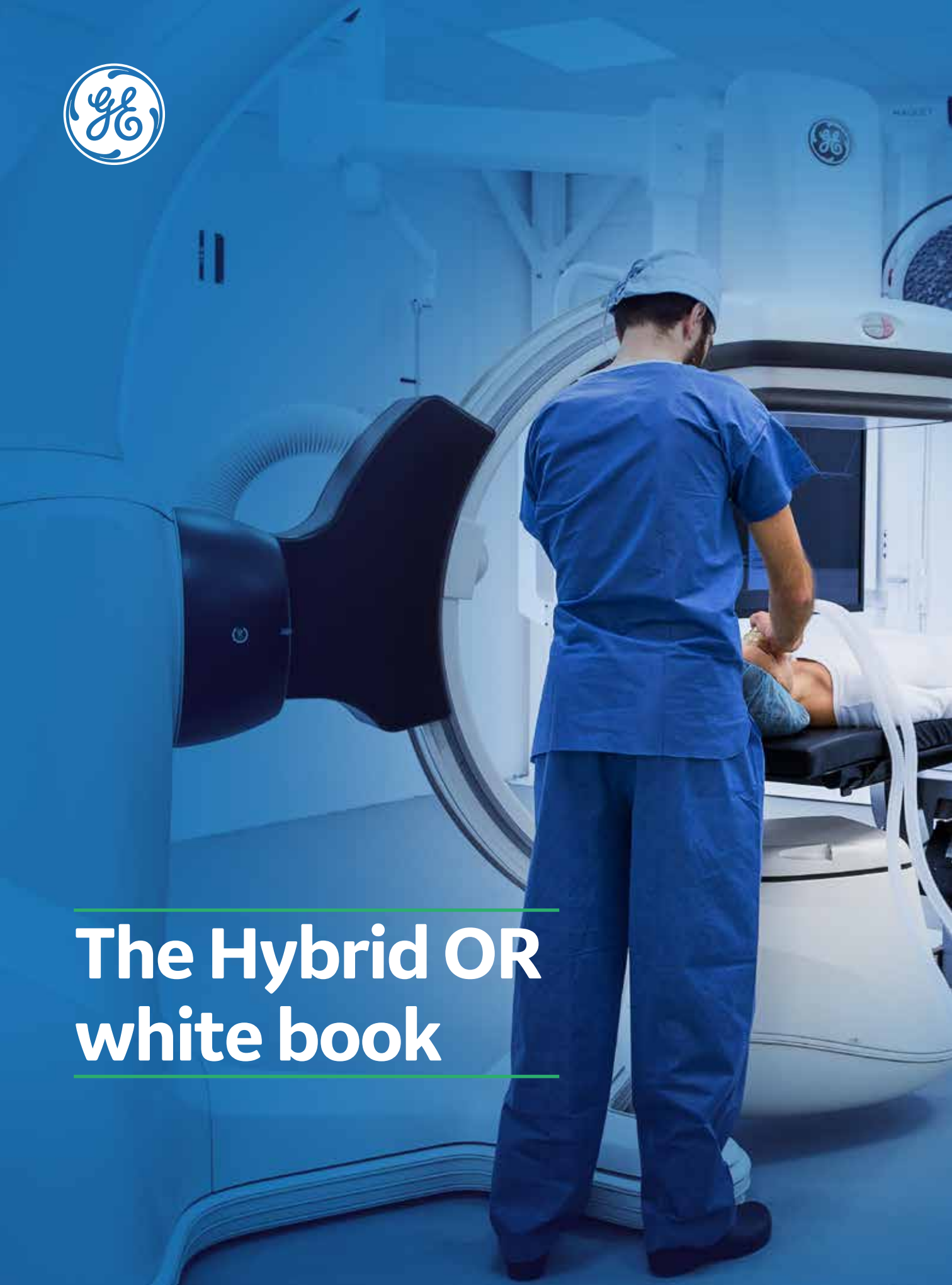


The Hybrid OR white book

Introduction

The explosion in image-guided minimally invasive therapies marks a paradigm shift in the surgical world. Success in this new world requires addressing new challenges:

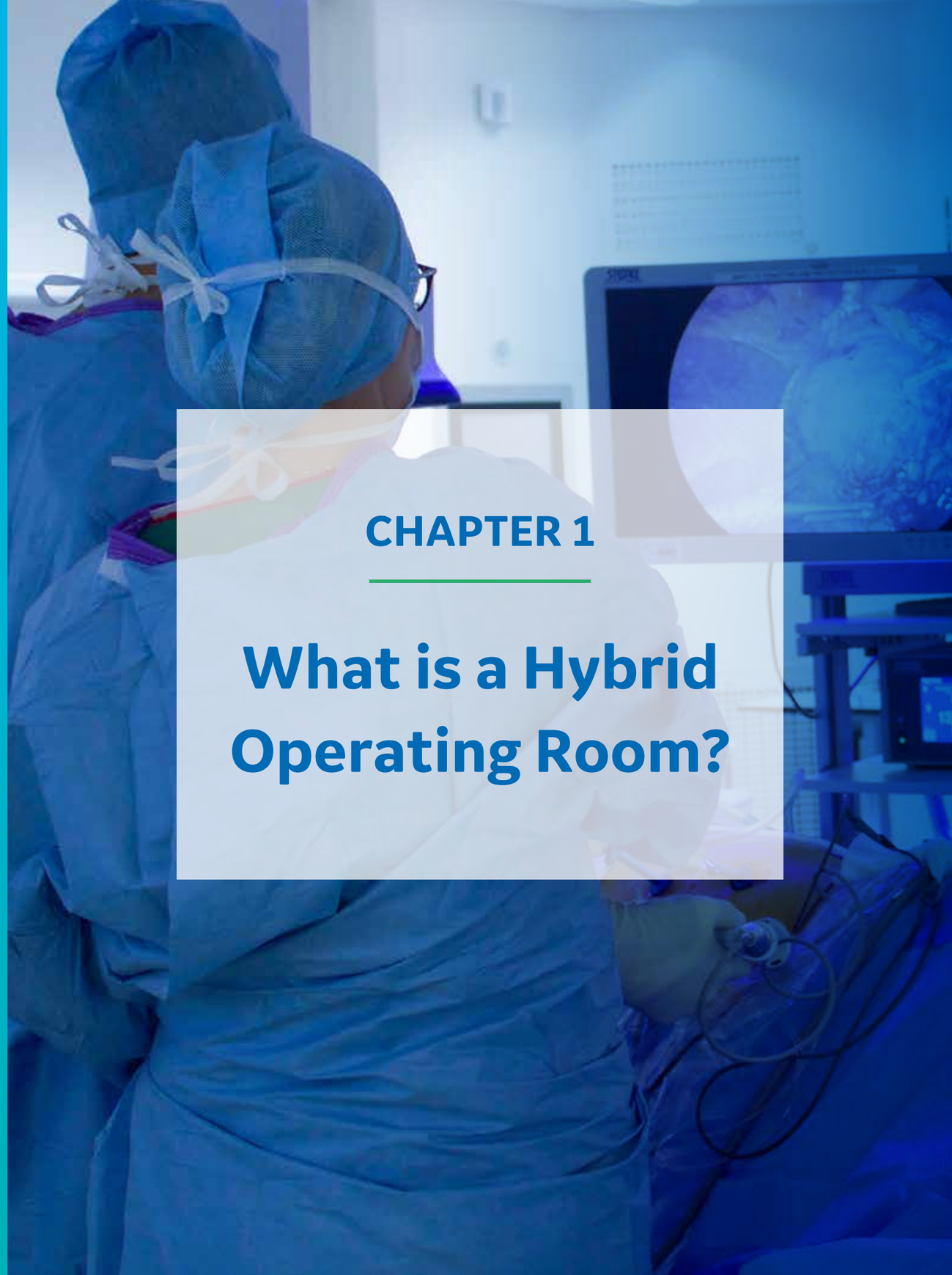
- Multidisciplinary collaboration to perform complex, patient-tailored procedures.
- Multidisciplinary usage to satisfy diverse imaging and workflow requirement.

And that, in turn, requires one sophisticated suite that provides advanced imaging and high flexibility for precise, image-guided therapies while maximizing OR utilization.

The intent of this book is to guide you in your Hybrid OR project journey, share with you some advices and key points to consider. Each project is different and needs to fit your specific needs and requirements. This book shall give some concrete elements to help you drive this initiative.

Enter GE Healthcare's multidisciplinary, hybrid operating suite. Offering a new standard of care for the OR of today and the future.

Content



CHAPTER 1

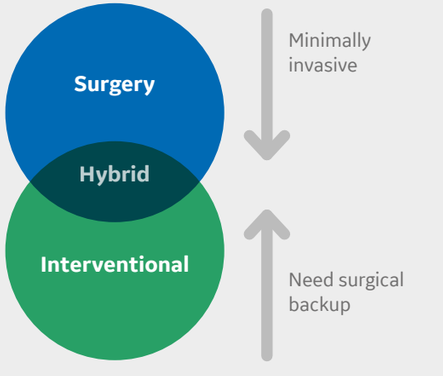
What is a Hybrid Operating Room?

