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Planning a Cardiovascular Hybrid Operating Room: the Technical Point of View

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ABSTRACT

Introduction: The integration of interventional techniques into cardiovascular surgery requires angiographic imaging capabilities in the operating room. A deep understanding of the technology and its implication for the surgical workflow is scarce.

Methods and Results: Before planning a hybrid operating room, a clear vision for the utilization should be established. Commonly, the theaters are in interdisciplinary usage by interventionalists, anesthesiologists, and surgeons of various disciplines. The multitude of requirements determines necessary resources—location, space, and imaging equipment. Besides fluoroscopy, intraoperative 3D imaging with the angiography system and its combination with fluoroscopy evolves as a very important imaging modality enabling the surgeon to navigate in 3D anatomy.

Conclusion: With the growing trend toward endovascular procedures during surgery, the hybrid operating room will become an integral part of every cardiovascular center. This new operating room concept enables new cardiac surgery therapies and will play a vital role for minimally invasive surgery. Careful planning and professional expertise is a key factor for every hybrid room project.

INTRODUCTION

Recent developments in cardiac surgery have led to new therapies integrating surgical procedures with skin incisions and interventions, such as transcatheter techniques with the puncture of a vessel. To allow these procedures, integrated operating rooms (OR) have to be installed. These hybrid operating rooms need, in excess of surgical equipment, high-end imaging equipment equivalent to the angiography systems used in interventional radiography and cardiology. Imaging devices have been used in an operating theater for a long time. Mobile C-arms, ultrasound, and endoscopy are standard for many operations; however, complex transcatheter techniques demand high-powered equipment to visualize thin guide wires, quantify small vessel diameters, and evaluate delicate anastomoses. Because of their size and complexity, these integrated endovascular suites or hybrid ORs require special considerations, planning, and design as well as new skills to be learned by the team.

USE OF A HYBRID OPERATING ROOM

Before a hybrid OR is planned, all stakeholders in the hospital should be identified and a detailed plan of room use developed. These high-tech rooms are too costly for part-time use. Once such a facility is constructed, however, the demand for it increases because of growing indications and increased referrals [Sternberg 2004].

Pediatric hybrid operations, hybrid coronary revascularization, transcatheter valve replacement and repair, and stent/graft placement in the thoracic aorta are just some of the new developments that are ideally performed in a hybrid OR. Although hybrid therapies were first developed in close

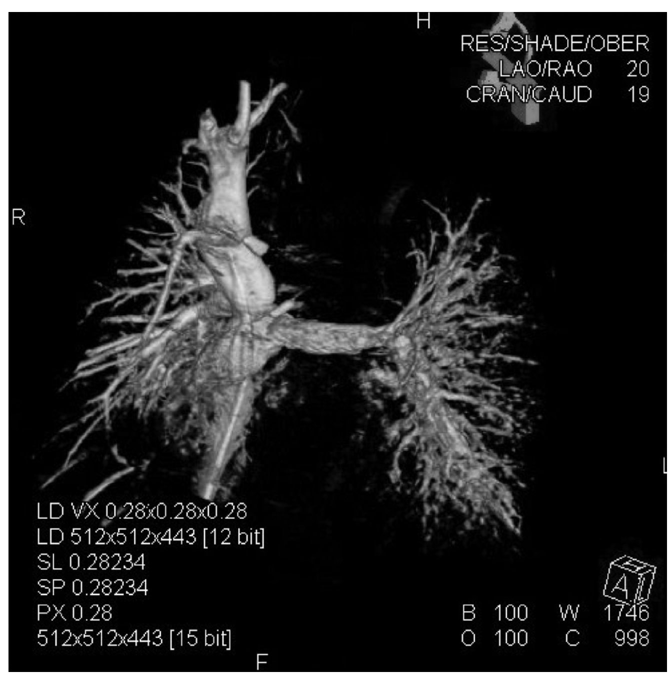

Figure 1. Hypoplastic left heart syndrome: intraoperative post-Fontan evaluation of the superior and inferior venae cavae and the stented pulmonary arteries. Courtesy of Professor Berger, Dr. Ewert Deutsches Herzzentrum, Berlin, Germany.

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teamwork of pediatric cardiology and pediatric cardiac surgery, the strongest driver for hybrid therapies currently is transcatheter replacement of the stenotic aortic valve.

