Diplomarbeit im Studiengang Audiovisuelle Medien

EVALUATION AND CONCEPTUAL DESIGN OF AUDIO FUNCTIONALITIES

as an Extension of a Medical Image Data Management System
for Use in an Operating Room

Vorgelegt von: Claudia Mattes

An der: Hochschule der Medien Stuttgart

Am: 18. April 2007

Erstprüfer: Prof. Oliver Curdt

Zweitprüfer: Dipl.-Ing. Uli Mezger (Firma BrainLAB AG)

Hiermit versichere ich, dass ich die vorliegende Arbeit selbstständig verfasst habe und keine anderen als die angegebenen Quellen und Hilfsmittel benutzt habe.

München, den 18.04.2007

(Claudia Mattes)

Abstract

The medical image data management system, BrainSUITE NET, a system enabling control of patient data and video signals in an operating room, shall be expanded to incorporate audio functionalities. This thesis establishes a basis for this implementation.

Within a market research, audio functionalities offered by market players are investigated. Being a functionality currently attracting attention, voice control is closer analyzed. The desires and requirements of the surgeons are ascertained within a demand analysis, primarily by performing an international survey among 65 surgeons with the results presented and discussed. According to the outcome of this survey, audio functionalities that shall be implemented in a conceptual design are determined.

During the design process of the concept, a risk analysis is performed detecting potential hazards for the patient and user and defining measures avoiding or diminishing those hazards. The operating room's acoustical characteristics are considered. The reverberation time and the critical distance are calculated, the effect of background noise on speech intelligibility is described and consequences for the system are drawn. Eligible microphone positions, directivities, and construction types are compared in consideration of the acoustical characteristics and the system conditions.

The overall results are carried out in a concept, which is presented by schematic drawings and a description of the components.

Kurzfassung

Das medizinische Bilddatenmanagementsystem BrainSUITE NET, das die Kontrolle über Patientendaten und Videosignale in einem Operationssaal ermöglicht, soll um Audiofunktionen erweitert werden. Diese Diplomarbeit schafft die Grundlage für eine Implementierung.

In einer Marktanalyse werden die von Mitbewerbern angebotenen Audiofunktionen untersucht. Da sie eine aktuell stark diskutierte Benutzerschnittstelle darstellt, wird die Sprachsteuerung detaillierter analysiert. Die Wünsche und Ansprüche der Chirurgen werden in einer Anforderungsanalyse ergründet, vorwiegend durch eine internationale Umfrage, die im Rahmen dieser Diplomarbeit unter 65 Chirurgen durchgeführt wurde. Die Ergebnisse werden präsentiert und diskutiert. In Anbetracht der Ergebnisse der Umfrage werden die Audiofunktionen bestimmt, für die ein Konzept entworfen wird.

Innerhalb des Entwurfsprozesses wird eine Risikoanalyse durchgeführt, die mögliche Gefahren für den Patienten und den Anwender aufdeckt und Maßnahmen zur Verhinderung oder Verminderung dieser Gefahren definiert.

Im Rahmen einer akustischen Betrachtung des Operationssaals werden die Nachhallzeit und der Hallradius berechnet sowie der Zusammenhang von Störgeräuschen und Sprachverständlichkeit erläutert. Die Konsequenzen für das Audiosystem werden dargestellt. In Anbetracht der akustischen Eigenschaften des Operationssaals und der Bedingungen des Systems werden mögliche Mikrofonpositionen, Richtcharakteristiken und Bautypen verglichen.

Die gesamten Ergebnisse werden in einem Konzept umgesetzt, das mit Schaltbildern und einer Beschreibung der Komponenten dargestellt wird.

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1 Introduction

Audio functionalities and an operating room - at first glance these two terms do not have any relation. What does audio associate with an operating room?

This question can be answered with the following examples:

Surgeons collaborate with other experts: they communicate via telephone.
Surgeons like entertainment: they listen to music during surgery.
Surgeons need to write reports of the surgery: why not by voice?
Surgeons have to control devices: what about voice control?

The current use of audio functionalities in the operating room entails problems. Portable music players that are brought into the operating room form a hygiene problem and the surgeon cannot operate a telephone, as he/she would loose sterility. An integration of these functionalities can solve these problems.

Such integration is planned for the image data management system BrainSUITE NET, which enables the operating room personnel to have full control of all video and data signals in the operating room, e.g., a video signal from the endoscope or diagnostic data of the patient. The system can be operated from a touch screen interface. An implementation of audio functionalities would extend the abilities of the system.

This thesis establishes the basis for this implementation. The goal is to find answers to following questions:

Which audio functionalities are offered by market players?
Which functionalities are desired and required by the surgeons?
How can these functionalities be implemented?

Within this thesis the approach to answer these questions is performed in the following steps. After giving the basic information on the subject, a market research analyzes the audio functionalities of the market players. Voice control is closer examined, as it is a controversially discussed functionality. The surgeons' desires and requirements are investigated in a demand analysis. The basis of this analysis is a survey that was performed within this thesis among 65 surgeons. The last step is the conceptual design. Before implementing the final concept, important requirements on the system are derived from the following considerations:

In order to detect potential hazards for the patient and user a risk analysis is performed and measures are defined avoiding or diminishing those hazards.

Acoustical characteristics of the operating room are taken into consideration by calculating the reverberation time and the critical distance and associating the ambient noise with speech intelligibility. According to the results the microphone position and directivities are discussed. Different microphone construction types are considered regarding compatibility with magnetic resonance imaging.

The results of the performed investigations are implemented in a concept and designed as an extension to the BrainSUITE NET system. With schematic drawings the signal connections and components are presented. Closer information on the system is given by a description of each component.

This thesis focuses on audio functionalities, but as audio functionalities are often closely connected with video and other functionalities, these functionalities are taken into account when regarded useful.

2 Basics

2.1 Integrated Operating Rooms and their Purpose

"Integration" today is one of the favorite words in medical technology. It is highlighted on websites and in advertising brochures, and it seems to be one of the key sales arguments for a medical product. And this is not without cause. Integration can provide solutions to several problems that the staff in an operating room is facing.

Nowadays more and more equipment enters the limited space of an operating room. Each device has its own user and control interface and those devices needing to display their application all come with their own monitor. Furthermore all devices need cabling and the cables lie across the floor. This ends up in clutter and for the operating room (OR) personnel it is hard to keep the overview.

Here integration can be of help. By mounting devices to the ceiling and doing most of the wiring through ceiling connections the cable clutter is reduced, cleaning is easier and devices can be situated more flexibly. Linking the devices and installing a system, which allows using one display for several applications and which has one central point for controlling several devices, reduces the amount of equipment in the OR and simplifies its use.

Centralized control systems are even more helpful because a lot of devices cannot be controlled without loosing sterility. This means that the surgeon, the assistant, and the scrub nurse, who have to wear sterile clothing as they are in close contact with the patient, are dependent on an unsterile person, usually the rotating nurse. Enabling the surgeon to control all devices himself can avoid communication errors[1], and can reduce the waiting times for the rotating nurse, who is also responsible for other operating rooms and might be engaged elsewhere.

Another problem results from the changing workflow that digitization brings into the hospital. Many hospital procedures are being digitized, e.g., imaging in radiology. While x-ray images used to be taken on film, they are nowadays increasingly recorded digitally and displayed on screens. The format that is used is called DICOM (Digital Imaging and Communication in Medicine). Due to a very high resolution that is needed for diagnosis an immense amount of data has to be handled and new networking systems for communication and archiving were developed. Those so-called PACS (Picture Archiving and Communication System) are increasingly installed.

[1] Gärtner, A.: "Medizintechnik und Informationstechnologie" Band 2, Cologne 2005, p.202

Often operating rooms do not have access to the PACS. This means that a surgeon who wants to bring diagnostic images into the OR has to print them on paper, which involves a great loss of quality. “Integration” in this case means connecting the operating room to the rest of the hospital and establishing a smooth workflow by giving the surgeon access to the PACS, pre-operative planning, and patient data.

A significant possibility of integration is making available imaging devices like a computer tomography scanner or a magnetic resonance imaging scanner in the OR. These allow intra-operative imaging and thus bring big advantages for the quality of surgery and the patient. In brain tumor cases for example, scans are usually made in advance and surgery is planned with these pre-operative images. By opening the skull, the brain slightly shifts and thus pre-operative images are obsolete. With intra-operative imaging a new scan can be performed during surgery. Often the surgeon uses the help of a navigation system, which creates a 3-dimensional model out of the scanned volume data and gives the surgeon an exact insight into the brain. If such a system is used, the navigation data can be updated by the scans that are made intra-operatively, and the surgery can be performed very precisely. Intra-operative imaging also brings great benefit in controlling e.g., whether a tumor has been removed completely or screws in an orthopedic case have been positioned correctly.

Integrated operating rooms can bring various benefits. The current workflow is made easier, state-of-the-art technologies are adapted, and new opportunities for an improved patient treatment are established. The basic goals of all integrated operating rooms are to achieve “higher efficiency, higher patient outcomes, and a better competitive position”[2]. Surgery times can be reduced by 5%-26%[3], which has a direct influence on treatment costs. However, integrated solutions are expensive to purchase. And in reality integration is quite complex as many products are not compatible with each other and compatibility often depends on mutual company agreements.

2.1.1 BrainLAB’s Integrated Operating Room Solution

With the background of navigation systems for image guided surgery and radiotherapy solutions, BrainLAB AG started to distribute integrated operating room solutions called BrainSUITE in 2003. These solutions provide two versions of intra-operative imaging: BrainSUITE iCT integrates a computer tomography (CT) scanner and BrainSUITE iMRI integrates a magnetic resonance imaging (MRI) scanner. The second version is much more complex as an MRI scanner requires a special environment. During a scan, electromagnetic radiation of other devices can cause strong image distortions. Therefore, the room, in which the scanner is operating, has to be constructed with special walls

[2] Bauch, T.: “Strategic Analysis of the Market for Integrated Operating Room Solutions”, MBA Thesis, Munich 2003

[3] Holzer, A.: “Potential Benefits of an Integrated OR System – An Efficient Solution for the Operating Room?”, electromedica 70 no.1, 2002

that provide electromagnetic shielding, and all devices in the operating room have to be switched off.

The MRI scanner causes a permanent magnetic field. The magnetic field is defined by the 50-Gauß-line and the 5-Gauß-line (see Figure 6-9 in Chapter 6.4.3). As the magnetic field intensity is strong enough to attract magnetic devices within the 50-Gauß-line, only non-magnetic materials and devices may be used there. Sensible electronic devices may not be positioned within the area of the 5-Gauß-line. Objects, which might be attracted (e.g., scissors) or destroyed (e.g. credit cards), and devices that have not been tested, may not be brought into the BrainSUITE iMRI for safety reasons. During scanning the MRI scanner causes strong electro-magnetic radiation. Therefore, devices have to be MR-compatible. Most devices must be switched off during a scan because their usage would cause image artifacts.

In order to provide more integration and display possibilities, an image data management system (IDMS) was designed based on outside company hardware. With a second version BrainLAB became independent of the external company and prepared the introduction of BrainSUITE NET, which, in contrast to IDMS, will also be available for the BrainSUITE iCT and as a stand-alone version for all kinds of operating rooms. The BrainSUITE NET system will be described in the following section.

2.2 The Image Data Management System BrainSUITE NET

In the operating room there are more and more applications being used that require to be displayed. An endoscope, a microscope, a navigation system, and ultrasound are only some examples. The limited space of an OR, that already is very crowded, does not allow to add dozens of displays. Therefore, a system that makes it possible to use one display for several applications or to show the same application on several displays is needed. It forms the basis for integrating different medical and non-medical devices.

BrainSUITE NET is such a system of hard- and software that manages images, e.g., patient data and video signals, in an operating room. Through a touch screen interface the signals can be routed to different displays. Thus, the personnel of the operating room can determine on which display the existing data and video signals (e.g. the microscope or endoscope) shall be shown, within or outside the operating room. The access to information is given where it is needed.

The first version of BrainSUITE NET is on the verge of being released. Figure 2-1 gives an overview of BrainSUITE NET v1.0. The rack in the middle of Figure 2-1 is situated in an equipment room outside the OR. It mainly contains a high-performance video processor, a matrix switch, a server, a network switch, and devices that assure the functioning of the system and fulfill the safety requirements for medical systems.

The video processor is the core of the system. It converts the input signals into the needed output signals and adapts the resolutions. The matrix switch multiplies the video signals and provides a real-time path for video signals that do not have to be converted and, therefore, need not pass through the processor. The server hosts all the system software, among it the software for the Graphical User Interface (GUI), which is displayed on the touch screen, and the Application Switch, which is the software responsible for the possibility of using several applications on one display. The network switch connects the devices and is the connecting piece to the hospital network.

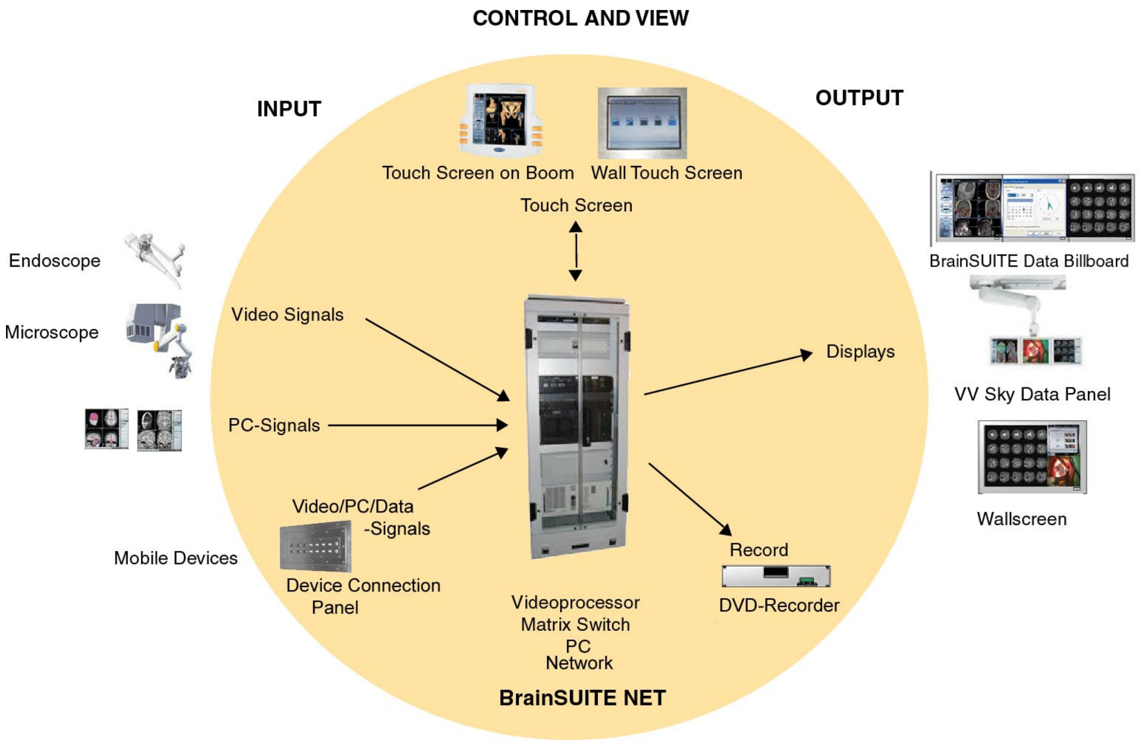

Figure 2-1 Overview of BrainSUITE NET v1.0[4]

BrainSUITE NET v1.0 offers the following image management features:

- A variety of imaging devices can be connected.
- Images can be displayed on all screens integrated to BrainSUITE NET, also on displays outside the OR.
- One image can be displayed on several screens at the same time.
- Multiple images can be displayed on one screen. The user can choose between a picture-in-picture function, a quad view (4 images parting 1 display) or tile display (1 image big, 2 others small next to it).

[4] Figure after Lang, G. Internal Training BrainSUITE NET Power Point Presentation, 2006

- Screen shots can be taken, stored, and displayed.
- Video can be recorded on DVD and recorded video can be viewed.
- A clock and a timer can be displayed (very important within BrainSUITE iMRI, as clocks are defective in magnetic environment).

Furthermore the navigation system is integrated and can be operated and viewed from one of the touch screens.

Future versions shall contain more functionality. One very important feature that will be implemented in the next version is a DICOM viewer (see Section 2.1), which allows the access to diagnostic image data in the operating room.

For further versions it is planned to integrate audio functionalities like a music and communication system, and teleconferencing capabilities. This thesis will deal with audio functionalities that are introduced in the next chapter. Teleconferencing will be touched on and investigated to some extent.

2.3 Audio Features in the Context of an Operating Room

There are several quite different applications for audio in an operating room. An introduction to the different applications is given in this section.

2.3.1 Background Music System

For some patients it is hard to believe, but it is widely common practice among surgeons to listen to music during surgery. It helps easing the stress they have to face everyday.

In a study the State University of New York investigated the effect of music on cardiovascular reactivity among surgeons. It shows, that the surgeons have a reduced automatic reactivity and a significantly better speed and accuracy of task performance when they listen to music[5]. Best results were achieved when the surgeons listened to music, which they selected themselves, in contrast to music selected by the experimenter and in contrast to not listening to music at all, which had the worst results. It has to be mentioned that in this study only surgeons participated who typically listen to music during surgery. There are also surgeons who feel quite disturbed by music and need silence in order to concentrate, as will be further described in Chapter 5.2.3.

Possibilities to get music into the OR are usually limited to bringing in a portable player e.g., a ghetto blaster or an iPod with external speakers. This is not a good solution regarding hygiene. It is also not possible for the surgeon to control the music because

[5] Allen, K. et al.: „Effects of music on cardiovascular reactivity among surgeons", The Journal of the American Medical Association, Vol. 272 No.11, 21-Sept-1994, accessible at http://jama.ama-assn.org

they may not touch the player due to sterility, and they have to rely on the unsterile team. In a BrainSUITE iMRI the magnetic field of the scanner causes problems.

2.3.2 Patient Music System

Some surgeries, e.g., knee surgeries, can be performed without general anesthesia. As general anesthesia always holds a risk for the patient's health, it should be avoided when possible. However, undergoing an ambulatory surgery can cause significant anxiety of the patient. Providing the patient with a headset and music saves him the trouble of hearing the unpleasant ambient noises of surgery. Furthermore music reduces the patient's anxiety and allows the decrease of sedative treatment[6] [7].

2.3.3 Telecommunication

During surgery there are several needs to communicate with locations outside the operating room, e.g.: Results of an instantaneous section have to be discussed with pathology, surgeons or nurses have to be summoned to the OR, and if someone needs urgent information from the OR-staff, it is a lot faster to talk to them by phone instead of going to the OR personally, for which the clothing has to be changed.

The special context of telecommunication in the operating room is based on requirements arising from sterility. During surgery, a surgeon cannot just pick up the phone and make a call. Unless the phone is sterile, the surgeon may not touch it. As it is not reasonable to sterilize a telephone (complex and extensive, and an unsterile person would not be able to use it), this problem is usually solved either by a speakerphone or by an unsterile person holding the telephone receiver close to the ears of the surgeon. As the telephone cannot be held in direct contact to the face the speaking quality is poor. In both cases a third person has to operate the telephone. This means that the surgeon always depends on another person, and as the telephone might be located at the edge of the operating room or even outside the operating room, the process of communication always means an interruption of surgery. Moreover, the surgeon has to take care not to get in touch with anything that is not sterile. If he/she did he/she would have to change his clothing.

Transmitting images and sound out of the OR has become of importance due to several advantages. Images of a surgery can be used for teaching purposes by transmitting them to an auditorium. With sound added the surgeon is able to explain his proceeding and answer questions. While only few students can participate in each surgery personally due to limited space, many students can be reached in an auditorium. Im-

[6] Lepage, C. et al: "Music decreases sedative requirements during spinal anesthesia" Anesthesia & Analgesia 2001;93:912-6

[7] Ayoub, C. M.: "Music and Ambient Operating Room Noise in Patients undergoing Spinal Anesthesia", Anesthesia & Analgesia 2005;100:1316-9

age and sound transmission can also be very attractive for live surgeries at conferences demonstrating new surgery methods.

Attending physicians often do not come to the OR until the surgery is prepared. Giving them the possibility to have a short “look” from their offices at the procedures that are going on in an OR can save waiting time for them. Additionally if a surgeon wants to consult a colleague it is a lot easier not only to talk to him but also to send him the corresponding video signals to his office e.g., through a teleconference system. That way the physician does not have to come to the OR and change his clothing, which means a big saving of time and effort. Through teleconferencing, specialists who are far away can be reached for obtaining a second opinion. Modern teleconferencing systems allow drawings and markers on the screen that can be seen from the remote viewer. This functionality is called telestration. It makes conversation easier and increases efficiency.

Intercom can be used in hospitals that have a so-called viewing room, a room that is directly situated next to an operating room but is accessible from a different area of the hospital. This area does not have special hygiene regulations, as it is not part of the surgery wing. Thus, visitors do not have to change clothing. Through a glass panel between the operating room and the viewing room the surgery can be observed. An intercom system allows the visitors to communicate with the surgeon. Furthermore it could be useful in a BrainSUITE for communication between the control room and the operating room. In the USA surgeons sometimes are supported by a radiologist, who sits in the control room. He/she helps to make a diagnosis from the scans. For quick consulting an intercom connection could be helpful.