HOR definitions

In the past two decades, Hybrid Operating Rooms have emerged as the new standard of care for cardiovascular minimally invasive surgeries, and they are now being considered for many other specialties in the hospital.

What is a hybrid operating room (HOR)?

The definition of an HOR is not set in stone, it is evolving with time, but the most commonly accepted definition is an operating room environment equipped with a high-end X-ray imaging equipment, such as the one you would normally find in the interventional radiology or cardiology departments. It represents the convergence of two worlds: surgery on one side, which is becoming more and more minimally invasive and therefore needs imaging guidance to support complex interventions - and interventional on the other side, which is addressing more and more complex interventions, and therefore is moving towards a surgical environment, in order to enable a surgical back up.



Procedures performed in an HOR vary greatly from one clinical site to another, as well as from early-stage HORs compared to more recently room creations. They can be:

- Truly hybrid procedures: combining one interventional procedure with one open surgical procedure at the same time, or one after the other.
- Interventional or minimally invasive procedures, where an open surgical back-up could be needed.
- A mix of surgical procedures on one side (some of which are open and do not require much imaging guidance), and interventional procedures on the other side.

The hybrid OR has therefore become a concept, which is closely related to a flexible environment, allowing diverse interventions and surgeries to be performed, with imaging guidance solutions for multiple clinical specialties.

The advent of Hybrid Operating Rooms

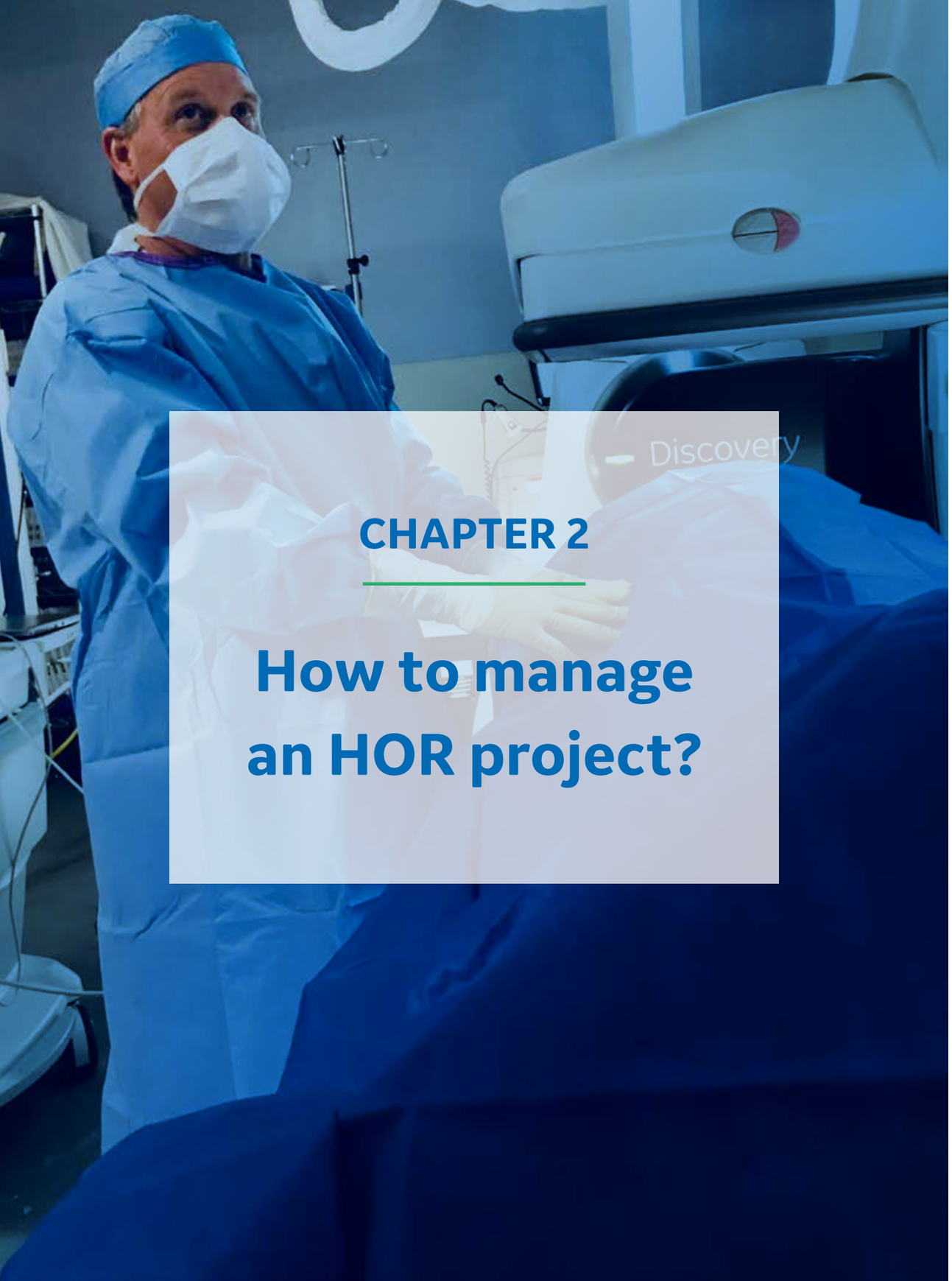
The need for hybrid operating rooms has emerged from various healthcare macro trends. Population trends first, with ageing population leading to increased demands for minimally invasive options for patients who were not open surgery candidates. Other growing risks factors such as obesity, hypertension or diabetes have also pushed healthcare providers and the industry to work hand-in-hand to develop options to address unmet needs, such as with the development of heart valves implanted percutaneously in high-risk patients. The prevalence of cardiovascular diseases, such as aortic aneurysms, has increased, and led to the development of aortic specialized centers, in order to treat patients, who were at risk of fatal complication, such as aneurysm rupture. At the same time, more and more patients were diagnosed with combined cardiovascular diseases, such as aortic aneurysms and aortic valve stenosis, and needed combined treatment procedures. EVAR (Endovascular Aortic Aneurysm Repair) and TAVI (Transcatheter Aortic Valve Implantation) were therefore the main drivers for the advent of Hybrid Operating Rooms in the 2000's.

Clinical specialties involved

The trend of hybrid OR started with the advent of two minimally invasive surgeries in the cardiovascular space: TAVR (Percutaneous Valve Repairs) or TAVI (Transcatheter Aortic Valve Implantation), and EVAR (EndoVascular Aortic aneurysm Repair). These two interventions along with the increasing endovascular peripheral interventions versus surgical bypass pushed the development of dedicated cardiovascular HOR. Indeed, the complexity of valve or endograft implantations, guided by live angiographic imaging, raised the need to be able to convert to open surgery as a back-up during the procedure procedure, and thus to be in a OR environment.

In the past years, many other specialties have developed an increasing interest for intra-operative 3D imaging in the OR to increase technical success for minimally invasive surgeries. First, complex neurospine interventions, such as spinal fusion, pushed orthopedic and neurosurgeons towards the HOR. Trauma centers also equipped themselves with HOR, as they needed large ORs, where various clinical specialties could be involved, and different types of imaging modalities were required. More recently, other specialties, such as thoracic surgery, urology or gastroenterology, have also emerged as new stakeholders in the HOR. It is safe to bet that in the future, this trend will continue to grow, opening HORs for virtually all specialties in the hospital.

Nowadays, new hybrid ORs are commonly shared ORs, as opposed to the first wave of HORs, which were often dedicated to cardiovascular specialists with a high volume of minimally invasive procedures. The use of one HOR shared between different specialties drives the constraints on the room, in terms of equipment and workflows. It highlights the need of a good project management to define the needs and requirements of the HOR, and the importance of room planning to satisfy all users. Last but not least, an HOR is a costly investment for the hospital, and the return on investment is not granted, unless the room utilization can be maximized thanks to a flexible environment.



CHAPTER 2

How to manage an HOR project?

In order to manage an HOR project,
some steps must be defined to help establish the entire timeline of the project and its budget.

Discover the Hybrid Suite

Once A Hybrid Suite becomes of interest for a hospital, a key step is to start defining the procedure mix that might be for it.

This step usually takes a long time from six months to several years and mainly includes:

- Identification of stakeholders and development of a common understanding of a Hybrid Room.
- Get closer to other hospitals to get feedbacks on their experiences with a Hybrid Operating Room.

Main reasons to invest in such project can be categorized as follow[1,2].

- Improved patient care
- Enhanced facility reputation with better clinical outcomes
- Optimized workflow
- Economic benefits

In the last chapter of this book, we will develop in detail these 4 reasons to invest in a Hybrid Operating Room and share some concrete outcomes.

Define the business case

To evaluate the feasibility of the project, hospital management investigates the rational for establishing the Hybrid Suite. For that, the amount of investment required is calculated and is compared against the expected returns.