Hybrid Surgery for Congenital Heart Disease

Although surgery remains the treatment of choice for most congenital cardiac malformations, interventional cardiology approaches are increasingly being used in simple and even complex lesions. The percutaneous approach can be challenging due to low patient weight, poor vascular access, induced rhythm disturbances, and hemodynamic compromise [Bacha 2007]. Difficult and complex anatomy, as in double-outlet right ventricle or transposition of the great arteries, or acute turns or kinks in the pulmonary arteries of tetralogy of Fallot patients can make percutaneous procedures challenging if not impossible [Sivakumar 2007]. On the other hand, surgery also has its limitations. Examples are operative closure of multiple apical muscular ventricular septal defects, adequate and lasting relief of peripheral pulmonic stenosis, or management of a previously implanted stenotic stent. Combining interventions and surgery into a single therapeutic procedure leads to reduction of complexity, cardiopulmonary bypass time, and risk and improved outcomes. The hybrid approach to hypoplastic left heart syndrome serves as a role model of the concept (Figure 1) [Bacha 2006; Gutgesell 2007].

Hybrid Surgery for Valve Disease

Transcatheter valve therapies are currently developed for the most common valve diseases: mitral valve regurgitation, aortic stenosis, and—in children—pulmonary valve disease. For repair of mitral regurgitation, more than 30 devices are currently under investigation and await FDA approval. Experimentally, prostheses for mitral and tricuspid valve replacement are under development and certainly will be available within the next years. Aortic stenosis is the most frequent acquired heart valve lesion in developed countries. Conventional aortic valve replacement for aortic stenosis is based upon standardized guidelines with excellent outcomes, particularly in younger patients at relatively low risk, and will remain the gold standard for aortic valve replacement in the coming years. Transcatheter techniques have developed valid alternatives in high-risk patients where conventional surgical techniques are considered too invasive and risky [Walther 2008]. Joint recommendations of the European Society of Cardiology and the European Society of Cardiac Surgery consider the hybrid OR the optimal environment for these new therapeutic options [Vahanian 2008].

Surgery for Coronary Artery Disease

Routine evaluation of bypass grafts is the first indication for imaging needs in coronary artery bypass grafting. Several groups reported a considerable number of technical bypass graft failures that could be diagnosed intraoperatively by angiography and immediately repaired [Mack 2008]. Surgical bypass grafting and percutaneous coronary artery revascularization are traditionally considered isolated options. A simultaneous hybrid approach may allow an opportunity to match the best strategy for a particular anatomic lesion. Revascularization of the left anterior descending artery with the left internal mammary artery is by far the best treatment option in terms of long-term results. Integrating this therapy with percutaneous coronary angioplasty (hybrid procedure) offers multi-vessel revascularization through a mini-thoracotomy. Particularly in high-risk patients, morbidity and mortality decrease in comparison to conventional surgery [Bonatti 2008; Reicher 2008].

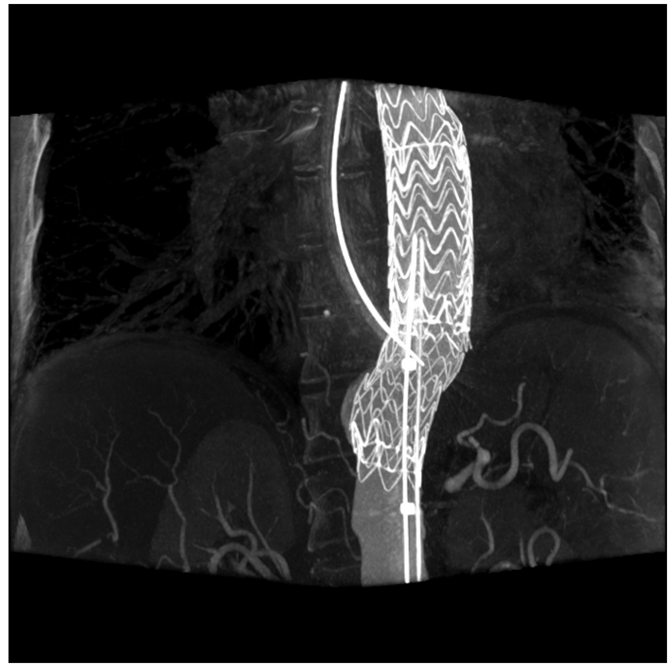


Figure 2. Aortic stent graft visualized with 3D computed tomography (CT)-like imaging. Courtesy of Deutsches Herzzentrum Berlin, Germany, Courtesy of Prof. Fosse, Rikshospitalet, Oslo, Norway.