2.3.4 Voice Recording

As medical staff has a lot of reports and documentations to write, dictations using voice recognition have already found entry into healthcare. In the operating room, voice recording could find application to support the surgeon in writing the OR report. As video is also recorded for documentation purposes, it is imaginable to record voice comments together with video.

2.3.5 Voice control

A device control system has to meet the high demands of sterility. Several possibilities to control devices have been developed. The most common ones are foot control, sterilizable mouse, keyboard or remote control, or a touch screen that is covered with a sterile drape. Voice control has also been applied for controlling medical devices for some years now. It has found application in minimally invasive surgery (MIS), angiography and in integrated operating rooms. Its big advantage is to provide the possibility to control a device while having both hands free. As voice control in medical application is currently intensively discussed it is closer described in Chapter 4.

2.4 Standards and Safety Requirements

In order to get an idea about regulations in the medical field the most important laws and standards shall be presented. They have to be considered during product development processes and will play a role for the conceptual design.

As medical products directly influence the health of patients there are important standards and laws that regulate the safety requirements for medical products. While the Food and Drug Administration (FDA) is in charge of the regulation of medical products in the USA, the Medical Device Directive 93/42/EWG (MDD) is the most important regulation instrument[8] in Europe. Each country adopts the specification of the MDD in its national law. In Germany this law is called Medizinproduktegesetz (MPG).

§ 3 of the MPG, which was fully adopted from the MDD Article 1-2(a), states, that a medical device is “any instrument, apparatus, appliance, material or other article […] intended by the manufacturer to be used […] for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process […]”[9] [10].

In order to ensure electrical safety and international conformity, the IEC (International electro technical commission) publishes standards that products have to comply with before they can be launched. The corresponding standard IEC 60601 does not know the term ‘medical product’ as described in the MDD, but defines the term ‘medical electrical equipment’ in IEC 60601-1. It is described as “Electrical equipment having an applied part […] to or from the patient […] and which is: a) provided with not more than one connection to a particular supply mains; and b) intended by its manufacturer to be used: 1) in the diagnosis, treatment, or monitoring of a patient; or 2) for compensation or alleviation of disease, injury or disability”[11]

Considering these two definitions BrainSUITE NET is neither a medical product according to the MPG nor medical electrical equipment according to IEC 60601-1.

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8 Wikipedia, free encyclopedia, http://de.wikipedia.org/wiki/Richtlinie_93/42/EWG, accessed 27-Dec-2006

9 Medizinproduktegesetz, http://bundesrecht.juris.de/bundesrecht/mpg, accessed 29-Dec-2006

10 Medical Device Directive, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!Prod!CELEXnumdoc&lg=en&numdoc=31993L0042&model=guichett, accessed 29-Dec-2006

11 IEC60601-1 3.63

Now the term of a medical electrical system (ME system) has to be introduced. IEC 60601-1-1[12] defines an ME system as a combination of non-medical electrical equipment with at least one item of medical electrical equipment. They have to be interconnected by either functional connection or by use of a multiple portable socket-outlet.

As BrainSUITE NET is connected to other devices, which are declared as medical electrical equipment (e.g. a microscope), it becomes an ME system. A future audio system will be part of BrainSUITE NET and, therefore, also belong to an ME system.

Being an ME system BrainSUITE NET needs to comply with special safety regulations. The ME system has to provide at least the safety that each component does and has to make sure, that it does not influence the functionality of the connected medical device. Within the patient environment it “shall provide […] a level of safety comparable to that provided by medical electrical equipment complying with IEC 60601-1, and outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO (International Organization for Standardization) safety standards.”[13] The regulation for the patient environment is described in Chapter 2.4.1. The corresponding standard for safety considerations of audio products outside the patient environment is IEC 60065 “Audio, Video and similar electronic apparatus-safety”.[14] In either case a risk management process has to be performed to cover potential risks. Additionally the special hygiene regulations in medical environments have to be considered.

In the USA, the IEC standards are adopted in the UL standards (Underwriters Laboratories), in Europe in the EN standards (European Standard). These standards can be more comprehensive than the IEC standards. For example, the UL 60601 is supplemented by means of fire protection. Most hospitals in the USA request devices conforming to UL because of insurance issues.

In Europe, for selling a medical product it is mandatory for the manufacturer to affix the CE mark[15] (Communauté Européenne) declaring conformity to the MDD 93/42/EWG[16] and the standards the product complies with. In Germany the CE mark is issued by the TÜV (Technischer Überwachungs-Verein), which can also certificate a manufacturer to issue the mark by himself. In an ME system usually each component has a CE mark.

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[12] In the new 3rd version of IEC 60601, the definitions and requirements for medical systems will be included in the part IEC 60601-1

[13] IEC 60601-1-1 part 3.201, Geneva 2000

[14] As the transition to information technology more and more blurs it might also apply the IEC 60950 “information technology equipment – safety”

[15] Wikipedia, free encyclopedia, http://en.wikipedia.org/wiki/CE_mark, accessed 20-Mar-2007

[16] Gärtner, A.: “Medizintechnik und Informationstechnologie” Band 1, Cologne 2005, p. 80

2.4.1 Patient Environment

The patient environment is “any volume in which intentional and unintentional contact can occur between patient and parts of the system or between patients and other persons touching parts of the system”[17]. Figure 2-2 shows the area of the patient environment.

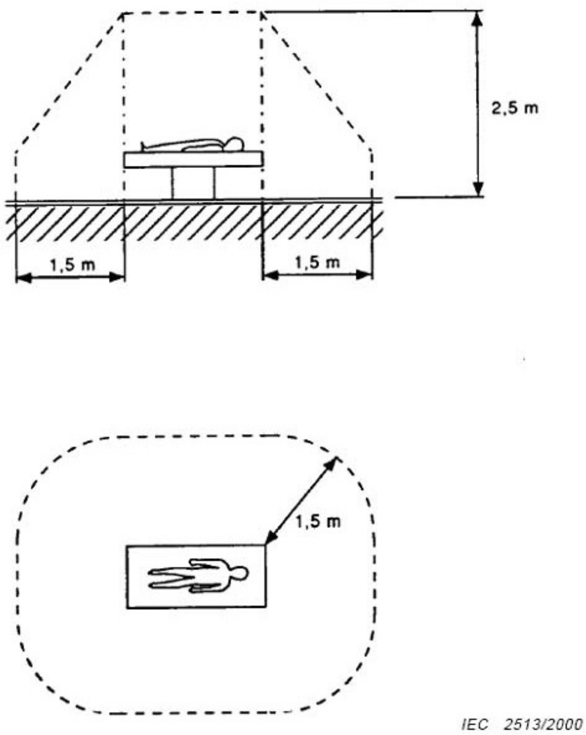

Figure 2-2 Scope of Patient Environment[18]

Being under anesthetic the patient does not have natural reflex mechanisms and no possibility to react consciously. If he/she gets in touch with anything that might hurt him/her, the patient cannot react. Another reason for providing special safety regulations for the patient is his/her skin. Skin has a resistance and protects the body to some degree from electrical current. When the skin is opened or removed during surgery its protection function is lost. When the patient gets in contact with a device or with a person touching a device at the same time, leakage current flows through vital parts of the patient’s body forming a significant hazard. Therefore, the normal leakage currents of devices within the patient environment have to be reduced. As defined in the IEC

[17] IEC 60601-1-1 part 2.202, Geneva 2000
[18] Extracted from IEC 60601-1-1:2000 Figure 201, Geneva, 2000, S. 27

60601-1 the maximum patient leakage current may be 0,5 mA in normal condition and 1 mA in single fault condition[19].

Devices that are to be touched by the surgeon have to be sterilized or protected by a sterile drape. Other devices have to be disinfected or cleaned according to the way the manufacturer specified it.

If a device causes airflow it can cause a contamination risk for the patient. Therefore, a laminar airflow field is installed in the ceiling above the patient. Nevertheless the airflow of a device has to be considered carefully.

All these regulations have to be taken into account when a device of the audio system shall be placed within the patient environment.

[19] IEC 60601-1, 3d Edition, Geneva 2005, p.171

3 Market Research Regarding Audio Functionalities

In this chapter the products of market players are described regarding audio and communication features. Afterwards, they are compared and discussed. To provide a better overview the products are separated into three groups. “Integrated OR solutions” covers the products in which audio functionalities are part of an overall concept for an operating room. “Communication, Documentation, and Control“ contains those products that are restricted to communication, documentation, and control functionalities but do not go beyond. “Teleconferencing solutions” are the products specialized on teleconferencing capabilities only.

3.1 Integrated Operating Room Solutions

The integrated OR solutions are mainly provided by companies that extended their core product to an overall OR concept. This core product mostly is endoscopy. With its main part being video technology, endoscopy is a good interface to a more comprehensive system.

3.1.1 Stryker - iSuite[1]

Stryker Corporation has its own division of about 150 employees[2] responsible for telemedicine and the integration of surgical equipment, lights and booms, called Stryker Communications[3]. It works closely with the division Stryker Endoscopy, which offers a family of integrated operating room solutions (iORS) named iSuite.

- Music System: The system can have a CD player, radio[4], and MP3. Two room speakers are offered.
- Telecommunication: Stryker’s communication abilities comprise teleconferencing and a telephone function, which enables the surgeon to make and receive calls in the sterile field.

[1] If not indicated otherwise, all information is derived from official product brochures and the company’s webpage www.stryker.com

[2] Cohn & Wolfe Public Relations, “Factsheet Stryker Op-Funktionen“, 3-May-2006, www.cwnewsroom.ch, accessed 13-Jan-2007

[3] http://www.stryker.com/communications/index.html, accessed 13-Jan-2007

[4] Installed in Medisch Centrum Leeuwarden (NL), according to Auke Meppelink, Sales, personal email 6-Dec-2006

- Voice Control: With the HERMES Voice control, the Sidne Device control can be operated by voice recognition of two surgeons. According to information on their website, training is not required.
- Voice Recording: Dictations can be recorded.
- Microphone: Two remote headsets are offered including speaker and microphone.

3.1.2 Storz - OR1[5]

Coming from endoscopy Storz offers integrated OR solutions since 1993. It includes a comprehensive audio and communication system.

- Music system: The OR 1 can integrate a CD-player and radio[6]. There are hints that Storz plans integrating the iPod[7]. Speakers are included.
- Telecommunication: Storz integrates a telephone function and teleconferencing capabilities that include the telestration technique[8] (explained in Chapter 2.3.3). Pager calls can be sent.
- Voice control: The Storz Communication Bus (SCB) for the control of components connects OR devices and communication technology and is operated via the so-called Media Control. Besides a touch screen the system can be controlled by voice control, which is sold under the name SESAM voice control.
- Voice recording: Image and data archiving is attained through the product family Karl Storz Aida. With AIDA™ compact and AIDA™ DVD the recording of voice comments on CD respectively DVD is possible. Before being stored, the wave-files can be reheard, renamed, and deleted if they are not needed.
- Microphone: For voice entry the surgeon needs to wear a wired headset for which an extension cord is offered. Additionally a room microphone with echo canceling and noise suppression is offered[8].

3.1.3 Smith & Nephew - Digital OR[9]

After a strategic partnership, Smith & Nephew's endoscopy division acquired Reed Medical Designs, Inc. in 2004 in order to provide multimedia-networking solutions. On their website Smith & Nephew describe the distribution of „real-time high quality au-

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5 If not indicated otherwise, all information is derived from the product brochure "Der integrierte OP"

6 Installed at Catharina Ziekenhuis Hospital, Eindhoven, according to Anke Weissenborn, personal conversation, 27-Sept-2006

7 Meppelink, A., Sales, personal Email 6-Dec-2006

8 Storz Presentation "The integrated operating room", accessed at http://www.vzi.nl/publicaties/20060609/08.pdf, 3-Nov-2006

9 All information is derived from official marketing brochures and the company's webpage www.endo.smith-nephew.com, accessed 14-Jan-2007

dio/video and digital images to locations inside and outside the operating room" as „key element" of their Digital OR. With the Condor Express Digital OR system Smith & Nephew provides a mobile version of the Digital OR that avoids the expense and inconvenience of an OR renovation. The devices are placed on a wheeled trolley.

- Music system: One hint was found that a CD-player can be integrated, but no closer information on a music system was available.
- Telecommunication: Teleconferencing capabilities are included. The integrated telephone function can be controlled from a touch screen, as well as the volume.
- Voice control: Smith & Nephew use the HERMES voice control for controlling devices. First distributed as HERMES Control Center the name was changed to CONDOR Control System. Training and voice cards are not needed. Commands are confirmed by "audio feedback through speakers and video feedback on the surgical viewing monitor" [10].
- Voice recording: Voice recording with voice recognition for audio documentation is possible.
- Microphone: For voice entry a wireless microphone headset is used. The microphone can be disabled.

3.1.4 Olympus - EndoALPHA[11]

The main industrial field of Olympus is endoscopy. The integrated OR system EndoALPHA is offered since 1997. It is a specialized OR for endosurgery.

- Music system: A CD-player is offered.
- Telecommunication: The system claims to have video conferencing capabilities but there is no precise information available what these capabilities comprise. A telephone is integrated.
- Voice control: Devices can be operated by a central touch screen or voice control.
- Voice recording: With the documentation system ENDOBASE voice comments can be recorded.
- Microphone: The microphone is positioned through a headset.

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[10] Product Catalog A , www.endo.smith-nephew.com, accessed 14-Jan-2007

[11] If not indicated otherwise, all information is derived from marketing brochures and the company's webpage www.olympus-europa.com, accessed 11-Jan-2007

3.1.5 Richard Wolf - Core[12]

Richard Wolf also is an endoscopy company. The OR solution Core can be installed ceiling mounted, on a mobile trolley or peripheral in forma of a nurse station.

- Music system: A music system is not supported.
- Telecommunication: Telecommunication solutions are offered including videoconference and a telephone system.
- Voice control: Voice control is available in 6 different languages and can control the OR-table, the OR-lights, a camera, and the DVD recorder. File names can be entered by voice.
- Voice recording: Voice recording is not offered.
- Microphone: A headset is used for voice control.

3.2 Communication, Documentation and Control

3.2.1 Conmed - Smart OR[13]

Conmed's OR system is based on a centralized room and device control, the Nurse's Assistant® OR control system. The control system, as well as communication and networking, can be operated by a touch screen interface. It cannot be used in the sterile field as it is situated at the nurse's workstation.

- Music system: The integrated music system can have a CD- or MP3-player, an FM tuner, and an iPod interface. A special add-on is the so-called „digital audio jukebox" for pre-selected music. Speakers can be wall mounted or inserted into the ceiling.
- Telecommunication: Teleconferencing is possible; a real-time communication between departments is claimed. Furthermore a telephone function is added.
- Voice control: Voice control is not possible.
- Voice recording: Voice recording is not offered.
- Microphone: To offer the surgeon communication possibilities without loosing sterility, a speakerphone is implemented. The microphone can be a wireless tie tack or handheld, or a wired microphone at the nurse's station.

[12] If not indicated otherwise, all information is derived from marketing brochures and the company's webpage www.richard-wolf.com, accessed 3-Nov-2006

[13] All information is derived from the marketing brochure "Innovation for the medical environment" and the company's webpage www.conmedis.com

3.2.2 Etacon - AMXMedical[14]

With AMXMedical the standard AMX system, which is an interactive control system for media and buildings, was adapted to medical needs. It is completed as a wall built-in station and cannot be controlled sterilely.

- Music system: A CD-player with a CD changer and radio are a part of AMXMedical, as well as speakers.
- Telecommunication: A telephone, videoconferencing, and pager call are included.
- Voice control: Voice control is not possible.
- Voice recording: Dictations can be recorded with the use of a voice recognition system[15].
- Microphone: Communication is performed via a room microphone or a headset.

3.3 Teleconferencing Solutions

Some medical technology companies like Berchtold and Maquet recognized the demand for teleconferencing in the OR. Their teleconferencing solutions are described below. Furthermore broadcast and video networking companies enter the market adapting their videoconferencing technologies to requirements of medical applications. An analysis of these products would go beyond the scope of this thesis, therefore, only the medical companies' solutions are considered.

3.3.1 Maquet - Communication Box [16]

Together with Oty GmbH, Maquet developed the so-called communication box (previous Maquet Oty View), which transmits one video signal (MPEG-4 with 1Mb/s) and one audio signal from the OR via the hospital network or the Internet to any place. The box is placed within the operating room, and two PAL or NTSC video signals can be connected to it. The selection of the signal that will be transmitted has to be taken by pushing a button on the box itself. This means that the viewers outside of the operating room cannot choose the signal, only members of the unsterile OR-personnel. For communication the surgeon wears a wireless headset. The transmitted video and audio signal can be received from any PC with Internet connection after a login. Using a PC-microphone the user can contact the operating surgeon.

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[14] If not indicated otherwise, all information is derived from the company's webpage www.etacon.de, accessed 2-Nov-2006 and the brochure “OP-Steuerung und Dokumentation” derived at EMTEC 2006

[15] According to Etacon employee Coopman towards BrainLAB employee Böttcher at EMTEC 2006

[16] All information is derived from the company's webpage www.maquet.com, accessed 15-Sept-2006

Since September 2006 the German Oty GmbH is incorporated in the Getinge Group. Before its acquisition Oty GmbH offered a more complex telemedicine solution with multi-point teleconferencing capability and DICOM integration in diagnostic resolution. Therefore, it can be expected that Maquet will offer more powerful communication solutions soon, maybe in relation with their integrated operating room solution, which so far does not include audio and communication.

3.3.2 Berchtold - ORCIS[17]

The communication system ORICS® C11 transmits 2 video signals and one audio signal in real-time over an existing network in PAL/NTSC resolution. It primarily consists of a box that needs to be situated in the operating room. Two analog video signals can be connected[18]. The audio signal is obtained either by a wireless headset with transmitter and receiver, or a wired headset with battery-powered supply unit. The signal is inserted in the box via an audio line input.

The signals can be received from any authorized PC connected to the network. The related software has to be installed. The user has to log in, and when a microphone is connected, he/she can talk to the operating room. In the operating room the voice can be heard either by connected active loudspeakers or earphones.

Once a user has logged in, a light at the ORICS box in the operating room is switched on informing the OR-personnel about viewers. The OR-personnel is not asked about permission. The first user who logs in gets the right to draw marks. These marks and the cursor can be seen on a screen in the operating room. When a Berchtold camera is used, the camera can be remote controlled. Other users can ask for getting the “operating rights” from the first user.

For documentation purpose Berchtold offers the ORICS® D21 Documentation system. This device has an audio line input and a microphone input. Sound is connected with recorded image and video and can be stored on DVD. Thus, it can be used for comments or dictations.

3.4 Comparison

Table 3-1 gives an overview of the audio functionalities that are offered by the market players as described in the previous sections.

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[17] All information is derived from the company’s webpage www.berchtold.de, accessed 25-Sept-2006 and a personal visit to the hospital “Rechts der Isar”, Munich, where this system was clinically proved.

[18] In the new version of the ORICS system, one digital video signal can be connected additionally.

Products	Music-System					Telecommunication					Microphone					
	CD-Player	Radio	MP3	iPod	Speakers	Telephone	Video-/ Audioconference	Pager Call	Telestration	Interactivity**	wireless headset	wired headset	wireless tie-tack	integrated	Voice Recording	Voice Control
Integrated OR solutions																
Stryker - iSuite	X	O	X		X	X	X				X				X	X
Storz - OR 1	X	O			O	X	X	X	O			O		O	X	X
Smith&Nephew - Digital OR						X	X				X				X	X
Olympus - EndoALPHA	X					X	X					X*			X	X
Richard Wolf - Core						X	X					X				X
Communication, Documentation+ Control																
Conmed - Smart OR	X	X	X	X	X	X	X						X	X		
Etacon - AMX-Medical	X	X			X	X	X	X				X*		X	X	
Teleconferencing Solutions																
Maquet - Communication Box							X				X					
Berchtold - ORICS					X		X		X	X	X	X			X	

X Information from website or marketing material
O Information from site-visits, trade-shows
* The headset presumably is wired, no closer information available.
** Interactivity = The communication partner can control something in the operating room e.g. choose the signal he wants to see

Table 3-1 Comparison of Audio Functionalities of Market Players

The companies providing a music system mostly have CD and Radio integrated. Conmed has the most comprehensive music system offering the possibility to play from numerous media formats and providing a digital audio jukebox for pre-selected music.

All integrated ORs offer voice control. According to Stryker, the iSuite can be operated by voice recognition of two surgeons while the products of other companies can only be controlled by one person. It is sold as an important future-oriented OR component. As voice control is discussed controversially, Chapter 4 investigates its importance and usability.

The fact that a telephone function is offered by all companies (except for the teleconferencing only solutions) expresses the upcoming need for communication. The companies give the surgeon the possibility to make a call whenever he/she wants to. Only two of the examined solutions provide the possibility to send a pager call from the operating room.

All products have video conferencing capabilities. The solutions can vary strongly, and in most cases no closer information about the options of the system are available. The mobile solutions of Maquet and Berchtold approach teleconferencing from different point of views. While the communication box of Maquet lets the unsterile OR personnel determine the signal, which shall be transmitted, the ORICS system of Berchtold steadily transmits two signals and puts the command into the hands of the viewer. Thus, the personnel can concentrate on the surgery. Anyhow, some surgeons might not like that the control, which signal is viewed and when, is partly out of their hands.

About half of the products offer the possibility to record voice. Some solutions have a voice recognition system included for documentation.