This step focuses mainly on the analysis and discussion in order to define procedure mix, approve Business case, secure financing and take Go / No-Go decision. It can take several months to do so.

Involve the stakeholders and define project leaders

This step remains very important and crucial to establish a Hybrid Suite in a hospital. In order to avoid costly errors and achieve a successful result, all stakeholders must be involved as early as possible in the process to make sure that all considerations are taken into account.

Stakeholders generally fall into the following groups:

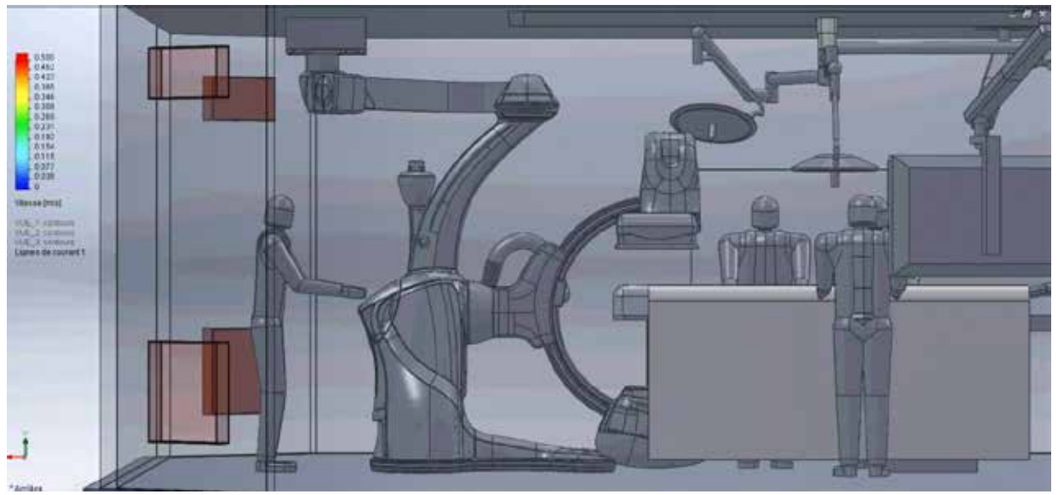
a. Facility management team
b. Clinical Staff (Surgeons, Radiologists, Anesthesiologists, Nurses,...)
c. Biomedical engineers
d. Radiopotection experts
e. Hygien department
f. Financial department
g. IT department
h. Civil works department (design, architect, specialized civil works companies, Design and controls offices...)
i. 3rd party providers (anestesia boom, surgery boom, light providers...)

To coordinate the different stakeholders, a project leader along with a clinical focal point shall clearly be identified early on to keep the focus and facilitate the decisions making process.

The project leader shall focus more on the technical requirements whereas the clinical focal point shall make sure decisions taken will meet expected clinical outcomes.

Define your requirements

Stakeholders need to discuss their requirements in order to make key decisions about the equipments required.
Depending on when stakeholders meet, this step can take from three to six months.
Below some key requirements to consider.



1. Use of the room

Keep in mind that there is no single solution, and the best solution depends first on who will be using the room, as there can be a variety of applications and set-up. Indeed, different users have different needs, which in turn will favor one solution over another. For instance, based on the procedures which will be performed in the room, different patient positions will be needed, influencing the choice of the patient table. The complexity of the procedures and case mix will push towards one imaging solution rather than another. Therefore, one of the first steps is to list the potential users of the room, define the procedures that will be performed in the HOR, and work on the exact requirements in terms of patient positioning, staff positioning, anesthesia positioning, imaging and surgical equipments, etc. It is good practice to try to imagine future usages of the room as well, especially if the current case mix identified does not fill completely the room operational capacity.

2. Hygiene requirements

Requirements in terms of hygiene in the HOR are one of the main factors to take into account from the beginning. Indeed, depending on country or hospital regulations on hygiene levels needed for specific interventions (such as ISO 7 or ISO 5 cleanroom standard compliance), some solutions are more suited than others. For ISO 5 certifications, laminar airflows installed above the patient table are nowadays the most common and are nowadays a very common and effective solution. It can be easier to install these airflows when the ceiling is free of rails, orienting towards a floor-based or mobile imaging system to avoid interference between the airflow and rails.

3. Radiation protection

Radiation protection should be an important part of the discussions and training as well, as for any X-Ray system. And all the more for an HOR, since many of

the users are not familiar with X-Rays unlike radiologists who have been using such equipment for decades. Indeed, anesthesia staff, nurses and surgeons themselves might underestimate the importance of radiation protection, or not be familiar with the main rules to decrease radiation. Nowadays, imaging equipments have been rationalized in terms of dose levels, and there are many solutions to tremendously decrease the level of radiation in the room. Dose awareness should be emphasized among the staff, in order to ensure safety for the patient and all the users.

4. Imaging requirements

Imaging requirements vary greatly from one user to another. Some surgeons will only need the X-Ray equipment to control the deployment or implantation of a device at the end of the case, while others will use it continuously along the procedure to guide the navigation of some devices. For some procedures, 2D guidance will suffice, whereas for other procedures, users will rely on 3D imaging to allow a more precise guidance and assessment. Thus, there are various imaging solutions corresponding to each of these scenarios, varying from a premium mobile C-arm equipment to a fixed angiography system or to a high-end mobile robotic system.

5. Clinical Training

Training on the HOR, including the new imaging equipment, but also patient workflows in and out of the room, is a key aspect to consider ensuring the success of a newly installed HOR. Indeed, since HORs are used by various department and staff, some of which is often rotating, and not too often using the advanced equipment, emphasis should be put on providing ample initial and continuous training. Finding a few clinical and technical champions, who are references for the remaining staff. This is also a good practice, which has demonstrated benefits in many situations. Before opening the room, it is also recommended to do a few “dry-run” sessions, in order to simulate workflows and use of the room and identify any bottleneck or additional training needs. The imaging equipment manufacturer usually provides at least two weeks of initial training to ensure good adoption of the HOR, and increase staff confidence.

6. Maintenance and continuous technical support of your Imaging system

Maximizing your Hybrid OR investment also means having the right maintenance level and service efficiency you expect. Thus, it is critical to select the right provider with the right offering ensuring the safety, reliability of your system but also minimizing unplanned downtime thanks to proactive monitoring.

Design and Build the room

1. Find the best location

To choose the best location, you have to face up technical considerations and construction work according to your access priorities such as: emergency rooms, intensive care, pharmacy, etc.

Usually, we have two choices: The radiology or cardiology department or OR facilities. Each location has its pros and cons.

For example:

OR facilities:

Sterile conditions and surgical infrastructure (equipment, anesthesia, lighting) are available. But on the other hand, interventional infrastructure needs to be created or supplies need to be moved and interventional team needs to move to surgical department.

Interventional facilities:

Interventional team is available and interventional infrastructure (equipment, supplies) is available but on the other hand sterile conditions need to be created, surgical team needs to move to another department, surgical infrastructure needs to be created or the patient needs to be moved to the surgical department if there is an emergency.

2. Design and build the room layout

Users, in partnership with the imaging system supplier, need to actively be involved in the room layout design so they project themselves in this new environment and anticipate their needs.

The need to discuss workflow and room design might take few months. It can be accelerated by using 3D simulation tools. As a result of this step, room is designed according to stakeholder requirements and equipment is ordered from suppliers.

The civil works can then start ensuring a prepared environment when the system is delivered and ready to install.