Hybrid Surgery for Rhythm Disturbances

The combination of the surgical epicardial approach with the interventional endocardial approach for the treatment of rhythm disturbances in particular atrial fibrillation offers theoretical advantages over conventional therapy. First reports emphasize the potential benefits [Bisleri 2008].

Endovascular Repair for Aortic Disease

Endovascular repair (EVAR) for the abdominal aorta in chronic aneurysms has become a valid alternative to open repair with superior survival [Schermerhorn 2008]. EVAR is also increasingly used for the thoracic aorta (Figure 2). In selected cases, EVAR in combination with open surgery is even applied for pathologies of the aortic arch and distal ascending aorta [Walsh 2008].

Pacemaker and Implantable Cardioverter Defibrillators Implantation

Pacemakers and implantable cardioverter defibrillators (ICD), particularly bi-ventricular systems, may be optimally implanted in a hybrid OR environment because the hybrid operating theater offers the required superior angulation and

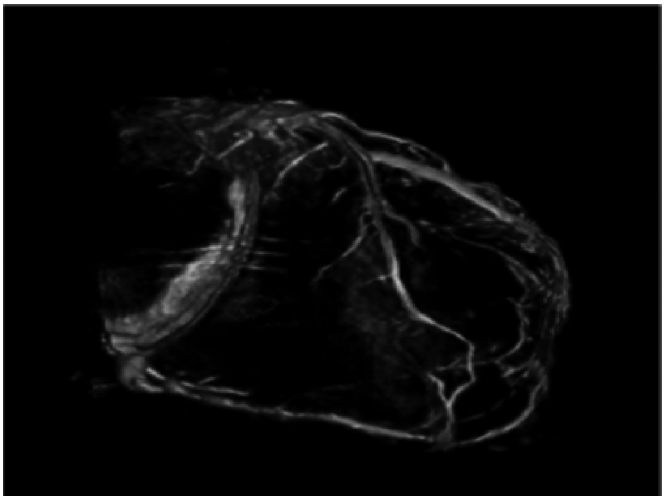


Figure 3. Visualization of the coronary sinus with 3D computed tomography (CT)-like imaging. The coronary sinus can be overlayed over live fluoro and thus offers the surgeons or interventionalists the ability to navigate live in 3D anatomy (3D-Roadmap). Imaging Courtesy of Dr. Gallagher, Central Baptist Hospital, Lexington, Kentucky, USA.

imaging capabilities in comparison to mobile C-arms and higher hygienic standards compared to cath labs (Figure 3).

Interdisciplinary Use

The need for hybrid operating theaters is not restricted to cardiac surgery. Vascular surgeons and neurosurgeons have equally developed hybrid procedures necessitating angiography systems in the OR. Furthermore, hybrid ORs are already in use by abdominal surgeons, traumatologists, orthopedic surgeons, and even urologists. Imaging needs, hygienic requirements, and room set-up—particularly for neurosurgery—may be considerably different. Other surgical disciplines may want to introduce navigation systems, magnetic resonance imaging, endoscopy, biplane angiography systems, or lateral position of anesthesia equipment; however, the hybrid ORs are more commonly shared with interventionalists including cardiologists, interventional radiologists, electrophysiologists, neuroradiologists, and pediatric cardiologists. Their specific needs have to be carefully considered and weighed when planning the hybrid theater.

BASICS OF THE HYBRID ROOM

Location

The hybrid room is used by an interdisciplinary team of surgeons, interventionalists, anesthesiologists, and others, and it is good practice to involve all stakeholders deeply into planning and keeping such a facility. Ideally, the hybrid OR is located next to interventional suites and ORs in order to keep logistics simple. If the ORs are separated from the interventional cath labs, however, it is recommend to establish the hybrid OR next to the other ORs [Bonatti 2007] because all OR equipment and personnel (eg, heart-lung machine and perfusionists) are immediately ready, and anesthesia and intensive care is available.