The microphone is almost always positioned close to the mouth by headsets. The reason can be found in the fact that all systems offer voice control, and voice control currently only works by close miking (see Chapter 6.3 Acoustical Characteristics of an Operating Room). A headset is the best solution here. Once having to provide a headset for voice control, all other audio applications that need a microphone, like the telephone function and voice recording, are also performed through it. The headsets are partly wired and partly wireless. Information about an additional microphone solution in the field of integrated operating rooms is only known of Storz who has a room microphone in its portfolio.

Since they do not offer voice control, both Conmed's Smart OR and Etacon's AMX-Medical use a speakerphone. Nevertheless they offer an additional possibility for voice input: Conmed a tie-tack microphone for wireless communication and Etacon a headset for dictations, which are supported by voice recognition.

3.5 Conclusion

Audio and communication functionalities of the market players are already very comprehensive. Communication and media have found entry into the operating room, and its usage is increasing. Considering the manifold offer of the market players, there is no way to ignore this trend. Not offering any of the functionalities would need very substantive arguments to get the customers understanding.

Nevertheless if these functionalities are offered, it does not mean that they are accepted and useful. Therefore, it shall be evaluated whether all functionalities fulfill the demands of the surgeons. The benefits have to be weighed up against potential effort. What does a fancy function serve, and do the surgeons accept it, when its usage is time-consuming or too complicated? On the way of providing an operating room with media equipment one may not loose sight of its main purpose: surgery.

However, if the OR team benefits from new audio and communication functionalities because they provide a higher quality, save time, ease work or just make the working atmosphere more pleasing, they definitely should be implemented.

4 Voice Control

As described in Chapter 3, voice control is offered by almost every company providing integrated OR solutions. The system that is in use most often is the HERMES control system. The company Computer Motion, which was taken over from Intuitive Surgical, developed it. Through various alliances with providers of integrated ORs (primarily Stryker, but also Karl Storz and Smith & Nephew), many OR devices are supported and can be controlled by voice.

Today HERMES is still the most common voice control system, though it is now marketed under multiple names. It is not quite clear whether companies are changing the name because the HERMES system has been replaced with different voice control technology, or due to marketing purposes. It may also indicate that the HERMES system was insufficient. It is known that it can be unreliable (see Section 4.2.1).

Other companies also provide voice recognition technology for the medical sector. For example, Philips is very strong in voice recognition for dictations of findings and is also trying to implement their technology for the control of medical devices (see Section 4.3).

Voice control in the operating room currently works as follows. The surgeon wears a headset and gives defined commands. These commands activate a determined action, e.g., move the OR table, turn the lights on and off or adjust the microscope. The surgeon must memorize the commands. However, because commands are displayed on a monitor in real-time, they can also be read off in the beginning. As the surgeon needs to talk to the OR staff, the system has to recognize when a command is given to the system and when not. This can be done by use of a keyword that activates the system. This keyword is then included in the command.

Voice control systems can be speaker independent or speaker dependent. Speaker dependent systems require the speaker to train the system by reading certain commands. Thus, the system can adapt to the voice of the speaker. This means that each user has personal settings that have to be saved. Speaker dependent systems can achieve a higher accuracy than speaker independent systems[1]. In contrast, speaker independent systems do not require training and can be used by anyone, which makes them more flexible.

[1] Haas, J. et al: “Spracherkennung und Sprachdialog: Stand der Technik, Einsatzbeispiele und zukünftige trends“, Design & Elektronik Entwicklerforum, Munich 2005, accesible at http://www.sympalog.de /cms/upload/ pdf/Artikel_Design_Elektronik_2004a.pdf, accessed 8 Dec 2006

For application in an operating room, companies provide speaker independent systems, as they do not expect surgeons to do trainings and use the personal settings.

Over the next few sections, the benefits and problems of voice control in the OR environment are described. The current practice of miking with microphone arrays is examined and a conclusion is drawn.

4.1 Benefits

Many devices in the operating room have to be operated. For controlling devices that cannot be operated sterilely (e.g. the operating table, lights), the surgeon gives commands to the rotating nurse. As the nurse is in charge of several tasks, it is possible that he/she is engaged outside of the operating room. If this is the case, the surgery has to be paused. Furthermore the surgeon cannot control these devices by him-/herself. He/she needs to explain his intentions and has to rely on somebody else. Communication errors might happen. Providing a sterile control possibility for these devices could ease the workflow, reduce errors, and save time.

A study of 30 laparoscopic procedures by the same surgeon, performed with the HERMES system, investigated the nurse's position during voice commands. In 23% of the voice commands, the nurse was immediately available in the OR. In 60%, the nurse was in the OR but engaged in other tasks, and in 17% the nurse was outside the OR. This shows that by using voice control, efficiency is increased.[2]

In a total of 100 laparoscopic cholecystectomy cases, another study measured the time required for three tasks performed with the help of an assistant or HERMES voice control. The tasks were: "the initial setting up of the light source and camera, the activation of the insufflator, and the deactivation of the insufflator and light source at the end of the operation"[3]. In all tasks, the HERMES voice control was about twice as fast.

An operating time reduction of 4.35 minutes was observed by an earlier study[4]. This reduction was considered practically insignificant, but the satisfaction of the nurses and surgeons with voice control was high. One possible reason for that is the integrated phone use, as surgery does no longer has to be interrupted to make a call.

These numbers show that voice control can increase efficiency. And after all, it gives direct control back to the surgeon, as he/she does not depend on the adjustments of a third person. However, the mentioned studies only compare the voice control interface

[2] Salama, I. A.: "Utility of a Voice-Activated System in Minimally Invasive Surgery" in Journal of Laparoendoscopic & Advanced Surgical Techniques, Vol. 15, No. 5, 2005, p. 443-446

[3] El-Shallaly G.E.H. et al: "Voice Recognition Interfaces optimize the utilization of theatre staff and time during laparoscopic cholecystecomy", in Minimally Invasive Therapy and allied Technologies, Vol. 14, No 6 2005

[4] Luketich, J.D: „Results of a randomized trial of HERMES-assisted versus non-HERMES-assisted for laparoscopic anti-reflux surgery", in Surgical Endoscopy, Vol. 16, No. 9, 2002, p. 1264-1266

with the work of an assistant. As other device control interfaces- like foot control, keyboard, mouse, touch screen and remote control- exist on the market, a comparison between those and a voice control interface is very interesting.

Voice control, touch panel control, and assistant control were evaluated by a study regarding efficiency, reliability and user satisfaction[5]. The study was performed in a pelvitrainer setting and the subjects had to control the zoom and light intensity of an endoscope, using either voice, a touch panel or an assistant. No significant difference in time was realized between touch screen control and assistant control, but they were both faster than voice control.

This shows that assistant control that is immediately available is usually faster than voice control. The time savings that were achieved by voice control in the other studies probably results from the fact that the assistant was not always instantly available. The time savings are achieved through the reduction of waiting times. Additionally, being independent of an assistant, or other control options like a touch screen probably reduces waiting times by the same amount. The fact that touch panel control was faster than voice control indicates that other control options might achieve an even greater time reduction.

The big advantage of voice control is that it can be operated hands-free. Another hands-free option is foot control. But the possibility of voice control has the advantage of not requiring the surgeon to look away from the operative field[6].

Despite its advantages, voice control has not yet broken through. The reason lies in continuing problems with implementation, which will be further explained in the next section.

4.2 Problems

Different problems with voice control in the operating room can arise. In the survey performed as part of this thesis (see Section 5.2) and in personal interviews (see Section 5.1.2) experienced surgeons with voice control report the following problems:

- The commands are recognized inconsistently.
- Background noise disturbs the voice recognition.
- When wearing a mask, the voice of the surgeon was not understood.

[5] Punt M. et al.: „Evaluation of Voice Control, Touch Panel Control and Assistant Control during steering of an endoscope" in Minimally Invasive Therapy and allied Technologies, Volume 14, No 3 2005, p. 181-187

[6] Allaf, M.E.: "Laparoscopic visual field voice vs foot pedal interfaces for control of the AESOP robot" in Surgical Endoscopy, Vol. 2, No. 12, 1998, p. 1415-1418

- To make the system work, the surgeon has to ensure silence in the OR, which is exhausting.
- The system is sensible to dialects and voice changes, e.g., if somebody has a cold.
- Responses lack or are delayed.
- Only one person is understood.
- Voice control in stressful situations or during a long surgery is not possible, or at least strongly limited, as the surgeon's articulation is affected ("aphasia of the surgeon").

Most of these problems arise from difficulties that are explained in the next Section 4.2.1.

Other problems are also related to the application of voice control in the OR. The psychological factor of talking and complying with a system should not be underestimated. Surgeons mention the increased dependency on technique as a negative. Additionally, social contact in the OR is affected and time is needed for practice[7].

4.2.1 Error-Rates and Safety Mechanisms

The problems of voice control in the operating room basically arise from the combination of voice control's fallibility and its application in a sensitive medical field that does not allow errors. As will be shown in Section 6.3, the operating room is a difficult acoustical environment. For example, background noise can complicate command recognition.

As described in the following, studies about error-rates are rare and contradictory. During the introduction of the integrated OR "SIOS"[8] (Siemens integrated operating room system) of Siemens, voice control was documented for the first 50 endoscopic cases. In a report, the system is described as reliable with an average recognition of 9 out of 10 commands[9]. If a command was not understood, the system did not react and a false interpretation did not occur. This totally disagrees with the experience that was made at hospital "Rechts der Isar" in Munich, where the system has been installed for several years now. In an internal study of the MITI Group (Workgroup for Minimally Invasive Therapy and Intervention), surgeons who use the system in their everyday work evaluated voice recognition. 1512 commands were registered during ongoing surgery and stress factors could be considered. 58% of the commands were interpreted correctly. In

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[7] Punt M. et al: „Evaluation of Voice Control, Touch Panel Control and Assistant Control during steering of an endoscope" in Minimally Invasive Therapy and allied Technologies, Vol. 14, No 3 2005, p. 181-187

[8] This system is has been discontinued.

[9] Schafmayer A.: "Der prozessoptimierte Operationssaal- Einführung eines integrierten OP-Systems in die klinische Routine", in electromedica 68 (2000), p.83-87

22% of the cases, the system did not react. 20% of all commands were interpreted incorrectly[10]. These numbers attest to an extremely low reliability.

The study comparing voice control with touch panel and assistant control reports that 3.1% of the voice commands were not interpreted, and 1.7% were incorrectly interpreted[11]. The HERMES system was used for this study. These numbers are significantly better than the previously mentioned results of the MITI Group. This probably results from the fact that the system was used in a training setting without disturbing effects like OR noise and other communications that may occur in a typical clinical setting. The strong difference may also indicate that reliability depends on the kind of voice control system.

Another study states that all voice commands were accurately interpreted by the HERMES system. In this study, the same surgeon performed 30 cases[12]. Considering the other studies, it is contradictory. An explanation can be found in the fact that all cases were performed by one surgeon. The system was probably adapted and trained to the voice of the surgeon.

It can be stated that voice control has not yet reached a 100% recognition rate. In the critical surgical environment a wrong action might have catastrophic consequences. Therefore, usage is often restricted to non-vital appliances, and errors have to be detected as good as possible. This is accomplished using the following measures:

- Menu structure: To command a special action, one has to be in the correct menu item. Menu items are called up by voice commands. If a command is given in the wrong menu item, the system does not react.
- Restriction of a command's scope: One command only causes a determined limited movement. For example, if the table needs to be moved more than the determined distance, the command has to be repeated several times until the desired movement has been made.
- Feedback: To confirm a command the menu structure is also shown on a display and audio feedback is provided.

These mechanisms reduce the user-friendliness of voice control. The user has to get through a complex menu and the command terms are sometimes very unnatural and require time to be memorized.

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[10] Marcos-Suarez P. et al: „Internal Report of the MITI Group to the Bavarian Research Foundation", Munich 2004

[11] Punt M. et al.: „Evaluation of Voice Control, Touch Panel Control and Assistant Control during steering of an endoscope" in Minimally Invasive Therapy and allied Technologies, Vol. 14, No 3 2005, p. 181-187

[12] Salama, I. A.: Utility of a Voice-Activated System in Minimally Invasive Surgery" in Journal of Laparoendoscopic & Advanced Surgical Techniques, Vol. 15, No. 5, 2005, p. 443-446

This problem is expressed by the neurosurgeon Dr. Esposito. When asked about problems with voice control in the integrated operating room (see Chapter 5.2) he said the following about the system installed in his hospital: “too many indications to give to the system for a simple action to do”.

The effect of an overly complex system or high error-rates is that the acceptance of the surgeons diminishes. The MITI Group in Munich experienced that the acceptance of voice control strongly decreased if other user interfaces exist that can be easily operated[13].

4.2.2 Headset

Another factor that causes problems is the fact that so far voice control needs close-miking. The reason for this is the acoustical environment of the operating room (see Chapter 6.3). For close-miking, several microphone positions can be used. The microphone can be positioned in front of the mouth by a headset, or attached to the clothing beneath the mouth in form of a tie-tack-microphone. It can also be attached to or integrated into the surgical mask.

The headset is the most common input device that is used for integrated OR solutions. The microphone has a fixed position and the system can be adjusted to that position. Even though modern microphone headsets are designed to be light and comfortable, they are considered to be very cumbersome by surgeons. During the implementation of a voice-interface for angiography, wearing a headset was seen as a potential problem. It is doubted that the surgeons would accept the additional work steps that are required[14].

Headsets require preparation and effort. The survey performed during this thesis confirms an averseness to headsets (see 5.2.3). The attachment to the mask is evaluated as less annoying than headsets, while the attachment to the clothing received the most positive ratings.

Several reasons can be found for the disapproval of headsets. The surgeons do not like to have something on their head. If they wear glasses, headsets are uncomfortable. During some surgeries protective masks have to be worn and headsets are not an option.

Additionally the headset has to be connected. Wired headsets restrict the movement of the surgeon. For remote headsets another device- the transmitter- has to be attached to the surgeon’s clothing. That means more necessary preparation and another attached device that is cumbersome.

[13] Schneider, A., Dipl.-Ing. MITI Group, personal email 30 Nov 2006

[14] Prümmer, M. et al.: “Mensch-Maschine Interaktion für den interkonventionellen Einsatz“, in Bildverarbeitung für die Medizin, Heidelberg 2005, p. 485-489

A solution to these problems would be to mike through microphone arrays, which supersedes the use of a headset.

4.3 Microphone Arrays

In the last few years a lot of research has been done in the field of voice recognition with microphone arrays. The significant advantage is that the speaker can talk from a distance and does not need a microphone close to his/her mouth. The voice is captured by an arrangement of several microphones surrounding the speaker.

The biggest problem associated with capturing sound from a distance is the noisy signal due to reverberation and background noise. These interfering signals have to be filtered out by complex processing. The use of several microphones helps to locate the speaker and to distinguish the desired signal. Without this processing a voice recognition system would not be able to recognize commands, as the quality of the voice signal would be too poor.

According to PD Dr.-Ing Nöth from the University of Erlangen, they managed to get the recognition rates with microphone arrays nearly to close miking levels[15]. The error-rate is a little higher, but is considered acceptable. False interpretations would have to be detected by confirming dialogs.

Philips announced a hands-free system using microphone arrays in 2005. It was tested under clinical conditions for controlling a cardiovascular x-ray machine during diagnostic and interventional procedures with the result to be "very promising"[16]. It is one of the first systems using microphone array technology in the medical field.

4.4 Conclusion

Surgeons are aware of the advantages that voice control can bring to the operating room. 71% consider error-free voice control as desirable, or even very important. In addition, it is advertised as a fancy, future-oriented functionality. This explains why hospitals buy voice control systems for integrated operating rooms.

But its reliability varies strongly and false interpretations may occur. Voice control only works with the aid of many safety mechanisms that significantly restrict user-friendliness.

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[15] Noeth, E. PD Dr.-Ing, Academic Director, Computer Science Department, University of Erlangen: personal email, 7 Nov 2006

[16] Philips Research, http://www.research.philips.com/newscenter/archive/2005/050921-hih.html, accessed 28 March 2007

In order to make surgeons accept a new control mechanism, big benefits are needed to justify the necessary effort. These benefits are not yet present in voice control, especially in comparison with other user interfaces, e.g., a touch screen. A touch screen offers the same benefits with greater reliability, comfortable operation and less effort.

Only for actions that require both hands is voice control really interesting. To have success, more progress has to be made to improve the reliability of voice control and to reduce the complexity of the system. Furthermore, voice control has to overcome the need to wear a headset.

5 Demand Analysis

The basis of a successful audio and communication system are the desires and requirements of the OR-personnel. If the system is integrated in a manner that does not interfere with the current workflow but furthermore allows a smoother, more comfortable and more effective workflow it will have success. To fulfill this demand the system needs to meet the requirements of the surgeons. In order to find out about these requirements information was gathered by pursuing different paths. BrainLAB employees of different departments were consulted for collecting all in-house information about audio demands of customers. Then potential customers of BrainLAB were interviewed. Furthermore the installed base of BrainSUITE systems was investigated regarding the audio and communication installations. The outcome of these investigations is presented in 5.1. As the best persons to know about the requirements are the surgeons themselves, a survey was performed to get meaningful conclusions. The survey procedure and its results are described in Chapter 5.2.

5.1 General Investigation of Demands

5.1.1 In-house Information

Within the last years a high demand for audio functionalities could be noticed. On several trade shows such as Medica and CNS (Congress of Neurological Surgeons) customers frequently asked for audio integration when visiting the BrainLAB booth[1] [2]. Sales contacts affirm that most of the larger hospitals, dependent on the type of OR, request a telephone, videoconferencing, and some type of audio system.[3] At installed sites it could be observed that surgeons bring their own music system into the OR, e.g., a portable CD-player or an iPod with external speakers, when no audio integration is provided by the OR system. Some surgeons even bring a remote control and put it in a sterile drape, in order to be able to control the system themselves[4].

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[1] Glimmann, J., BrainSUITE NET Product Manager: personal telephone interview, 25 Oct 2006

[2] McGuinn, B., iORS Product Manager, personal interview, 25 Oct 2006

[3] Carino, P., iORS Sales Manager North America, personal email, 26 of Sept 2006

[4] Seifert, U., Area Support Specialist IGS/BrainSUITE, personal email, 19 Dec 2006

5.1.2 Expert Interviews

Even though most ORs do not include an audio system as such, hospitals have a need for these functionalities and have found different solutions in order to meet their needs. Within interviews with prospective customers of BrainLAB the existent installations and their usage were described and the customers expressed their desires and opinions about different audio functionalities. The interviews were seen as preparation for the survey and were performed to get general information about the actual situation and ideas about audio functionalities. Some of the encountered setups shall be presented in the following. Because of privacy reasons, hospitals will not be mentioned by name.

In a hospital in Sao Paolo, Brazil, a radio and a TV are placed in the operating room. At present a portable player is put on the table but it is planned to integrate speakers in the walls. From the anesthetist's point of view, a radio is not suitable due to the broadcasting of talks and news. He sees the solution in the iPod, as CDs have a limited length. The surgeon talks to pathology by a hands-free speaking system. For this communication a button has to be pushed by an unsterile person. A videoconferencing system has been installed for 5 years now. During that time the point-to-point system was replaced by a multipoint system. It is used for teaching purposes and second opinion. Some devices in the OR can be voice-controlled with a headset, providing personal settings for each surgeon. It is not used very much, as the system has problems in recognizing the commands, especially if somebody has a cold. Currently a remote control is considered faster.

In a hospital in Singapore a HIFI system is installed. The OR staff always listens to music. The currently used media are CDs, controlled by the nurse or the anesthetist. No sterile control possibility exists. For communication, the OR is equipped with a portable phone including a hands-free function. When somebody calls, the phone is brought to the surgeon. As the sound quality of the hands-free function is bad due to noise and reverberation, the partners hardly understand the surgeon. A regulation for incoming calls is desired, as not all calls may get through to the surgeon. A videoconferencing system is not installed, but considered as necessary for teaching purposes. Voice control is regarded critical. With rotating teams including many foreigners, the system would have to work with many different voices and accents. For voice input the surgeons are expected not to accept headsets. It is indicated that with wearing glasses, a headset would disturb, and with wearing protective masks in orthopedic cases it is not possible to wear a headset. An application for voice recording can be imagined in taking notes that make it easier to write the report at the end of long operations, as people sometimes change during surgery.

In a hospital in Cleveland, USA, surgeons listen to music during surgery by placing a portable device in the OR. The currently used media is CD, but an iPod is desired with the possibility to create play lists. A video conferencing system is installed. A sterile telephone function, supplemented with access to Outlook and the address book, is regarded as an interesting functionality for waiting times. Voice control is currently not used but is desired. A purpose for voice recording is not seen.

In a private hospital in Australia some surgeons listen to music with a portable device. A videoconferencing system is not installed but regarded an interesting functionality. The director does not think the surgeons would accept a headset. Regarding voice control a very positive impact would be needed to make the surgeons change their workflow.

In a hospital in Erlangen, a microscope with voice control was in use but it did not work and only understood one person. Currently a touch screen is expected to be faster. A telephone function at the touch screen is considered a good idea. Sending images and samples and discuss it directly is a desired functionality.