Organize for the Hybrid Suite and Implement trainings

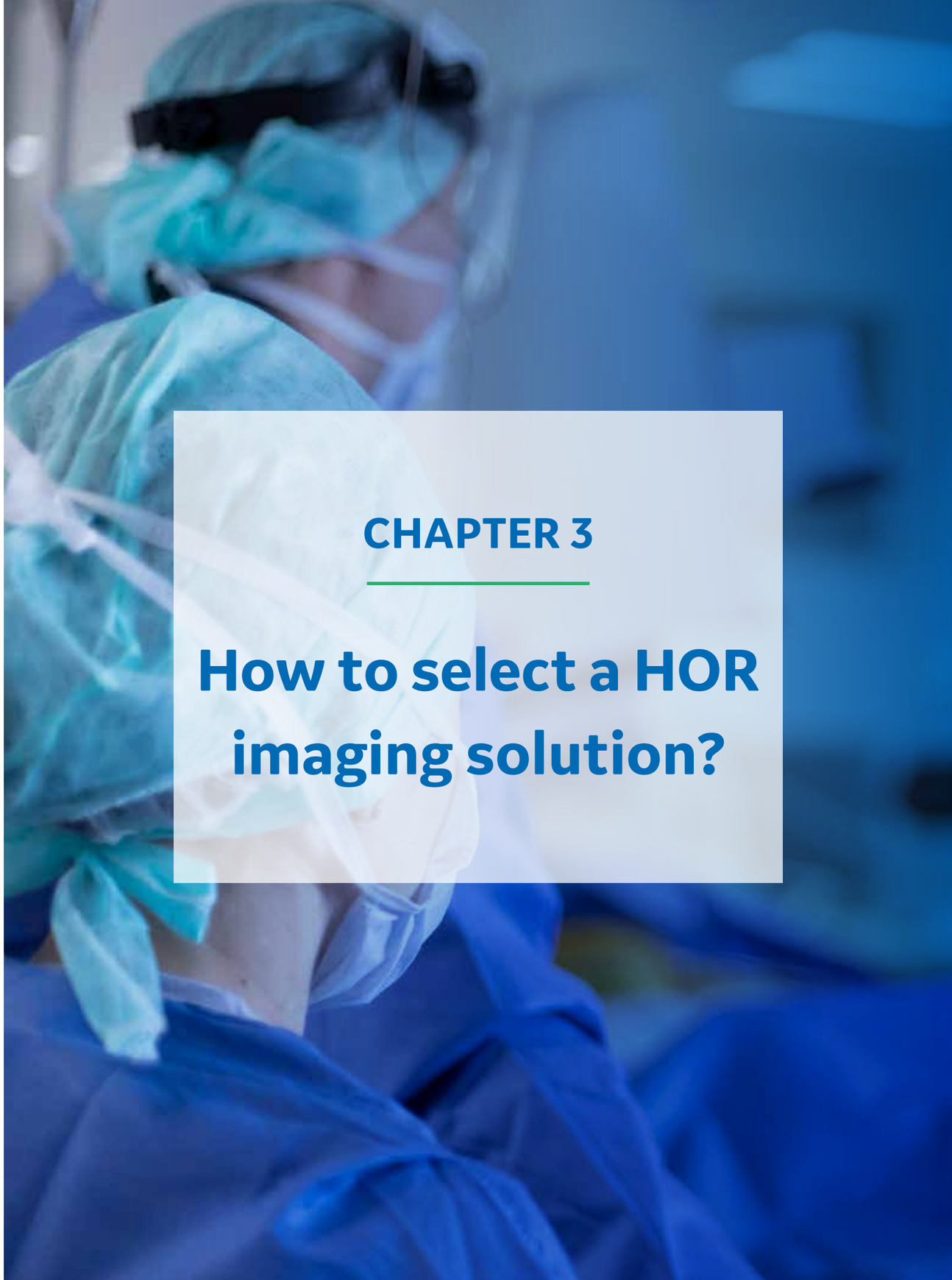
The organization should prepare and train for the Hybrid Suite to guarantee its successful utilization. Also, by setting up a process for acquiring patients and referrals to the new facility.

To use the Hybrid Suite properly, staff must be trained and be comfortable with the suite. Indeed, with well-trained staff, we will have a better use of the suite and therefore a good preparation to receive the first patients. There are mainly 2 types of trainings to consider: clinical trainings and Dose awareness trainings.

As part of clinical trainings GE Healthcare offers a full range of possibilities to meet your individual training needs.

Courses can be followed in a classroom setting or via e-learning online. Demonstrations can be given on-site in your own Hybrid Suite or off-site in our continuing education center in Buc or in another location.

Also, we have set up a training program that will allow your people to easily learn difficult topics and advance their personal development and performance. Though our GE cares platform, your staff members will be able to reach out our clinical experts and integrate a community of experts sharing their expertise and experience through articles and webinars.



CHAPTER 3

How to select a HOR imaging solution?

The different X ray imaging systems

Different type of HOR imaging systems can be envisioned. For each of them you will find in the table below the main advantages and constraints. The optimal solutions that GE proposes are The Discovery™ IGS 7 OR and the Discovery™ IGS 7 For Hybrid OR-GE OR Table. Both solutions benefit from a Robotic Gantry, rails free.

	Floor Mounted	Ceiling Mounted	Robotic Gantry, rails free
+	• Suspension free design removing a source of contamination and helping to meet ISO 5 classification • No Gantry overhead rails, enabling to position monitors as required, for comfortable viewing without straining	• Head to toe imaging • Parking positions	• Head to toe imaging • Excellent patient access for all procedures • Precise and predictable motions • Back-out trajectories and customizable parking positions • Suspension free design removing a source of contamination and helping to meet ISO 5 classification
-	• Cannot be installed if floor load capacity requirements are not met • Head to toe imaging requiring table motions	• Rails above the patient table can increase contamination and thus prevent from consistently meeting stringent hygiene requirements in the entire OR • Heavy requirements on ceiling structure and ceiling height • Some systems can be limited in their movement, and teams may need to move the patient and the staff to adapt	• Cannot be installed if floor load capacity requirements are not met

Excellent patient access for all procedures

Head
Complete head and neck access with gantry positioned on left or right.

Groin
Femoral access with easy head-to-groin coverage with offset C-arm.

Left
Full left side access with gantry positioning on the right.

Anesthesiologist Access
With the offset C-arm, the anesthesiologist can work comfortably at the patient's head

The different patient support options

1. GE OR table with the Discovery™ IGS 7 For Hybrid OR

The GE OR table is fully integrated with the X ray system, and its long free-floating tabletop (333 cm) with power-assisted motion facilitates panning for heavy patients. It has a longitudinal travel of up to 170 cm, and accommodates long catheters.

The OR Table with covers and tableside user interfaces is specifically designed to reach the IPX4 level.
Combined gantry and GE OR table movement enables you to image from head to toe.
This configuration is performed by Interventional cardiologists, Electrophysiologists, Interventional radiologists, vascular surgeons and or thoracic surgeons.

2. Maquet Magnus table[3] with The Discovery™ IGS 7 OR

The Discovery™ IGS 7 OR is fully integrated with the Maquet Magnus table, enabling advanced patient positioning and imaging such as intra-op cone-beam CT, to meet the requirements of diverse minimally invasive surgery and conventional open surgical procedures. The flexibility to use different tabletops allows you to expand into additional surgical procedures in cardiology, heart surgery, vascular surgery, neurosurgery, orthopedics and traumatology. The breakable tabletop enables complex patient positioning that can be required in surgery procedures.

This configuration is usually recommended when Cardiac surgeons and/ or neuro/spine/orthopedic surgeons will work in the HOR.

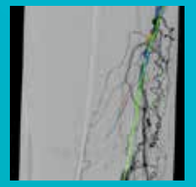
Advanced clinical solutions designed for specific clinical procedures

Depending on the complexity of the procedures performed, it might be key to invest in 3D advanced applications to aid the physicians planning the procedures, guiding him/ her during the procedure, and finally facilitating the assessment post-procedure.

Enter a new world of possibilities with our exclusive augmented reality solutions...

EVAR ASSIST 2[4]

EVAR ASSIST 2 consists of a dedicated planning application to perform and save key anatomical information and measurements for sizing, along with a dedicated image fusion application to provide 3D guidance during the procedure.

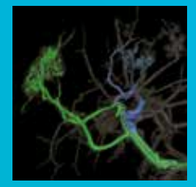


Vessel ASSIST[5]

Vessel ASSIST provides easy to use and accurate planning and guidance tools. For example, Vessel ASSIST enables you to create and edit a vessel centerline, trace through an occlusion, and fuse it on the live fluoroscopy with 2D/3D fusion.

Needle ASSIST[6]

With Needle ASSIST, you can perform complex percutaneous procedures in the angio room. It provides real-time visualisation of needle positions in the 3D space by automatically fusing CBCT data over live fluoroscopic images.

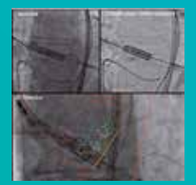


Liver ASSIST V.I.[7]

Liver ASSIST V.I. improves the sensitivity of tumor-feeding vessels identification to reach up to 97%[7abc]. With Virtual Injection, it simulates in real-time your injection before you treat. This real-time simulation helps you to define your injection points thus aiding injection strategy decision making.

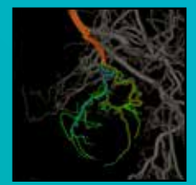
PCI ASSIST[8]

PCI ASSIST significantly helps to improve contrast and visibility without increasing dose[8a]. You can clearly see even small details to accurately position and deploy stents thanks to advanced stent visualisation softwares. It all adds up to more efficient PCI procedures.



Valve ASSIST 2[9]

Valve ASSIST 2 provides enhanced planning and real-time visualisation enabling you to position the valve and guide devices with precision. You can choose the appropriate x-ray projection with no use of contrast media and minimal radiation dose[9a].



Embo ASSIST[10]

Embo ASSIST with Virtual Injection, powered by Edison, is a 3D Visualization software solution designed to help clinicians simulate injections dynamically and thus perform embolization procedures with confidence.

CHAPTER 4

How to design and build the HOR?