Room Size and Preparation

Interventional rooms have excellent imaging capabilities but frequently lack the prerequisites, size, and equipment required for formal ORs. ORs meet those required standards, but usually lack high-level imaging capabilities. A hybrid OR should be larger than a standard OR, and the basic principle for planning is the larger the better, because it is not only the imaging equipment that needs sufficient space. Staff calculations have shown that in hybrid procedures 8 to 20 people are needed in the team including anesthesiologists, surgeons, nurses, technicians, perfusionists, experts form device companies, and so forth [ten Cate 2004]. Expert opinions recommend for newly built ORs at least 70 m^2 [Benjamin 2008]. Additional space for a control room and a technical room is mandatory, adding up with washing and prep rooms to a total of approximately 150 m^2 for the whole area. If a fixed C-arm system is considered, an OR size of 45 m^2 is the absolute lower limit. Rebuilding in terms of lead shielding (2 to 3 mm) will be needed. Depending on the system, it may be necessary to enforce the ceiling or the floor to hold the weight of the stand (approximately 650 to 1800 kg).

Planning

Planning of the hybrid room is truly an interdisciplinary task. Clinicians and technicians of all involved disciplines should define their requirements and form a responsible planning team. The concrete planning is refined in several steps by specialized architects and vendors of OR equipment and imaging systems in a close feedback loop with the planning team. Virtual visualization of the room, visits to established hybrid rooms, and information exchange with experienced users help tremendously during the planning process. Several case studies for planning guidance have been published in recent literature [Eagleton 2007; Hirsch 2008; Peeters 2008; Sikkink 2008].

Lights, Monitors, and Other Devices

In general, all members of the team need access to all important information. Therefore, multiple moveable and flexible booms need to be installed in the operating room. If there are 2 booms to be installed, a boom on every side of the OR table serves the operative team. Collision of the ceiling-mounted displays with operating lights or other ceiling-mounted equipment should be avoided. Large displays are now available capable of showing multiple video inputs in various sizes and decreasing the need for multiple screens. A dedicated ceiling plan with all ceiling-mounted components including air conditioning should be drawn to ensure the function and usability of all devices.

Conventional surgical lights may collide with the imaging equipment, particularly with ceiling-mounted systems. If a laminar air flow is present in combination with a ceiling-mounted system, light pendants need very long arms making them cumbersome to handle. An alternative may be new light concepts with ceiling-integrated multiple theater lights, as developed at the Interventional Centre at Rikshospitalet in Oslo, which therefore solve the problem of collision with the imaging equipment. A remote control offers the possibility to focus the light where needed (www.lightor.com; Figure 4).

Figure 4. Set-up of a hybrid operating room at Rikshospitalet in Oslo, Norway. The robotic multi-axis system offers high flexibility and advanced 3D imaging capabilities in the operating theatre. Convenient park positions maximize space in the room and keep the system out of the way when not needed. Courtesy of Professor Fosse, Rikshospitalet, Oslo, Norway.

Hygiene

Hygienic requirements differ from country to country and even among surgical disciplines, with the highest standards in orthopedic surgery. In order to guarantee the highest flexibility in room use, hospitals tend to equip all ORs according to the highest standards, and that includes a laminar air flow ceiling. Some hospitals even require skirts around the laminar air flow field, and this set up may preclude ceiling-mounted systems. In any case, ceiling-mounted systems with running parts above the operating field, which are difficult to clean and interfere with the air flow by causing turbulences, are least recommended from a hygienic standpoint [Bonatti 2007].