5.1.3 Installed BrainSUITE Systems

Customers of the integrated OR solution “BrainSUITE” are able to choose different system modules according to their demands. The functionalities are then implemented according to the desires of the customer. In order to find out about the customers’ decisions all BrainSUITE iMRI systems that have already been installed and those that are currently being installed were investigated. 7 of the 13 customers chose built-in speakers, 6 decided to implement a microphone, and also 6 bought a room camera. Another 6 of the BrainSUITEs were provided with a phone line. 2 customers use intercoms: in one case to a viewing room next door, in the other to a laboratory. These numbers show that the interest in features for audio and communication is high. About 50% of all customers require audio and communication functionalities. This number is higher when only private hospitals are considered.

5.2 Survey

As Chapter 5.1 demonstrated, a general demand for audio exists. But what are the detailed requirements of the surgeons? Which functionalities are important, and which not? In order to investigate these questions, a survey was performed.

5.2.1 Survey Procedure

The survey was performed as a written survey in form of a questionnaire. This type of questioning was preferred to a face-to-face interview because the face-to-face interview would have been too time consuming, cost-intensive, and only few persons could have been reached. A written survey in contrast allows to question more people in less time, is easier to analyze, and the interviewee feels less pestered[5]. As the surgeons are known as busy people who are steadily bothered by surveys the survey requirements were the following:

- The interviewee needs to be able to answer the survey with as least effort as possible: it should be fast, easy to understand, and easy to operate
- The questionnaire needs to have a professional appearance
- The surgeon should not feel pestered as he/she shall be kept as contacts and because the company should not appear in a bad light.

Fulfilling those requirements the best, an online-questionnaire was chosen, and the interviewees were contacted by email. This procedure is much easier and more reliable than to fill out a questionnaire on paper that has to be sent back. Nevertheless, for the surgeons who prefer filling out the questionnaire on paper the questionnaire was attached as PDF-file to fax it back after completing.

To have a professional appearance the questionnaire was designed in a pleasing and a clearly arranged way. Being a big relief for filling out a questionnaire, mostly closed questions were used. They furthermore support the memory of the interviewee and allow a better interpretation and comparison of the answers[6]. The specified answers were extracted from talks with experienced colleagues, the expert interviews and partly from face-to-face interviews that were performed in a thesis[7]. Whenever it was possible that the interviewee might want to give an additional answer, a text field was added. In the cases that answers were not known or a spontaneous answer was required, open questions were applied[8]. However, as answering open questions is more time-consuming and extensive, they were avoided when possible. Usually an odd number of checkboxes was used to avoid the possibility to choose “middle”. Whenever it was regarded useful the choice “don’t know” was added.

As BrainSUITE NET has the goal to be installed in every kind of operating room the target group was not restricted to special clinical disciplines: every performing surgeon was considered adequate. The intention was to reach predominantly surgeons in higher positions as they have more experience and more influence on purchase decisions. Being a popular target for surveys, surgeons are difficult to convince to participate in a survey. Therefore, as many clinical connections of BrainLAB employees as possible were sought and the surgeons were addressed by referring to the contact person. Through this and a motivating letter a high rate of return could be reached. The questionnaire is attached in the appendix (see A).

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[5] Kastin, K. S.: „Marktforschung mit einfachen Mitteln“, Munich 1999, 2. Edition, p. 37

[6] Kastin, K. S.: „Marktforschung mit einfachen Mitteln“, Munich 1999, 2. Edition, p. 94

[7] Beier, A.: „Konkurrenzvergleich und Erstellung eines Produktanforderungskataloges für ein integriertes Bild- und Datenmanagementsystem am Beispiel der Firma BrainLAB AG“, Hochschule Pforzheim 2006

[8] Kastin, K. S.: „Marktforschung mit einfachen Mitteln“, Munich 1999, 2. Edition, p. 94

5.2.2 Participants

In total 65 surgeons were questioned within the period of two months. With 78% the major part are surgeons working in Germany. Table 5-1 gives the exact numbers in relation to the country of origin.

Country	Number of Surgeons
Germany	51
USA	5
Switzerland	4
Japan	1
Mexico	1
Italy	1
Denmark	1
Singapore	1
Total	65

Table 5-1 Number of Surgeons by Country

In order to get better analysis possibilities the surgeons were asked about their main surgical field and their position. The positions were classified into three categories: surgeon, senior surgeon and chief surgeon. The senior surgeons form the major group with 30 participants. Neurosurgery and Orthopedics are the surgical fields that are represented the most with 27 and 23 persons. Table 5-2 itemizes the number of interviewees by position and surgical field. The rate of return was 42% considering the surgeons who were personally addressed[9].

Surgical Field	Number of				Total Number by surgical field
	Surgeons	Senior Surgeons	Chief Surgeons	Others	
Neurosurgery:	10	10	7		**27**
Orthopedy / Trauma:	7	12	4		**23**
ENT:		4	1		**5**
Oral and maxillofacial surgery:	2	2			**4**
Plastic, hand and microsurgery:		1	1		**2**
General & vascular surgery:		1			**1**
Urology:	1				**1**
Visceral surgery:	1				**1**
Biomedical imaging				1	**1**
Total Number by Positions	**21**	**30**	**13**	**1**	

Table 5-2 Number of Surgeons by Position and Surgical Field

[9] One participant forwarded the questionnaire to all 154 surgeons of his hospital; the rate of return was 8%

5.2.3 Results

Music

To adapt the planned music system to the desires of the surgeons, they were asked about different media and players for playing music. The preferred media is a CD and an MP3-Player/iPod. The exact results can be seen in Table 5-3. While many surgeons enjoy listening to music in the OR there are also some surgeons who consider it as very critical. For example, neurosurgeon Dr. PD Scholz comments that he experiences music in the OR as very disturbing and even dangerous, especially during challenging surgery steps. This opinion is shared by the neurosurgeon Prof Fahlbusch. He regards music as unnecessary and points out, that many surgeries need elevated concentration and that some phases require almost absolute silence.

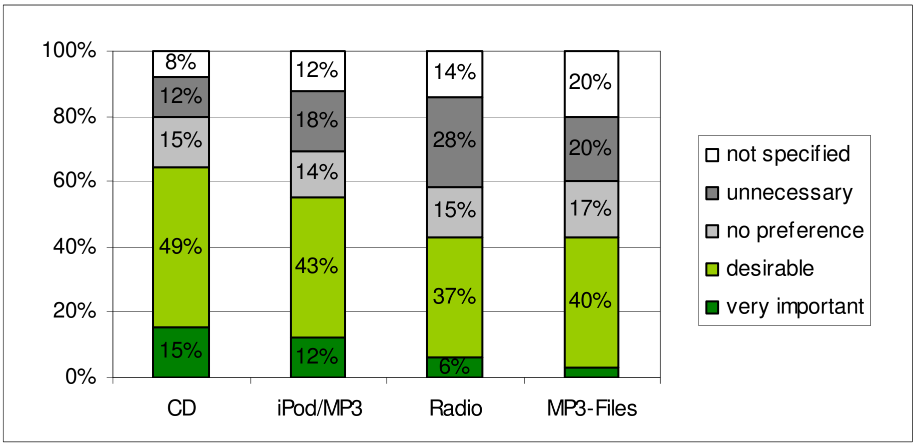

Table 5-3 How important would it be for you to play music in the operating room from the following media?

The basic OR team consists of sterile persons and unsterile persons. The sterile persons are the surgeon, his assistant and the scrub nurse. The unsterile persons are at least the anaesthetist and the rotating nurse. These five persons form the minimum composition of an OR team. The surgeons were asked, which of those persons should be able to operate the play back of music.

The surgeons answered: Rotating nurse 77%
Surgeon 40%
Anaesthetist 25%
Assistant 22%
Scrub nurse 12%.

Transmission of Sound and Video

The connection of the OR to other places in the hospital or outside of the hospital is an important field. From closer information about the type of connection and the communication partners, conclusions can be drawn on requirements for a communication system. Being of importance for the development of future audio and communication functionalities this subject is investigated with several questions. First the surgeons were asked about their general opinion towards sound and video transmission to get an appreciation of its importance. The evaluation of video and sound transmission out of the OR shows, that 91% respectively 88% classified video and sound transmission as "desirable" or even "very important" (see Table 5-4). These numbers strongly express the surgeons' desires to communicate with places outside of the OR.

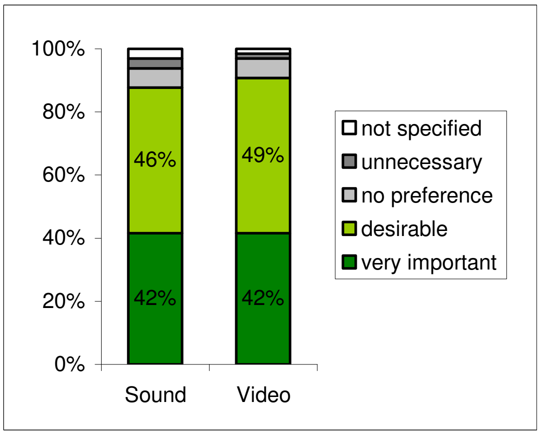

Table 5-4 How would you evaluate the possibility of transmitting sound/video out of the operating room?

Communication Partners

For the next question, a list of potential communication partners is presented with the request to choose those, the surgeon wants to communicate with. For each partner, the location is inquired, which gives information about the network and type of transmission that could be used for the communication system. Additionally for each partner the frequency of several communication functionalities is asked to get a more detailed idea about the kind of communication the surgeons need and which priority different functionalities have.

The primary communication partners are the office of a physician and the pathology with 68% each, closely followed by an auditorium/conference room. Table 5-5 gives an overview over the results and indicates, whether the partners are located within the hospital, externally or both.

The high choice of pathology mainly results from the large amount of neurosurgeons among the interviewees (42%). During neurological surgeries it is very common that tissue samples must be analyzed by pathology. If only the statements of neurosurgeons are considered, the result rises up to 94%. It is interesting that a big amount of pathologies is located outside of the hospital. About 2/3 of the mentioned experts are situated outside of the hospital. The communication to other ORs occurs almost completely within the hospital. Communication partners mentioned additionally were: product manufacturer/industry, intensive care unit, and live surgeries for congresses.

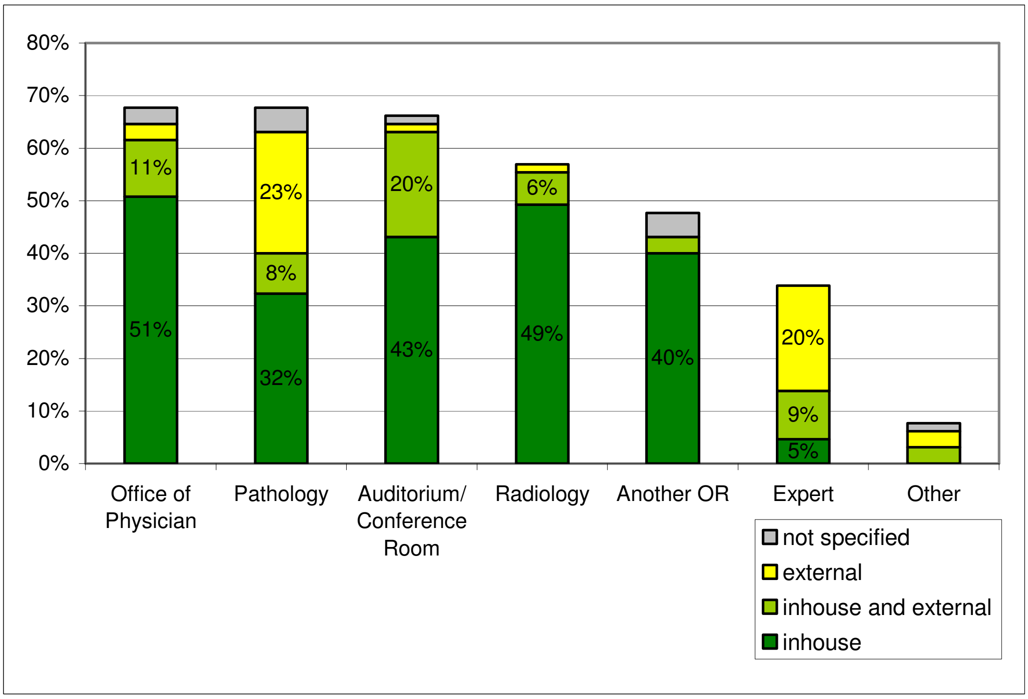

Table 5-5 With whom of the listed partners would you like to communicate in the operating room and where are they located?

Regarding the results divided by the different positions, the chief surgeons mainly desire a communication to the office of a physician and to an auditorium/conference room, as well as the senior surgeons (see Table 5-6). This is comprehensible as they are the surgeons who would like to contact the ORs from their offices and be contacted by them in order to avoid waiting times. Also they have the main teaching and lecturing responsibility. In contrast thereto the group of the "surgeons" shows a higher interest in contacting an expert.

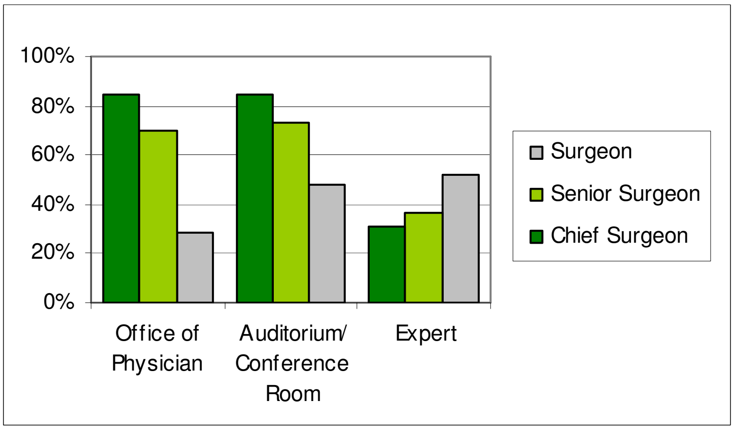

Table 5-6 Results of Table 5-4 divided by the positions of the surgeons

Communication Functionalities

The interviewees were also asked how often they would like to use predetermined functionalities for the conversation with each partner. The most important points are presented here. The complete results can be viewed in the appendix B. Generally it can be said that talking is the most often used type of communication (see Table 5-7). Sending a video signal additionally is very important for the office of a Physician ("regularly" 27%, "sometimes" 43%), the auditorium ("regularly" 28%, "sometimes" 49%), and another OR ("regularly" 23%, "sometimes" 42%). 64% of the surgeons would want the communication partner to initiate the conversation regularly or sometimes (see Table 5-8). Only 9% do not want the partner to be able to start the conversation. Asked whether the partner should be able to select and see any video source in the OR autonomously -after asking for permission-, the reaction was differing. The same question was asked again with the changing -without asking for permission. Here the prevailing answer was "never".

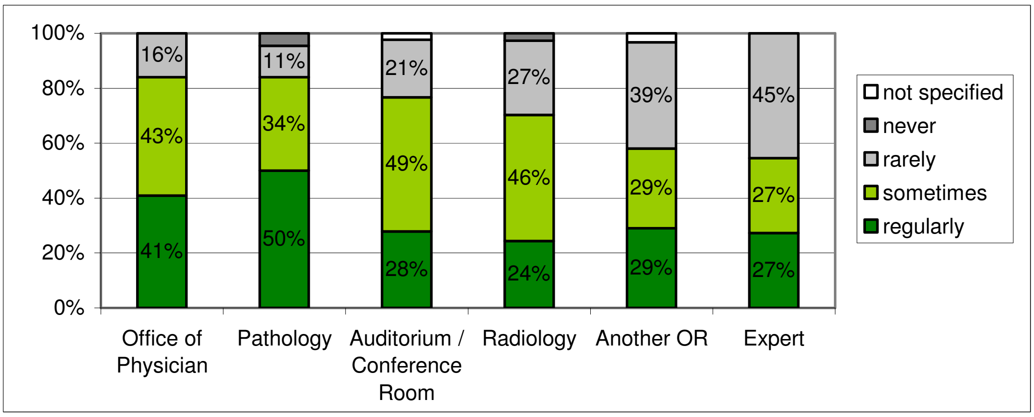

Table 5-7 How often do you need the given functionalities for this communication? I would like to talk to the partner.

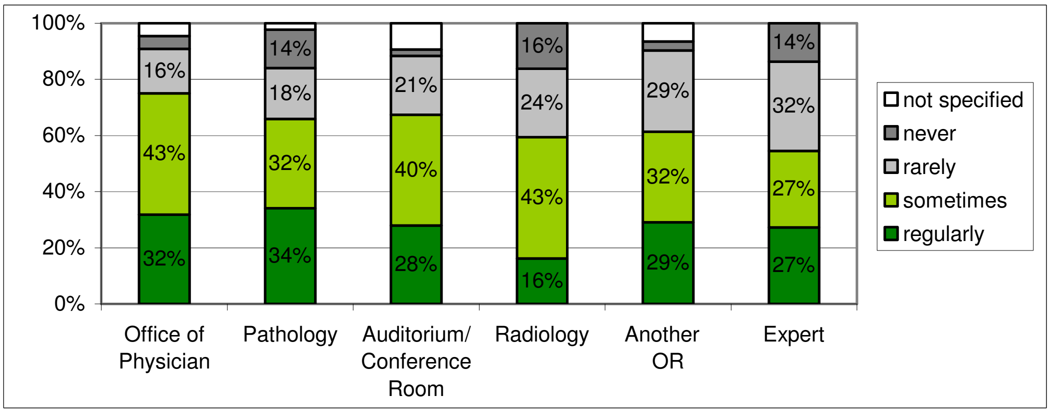

Table 5-8 How often do you need the given functionalities for this communication? The partner should be able to initiate the conversation.

Videoconferencing

For the evaluation of the current status of videoconferencing and telemedicine systems, the surgeons were asked, whether such a system is installed in an operating room of their hospital. 18 persons (28%) answered with yes. The satisfaction with these systems turns out diverse, as can be seen in Table 5-9. While some surgeons like Dr. Esposito report full satisfaction saying ”we can do whatever we want to do with it”, others mention the following problems: The systems are easily defective, complicated, cannot be operated sterile, are rarely used, and demand high effort.

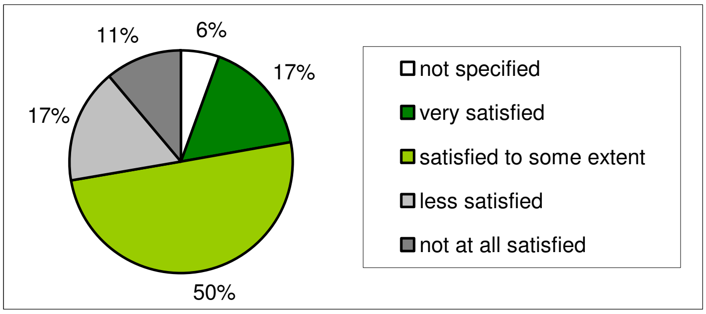

Table 5-9 Are you satisfied with the functionalities of your videoconferencing/telemedicine system? (18 persons)

Telephone Function

To find out how important a telephone is for the surgeons and which functionalities they predominantly need, the surgeons were interviewed about different call functionalities. Table 5-10 shows the results.

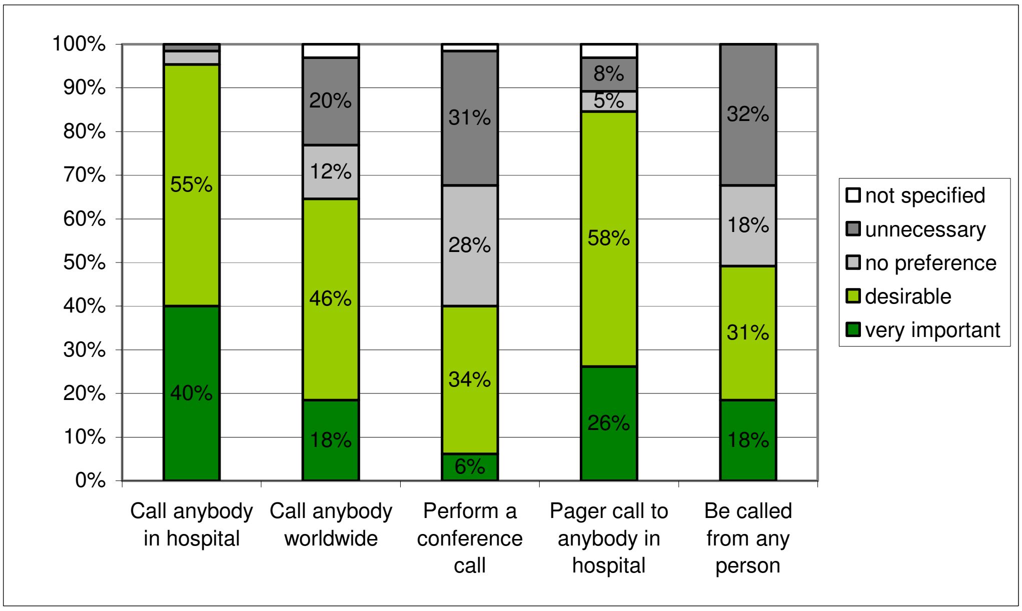

Table 5-10 How important are the following call functionalities for you?

“To call anybody in hospital” is rated as “very important” and “desirable” by 95% of all surgeons. Calling anyone worldwide is of less importance, but still desired, while the possibility to perform a conference call is a nice but unimportant functionality. One third of the interviewees think that being called is unnecessary. Nevertheless the same amount considers it as “desirable” and 18% as “very important”. This conforms better to the perception mentioned above, that the communication partner should be able to initiate the conversation. One interviewee adds that the surgeon may not be distracted by incoming calls. Being able to send a pager call to anybody in the hospital is evaluated as “important”.