1. Define the project leadership team

As mentioned previously, defining a project leader is key for success: He/ She will act as a real coordinator, facilitates the decision-making process and be the focal point for any external providers. He/ She will work hand in hand with the clinical focal point previously mentioned.
On the GE side, you will benefit from the expertise of a diverse and skilled team with:

- The Project Manager of Installation (PMI) that will support the technical project from pre-tender phase to handover of the room. He/ She will focus on your needs, proposes different room layouts, consider the third-party elements to install and anticipate risks. They are trained on project management and can benefit from a specific Interventional advanced training. They work with a European design center and are supported by a European Interventional project manager. They will work hand in hand with the Account manager and the Product Sales Specialist to ensure the success of your project.
- The Account Manager is your key GE commercial contact point and has an exhaustive view of GE Healthcare portfolio.
- The Product Sales Specialist is dedicated to Interventional products segment and is your key contact point for clinical aspects and product specific topics. He/ She will collaborate with the PMI to make sure your clinical requirements match the technical proposals GE will offer.

Whatever your scenario, GEHC will adapt to your needs. Either the room is clearly identified and GEHC will plan the room layout accordingly or you have different options for the room locations and our teams will propose different alternatives envisioning the patient and staff workflow. GEHC also has the capability* to take the responsibility for a turnkey project and coordinate all external suppliers so we remain your key interface.

2. Define Pre-Installation and Installation project steps

Study & Initial feasability	**Exchange with Users** (Participate in a surgical operation)	**Layouts proposals In 2D & 3D & Validation**	**Video management**	**Drawings for civil works and Kick off meeting**	**Civil works follow up**	**Installation Training and Handover**
Very early, it is key to consider constraints due to location, architecture, a specific environment. For example, if you have a heat production, a laboratory, a magnet room close by, you might face limitations to drill holes and perform the required civil works. Our PMI will check these aspects at that stage and provides advices and solutions.	A deep understanding of the habits of the clinical staff and their requirements is key. Thus the PMI along with the Account Manager and the Product Sales Specialist will spend time with the users to make sure the room layouts proposals will match the needs.	To help you better visualize the room layout, the GE team will simulate it in 3D. They can propose you to benefit from virtual reality technology so the clinical staff can immerse itself in the room and validate the proposed layout.	It is key to anticipate the video signals that the clinical staff expects to see displayed in the room. In a HOR, multiple imaging and/ or recording systems can be used and the physicians will have to decide how hey want to display the images.	Once the equipment and the layout choices are frozen, the Project Manager of Installation will provide some detailed drawings with all the technical specifications to follow. Cross functional meetings including third parties are often needed to ensure roles and responsibilities are clearly understood.	The Project Manager of Installation will track the progressions of the project through regular site visits and coordination with the Project Manager of Installation and the different suppliers.	GEHC will perform the installation of the imaging system. The Project Manager of Installation will ensure that the installation is on track. The installation includes the mechanical installation, the power on and calibration of the system, functional checks, the IT set up and the remote connection of the system.

3. Design the room Layout

a. Define the clinical staff positions depending on the required procedures

As we mentioned already, defining the procedures that will be performed is critical. That way, when drafting the first feasibility layout, the positions of the clinical staff can correctly be anticipated.

b. Define an accurate location for each element in the exam room

The exam room is a busy room where each element needs to have an accurate location to ensure an optimal patient access and a comfortable working space for the clinical staff. Below some key elements that need to be considered when drafting the room layout:

- Laminar Flow system
- Anesthesia boom
- Surgery boom
- Table cart
- Display solutions
- Lamp, injector, radiation shield and any ceiling mounted accessories
- Heart lung by-pass machine
- Additional imaging, patient monitoring & recording equipments

Most of these equipments are ceiling mounted, thus it is critical to anticipate their exact locations and movements to ensure a comfortable workplace and avoid any risk of collisions.

With their Gantry, rails free on the ceiling, The Discovery™ IGS 7 OR and the Discovery™ IGS 7 For Hybrid OR-GE OR Table, give the flexibility to draw the laminar flow, monitors, surgical lights and rad shield at various locations and define the ones your clinical staff need.

c. Anticipate the workflows

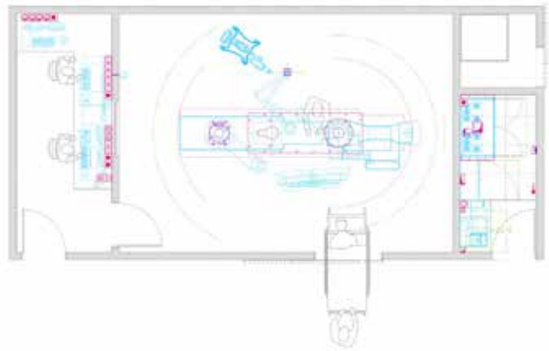
The room layout cannot be limited to the exam room only and needs to include:

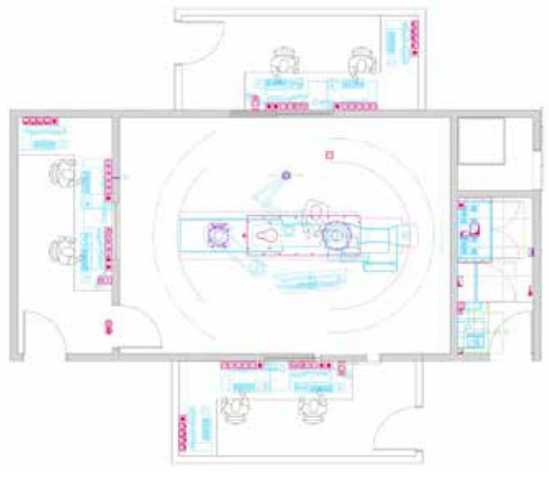
- The exam room (the Lab)
- The control room
- The technical room
- The preparation room
- The post-op room
- The Storage rooms

The workflows within these different rooms need to be anticipated.

3 main workflows shall be considered

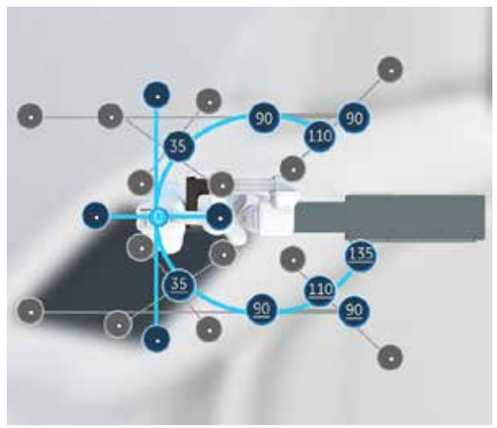
- **Patient workflow:**
  How will the patient get into the exam room? How will he/she get out of the room, to go where? Are the different elements in the exam room properly located to ensure a smooth path for the patient?
- **Staff workflow:**
  How will the staff get into the exam room? How will it get out of the room, to go where? Are the different elements in the exam room properly located to ensure the physicians can easily reach their different positions depending on their procedures? For each procedure, do the clinical staff, especially the physicians and the anesthesiologist, have an easy patient access and easy visibility on the video displays?
  Does the control room location match the way the staff is working? Some physician prefers to have the control room in front of them so they can see the operators in the control room, others prefer to have the control room in their back and not be distracted by activities happening in this area.





- **Material workflow:** What is the required path for the surgery material? What is the required path for surgery wastes? Usually these wastes need to get out of the room from a different path than the patient and this needs to be anticipated when drafting the layout.

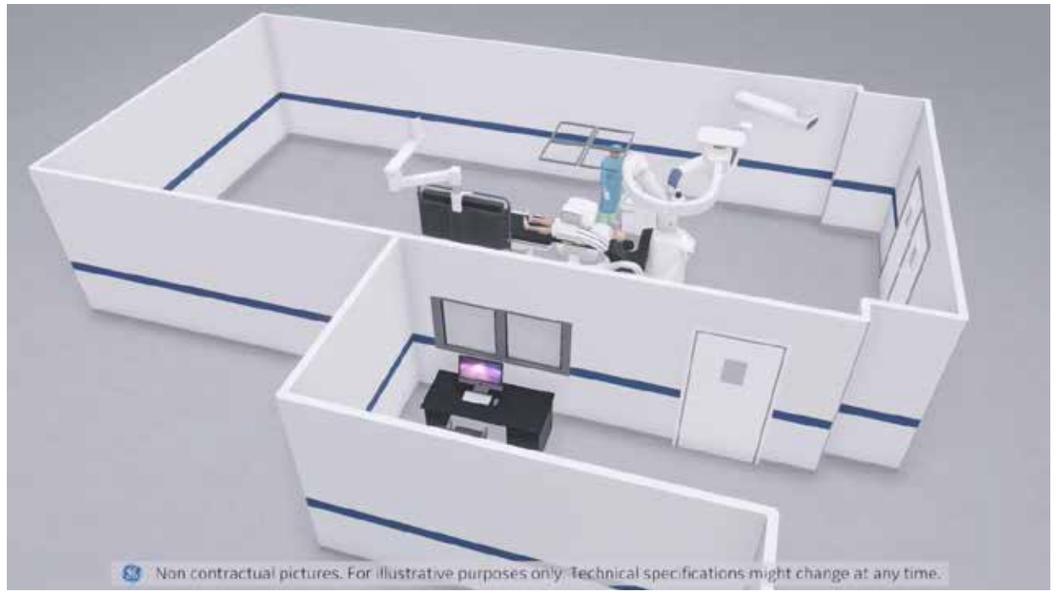
d. Define the parking positions and simulate the switch from minimally invasive procedure to open surgery procedure.
To ensure an optimal ergonomy and an ease of use of the room, the back-out and parking positions shall be anticipated during the design phase.
With the Discovery™ IGS 7 OR and the Discovery™ IGS 7 For Hybrid OR-GE OR Table, the back out and parking positions are customizable to adapt your room size and shape. It benefits from up to 11 back-out trajectories and 2 customizable parking spaces to move the gantry aside completely.



e. Benefit from 3D Virtual reality
As we have just described, designing a Hybrid Operating Room layout can be complex and it can be difficult for the clinical staff to project themselves in the room only using 2D drawings. Thus, benefiting from 3D simulation is key.