IMAGING EQUIPMENT

Mobile and Fixed Systems

Mobile C-arms have been commonly used in cardiac surgery and are readily available in every department, eg, for pacemaker implantation. Mobile C-arms may depict larger stents or catheters well; however, their technical specifications do not meet the recommendations of the cardiology societies [Bashore 2001]. The power (2 to 25 kW versus 80 to 100 kW recommendation) and the frame rate (up to 25 f/s 50 Hz or 30 f/s 60 Hz versus 30 to 60 f/s 50Hz recommendation) are below the standards. The cardiology recommendations are to be met, because cardiologic or neuroradiologic interventions are often part of the hybrid procedure. Thin guide wires (0.2 mm) and stents must be visualized even in obese patients, and stenoses of small vessels have to be quantified, which requires adequate power. Mobile C-arms generally have a heat storage capacity of up to 300,000 heat units (HU) (exception: rare water-cooled systems). A heat storage capacity of more than 1 million HU is recommended by cardiology societies for cath labs to avoid overheating and a dangerous shut down during complex procedures, which may occur in mobile C-arms. For these reasons, expert consensus recommends use of fixed C-arms [Bonatti 2007]. A semi-mobile system with a fixed generator (80 kW, AXIOM Artis U; Siemens AG, Forchheim, Germany) may accommodate high-power imaging demands even in average sized operating rooms too small to house a fixed C-arm (<45 m^2).

Image Intensifier and Flat Panel Detector Systems

Modern fixed C-arm systems are equipped with a flat panel detector (FD). Contrast resolution is far higher compared to image intensifier (II) systems, leading to a higher image quality in detector systems. Additionally, in II systems the image is slightly distorted at the edges compared to the center. As a consequence, II systems are not capable of 3D imaging with soft-tissue contrast resolution.

Ceiling- and Floor-Mounted Systems

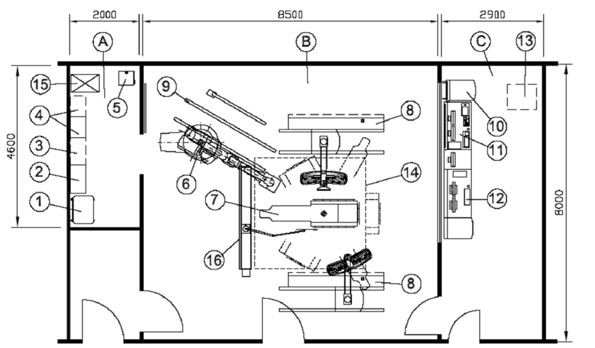
Expert consensus recommends floor-mounted systems for hygienic reasons. In fact, some hospitals do not allow running parts immediately above the operative field because dust may fall down and cause infections. Despite these facts, a large number of hospitals decide to have ceiling-mounted systems because they certainly cover the whole body with more flexibility and, most importantly, without moving the table, which is a sometimes difficult and dangerous undertaking during surgery because many lines and catheters have to be moved as well. Some ceiling-mounted systems are capable of 3D imaging from a surgical position, perpendicular to the patient from both the right and left table side. Moving from a parking to a working position during surgery, however, is easier with a flexible floor-mounted system because the C-arms turn in from the side without interference with the anesthesiologist, whereas ceiling-mounted systems can hardly move during surgery in the park position at the head side without colliding with the anesthesia equipment.

Mono- and Biplane Systems

In an overcrowded environment like an OR, biplane systems add to the complexity and interfere with anesthesia, except for neurosurgery, where anesthesia is not at the head side. Monoplane systems (Figures 4 and 5) are therefore clearly recommended for rooms mainly used for vascular, cardiac, and orthopedic surgery. There are certainly exceptions: If pediatric cardiologists, electrophysiologists, or neuroradiologists are important stakeholders in room usage, a biplane system may also be considered.

Table Considerations

The operating table should meet the expectations of both surgeons and interventionalists. This is in fact a special challenge, because the expectations may be mutually exclusive. Surgeons expect a table with a breakable tabletop. For imaging reasons, the table has to be radiolucent and should allow coverage of the patient in a wide range. Therefore, unbreakable carbon fiber tabletops are used. Cardiovascular surgeons in general do not have very sophisticated positioning needs and are used to having fully motorized movements of the



Pos. A. Equipment room | Pos. B Examination room | Pos C. Control room
1. Floor stand cabinet | 2. Generator | 3. Cable cabinet (option)
4. System control cabinet | 5. Cooling unit | 6. Floor stand
7. Patient table | 8. DCS PRO | 9. Floor stand overhead carriage
10. Imaging System | 11. Control console | 12. Measuring station
13. Hardcopy | 14. LAF Ceiling | 15. USV
16. Flexible radiation protection

Figure 5. Example of a room plan with a robotic floor-mounted imaging system. A room size of 70 m^2 or larger is recommended for hybrid operating rooms because of the large amount of equipment and people needed.

table and the tabletop. Inflatable cushions are sometimes used for positioning of the patient if no breakable table is available. Interventionalists require a floating tabletop to allow fast and precise movements during angiography, and in some countries floating tabletops are among the technical requirements (or are at least highly recommended by expert consensus) for performing coronary angiographies [Hamm 2001]. Floating tabletops are not available with conventional OR tables. The radiolucent area of the OR table only meets the needs in pediatric cases; complete coverage of an adult can not be achieved with today's systems.