Communication from Sterile Field and Participation in Communication

Very consistently answered was the question whether the surgeons wanted to communicate from the sterile field (Table 5-11). The numbers of 43% saying “very important” and 51% saying “desirable” make clear that the surgeons are tired of depending on an unsterile person when communicating.

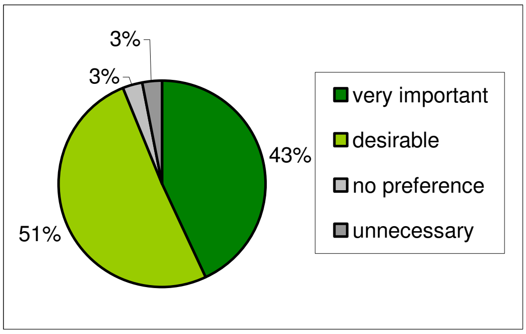

Table 5-11 How do you evaluate the importance to communicate in the sterile field?

In order to find out, who of the OR personnel wants to participate in the communication, the interviewees were asked to choose one or several of the basic OR persons that have been described previously. This information is important to find an adequate solution for positioning a microphone or several microphones and to know whether the control function should be sterile, unsterile or both. The answers were: “surgeon” 95%, “assistant” 62%, and “anaesthetist” 52% (see Table 5-12).

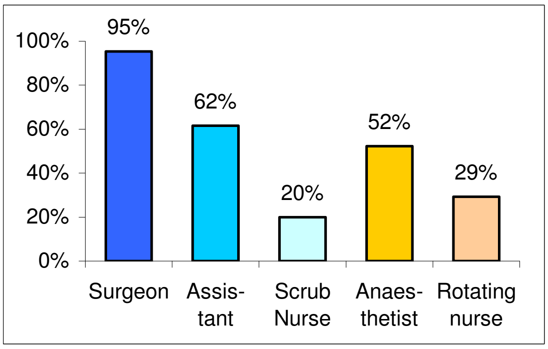

Table 5-12 Who of the OP-personnel should have the possibility to participate the communication?

Microphone Position

As ascertained in Chapter 1 most communication products for the OR work with a headset. The surgeons agree on the opinion about headsets: They declare it annoying. Almost 50% think that a headset is so annoying that it is not acceptable, while the other half considers it as annoying but acceptable. Only 6% rate it as not annoying (see Table 5-13). About the same opinion applies for a microphone that is attached to the surgical mask. A lot better is the judgement of a microphone that is attached to the clothing: half of the surgeons describe it as "not annoying". Representative for other microphone positions that are not directly influencing the surgeon, the possibility of integrating a microphone into the touch screen was added. As expected, this possibility was mainly appraised "not annoying".

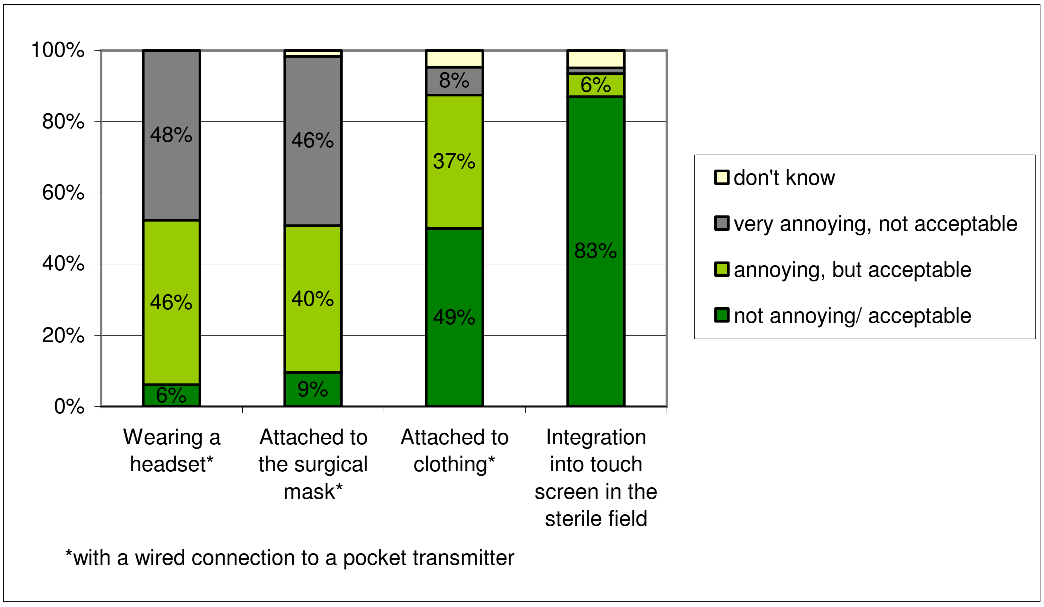

Table 5-13 How would you evaluate the following possibilities of microphone placements?

Voice Recording

Voice Recording attained a good rating. The majority of 65% describes it as "desirable" with another 14% as "very important" (see Table 5-14). It can be seen as functionality that is not an absolute must, but is in demand. No differences were made in the judgement of voice recording in addition to video recording and voice recording independent of video recording e.g., for dictations as support of the OR-report.

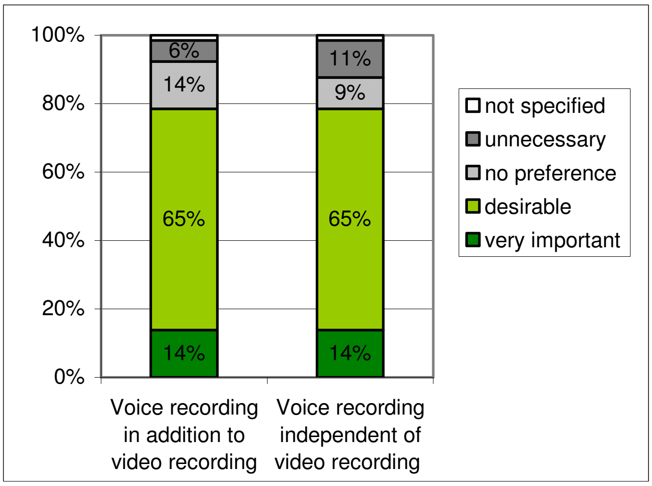

Table 5-14 How would you evaluate the following functionalities of voice recording?

Voice Control

As already mentioned voice control is a controversially discussed possibility of device control. To get a general impression about surgeons' bias towards voice control, they were asked whether they thought that voice control in the OR works. The result (see Table 5-15) expresses that the surgeons have a very critical attitude towards voice control. With blaming that it works "not very good" 42% have a quite negative opinion about voice control's reliability. About the same numbers of interviewees grant voice control to work "reasonable", while only 9% think it works "perfectly".

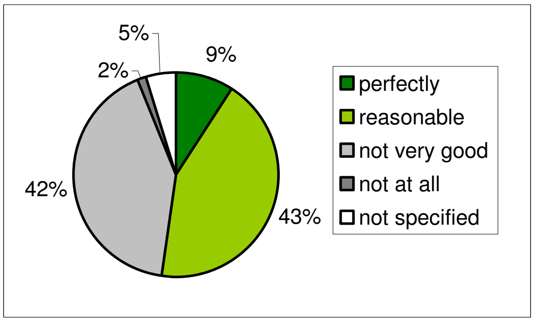

Table 5-15 Do you think that voice control in the operating room works?

The judgement of 14 surgeons, who have experience with voice control, is a little worse. Table 5-14 shows the answers regarding their satisfaction of voice control. No surgeon is "very satisfied", 5 say they are "satisfied to some extent", while 6 are "less satisfied", and 2 are "not at all satisfied". One surgeon adds that with people talking a lot it is bothersome for the surgeon to see about silence in the OR for making the voice control work. Another one points out that voice control in stressful situations or during a long surgery is not possible or strongly limited as the surgeon's articulation is affected ("aphasia of the surgeon").

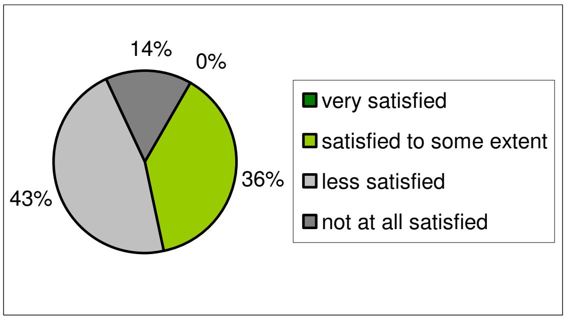

Table 5-16 Were you satisfied with the voice control? (14 persons)

Nevertheless the surgeons show noticeable interest in voice control- as long as it works. Slightly more than 50% of all questioned surgeons consider an error-free voice control as desirable, 17% rate it as "very important" (Table 5-17).

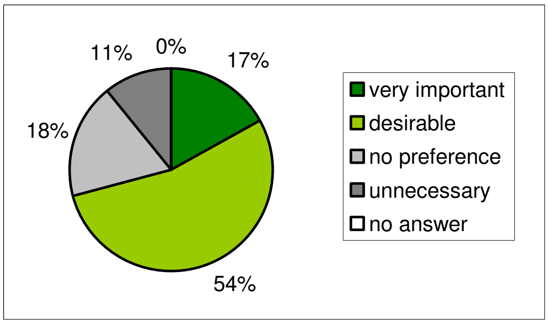

Table 5-17 How important would it be for you to use an (error-free) voice control in the operating room?

Device Control

In order to get a comparison of voice control with other device controls, the interviewees were asked for evaluating the most frequently used device controls. The result is shown in Table 5-18. A sterile touch screen scores best, with 60% of the participants describing it as "good", while voice control gets the worst judgement with 18% saying "good". It has to be recognized that 28% said: "don't know". Foot control notably is evaluated well.

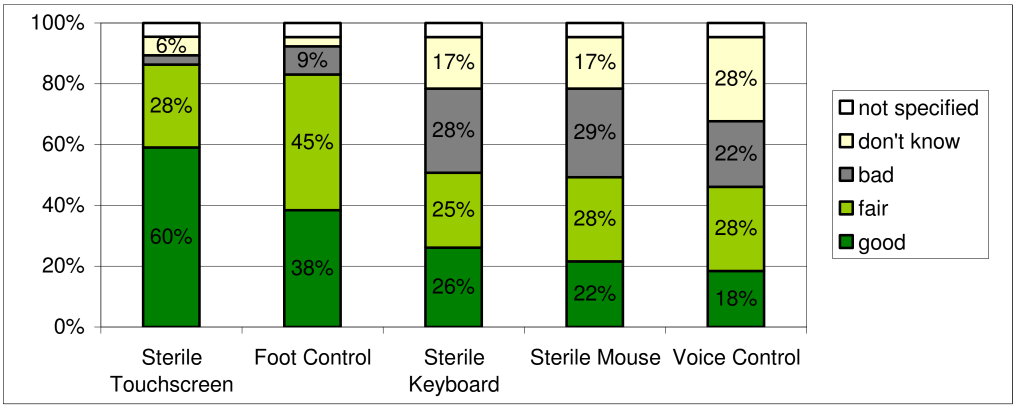

Table 5-18 How would you evaluate the following device controls?

5.3 Conclusion

The information gathered in-house shows that a general demand for audio integration exists. The expert interviews gave an insight to customers' opinion and desires and their current use of audio functionalities. The view at the installed BrainSUITEs shows that customers do not only have interest but also implement the desired functionalities. The following conclusions can be drawn from the survey:

A music system should be able to support CDs and iPod/MP3-Player. As the rotating nurse is the desired person to control the playback of music, an unsterile control possibility is needed. The surgeons themselves would also like to control the system. Therefore, the system should have both control possibilities and allow sterile and unsterile controlling.

The same can be said for communication. Surgeons definitely want to communicate from the sterile field. With 62%, the assistant is also a potential candidate for conversation in the sterile field. Additionally, 50% of the surgeons see communication purposes for the anaesthetist, and a few for the rotating nurse as well, which makes an unsterile option necessary. This means for a communication system that it should not be designed for one person but be independent of the person. With a headset this would be difficult to achieve, as either every person would have to wear one or it would have to be handed on. Considering the high numbers of surgeons saying headsets are annoying, headsets should definitely be avoided. If close miking is needed for any reasons, a tie-tack microphone is the most accepted position of a microphone that is attached to the body or the clothing of the surgeon.

A transmission of sound from the OR to other places is very important. If the system cannot cover it, it should provide at least the microphone signal and a corresponding interface so that the signal can be distributed by the hospital systems.

A telephone function, which allows calls within the hospital, is highly demanded. If a functionality to make worldwide calls can be implemented it would be good. Letting people make calls to the OR can make sense, but a control function is required, which lets only important calls get through to the surgeon, and which does not disturb the surgery through sudden and loud ringing. For partners with which a communication is needed regularly, like the office of a physician or an auditorium, a fix connection could be installed. This might be a kind of intercom system.

Voice Recording is an interesting functionality and should be implemented. Voice control is a desired function, but the surgeons have little confidence in it. The experience with voice control is not satisfying.

6 Conceptual Design

In this chapter an audio and communication system is designed. The functionalities are selected according to the results of the preceding chapters. A risk analysis is performed to consider important requirements for the design. Then the operating room is considered from an acoustical point of view. Different microphone positions and patterns are compared. The results are implemented in a concept that is presented and described by schematic diagrams and closer information on the components.

6.1 Selected Audio Functionalities

According to the results of the preceding chapters, especially the results of the demand analysis, the audio functionalities have been chosen as described in the following. For these functionalities a detailed concept is designed in the next sections.

Background Music

The system enables the OR-staff to listen to music in the operating room. The music can be played from CDs, an iPod or an MP3-Player. Speakers are integrated into the ceiling or the wall. The system can be controlled through one or two touch screens, of which one is always in the sterile field. A patient music system will not be considered. Not sufficient information could be gathered. If possible, a headphone jack will be added to the background music system, so that the same system can be used for patient music.

Communication

With a telephone function calls to other hospital locations as well as worldwide calls can be made from the sterile field. Additionally persons can call to the operating room. A pager call can be sent from the sterile field. A conference call function shall only be integrated if it does not cause much expense because it is not rated very important and does not have priority. The system shall be open to an integration of intercom so that the microphone and the speaker can be used for an intercom connection. An intercom system itself is not planned, as it very much depends on the particular demands of each hospital and probably is not needed by each one.

Documentation

Voice recording will be attained with the existing DVD-recorder for the time being. Another recording function on a different media, e.g., with support of voice recognition, makes sense, but will not be considered in this concept. The reason is that more detailed information on the exact purposes is still needed.

According to the results of Chapter 4, voice control will not be integrated.

6.2 Risk Analysis

In this section the subject and purpose of a risk analysis are explained. The risk analysis is then approached in order to determine requirements for the designing of the audio system. Finally the results are outlined.

6.2.1 Subject and Purpose

As the health of people depends on medical products, their quality always has to be at a high level. For ensuring this high quality, medical device companies are obligated to establish a quality management system[1]. Its duty is to introduce, perform, and control procedures in a company that are necessary to assure quality. According to the international standard ISO 13485 one “key requirement in many activities and requirements associated with quality management systems for medical device organizations” is “risk management“[2] The manufacturer is instructed “to establish documented requirements for risk management throughout product realization” and that records of the same be maintained[3].

Risk Management is needed to “make sure that the product is safe and effective to use for the patient and the user“[4]. Foreseeable hazards that might be caused by the device are identified and preventive measures must be taken. In the International Standard ISO 14971 all risk management requirements are described. It says that the “risk management process exists of: risk analysis, risk evaluation, risk control”, and ”post-production information“[5]. Figure 6-1 gives an overview over the approach to perform a risk analysis.

[1] DIN EN ISO 9001:2000, 4.1 General requirements, page 17

[2] ISO 13485:2003(E), Geneva 2003, p. 29

[3] ISO 13485:2003(E), Geneva 2003, p. 41

[4] Persson, P.: “BrainLAB SOP 04-01 Risk Management”, Revision 8, Munich, 2005 p. 1

[5] ISO 14971, Geneva 2000

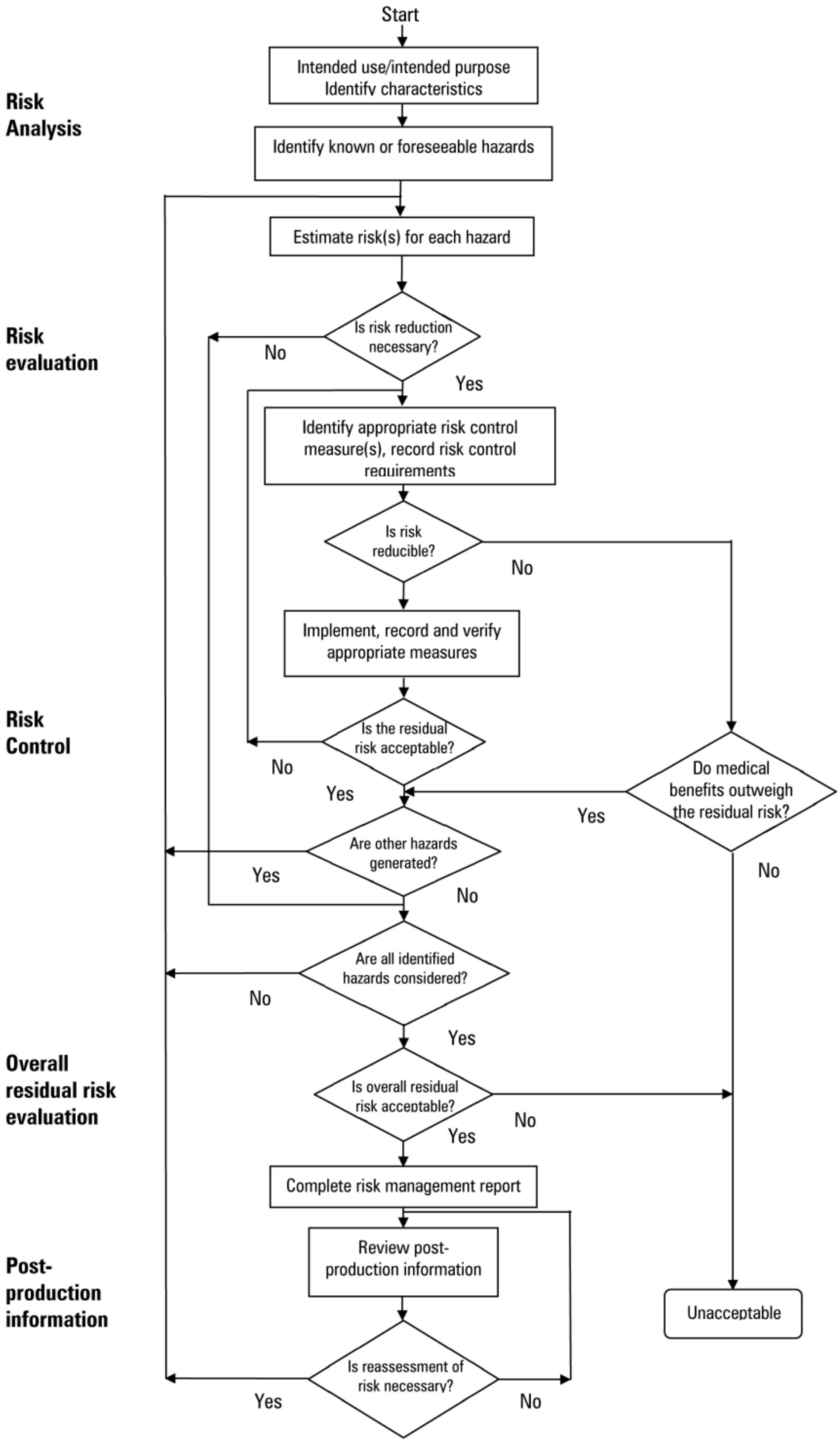

Figure 6-1 Overview of Risk Management Process[6]

[6] After Persson, P.: “BrainLAB SOP 04-01 Risk Management”, Revision 8, Munich, 2005

After identifying the purpose of the product, hazards have to be identified, and for each hazard the risk has to be estimated. This estimation incorporates an analysis of the probability of occurrence and the consequences. In the BrainLAB Standard Operating Procedure 04-01 Persson describes 6 levels of probabilities of occurrence and 4 severity levels of consequences:

Probability of occurrence

Frequent:	Most likely, has been continuously experienced
Probable:	Quite possible, will occur often
Occasional:	Unusual coincidence, will occur several times
Remote:	Remotely possible, unlikely but can reasonable happen
Improbable:	Conceivably possible, unlikely to occur but possible
Incredible:	Practically impossible, never known to happen

Severity of Consequences

Catastrophic:	Fatality
Critical:	Extremely serious injury (amputation, permanent disability, severe over exposure, serious shock)
Marginal:	Minor shock or injury (minor over exposure, non disabling injuries like cuts, bruises, bumps)
Negligible:	Less than minor injury

The estimated risks need to be arranged in a risk graph (see Figure 6-2). The risk graph shows three different areas: “broadly acceptable”, “ALARP” (=as low as reasonable possible), and “intolerable”. A risk is acceptable if it is rated into the “broadly accepted” or the “ALARP” region.

To reduce risks, appropriate measures should be implemented and the risk has to be estimated again after the implementation. If a risk is rated as intolerable and no further measures can be taken, it has to be decided on the basis of review data and literature, whether the medical benefit outweighs the residual risk or not.[7] If it does, the risk can be accepted.