GE Healthcare proposes 2 types of 3D simulations:

- **3D view of your 2D drawings** with all the key elements represented, including the different positions of the staff and all 3rd party equipments. On this 3D view, we can easily simulate the movements of the different elements and you can see the rooms from any angle. We can record videos so all these simulations can easily be shared among your stakeholders.
- **Virtual reality experience in your 3D room** thanks to high end technology to immerse your staff in their future working environment.

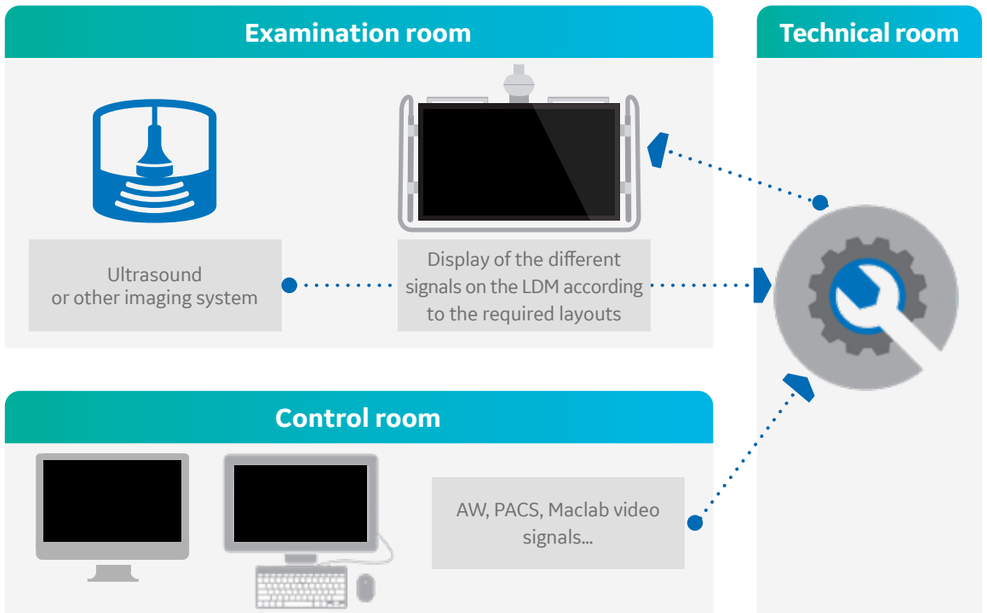


4. Define the video management you need

A Hybrid room includes many types of imaging, monitoring and recording systems. It is key to display the video signals from these different equipments in an optimal way. Your staff shall decide what they want to see and when. This needs to be anticipated before the finalization of the civil works drawings and so before civil works starts.

GE Healthcare proposes display solutions for equipments remaining all the time in the room or for temporary systems required for a specific procedure, a specific patient. Our Large display monitor enables up to 16 video signals to be displayed, and pre-configured display layouts.

In addition, Hybrid rooms are centers of excellence and the capability to broadcast, outside the exam room, live procedures, is more and more required. This shall be considered when defining the video management needs.



5. Anticipate connectivity requirements

Making sure your system is connected at installation is key to ensure remote monitoring of your system and timely response of technical experts, day 1. Your IT departments shall be involved to review the connectivity requirements early in the project.

6. Consider risks and mitigate them

In the design and building phase of a HOR project, different risks shall be considered and mitigated.

- **Electrical risks**: How to secure power in the room? How to make sure the norms are fulfilled? GE Healthcare proposes different alternatives of Uninterrupted Power supply solutions and will work with your teams and facility providers to review these aspects.
- **Hygienic and air flow risks**: How to make sure the room will comply requirements for an OR environment: Iso 7, Iso 5 (NFS 90-351)?
  The Discovery IGS 7 mobile gantry leaves the room ceiling suspension-free, helping prevent contamination from air borne agents. It allows laminar flow above the surgical field even when in position for imaging, helping to meet the criteria for ISO 5 classification.[11]
- **Fire security risks**: How to make sure to minimize fire incidents and that your location/ infrastructure comply with fire security regulations?
  The PMI and the project team will help answer these questions according to your constraints along the project. Things such as ensuring fire protection after cabling needs to be anticipated.
- **X-Ray radiation risks**: What type of protection is required depending on the area around the HOR? Having X ray protection requirements in a OR environment is not obvious but is mandatory for HOR. Our PMI along with radioprotection experts and your facility members will review these aspects so your room meet the local regulations.

7. Anticipate the civil works and the impact on external departments

The required civil works required might have an impact on other departments and services in the facility. This impact shall be identified and communicate to the relevant people so they can anticipate the disturbances and develop an action plan accordingly. Precise planning of these disruptions shall be defined and any slippage in the planning shall be timely communicated.

8. Track civil work progress through frequent synchronization meetings

Once the detailed drawings including civil works requirements are finalized, a kickoff meeting shall be held by the project leader so all parties can define a detailed planning and synchronize among them.

Such synchronization meeting shall be held on frequent manner to assess progressions and anticipate any risks in the schedule.

On GE Healthcare side, the Project Manager of Installation will remain your key focal point during this period.

CHAPTER 5

What are the investment outcomes?

The investment in HOR rooms is significant: 4 to 6 M$. It is key to make sure this investment is protected and that you can get the maximum out of it.

Each project and each site is different: the expectations out of such investment may vary a lot. The main outcomes could be categorized in 4 categories as highlighted below.

Patient, economic, workflow, clinical benefits

PATIENT

Improvements in procedural outcomes and reduction in some complications with advanced technologies

Recovery time is potentially shortened due to less invasive procedures

ECONOMIC

Cost savings from shorter length of stay and hospitalization when compared to surgery

Cost savings realized from increased efficiciencies and less use of materials

WORKFLOW

OR times may be cut by using hybrid OR systems in aortic valve replacement

Hybrid OR systems can improve efficiency, turnover time, and productivity

CLINICAL

An increase in referrals and internal capability to effectively treat complex cases

Ability to recruit highly qualified physiciens who demand the most advanced technology

Below some concrete examples illustrating each of these benefits.

Patient:

- **Improvement in procedural outcomes and reduction in some complications with advanced technologies**
  According to the journal Vascular surgery article (Tenorio, E. R., et al. (2018)): "Impact of onlay fusion and cone beam computed tomography on radiation exposure and technical assessment of fenestrated-branched endovascular aortic repair", with the use of Cone Beam CT along with advanced 3D applications, we lower from 10% to 4% the secondary intervention 30 days after EVAR procedure.

- **Recovery time potentially shortened due to less invasive procedures.**

- **Easy switch to open surgery when required.**
  In November 2012, Advocate Aurora Health St Luke's Medical, a medium-sized teaching hospital in Bethlehem, Pennsylvania, became the first in the United States to install the Discovery IGS 730 Hybrid Operating Room from GE Healthcare. The hospital is the main campus of St. Luke's University Health Network (SLUHN), a non-profit network comprised of six hospitals in Pennsylvania and New Jersey. The 480-bed hospital is a fully accredited Level I trauma center and has a nationally recognized open-heart surgery program.
  Dr. James Balshi, Vascular Surgeon in Advocate Aurora Health St Luke's Medical shared his experience: "The Discovery system gives us the ability to do complicated procedures. We don't feel any constraints by the physical presence of the system. We feel more comfortable in performing complex cases in this room because we know we can manage any potential complication and easily switch from minimally invasive to open surgery."

Clinical:

- **Radiation dose reduction:**
  Keeping dose to a minimum has become a goal for image-guided therapies as well as a research topic for many experts in minimally invasive vascular surgery, as exemplified by the REVAR study (Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study published in 2018 in the European Journal of Endovascular Surgery. Results showed a median DAP of 14.7 Gy.cm2 achieved across 6 centers of the study[15]. These results are 12 times lower than the mean DAP of 181 Gy.cm2 reported in a meta-analysis published in 2016 by de Ruiter et al. in the non-complex EVAR subset with fixed C-arms[16].