As a compromise, tables with a floating tabletop and vertical and lateral tilt are recommended [ten Cate 2004]. Special rails for mounting special surgical equipment such as retractors or camera holders should be available on the table. Placing the operating table in a diagonal position in the OR may give more space. A crucial element when selecting the imaging system and table is the possibility of having access to the patient from all sides and tilting of the table both head up, down, and sideways. In order to perform 3D imaging on the operating table, the C-arm has to be fully integrated with the table, because a fast and precise rotation around the patient lying in the isocentre is necessary. Breakable OR tables are currently not fully integrated, and therefore 3D computed tomography (CT)-like imaging on these tables is impossible.

IMAGING METHODS AND TECHNOLOGIES

Intraoperative transesophageal echocardiography is standard of care in cardiac anesthesia. New technologies, however, such as 3D real-time echocardiography or intracardiac ultrasound (ICE), may complement conventional techniques, particularly in structural heart disease, where optimal imaging of valves, myocardium, and devices is crucial. The combination or even fusion of ultrasound with x-ray images may in the future further optimize imaging in the OR.

Fluoroscopy and acquisition are the basic and most important imaging modes and are offered by all angiography systems. Since fluoroscopy requires a smaller radiation dose, brilliant fluoroscopy images are the predominantly used images during surgery; however, modern angiography systems offer advanced imaging and post-processing capabilities including image fusion with any type of previously acquired 3D volumes (eg, CT, magnetic resonance [MR], positron emission tomography [PET], or single photon emission computed tomogrphay [SPECT] images), guidance, or 3D imaging.

CT-Like 3D Imaging with the Angiography System

Surgery very much depends on 3D visualization of the anatomy, and therefore 3D CT-like imaging with the angiography system is an important feature because it enables the surgeon to navigate in real time in 3D volumes. In principle, CT-like imaging of the heart is performed by 1 or 2 sweeps of up to 220° of the C-arm around the patient. During the rotation, several hundred images are acquired and then reconstructed as a 3D volume. If the acquisition is gated by electrocardiograph (ECG), 3D volumes over time can be generated to depict the beating heart. Radiation dose is comparable to a conventional multi-slice CT. The OR staff can move out of the OR completely during a CT-like run because it lasts only approximately 10 seconds. Reconstruction is performed within 1 minute. Accurate information about the cardiac anatomy in the OR supports planning of complex procedures like redo operations, surgery for complex congenital heart disease, and transcatheter valve replacement. Segmentation of anatomical structures and overlay of the 3D volumes over live fluoroscopy (3D roadmap) enable the surgeon to virtually navigate in 3D anatomy (Figure 2). First investigations demonstrate the value of this new technology in transcatheter valve replacement [Kapadia 2008] and EVAR [Bisasi 2009].

CONCLUSIONS

The hybrid OR facilitates a whole new spectrum of cardiac surgical therapies and will therefore become an essential resource of every cardiovascular center. The trend toward hybrid techniques is more a revolution than an evolution due to the rapid integration into the surgical techniques. All areas of cardiac surgery—surgery for ischemic, structural, and rhythm heart disease—are deeply affected. Fluoroscopy represents the basic imaging mode during surgery. Furthermore, image fusion, 3D/4D imaging, soft tissue visualization, modelling, and navigation allow very advanced surgical applications. The hybrid OR itself represents an extremely complex working environment that demands careful planning by all stakeholders. Bundling of clinical, technical, and architectural expertise as well as a realistic view of what is achievable is key for a successful hybrid OR project. Due to wide variations in use, generic recommendations are only of limited use for these highly individual rooms and certainly cannot replace the diligent work of the project team. Once the room is successfully established, however, it really transforms surgical techniques and paves the way for revolutionary new minimally invasive therapies.

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