[7] ISO 14971, Geneva 2000, p.10

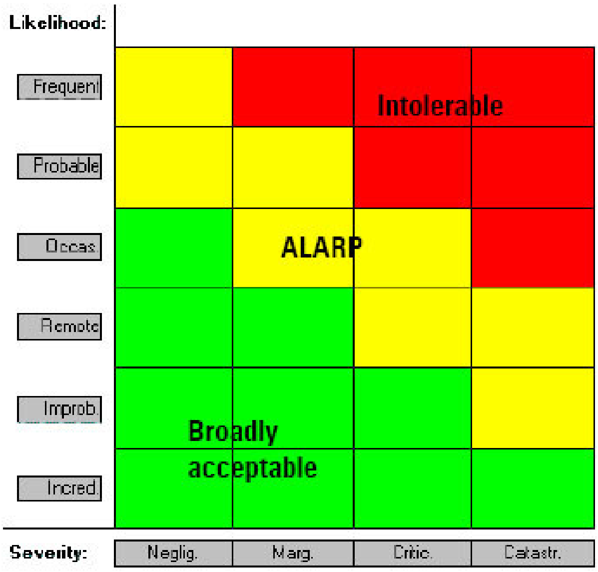

Figure 6-2 Risk Graph[8]

6.2.2 Performance

The basic functionality of the audio system has been described in Chapter 6.1. According to this description the risks have been identified. The risk analysis was performed in XTool, a particular program from BrainLAB that is used for the risk management process.

On the following pages the risk analysis of the audio system is presented.

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[8] Extracted from Perrson, P.: "BrainLAB Standard Operating Procedure 04-01", Revision 8, Munich 2005, p. 5

Hazard	Cause	Risk Before	Measures	Risk After
Risk Analysis				
A. Patient injury due to electric shock	**A.1.** Increased leakage current due to electrical failure	Probable / Catastrophic	**A.1.1. (1., BrainSUITE_NET_Audio_Processing) Functional:** All inputs and outputs, that are electrically connected or could foreseeable be connected to medical devices which influence leakage currents, have to be galvanically isolated according to IEC 60601-1-1.	Improbable / Catastrophic
			A.1.2. (2., BrainSUITE_NET_Audio_Processing) Statutory: The devices within the patient environment shall be powered through a medical power supply providing SELV or an electrical insulation transformer according to IEC 60601-1.	
			A.1.3. (3., BrainSUITE_NET_Audio_Processing) Functional: The devices in the patient environment must be permanently connected to protective earth.	
			A.1.4. (4., BrainSUITE_NET_Audio_Processing) Functional: The signal lines of devices that shall be integrated into the chassis of a device in the patient environment (e.g. the touch screen) are to leave that chassis only by optical transmission.	
B. Patient injury due to interference or drop-out of important devices	**B.1.** Devices disturb others through electro-magnetic radiation	Occasional / Catastrophic	**B.1.1. (5., BrainSUITE_NET_Audio_Processing) Statutory:** Devices must fulfill EMC requirements according to IEC, CE or FCC.	Improbable / Catastrophic
			B.1.2. (6., BrainSUITE_NET_Audio_Processing) Functional: For wireless signal transmission a frequency that is not used by other devices shall be used. If the frequency is not known a possible interference must be tested.	
			B.1.3. (7., BrainSUITE_NET_Audio_Processing) Functional: It shall be tested whether the usage of wireless transmission disturbs the functionality of the other devices used in an operating room.	

Hazard	Cause	Risk Before	Measures	Risk After
C. Injured persons and destroyed devices due to fire	**C.1.** Overheated device	Remote / Catastrophic	**C.1.1. (8., BrainSUITE_NET_Audio_Processing) Statutory:** All devices must fulfill the requirements of the corresponding standards IEC, UL, CE **C.1.2. (9., BrainSUITE_NET_Audio_Processing) Functional:** If necessary adequate cooling shall be provided for the devices . **C.1.3. (10., BrainSUITE_NET_Audio_Processing) Functional:** For critical devices a temperature test must be performed. The maximum ambient temperatures of devices may not be exceeded.	Improbable / Catastrophic
D. Patient injury due to startle response of surgeon	**D.1.** Music too loud when switching on the system	Probable / Catastrophic	**D.1.1. (11., BrainSUITE_NET_Audio_Processing) Functional:** A low sound pressure level must be preset.	Incredible / Catastrophic
	D.2. Acoustic crack due to input/output of jack plugs	Probable / Catastrophic	**D.2.1. (12., BrainSUITE_NET_Audio_Processing) Functional:** XLR connectors shall be used whenever possible. **D.2.2. (13., BrainSUITE_NET_Audio_Processing) Functional:** A sound pressure level limiter shall avoid sudden high sound levels.	Incredible / Catastrophic
	D.3. Incoming call ring tone	Frequent / Catastrophic	**D.3.1. (14., BrainSUITE_NET_Audio_Processing) Functional:** The call shall be shown visually or very low in volume.	Incredible / Catastrophic
E. Patient injury due to fallen off object	**E.1.** Microphone is not fixed correctly on boom or elsewhere	Occasional / Critical	**E.1.1. (15., BrainSUITE_NET_Audio_Processing) Functional:** Correct material must be used for the attachment of the microphone and the fixing technique is to be controlled.	Improbable / Critical
	E.2. Broken attachment of speaker	Occasional / Critical	**E.2.1. (16., BrainSUITE_NET_Audio_Processing) Functional:** Correct material must be used for the attachment of the speaker.	Improbable / Critical
	E.3. Speaker is not attached correctly	Occasional / Critical	**E.3.1. (17., BrainSUITE_NET_Audio_Processing) Functional:** The attachment of the speaker must be controlled and tested . **E.3.2. (18., BrainSUITE_NET_Audio_Processing) Functional:** The ceiling- or wall-mounted speaker shall be positioned outside of the patient environment.	Improbable / Critical
	E.4. Magnetic attractive force loosens attachment of speaker	Probable / Critical	**E.4.1. (19., BrainSUITE_NET_Audio_Processing) Functional:** The ceiling- or wall-mounted speaker shall be positioned outside of the 5-Gauss-Line.	Improbable / Critical
F. Patient injury due to misunderstanding or not hearing of accoustic warning signals	**F.1.** Music overlays warning signals	Probable / Critical	**F.1.1. (20., BrainSUITE_NET_Audio_Processing) Functional:** A maximum sound pressure level shall be implemented for the playback of music. This might be realized by a sound pressure level limiter.	Improbable / Critical
	F.2. Telephone overlays warning signals	Occasional / Critical	**F.2.1. (21., BrainSUITE_NET_Audio_Processing) Functional:** The call shall be shown visually or very low in volume.	Improbable / Critical

Hazard	Cause	Risk Before	Measures	Risk After
G. Patient infection due to contact with unsterile object	**G.1.** Tie-tack microphone or headset microphone is wrongly attached at surgeon and falls down.	Occasional / Critical	**G.1.1. (22., BrainSUITE_NET_Audio_Processing) Manual:** Detailed instructions have to be given about how to attach the headset or the microphone correctly. **G.1.2. (23., BrainSUITE_NET_Audio_Processing) Manual:** The users shall be trained how to attach the headset or the microphone correctly. **G.1.3. (24., BrainSUITE_NET_Audio_Processing) Functional:** For a tie-tack microphone or headset microphone safe fixing measures shall be used and the fixing shall be tested.	Remote / Critical
	G.2. Unsterile tie-tack microphone or headset microphone contaminates surgeon due to wrong attachement.	Occasional / Critical	**G.2.1. (25., BrainSUITE_NET_Audio_Processing) Manual:** Detailed instructions have to be given about how to attach the headset or the microphone correctly.	Remote / Critical
	G.3. Microphone is wrongly attached at boom or other device and falls down.	Occasional / Critical	**G.3.1. (26., BrainSUITE_NET_Audio_Processing) Functional:** Safe fixing technics for the microphone shall be used and tested.	Remote / Critical
	G.4. When the microphone is positioned in front of the mouth, the surgeon blows dirt from the microphone to the patient by talking	Occasional / Critical	**G.4.1. (27., BrainSUITE_NET_Audio_Processing) Manual:** The microphone must be covered with a sterile drape.	Remote / Critical
H. Patient or user injury	**H.1.** Cord of wireless transmitter interferes movement, gets caught	Remote / Marginal	**H.1.1. (28., BrainSUITE_NET_Audio_Processing) Manual:** It shall be advised about how to attach the transmitter and the cable. The transmitter has to be attached securely. The transmitter and the cord should be inside of the clothing. The cord has to leave enough length for the freedom of movement. If needed the cord shall be fixed with adhesive tape. **H.1.2. (29., BrainSUITE_NET_Audio_Processing) Manual:** The user shall be trained about how to attach the transmitter and the cable correctly.	Improbable / Marginal
	H.2. Stumbling over cord of wired headset or tie-tack microphone	Occasional / Marginal	**H.2.1. (30., BrainSUITE_NET_Audio_Processing) Manual:** It shall be advised about how to deal with the cable of a wired microphone. The cable may not lead over the patient and may not disturb other persons. The cable shall be put inside of the clothing.	Remote / Marginal

Numbers shown in **bold** font mark ALARP Risks (As Low As Reasonably Possible). Numbers for intolerable and acceptable Risks are shown in normal font.

Before measures

Likelihood				
Frequent	**0**	0	0	1
Probable	**0**	**0**	2	3
Occasional	0	**1**	**8**	1
Remote	0	1	**0**	**1**
Improbable	0	0	0	**0**
Incredible	0	0	0	0
Severity	Negligible	Marginal	Critical	Catastrophic

Number of risks: 18

After measures

Likelihood				
Frequent	**0**	0	0	0
Probable	**0**	**0**	0	0
Occasional	0	**0**	**0**	0
Remote	0	1	**4**	**0**
Improbable	0	1	6	**3**
Incredible	0	0	0	3
Severity	Negligible	Marginal	Critical	Catastrophic

Number of risks: 18

6.2.3 Results

18 risks have been identified and measurements have been defined. The resulting risks are mainly in the “broadly accepted” area of the risk graph, 7 stay in the lower “ALARP” area. The most important results for the designing of the system are summarized here.

Specifications resulting the risk analysis, which are important for the system design, are:

- The connection of devices in the OR and devices outside of the OR must be carried out via an optical transmission.
- Whenever possible, XLR connectors should be preferred to jack connectors.
- Devices are to fulfill EMC requirements according to UL, CE or FCC.
- In the patient environment:
  - Devices in the patient environment have to be powered by a medical power supply with SELV (safety extra-low voltage), which is restricted to 60V DC.
  - Signal lines of devices integrated into the chassis of a device in the patient environment are to leave that chassis by optical transmission.
- For devices in the operating room the correct types of cleaning and resistance to humidity have to be considered.
- A sound pressure limiter has to be implemented.
- For the music a low dB-level shall be preset.
- As many devices as possible shall be kept out of the OR.

Specifications that were detected during the risk analysis and have to be documented in the manual are:

- The OR staff is responsible to the effects of listening to music during surgery.
- Only professional CDs should be played to avoid problems with playing and to avoid different sound levels of songs.
- The patient's health or surgery may not be affected when recorded information is not available. This may happen when there is a lot of background noise, a defective microphone or a defective connection. If a wireless transmission is used, the battery can be empty or the transmission can be interfered.
- The surgeon must always be able to continue surgery correctly without the communication system.

The following specifications, which do not cause a risk for a person but are important for the system design, were also discovered during the process of the risk analysis:

- A microphone positioned in the patient environment might come in contact with liquid, blood or humidity. Therefore, a water-resistant microphone should be used or a protection drape must be applied. Otherwise the microphone might be damaged. Additionally invading liquid can reduce or eliminate insulation barriers.
- Ground loops might occur. Ground loops are caused if devices are connected to different power supplies with potential differences. In an audio system it can be heard as a steady humming sound. Ground loops can be avoided using symmetrical transmission or a galvanic isolation, e.g., through optical transmission.

6.3 Acoustical Characteristics of an Operating Room

In an operating room basically hard surfaced materials are used. As they can be cleaned easily these materials are needed for fulfilling hygiene regulations. Their disadvantage is that they absorb sound very little. Materials like cloth, which absorb sound very well, can hardly be found. This leads to a very reverberant acoustic environment. Sound is reflected several times causing echoes. In this chapter the reverberation time and the critical distance are explained, calculated, and its meaning for the audio system is described.

6.3.1 Reverberation Time and Critical Distance

A free field is a field without any reverberation. In reality only "outdoor conditions may approximate it"[9]. Inside of buildings we always face material, e.g., walls that reflect sound and cause reverberations. The farther we move away from a sound source the lower becomes its sound pressure while the sound pressure of the reflections becomes stronger in relation. The area in an enclosed space where sound has already experienced multiple reflections before arriving is called *reverberant field*. By contrast the *direct field* is defined as the area where sound reaches without having been reflected before. There is one certain distance to the sound source where the sound pressure level of the direct sound and the reverberant sound are equal. This distance is called *critical distance* D_c. It plays an important role in sound recording because sound quality decreases outside of the critical distance and microphones loose their directional characteristics when positioned in the reverberant field.[10] Therefore, microphones should

[9] Eargle, J.: "The Microphone Book", 2nd Edition, Oxford 2004, p. 14

[10] Sengpiel, E.: "Relativer Abstandsfaktor DSF=Distance Factor", Berlin 1994, accessible at www.sengpielaudio.com

always be positioned within the critical distance (except those that aim to capture the ambient sound).

The critical distance is defined by the following equation:

$$D_c = 0{,}057\sqrt{\frac{V}{RT_{60}}} \qquad V = \text{Total room volume} \qquad (6.1)$$

$$RT_{60} = \text{Reverberation Time}$$

For the determination of the critical distance the reverberation time (RT_{60}) is needed. The reverberation time is the „time required for the reverberant field to diminish 60 dB after the direct sound source has stopped“[11]. It gives important information about the acoustic characteristics of a room. RT_{60} can be calculated after Wallace Clement Sabine:

$$RT_{60} = 0{,}161\frac{V}{A} \qquad (6.2)$$

with

$$A = \sum_{i=1}^{n}\alpha_i \cdot S_i + \sum_{j=1}^{k} A_j + 4\cdot m\cdot V \qquad (6.3)^{12}$$

$A =$ Equivalent absorption area [m²]

$S_i =$ Partial interior surface [m²]

$\alpha_i =$ Absorption coefficient of surface

$A_j =$ Equivalent absorption area of devices and persons in the room [m²]

$m =$ Damping coefficient of air [m^{-1}]

$V =$ Total room volume [m³]

The equivalent absorption area expresses the overall surface that absorbs sound to 100%. It is calculated from the sum of all partial areas multiplied with their corresponding absorption coefficient. The absorption coefficient of a material is the ratio of the sound that is absorbed to the sound that is reflected. Additionally the equivalent absorption area of devices and persons is considered, as well as the damping of air.

6.3.2 Calculation

For getting closer information on the acoustical characteristics of an operating room, the reverberation time was calculated with the formula of Sabine. Therefore, the equivalent absorption area is needed and has to be approximated. This calculation

[11] Eargle, J.: “The Microphone Book“, 2nd Edition, Oxford 2004

[12] Willems, W.M.: „Vorlesungsskript Bauhysik I“, Ruhr University of Bochum, accessible at http://www.ruhr-uni-bochum.de/bauko/downloads/bph1_uebung11.pdf, accessed 30 March 2007

does not claim exact correctness. It is an approximation to get a general idea and orientation for further considerations. A more detailed calculation is complex as the position of each device and person influences the acoustical conditions. For such a detailed calculation special programs exist, which simulate the whole room with all objects and their positions. Also measurements can be taken. This would have to be done for each project particularly.

Calculation of the Equivalent Absorption Area

For determining the equivalent absorption area, information on the size and materials of the walls, the ceiling, and the floor is needed, as well as the surface and material of devices. As operating rooms differ in size and layout, the BrainSUITE iMRI with its recommended room sizes of 10 m x 6 m x 3 m is chosen as example for the calculation. It is one probable usage site for a BrainSUITE NET system. Figure 6-3 shows the devices within a BrainSUITE iMRI.

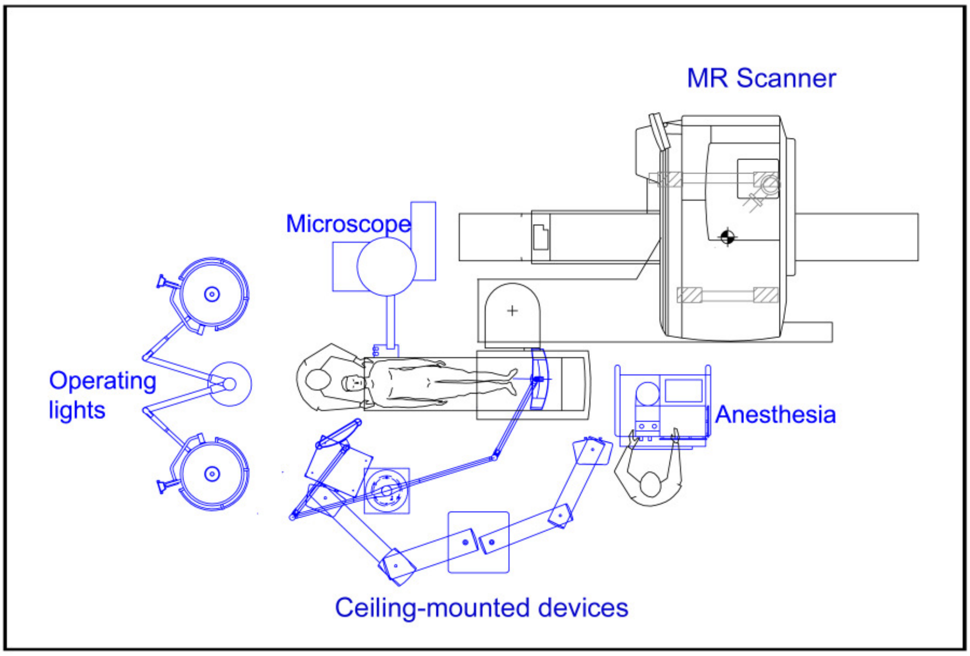

Figure 6-3 Devices within BrainSUITE iMRI[13]

The walls are made of panels of stainless steel and panels of glass. The floor is of linoleum and the material of the ceiling can vary. For the calculation gypsum was assumed. The surfaces of the following devices were considered: scanner, microscope, OR table, ceiling-mounted operating lights, ceiling-mounted devices, and patient monitoring devices (anesthesia). As the absorption coefficient was not found for all materials, some were estimated. The OR table was calculated with the equivalent absorption area of 3 chairs with a textile cover. As persons change the acoustic conditions of a room considerably, the presence of the following persons was assumed for the calcula-

[13] After iORS Site Planning, BrainSUITE iMRI Master Layout

tion: 4 persons standing (surgeon, assistant, scrub nurse, and rotating nurse) and 2 persons sitting (anesthetist, patient[14]). The damping coefficient of air was chosen for a humidity of 40%. The whole calculation of the equivalent absorption area according to equation (6.3), with the used absorption coefficients and the indication of their source, is attached in the appendix (see C). As the absorption coefficient varies for different frequencies, the equivalent absorption area A is frequency-dependent. The calculation was performed with 500 Hz and 1000 Hz, as these are the common values later needed for calculating the reverberation time.

The result of the calculation of the equivalent absorption area according to equation (6.3):

$$A_{500} = 13.75 \text{ m}^2$$

$$A_{1000} = 15.10 \text{ m}^2$$

Calculation of the Reverberation Time

With A needed for the calculation of the reverberation time (see equation (6.2)) the reverberation time RT_{60} is also frequency-dependent. Usually it is given for 500 Hz. Additionally 1000 Hz have been calculated.

The result of the calculation of the reverberation time according to equation (6.2):

$$RT_{60/500} = 2.1 \text{ s}$$

$$RT_{60/1000} = 1.9 \text{ s}$$

An RT of $RT_{60/500}$=2.1 s is very long and can cause problems for speech intelligibility. For 1000 Hz the reverberation time decreases to $RT_{60/1000}$=1.9 s. The reasons are mainly the persons absorbing higher frequencies stronger than lower ones. The ideal reverberation time for rooms that are supposed for speaking (e.g. teaching rooms) is between 0.6 s -0.8 s for room sizes of V=125 m³ to 500 m³ [15]. Reverberation times over 2 seconds usually can be found in churches or big concert halls. A reverberation time of $RT_{60/500}$=2.1 s seems very high in consideration of the room size. But it is explicable as the only absorption in an OR is caused through persons and devices while the walls, the ceiling and the floor practically absorb no sound. A similar value is affirmed by an article about the effects of physical environment on speech intelligibility in teleconferencing[16]. During the testing, a reverberation time of RT_{60}=2.4 s was determined in an operating room 20 m³ smaller than the exemplary OR used in the calculation above.

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[14] No equivalent absorption area could be found for a lying person. Therefore, the patient was calculated as a sitting person.

[15] Voigt, B.F.: „Bauphysik“, Hamburg 1994, p. 177

[16] Wu, M. et al: „Effects of Physical Environment on Speech Intelligibility in Teleconferencing“, 2005, accessible at http://digitalcontentproducer.com/web_exclusives/speech_intelligibility/, accessed 16 Feb 2007

Calculation of the Critical Distance

With the reverberation time the critical distance was calculated. The critical distance is also frequency-dependent due to the relation to the reverberation time. Therefore, it was calculated for $RT_{60/500}$ and $RT_{60/1000}$.