- **An increase in referrals and internal capability to effectively treat complex cases.**
  Advocate Aurora Health St Luke's Medical has been able to optimize its investment in the Discovery IGS 730 for Hybrid OR by growing the range of procedures offered, using the HOR for a variety of complex and routine procedures across specialties, and providing better options for patients.
  "The installation of the HOR has absolutely impacted our procedure mix," observed Dr. Raymond Durkin, Interventional Cardiologist and Chief of Cardiology. "We are definitely seeing more combined procedures. Now we can perform procedures that we couldn't do before."

A world premiere was achieved at the CHU d'Angers hospital in France on July 4th 2015. A patient was treated for his renal tumor in a two-stage hybrid procedure combining hyper-selective renal embolization and laparoscopic partial nephrectomy (LPN) on the same day. The patient was discharged two days later, tumor-free, with no complication and with two functional kidneys. Since then, Dr. Antoine Bouvier and Pr. Pierre Bigot, respectively Interventional Radiologist and Urological Surgeon at the CHU d'Angers, have been using this revolutionary technique to improve outcomes for more than a hundred patients with renal tumors. This medical innovation and the collaborative effort between teams were made possible thanks to a hybrid operating room equipped with the Discovery IGS 730 configuration.

- **Ability to get and retain high qualified physicians who demand the most advanced technology.**
  University hospital of South Manchester (UHSM) in Wythenshawe is a major acute care teaching hospital, offering district general hospital services and also specialist tertiary services to the population of greater Manchester, with a large cardiothoracic and vascular center and a transplant center. In 2016, UHSM opened two new hybrid operating rooms (HOR), equipped with the Discovery IGS 730 hybrid angiography system from.
  Donna Young, Director Manager for Surgery at UHSM said: « making this sort of investment in a brand new HOR is critical for staff retention. The teams love working in a state-of-the-art environment, knowing that they are delivering the best possible care".

Workflow

HORs can save critical time by avoiding patient transfers from one unit (Interventional Radiology) to another (OR).
Productivity and room utilization are enhanced due to the flexibility of the room and the ability to perform multiple complex procedures and combined procedures.

Dr. Jonathan Ghosh, vascular surgeon at USHM said: "About 50% of my peripheral work is in combination with Interventional Radiology. Of interest to me personally has been the opportunity to do more complex work with other specialties, such as cardiothoracic surgery, plastic surgery and surgical oncology. The HOR allows us not to have to compromise any aspect of the operation for combined cases. We have excellent imaging together with the advantages of a modern operative ward".

Economic

Cost savings from shorter length of stay and hospitalization when compared to surgery.

Donna Young, Director Manager for Surgery at UHSM explained: "We are now performing minimally invasive procedure on patients, so we are operating on patients on a daily basis, whereas historically we would admit these patients into a bed, and they would potentially stay for two or three days. Overall, we are now reducing the length of stay for suitable cases, and the HOR has allowed us to do that for the first time ever". "There is pressure each year for the organization to save money. We can now deliver minimally invasive procedures in the hybrid room, which reduces requirement for beds, and helps bringing hospital costs down".

"This combined approach has the benefit of avoiding risks of renal ischemia."
Pr. Bigot, Professor of Urology and Chief of the Urology department at the CHU d'Angers

"Instead of clamping the renal artery, we decided to embolize selectively the artery going to the tumor to avoid bleeding during subsequent resection."
Dr. Bouvier, Interventional Radiologist at the CHU d'Angers

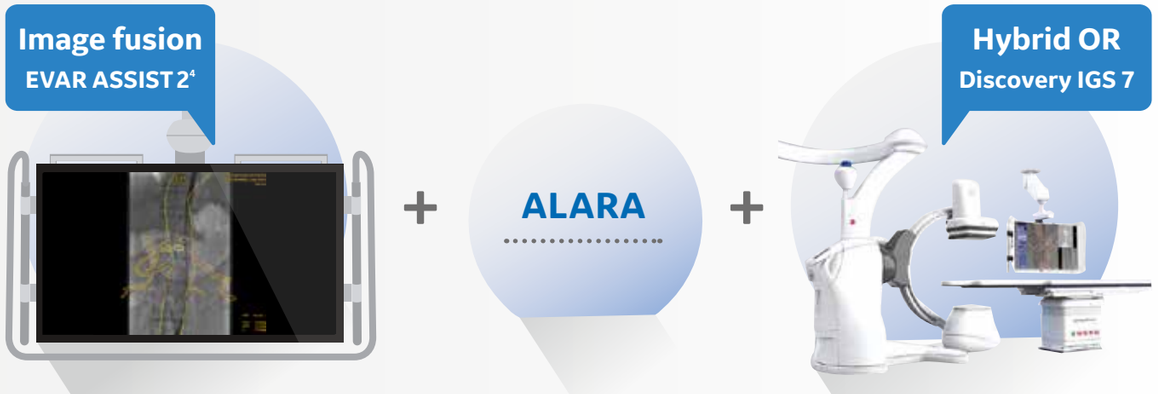
"The HOR allows us not to have to compromise any aspect of the operation for combined cases. We have excellent imaging together with the advantages of a modern operative ward."
Jonathan Ghosh, Vascular Surgeon at UHSM

"Making this sort of investment in a brand new HOR is critical for staff retention. The teams love working in a state-of-the-art environment, knowing that they are delivering the best possible care."
Donna Young, Director Manager for Surgery at UHSM

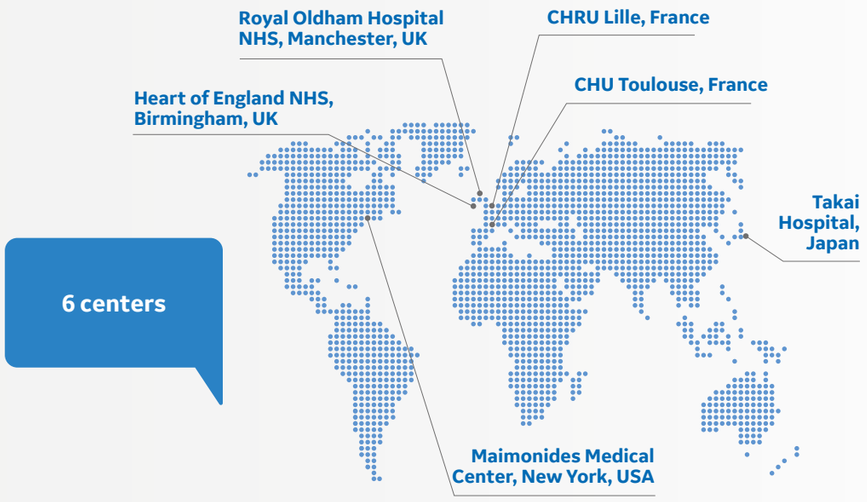
THE REVAR STUDY[15]

RADIATION DOSE REDUCTION DURING EVAR

Evaluate radiation exposure in standard EVAR using image fusion & ALARA guidelines in a hybrid OR



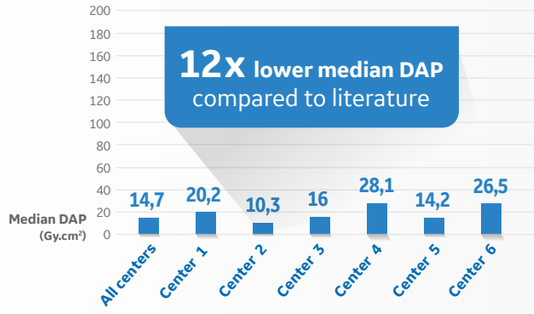
PROSPECTIVE MULTICENTER STUDY[15]



RESULTS

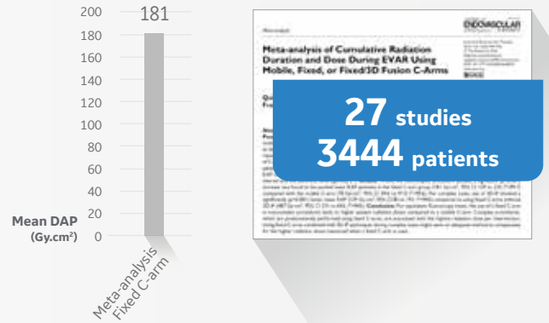
Median DAP of 14,7 Gy.cm²

Achieved across all 6 centers of the prospective multicentre observational study[15]



