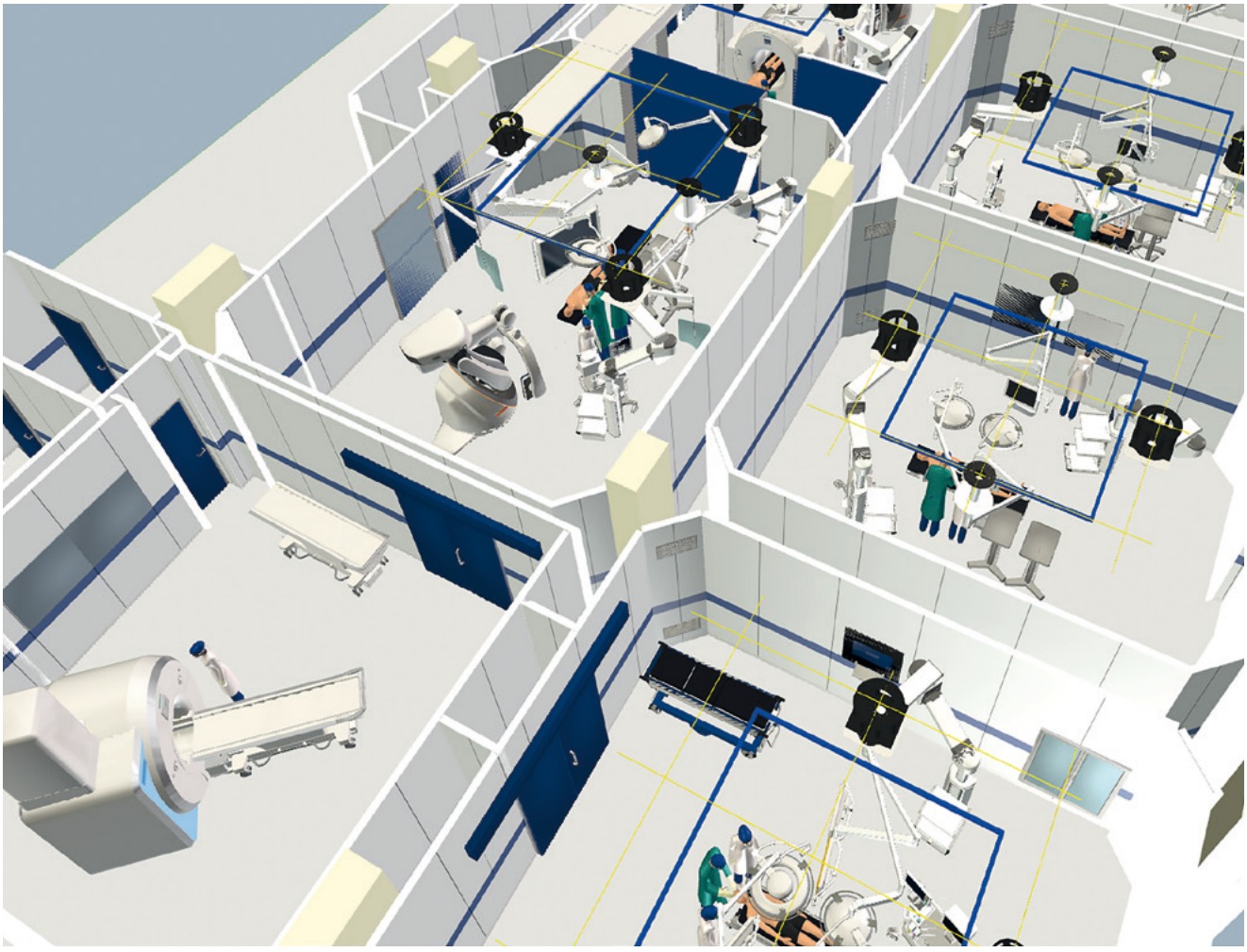
- The planning and commissioning of a Hybrid OR require the active participation of a diverse group of stakeholders and consultants whose decisions contribute to the effective and seamless interaction among all selected hardware and software platforms that enable image-guided, interventional and traditional surgeries.
- The reliance on a limited number of solution-oriented vendors can lower the risk of failure, prevent compromised performance, and eliminate delays by reducing the inherent inefficiencies of multiple service and maintenance interfaces.
- Hospitals should allow sufficient time to complete initial analysis and evaluation plus budgeting and planning prior to preparing the tender that requires the establishment of clear targets to help ensure project success. Adequate lead times must also be allocated for installation and commissioning to avoid problems and mistakes that often occur when unrealistic deadlines are trying to be met.
- 3D modeling of the Hybrid OR, including the placement of equipment and staff (to scale), helps stakeholders visualize workflows and relative positioning of multiple elements in the hybrid environment.
- An increasing number of hospitals are installing multiple modalities of imaging systems (angio, CT, MRI) to handle intraoperative imaging for planning, guidance, and final check-up without having to reposition or transport the patient.
- Budgeting is more complex than allocating funds for a traditional OR, requiring the proper analysis and evaluation of clinical needs and workflows; building-related aspects; imaging modalities; OR table systems; hygienic and safety considerations; and usability and ergonomic factors.
- The relative placement of the OR table and imaging system with the room's ceiling supply unit and surgical lighting system deserves particular attention during the planning process to ensure ergonomic and collision-free utilization across multiple disciplines and procedures.
- User and application training is fundamental in reducing room adaptation time and increasing staff confidence while satisfying regulatory requirements and meeting internal performance standards.

Examples of Hybrid ORs in use

Multi-modality setup – angiography / MRI / CT

Location:	Turkey, Istanbul
Description:	Multi-room setup combining intra-operative imaging using angiography, sliding gantry CT and MRI
Disciplines:	Neurosurgery, cardiac surgery, vascular surgery, thoracic surgery, orthopedic surgery, trauma surgery, urology



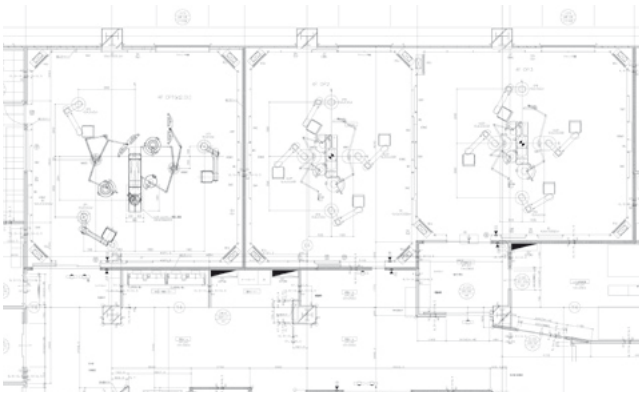


Multi-modality setup – angiography / CT

Location: Taiwan, Changhua
Description: Double-room setup using angiography in one OR and sharing a sliding gantry CT in both ORs
Disciplines: Neurosurgery, cardiac surgery, vascular surgery

Single-modality setup – angiography

Location: Japan, Okayama
Description: Single-room setup with ceiling-mounted angiography system
Disciplines: Cardiac surgery, vascular surgery



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