The result of the calculation of the critical distance according to equation (6.1):

$$D_{c/500} = 0.53 \text{ m}$$

$$D_{c/1000} = 0{,}56 \text{ m}$$

As expected it is very small. In rooms with less reverberant environment it is usually about 1 m. This distance is needed for positioning the microphone, which is closer described in Section 6.4.1. In the following section the ambient noise in an OR and its influence shall be investigated.

6.3.3 Ambient Noise

Devices causing noise in the OR are the air conditioning, patient monitoring devices, suction, and sometimes devices like a saw. In the case of a BrainSUITE iMRI the cooling pump of the MR scanner permanently makes noise. Furthermore the personnel might be talking.

The background noise might cause problems for communication as it influences the intelligibility of speech. Speech intelligibility is a basic criterion for the quality of sound transmission. Usually the understanding of syllables within continuous speech is tested. An understanding of 80% of the syllables is a good comprehensibility and conforms to a 100% understanding of sentences[17]. The understanding of words lies between both, the mentioned values correspond with a word intelligibility of 95%.

Table 6-1 shows the word intelligibility in relation to the signal-to-noise ratio (SNR). The signal-to-noise ratio of a signal is the difference between the level of the signal and the level of the noise[18]. The value of Table 6-1 show that below 6 dB SNR the intelligibility of words decreases tremendously.

[17] Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 68
[18] Görne, T.: „Tontechnik“, Leipzig 2006

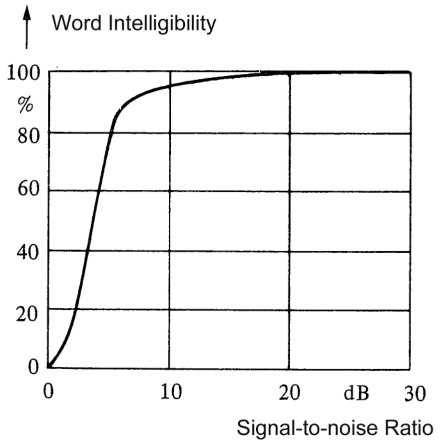

Table 6-1 Dependency of word intelligibility on signal-to-noise ratio[19]

In the following the ambient noise inside the OR is closer described and is associated with the sound levels of speech.

For protection of labor the ambient sound level should not exceed 55 dBA[20]. The unit dBA gives the sound pressure level (dB) weighted with a filter (A-weighting filter), which considers the frequency-dependency of the human perception of sound intensity. Regarding a study measuring the sound levels in different surgical disciplines[21] 55 dBA seem hard to realize. The levels reach from 53 dBA to 70 dBA with an average level around 64 dBA, depending on the discipline. This is about the level of a lawn mower from 10 m distance (60 dBA)[22]. In the tests about speech intelligibility in teleconferencing that was mentioned in the section before, the ambient noise of the operating room was lower with 45-55 dBA[23]. From these information the ambient noise can be estimated at 55 dBA. The first study gives louder levels. But during sound transmission it can be expected that devices making loud sounds, e.g., a saw, are not being used and that persons stop most of their conversation.

The sound level of voice in 60 cm distance from the mouth is about 60 dBA[24]. At a distance of 30 cm it increases by 4 dB, while it decreases by 4 dB in 120 cm distance. In a distance of about 50 cm, where a microphone would be positioned (critical distance $D_{c/500}$=53 cm, see Section 6.3.2), the voice level is then about 61 dBA. In case of an

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[19] After Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 68

[20] Ast, G.: “Verordnung über Arbeitsstätten“, 15th Edition, Stuttgart 2001, p. 19

[21] Kracht, J. et al: “Noise in the Operating Room“, 151st ASA Meeting, Providence, RI, June 2006, accessible at www.acoustics.org/press/151st/Busch-Vishniac.htm

[22] Sengpiel, E.: „Der Schallpegel“, www.sengpielaudio.com/TabelleDerSchallpegel.htm, accessed 15 Feb 2007

[23] Wu,M. et al: „Effects of Physical Environment on Speech Intelligibility in Teleconferencing“, 2005, accessible at http://digitalcontentproducer.com/web_exclusives/speech_intelligibility/, accessed 16 Feb 2007

[24] Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 65

operating room the speaker always wears a surgical mask. This mask might reduce the sound level. It is also possible that it merely attenuates some frequencies. For this calculation it can be assumed that the mask slightly reduces the sound level. The sound level of the voice of a person wearing a mask can be estimated at about 60 dBA in a distance of 50 cm to the mouth.

With the assumption of a signal level of 60 dBA (voice in 50 cm distance to the person) and a noise level of 55 dBA, the signal-to-noise-ratio is SNR=5 dB. Regarding Table 6-1 the word intelligibility would then be 80%. This value is critical. It has to be seen as absolute minimum. An SNR of at least 10 dB is desirable, as the word intelligibility would then be about 95%, which means a sentence intelligibility of 100%. The SNR can be increased by the microphone characteristic. Additionally noise canceling measures should be applied, e.g., the use of filters during signal processing.

6.3.4 Effects on the System

The system has to consider the difficult environment. The microphone should be placed within $D_{c/500}$=53 cm of the system, depending on the type of microphone that also has influence on the critical distance. This will be closer discussed in Section 6.4.1.

It is foreseeable that music in the operating room will miss low frequencies as hard surfaced materials, e.g., glass, absorbs them more than high frequencies[25]. An equalizer would make an adaptation of the sound to the acoustic behavior of the room possible and would thus make the sound more pleasant.

The same applies for the microphone signal. Its frequency response should be adapted to the room characteristics of the specific operating room. The surgical mask and maybe drapes that might have to cover the microphone probably change the frequency of the voice.

As the microphone position and characteristic influence the level of ambient noise that is picked up, they should be chosen well.

Noise canceling measures should be applied. Frequencies with strong noise, which are not determinative for the understanding of voice, can be attenuated during signal processing. Voice in total uses frequencies up to 10 kHz but the basic parts that are needed for understanding are below 4 kHz. Table 6-2 shows the effects of the transmission of a maximum frequency on speech intelligibility.

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[25] Tenbusch, W.J.: „Grundlagen der Lautsprecher“, Oberhausen 1989

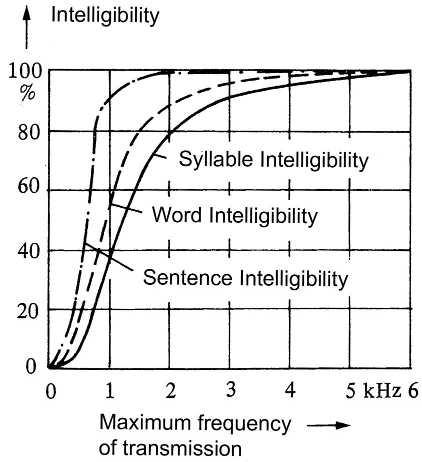

Table 6-2 Speech Intelligibility in relation to the maximum frequency of transmission[26]

It shows that with transmitting voice with a maximum frequency of 2 kHz, 100% sentence intelligibility respectively 80% syllable intelligibility can be achieved. From 4 kHz upwards the change of intelligibility is negligible. Therefore, it is proposed to attenuate frequencies above 4 kHz. With measures like these the SNR and with it the speech intelligibility can be improved.

6.4 Microphone

In Section 6.3.2 the critical distance D_c has been calculated. With this information the position of the microphone can be determined. It should be within the critical distance or about at the critical distance. At a greater distance the sound gets poor and the microphone looses its directivity. In the following section different microphone positions and patterns shall be discussed according to the results of the preceding chapter. Then the specialties of a microphone in the environment of the MR scanner and the patient are described.

6.4.1 Characteristics of Different Positions

The best sound can be obtained through close miking. With this technique noise and reverberation have the least influence. As the microphone has to be very close to the mouth, it can only be positioned through headsets or attached to the mask or to the clothing of the surgeon. Its advantage is not only the sound, but, if a wireless solution is used, the surgeons can also move freely and talk wherever they want.

However, as the survey showed (see Chapter 5.3), the surgeons dislike the attachment of microphones. Furthermore their usage has to be planned and prepared, which

[26] After Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 68

means effort and expenditure of time. The danger of user errors exists. The unsterile microphone might fall down and contaminate the sterile area, which is a hazard for the patient. Additionally each person participating in the communication has to be provided with a microphone. On this account a solution without the need of attaching a microphone at the body of the surgeon is wanted.

Another close miking position is thinkable: attaching the microphone at the microscope. As not all surgeries use a microscope and as only the operator of the microscope can use it, this solution is not considered as a general one for the system. It would be a single and very specialized solution, e.g., for teaching purposes. For handling phone calls the inflexible position at the microscope is not appropriate.

Considering fix microphone positions, several possibilities occur. The microphone could be attached to the ceiling, to a ceiling-mounted boom, to the OR table or other devices. Considering the acoustic characteristics of an operating room, as derived in Chapter 6.3, the possibilities diminish significantly. The microphone has to be within the critical distance $D_{c/500}$=53cm. The distance can be increased to about 90 cm by using a directional microphone as explained in detail in Section 6.4.2. Nevertheless it is a short distance and with this restriction only two microphone positions remain. These are miking from a boom and miking from the touch screen.

Miking from a Boom

At a ceiling-mounted boom the microphone can be positioned very flexible and can be used for every person. Its use does not have to be planned and requires only little effort to prepare, namely positioning the microphone, when the use is desired. A speaker used for the voice of the communication partner would also have to be fixed at the same boom in order to have a fix position of the microphone in relation to the speaker. This eases the settings for echo cancellation.

The problem occurring with miking from a boom is that providing an extra boom for the microphone would be a big effort for a microphone. Moreover, the boom would most probably get in conflict with other booms. Fixing it at an already existing boom of another device does not make sense, as the position would not be correct.

Miking from the Touch Screen

Like the miking from a boom the use of a microphone integrated into or permanently attached to the touch screen does not have to be planned and prepared. The positioning means little effort as well, which only has to be raised when needed, and it can also be used for every person.

A microphone on the touch screen would not be disturbing. The touch screen is the central element for controlling BrainSUITE NET and providing it with communication would emphasize its central function. When teleconferencing will be added in the future the corresponding video signal will most likely be shown on the touch screen. Having the microphone positioned will establish a basis for future teleconferencing. Attaching a speaker at the touch screen as well would make all positions fix and ease the setting for echo cancellation.

Result

Considering these two possibilities the positioning at the touch screen is more efficient and realistic. Providing an additional boom does not seem realistic. In contrast thereto the touch screen is the central control device and the communication will be operated through it as well. Therefore, the microphone shall be positioned at the touch screen or integrated into the touch screen.

The only inconvenience with miking from the touch screen is that the touch screen should be positioned within the critical distance, which is $D_{c/500}$=53 cm (or 90 cm, dependent on the type of microphone, see Section 6.4.2) of the speaking person. The surgeons have to be trained to do so. For a telephone talk the touch screen would be the “communication partner” with the lookout to video-conferencing.

When the microphone shall be used for a steady sound transmission during a teaching lesson e.g., to an auditorium a problem might occur. The reason is that the speaking direction is then not directed towards the touch screen. It depends on the microphone that will be used and on the positioning of the touch screen whether such a sound transmission is possible with the use of a touch screen microphone. This would have to be tested. A solution avoiding problems would be providing an additional microphone solution for these cases, e.g., a tie-tack microphone. For the special cases of a transmission during the whole surgery this extra effort is acceptable weighed up with an increased sound quality.

The sterile drape that is put on the touch screen and allows a sterile operation will also be covering the microphone. This might have influence on the sound. During the development process of another BrainLAB product it was found that the drape did not have major impacts on the quality of sound[27]. Nevertheless it has to be expected that some frequencies will be attenuated. Filters can correct this distortion during signal processing.

Conclusion

The microphone shall be attached to or integrated into the touch screen. For constant sound transmission the use of this microphone has to be tested. For more flexibility an additional microphone input shall be provided.

[27] Pittroff, T., Customization Engineer iORS BrainLAB, personal interview 19 Dec 2006

For the integration into or attachment at the touch screen microphones with different directivities are to be considered. These directivities are explained and discussed in the next section.

6.4.2 Comparison of Directivities

Different construction types cause different microphone directivities. Two types have to be distinguished: The pressure microphone and the pressure gradient microphone.

Construction Types and Directivity

Figure 6-4 shows the pressure microphone with sound incidence from the front, lateral and from the back. Sound incident from the front directly causes the diaphragm to vibrate. Sound from the back and laterally arriving sound is diffracted and also enters the diaphragm, which means that the membrane vibrates from whatever direction the sound comes.

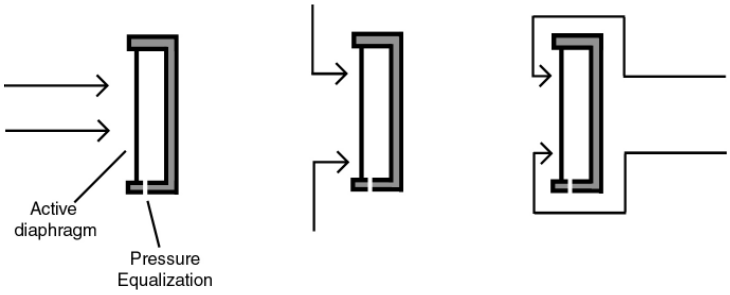

Figure 6-4 Pressure Microphone

This is different for the pressure gradient microphone, the membrane of which can be activated from both sides. Figure 6-5 shows the basic principle of the pressure gradient microphone with the different sound incidents. It can be seen that lateral sound arrives at the same time on both sides of the membrane. This impedes a vibration of the membrane. The microphone is insensible towards lateral sound incident.

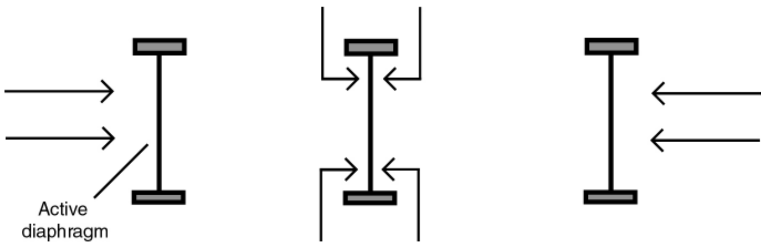

Figure 6-5 Pressure Gradient Microphone

The pressure microphone has omnidirectional directivity while the directivity of the pressure gradient microphone has the form of an 8, which is why it is called “Figure-8”. The left and middle polar response patterns in Figure 6-6 express these directivities.

Note that sound incident from the front is expressed as 0°, which is on the top of the patterns.

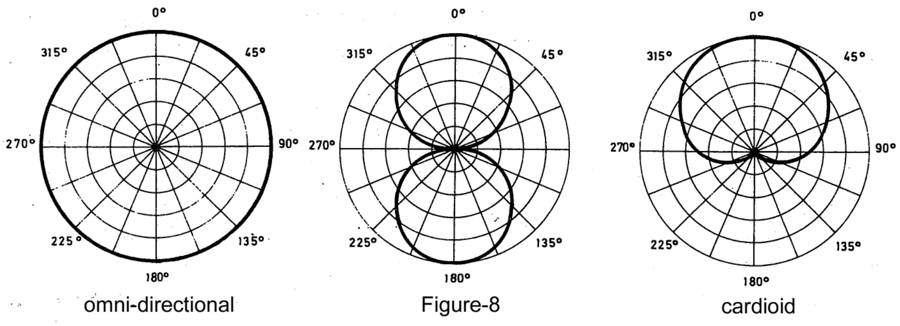

Figure 6-6 Polar Response Patterns [28]

By combining the construction type of a pressure microphone with a pressure gradient microphone other microphone directivities can be created, e.g., a cardioid microphone. A cardioid microphone additionally can be created by an internal delay path. This type is shown in Figure 6-7.

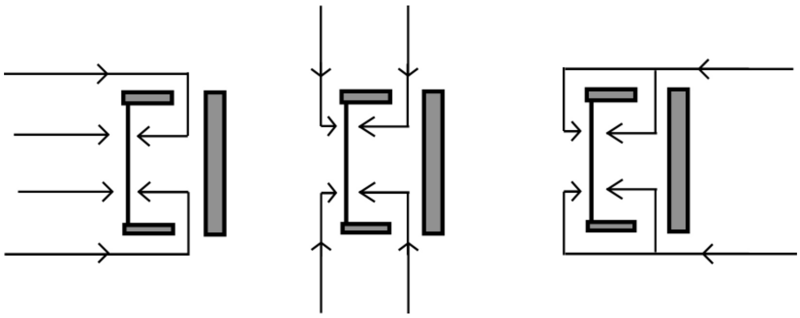

Figure 6-7 Cardioid Microphone with Internal Delay Path[29]

Sound incident from the front arrives at the membrane from both sides. It causes vibration as it arrives at different times and, therefore, does not compensate each other. For lateral sound incident the delays are about the same and the sound is strongly attenuated. Whether the membrane is activated strongly depends on the angle of incidence. Sound incident from the back does not cause any vibration as it arrives at the same time on both sides of the membrane. The resulting polar response can be seen in Figure 6-6 on the right.

Further microphone directivities exist, e.g., supercardioid and hypercardioid. These are directivities picking up sound from the front stronger than the cardioid but they also pick up sound from the back. Therefore, they shall not be considered. In the following the omnidirectional microphone shall be compared with the cardioid microphone.

[28] Figure after Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 161

[29] Figure after Dickreiter, M.: „Handbuch der Tonstudiotechnik“ Band 1, Munich 1997, p. 168

Comparison of Omnidirectional and Cardioid

The pressure microphone with its omnidirectional pattern is very easy to operate. It is resistant to structure-borne sound. Structure-borne sound is sound transmitted through the material, in this case the touch screen. The membrane of a microphone that is sensitive to structure-borne sound might vibrate slightly when buttons on the touch screen are pressed. With a pressure microphone the position of the person speaking is flexible as sound is taken from all sides. At the same time this is a disadvantage: as it takes all sound equally, noise is also picked up. This kind of microphone can easily be integrated into the touch screen and is very unobtrusive supporting a good-looking design.

The cardioid microphone is more sensitive to structure-borne sound. This might cause problems when during a conversation the touch screen is moved or buttons are pushed.

The advantage of this kind of microphone is that it has a high Distance Factor (DSF). The distance factor "is a measure of the 'reach' of the microphone in a reverberant environment, relative to an omnidirectional microphone"[30]. The cardioid microphone has a DSF=1.7. A distance factor of 1.7 expresses that the microphone can be placed 1.7 times farther away from the sound source than an omnidirectional microphone, picking up the same relation of direct sound to reverberant sound. Thus, the critical distance is increased in relation to the critical distance D_{c500}=53 cm (see Chapter 6.3.2) of an omnidirectional microphone.

The critical distance for the cardioid microphone is:

$D_{c500/1.7}$=53 cm (see Chapter 6.3.2)*1.7=90.1 cm

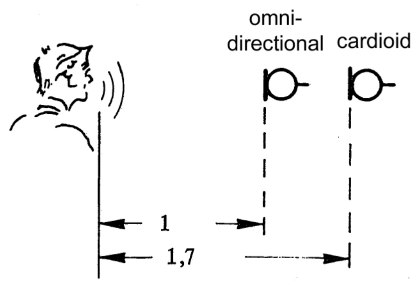

Figure 6-8 Distance Factor[31]

The increased critical distance is caused by the lower sensitivity to sound off-axis and, therefore, significantly attenuates ambient noise. The disadvantage is that the position of the speaker is less flexible. The more he/she talks from the side the lower is the

[30] Eargle, J.: "The Microphone Book", 2nd Edition, Oxford 2004, p. 70

[31] Figure after Dickreiter, M.: „Handbuch der Tonstudiotechnik" Band 1, Munich 1997, p. 161

quality. Furthermore a cardioid microphone exhibits the so-called “proximity effect”. This effect causes an “increase in low frequencies output when it is operated from close to the sound source”[32] and is dispositional in the type of construction. The effect can already begin from 0,5-1 m talking distance. It is possible to counterbalance this effect by adapting the frequencies. Many modern cardioid microphones are constructed reducing this effect as best as possible. Cardioid microphones designed for a close speaking distance produce a ‘thin’ sound when used for a large speaking distance caused by the suppression of low frequencies. A disadvantage of a cardioid microphone is that it has to be positioned free because the sound has to be able to arrive at the microphone from the side and back.

Conclusion

A final decision about which type of microphone delivers the best sound cannot be made theoretically. Whether the attenuation of ambient noise and the farther talking distance of the cardioid microphone outweigh the flexibility and easy handling of the omnidirectional microphone, has to be tested in the real environment.

6.4.3 MR Environment

The microphone will be positioned at the touch screen. The touch screen is attached to a ceiling-mounted boom that can be moved. In the case of a BrainSUITE iMRI the boom is fixed so that the touch screen might enter the 5-Gauss-Line but does not enter the 50-Gauss-line. Figure 6-9 shows both Gauss-lines and the radius of the touch screen.

In the area between the 5 and the 50-Gauss-Line the devices should not be very sensitive to an electro-magnetic field. Therefore, the behavior of a microphone in the MR environment shall be investigated.

Two construction types have to be distinguished: The dynamic microphones (electrodynamic) and the capacitor microphones (electrostatic). Furthermore a new technology, the optical microphone is mentioned.