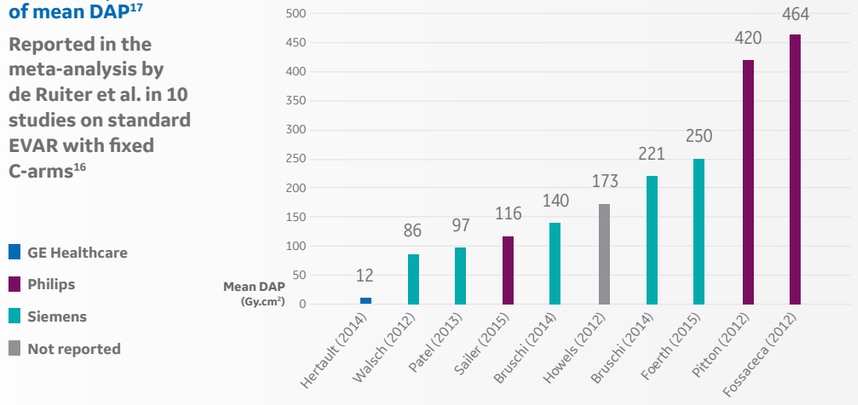
Mean DAP of 181 Gy.cm²

Reported in the meta-analysis by de Ruiter et al. in the non-complex EVAR subset with fixed C-arms[16]



Meta-analysis of mean DAP[17]

Reported in the meta-analysis by de Ruiter et al. in 10 studies on standard EVAR with fixed C-arms[16]

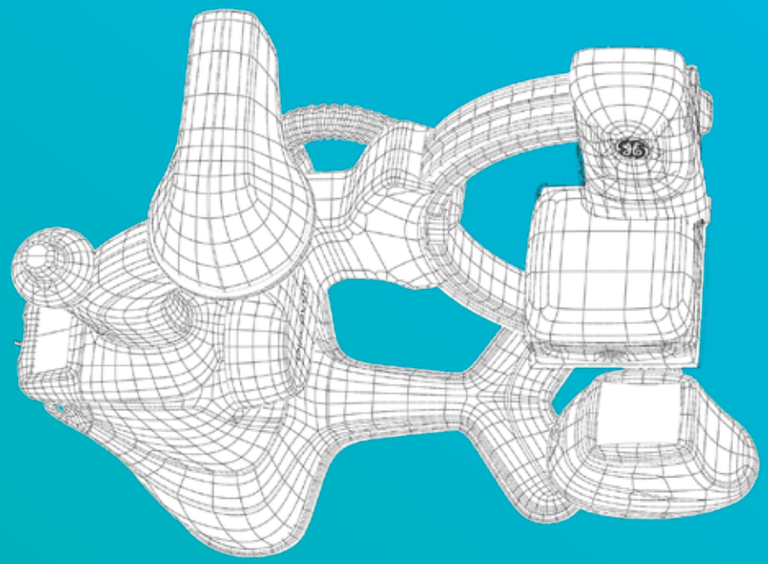


By following the ALARA principle in a modern hybrid room with routine use of fusion imaging guidance for EVAR, low radiation exposure compared with the published literature can be achieved in a real world setting.

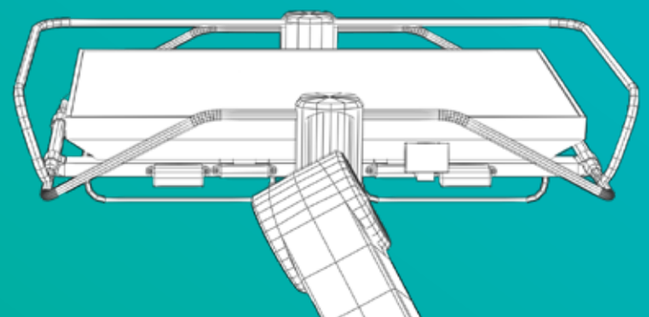
DREAMSUITE

WITH THE NEW VIRTUAL REALITY 360° EXPERIENCE,

IMAGINE YOUR FUTURE HYBRID OPERATING ROOM!



With DreamSuite, you can immerse yourself in your new room. This will allow you visualise your workspace, patient access, display positioning and simulate your workflow[18]...



References

1. Criado, FJ., Fairman, RM., and Becker, GJ. "Talent LPS AAA Stent Graft: Results of a pivotal clinical trial," Journal of Vascular Surgery, April 2003

2. Evidence Base Review of the Value of Hybrid Operating Rooms," Bridgehead International

3. Maquet table is sold by Getinge.

4. EVAR ASSIST 2 solution includes FlightPlan for EVAR CT, EVARVision and requires AW workstation with Volume Viewer, Volume Viewer Innova, VesselIQ Xpress, Autobone Xpress. These applications are sold separately.

5. Vessel ASSIST solution includes Vision 2, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

6. Needle ASSIST solution includes TrackVision 2, Stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

7. Liver ASSIST V.I. solution includes Hepatic VCAR and FlightPlan For Liver that can be used independently. It also requires an AW workstation with Volume Viewer and Volume Viewer Innova. These applications are sold separately. May not be available in all markets.
The above Liver ASSIST V.I. performances aspects reflect the results of three published journal articles conducted by using a previous version of FlightPlan for Liver software (b) (c) or its prototypes (a) for the validation and they do not necessarily represent individual performance of FlightPlan for Liver:
a. Computed Analysis of Three-Dimensional Cone-Beam Computed Tomography Angiography for Determination of Tumor-Feeding Vessels During Chemoembolization of Liver Tumor: A Pilot Study – Deschamps et al. Cardiovasc Intervent Radiol. 2010.
b., Tracking Navigation Imaging of Transcatheter Arterial Chemoembolization for Hepatocellular Carcinoma Using Three-Dimensional Cone-Beam CT Angiography –Minami et al. Liver Cancer. 2014
C. Clinical utility and limitations of tumor-feeder detection software for liver cancer embolization. Iwazawa et al. European Journal of Radiology. 2013.

8. PCI ASSIST solution includes StentViz and StentVesselViz.

8a. IQ improvement is measured on Innova IGS530 with phantoms using various PlexiglasThicknesses, acquisition parameters and the NEMA spoke wheel tool (ref 1), calculating the ratio of the contrast of the moving wires to the background noise level. The amount of IQ improvement related to HCF depends on the acquisition parameters, clinical task, patient size, amount of motion in the image, anatomical location, and clinical practice. Ref1: A new tool for benchmarking cardiovascular fluoroscopes; S. Balter, Radiation Protection Dosimetry, Vol. 94, No. 1–2 pp. 161–166 (2001). Applicable to Innova IGS 5 (IGS 520, IGS 530 configurations), Innova IGS 6 and Discovery IGS 7 (IGS 730 configuration).

9. Valve ASSIST 2 solution includes TAVI Analysis, HeartVision 2 and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

9a. Compared to a workflow which does not involve image fusion.

10. Embo ASSIST solution includes FlightPlan For Embolization and requires an AW workstation with Vessel ASSIST and Vision 2. These applications are sold separately. Not available for sale in all regions.

11. According to simulations performed with a surgical monitors suspension using the open monitor suspension option.

14. TenorioER, OderichGS, SandriGA et al. Impact of onlay fusion and cone beam computed tomography on radiation exposure and technical assessment of fenestrated-branched endovascular aortic repair. J VascSurg2019;69:1045-1058 e3. link: https://pubmed.ncbi.nlm.nih.gov/30527938/

15. Hertault et al. Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study (The REVAR Study). Eur J Vasc Endovasc Surg (2018). https://doi.org/10.1016/j ejvs.2018.05.001 | The sites in the REVAR study used Discovery IGS 730 and Discovery IGS 740, previous product versions of Discovery IGS 7 with GE OR table. They also used EVAR ASSIST image fusion, a previous version of EVAR ASSIST 2.

16. de Ruiter et al. Meta-analysis of cumulative radiation duration and dose during EVAR using mobile, fixed, or Fixed/3D fusion C-Arms. J Endovasc Ther (2016). https://doi.org/10.1177/1526602816668305

17. Data points were extracted from the meta-analysis by De Ruiter at al (2016). The differences between DAP levels reported in the graph account for several parameters, such as the fusion, the equipment used, the patients characteristics, the operators, the use of ALARA principles, the institution, etc. Therefore, results may vary from one site to another. The results described here were obtained in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g. hospital size, case mix), there can be no guarantee that other customers will achieve the same results.

18. 3D images and movies are for illustrative purposes only. Technical specifications may vary at any time.

The Statements by GE's customer described here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist i.e. hospital size, case mix, there can be no guarantee that other customers or patients will achieve the same results.

GE Healthcare

GE Healthcare provides medical technologies and services to help solve the challenges facing healthcare providers around the world. From medical imaging, software, patient monitoring and diagnostics, to biopharmaceutical manufacturing technologies, GE Healthcare solutions are designed to help healthcare professionals deliver better, more efficient and more effective outcomes for more patients.
GE Healthcare is betting big on digital; not just connecting hospital departments and physicians more effectively, but utilizing the masses of data from its equipment and the collaboration between hardware and software –"digital industrial" – to help clinicians make better care decisions. Sensors, software and smart data analytics are converging to enhance GE Healthcare's offerings not just in diagnostics, but also pathology, gene sequencing and even hospital asset tracking.

GE interventional imaging systems help you plan, guide and assess your wide range of interventional procedures precisely and efficiently. The new generation of ASSIST advanced applications allow you to extend your clinical capabilities and help simplify and streamline your procedural workflow.

Gehealthcare.com/ASSISTInterventional