[32] Eargle, J.: “The Microphone Book“, 2nd Edition, Oxford 2004, p. 64

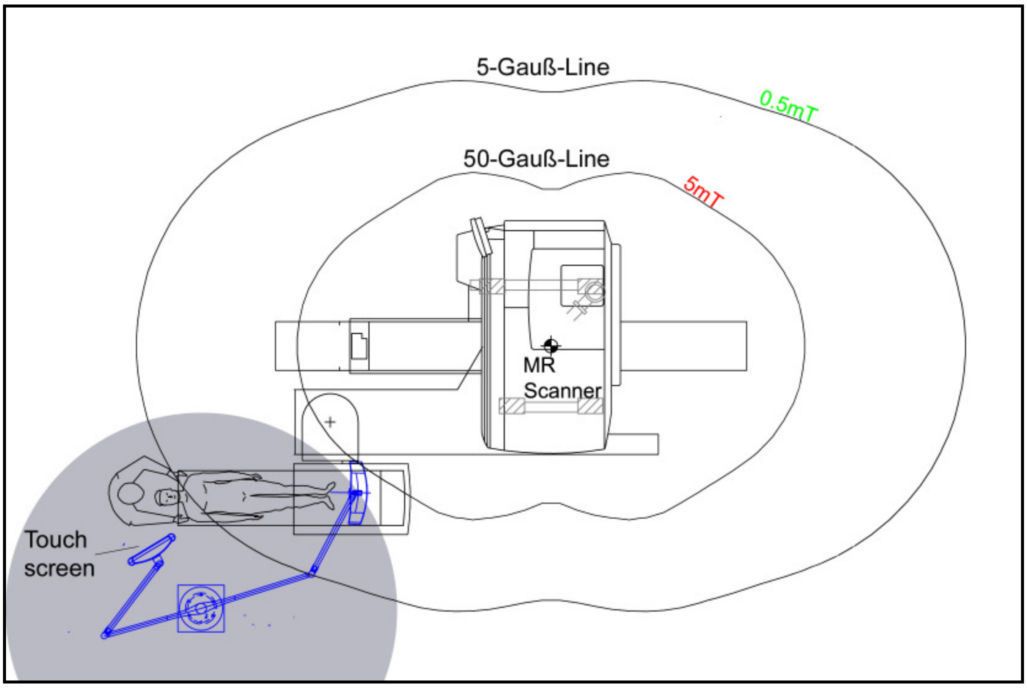

Figure 6-9 Magnetic field of MR scanner[33]

Dynamic Microphone

The dynamic microphone is based on the principal of magnetic induction. The membrane is connected to a conductor, which is placed in a permanent magnetic field. Movements of the membrane move the conductor and voltage is generated through induction. The conductor usually is a multi-turn coil of wire, but it can also be a thin corrugated ribbon.

Capacitor Microphone (Condenser Microphone)

The capacitor or condenser microphone bases on the capacitor principal. The membrane consists of a metal foil and acts as an electrode next to a counter electrode. Movements of the membrane change the distance between the electrodes and the capacity is changed, which causes voltage fluctuations.

Optical Microphone

A microphone that is totally resistant to magnetic environment is the optical microphone. In the optical microphone the vibration of the membrane is detected by light. An LED sends light through an optical fiber onto the membrane. Due to a reflecting spot on the membrane it is reflected and transported by the receiving fiber towards a photo di-

[33] After iORS Site Planning, BrainSUITE iMRI Master Layout

ode.[34] Depending on the vibration of the membrane more or less light is received by the fiber and arrives at the photo diode, where it is converted in an electrical signal. The principle can be seen in Figure 6-10.

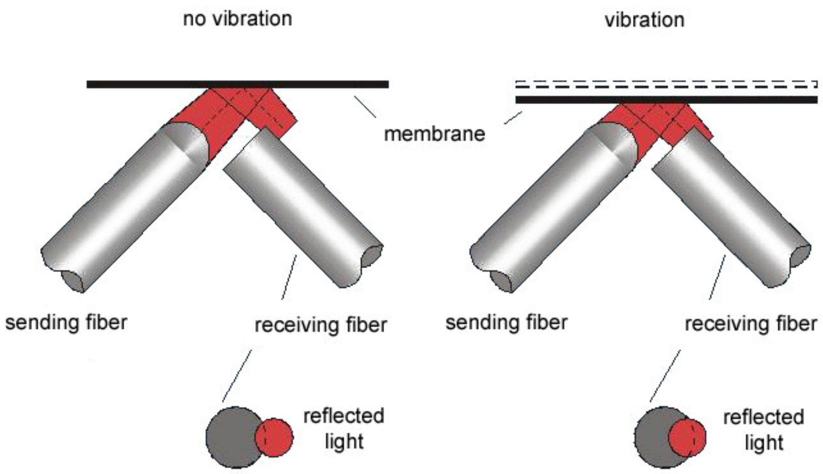

Figure 6-10 Principle of an Optical Microphone[35]

Some companies (Sennheiser, Optoacoustics) offer the optical microphone for communication from within an MRI scanner to the control room. Its frequency response differs from 100-4000 Hz ("FOMRI" from Optoacoustics) to 20-40000 Hz ("MO2000H" from Sennheiser). Professional condenser microphones have a frequency response of about 20-20 000 Hz. An optical microphone for this application costs from 2500 Euro (only microphone) to 5000 Euro (with a system).

Conclusion

Due to its type of construction a dynamic microphone is not suitable. In contrast thereto capacitor microphones are mostly resistant to MR environments. They are used for MRI noise measurements[36] [37].

The optical microphone is not required, as the touch screen must be positioned outside the 50-Gauss-line and, therefore, the magnetic field is not that strong. Therefore, a condenser microphone shall be used. A condenser microphone needs a steady voltage supply during operation to keep up polarization and feed the included preamplifier. Usually 48V or 12V are supplied through so-called phantom powering via the micro-

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[34] Feldmann, M.: "Optical microphone for Acoustical and Metrological Applications", Institute for Microtechnology, Technical University Braunschweig, accessible at http://www.imt.tu-bs.de/imt/institut/mitarb/feldmann/projekte/mikrofon, accessed 1 April 2007

[35] Figure after Laserlaboratorium Göttingen e.V., accessible at www.llg.gwdg.de/micro/default.htm

[36] Ravicz M. Et al: „Acoustic noise during functional magnetic resonance imaging" in Journal of Acoustical Society of America, 108 (4) 2000, p. 1683-1696

[37] Hoiting G.: „Measuring MRI noise", thesis university of Groningen 2005, ISBN 90-367-2234-9

phone cable (the signal is carried between pin 2 and 3, the voltage between 2/3 and 1). Alternatively, a digital condenser microphone needs a voltage supply of 10 V. These values are low enough to be supplied by SELV in the patient environment (60V DC, see Chapter 6.2.3). In the next section the digital microphone shall be described.

6.4.4 Digital Microphone

The risk analysis came to the result that a signal leaving the chassis of a device in the patient environment may only leave optical. This would apply for the audio signal of a microphone in the sterile field.

A possibility to fulfill this demand would be a digital microphone as its signal can easily be converted to optical. Digital microphones are not digital in the sense of directly generating a digital signal from the membrane. The signal is still generated with an analog transducer, but immediately after that step it is converted to digital within the microphone. The advantage is that parts of the signal processing can already be dealt with in the microphone[38]. Through the immediate converting an increase in dynamic range is achieved and the use of filters is less critical. Additionally the signal can be distributed digitally from the beginning. A digital transmission has the advantage to be more robust towards interferences than an analog transmission as only two states exist. If these two states are slightly changed by interferences during the transmission, they can still be separated and the signal is interpreted correctly. During analog transmission interferences always mean a permanent change of the signal.

The professional standard for digital audio signals is AES 3, also called AES/EBU (Audio Engineering Society and the European Broadcasting Union). The standard for the digital interface for microphones is AES 42. It defines a current supply of 10V digital phantom power (DPP). The data format of the transmitted audio signal is AES3.

Digital microphones usually consist of a capsule and the microphone preamplifier. Exchangeable capsules with different directivities are provided. They are all working after the capacitor principle. The microphone preamplifier can have several digital features implemented, e.g., different sampling rates and to some degree digital signal processing (DSP). Remote control functions may also be included for a remote control of microphone settings.

The digital microphone is suitable for an application at or in the touch screen. It easily provides a digital audio signal and it can be supplied with 10V. The capsules work well in MR environment due to the capacitor principle. The preamplifier has to be tested in MR environment.

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[38] Eargle, J.: “The Microphone Book“, 2nd Edition, Oxford 2004, p. 140

6.5 Concept

The selected audio functionalities have been described in Chapter 6.1. These functionalities are implemented in a conceptual design considering the requirements on the system that have been gathered in Chapter 6.1 to Chapter 6.4.

BrainSUITE NET is designed as a digital system. The audio system should also be designed digital whenever possible. BrainSUITE NET can be bought in different configurations. As control and viewing device the customer can purchase one touch screen or two. One is always situated in the sterile field, while the optional one is built in the wall for unsterile use. The requirement that a sterile as well as an unsterile possibility exists can only be achieved when the system is used with two touch screens. For the systems with one touch screen sterile or unsterile use can be attained, depending on whether a sterile drape is put over the touch screen or not.

Schematic diagrams show the connections and devices giving an overview. Then the music and communication systems are explained in detail.

6.5.1 Schematic Diagram

The schematic diagram in Figure 6-11 shows the signal lines and components for the configuration of two touch screens, Figure 6-12 for the use of one touch screen. Three rooms are displayed: the operating room, the equipment room, and the control room. The control room is located next to the operating room. From here the OR-personnel controls the scanner in the operating room during a scan in case of the BrainSUITE iMRI. As many equipment as possible should be placed in the equipment room in order to keep the operating room free. The maximum distance between the operating room and the equipment room may be 100m as has been defined for BrainSUITE NET. For the hospitals, where an equipment room is not present, the equipment is placed in the control room. As all connections between these two rooms are carried out via optical fiber, the distance does not cause any problems.

The music system and the communication system are designed in two separated systems. Thus, they can be purchased single, e.g., if a hospital does not desire the music system but wants to integrate the communication system. If both systems are used they are connected through the server, which performs the control function. The server has to regulate, e.g., the volume of the music when a phone call is made. In the case that both systems are implemented it is possible that both use the same audio processor. This saves space and is probably more cost-effective.

In the next sections the two systems including their components are explained.

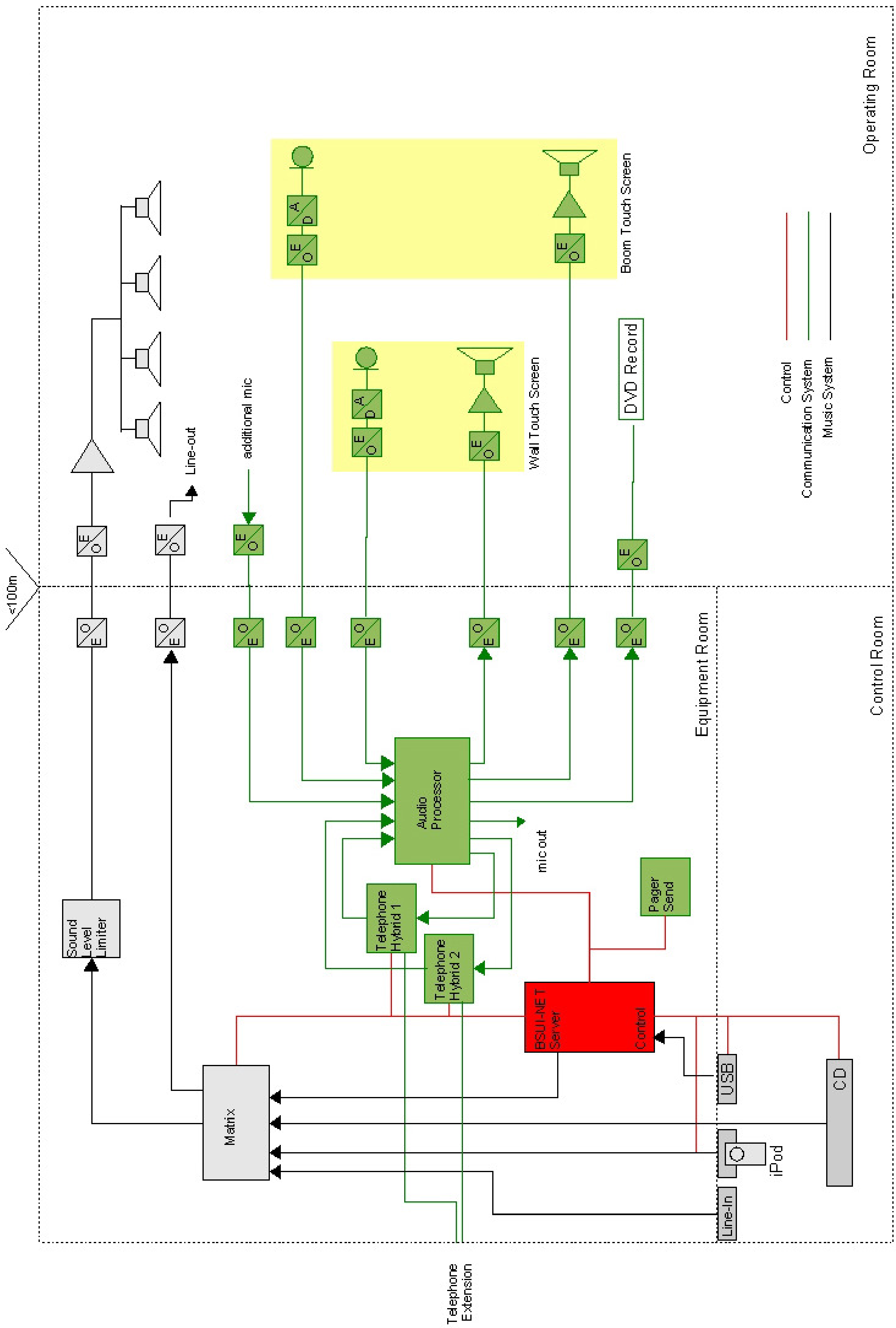

Figure 6-11 Concept for Two Touch Screens

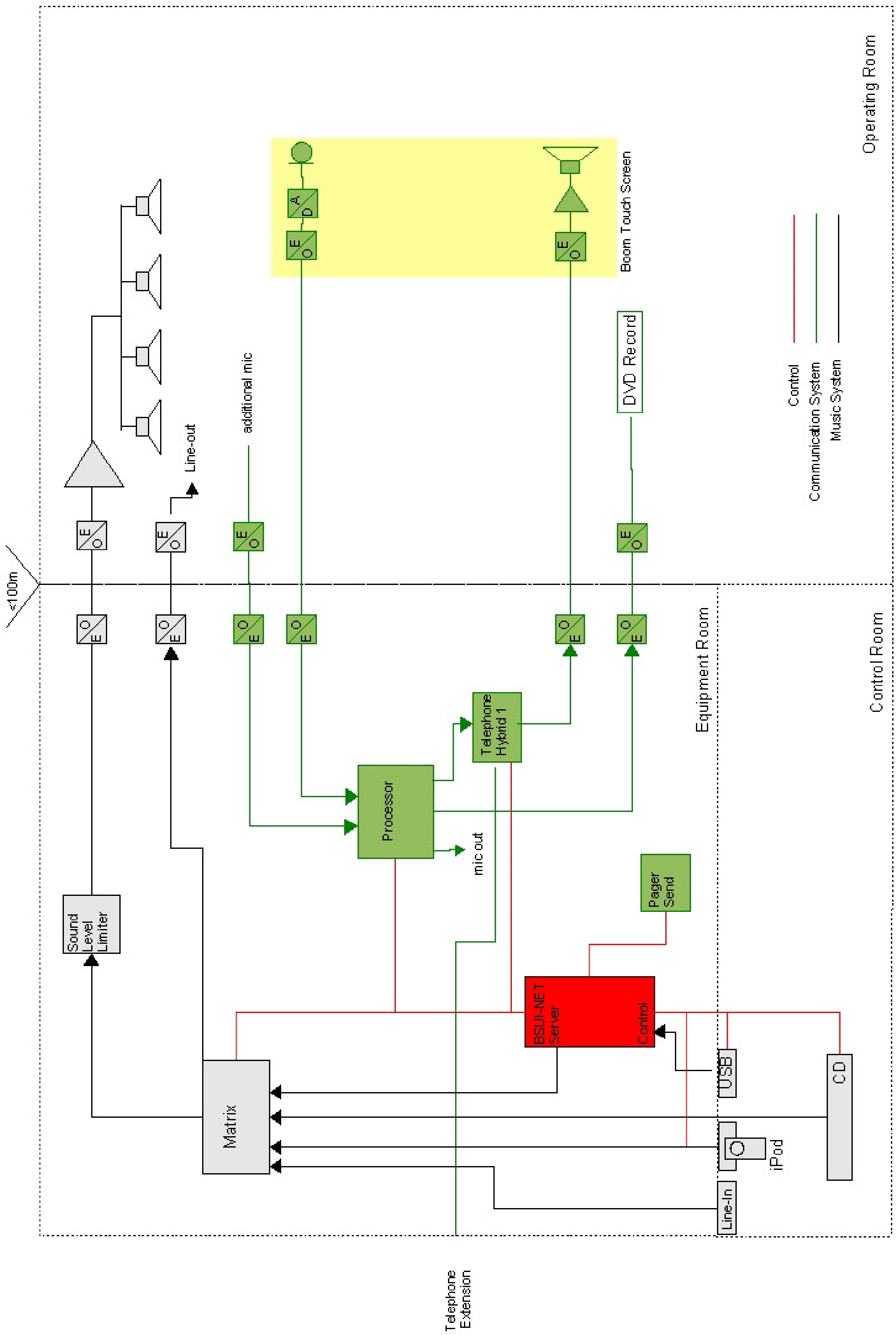

Figure 6-12 Concept for One Touch Screen

6.5.2 Music System

The music system consists of the following devices:

In the control room:	CD-player
	iPod docking station
	USB interface for MP3-player
	Line in plug
In the equipment room:	Matrix with Volume Control
	Sound Level Limiter
	BrainSUITE NET Server
In the operating room:	Active speakers

Between the control room and the operating room the signals are transmitted via optical fiber to guarantee galvanic isolation. The conversion is carried out by so-called electrical/optical converters (E/O-Converter), which usually consist of pairs of one transmitter and one receiver.

The devices, by which the music is played, are placed in the control room because the operating room should be kept free of as many devices as possible. The user can insert CDs into the CD-player, put his iPod into a docking station and connect his MP3-Player or another portable device with a line output. The music can then be controlled from within the operating room using a touch screen. The following functionalities can be controlled from the touch screen:

- The device, of which the music shall be played, can be chosen
- The track can be selected (This does not apply for a device connected by the line-in plug)
- The volume can be controlled
- From the iPod or the MP3-Player a play list can be started
- A CD from the CD-changer can be selected

In the following the components of the system are closer explained. Being a part of both systems, the BrainSUITE NET Server is described at the end of the description of the Communication and Documentation System in Section 6.5.3.

Matrix with Volume Control or Mixer

This device switches the music signal, which has been selected, to the speakers. It has to be remote controlled. The signals arrive with line-level (a reference level). For the outputs the gain must be controlled as thus the volume control is achieved. When the device, which is playing the music, is changed, the volume automatically has to be faded out and the music from the new device has to be faded in to a preset sound level. Thus, the changing of devices is smooth without a sudden stop of music. A preset sound level is needed to guarantee a low starting volume of the music.

The matrix that is currently used for video switching for BrainSUITE NET also allows implementing audio modules with volume control.

By using a more powerful device e.g. a mixer with integrated filters, more functionality could be implemented. An integrated equalizer could help adapting the sound of the music to the operating room. Thus, it can be avoided that the music sounds too 'thin' due to the hard acoustic environment.

Speaker

As the transmission to the operating room is carried out via optical fiber, the signal cannot be amplified before the transmission. Therefore, active speakers are needed. Alternatively an amplifier could be built in the wall providing an amplified signal for the speakers. The speakers are built in the ceiling or wall. The surface has to be cleanable. The risk analysis (see Chapter 6.2) showed that they have to be positioned outside of the patient environment and outside of the 5-Gauss-line for safety reasons. The speakers have to be EMC-compliant.

Sound Pressure Level Limiter

The sound pressure level limiter regulates that no sound pressure level above a determined dB-level is played. This acts as a security measure to avoid that the music overlays important warning signals of medical devices. The maximum dB-level still has to be determined. Furthermore sudden loud acoustic noises that might be caused by the disconnection of jack connectors are avoided.

CD-Player

As one CD has a limited playing time the CD-player should have a CD-changer integrated. The CD player is placed outside of the operating room. Therefore, remote control including the selection of a CD must be supported. The possibility to play MP3-files from CD would complete its abilities.

iPod Interface

iPod interfaces often are designed as a docking station that can be built in the wall or as a stand-alone version. Such a docking station is needed for the system[39]. The iPod can be inserted easily and depending on the station it is also charged during playing. The docking station allows the remote control of play-lists and tracks and the transmission of the audio signal to a music system.

[39] For example http://www.iportmusic.com/

Line-in Plug Module

A 3.5 mm jack plug is provided. Thus, mobile devices with a line-out signal, e.g., a Minidisk-player can be attached.

USB-plug Module for an MP3-Player or an USB-Stick

Through an USB plug an MP3-player or an USB-stick with MP3s can be connected. The signal is transferred to the BrainSUITE NET server. The server plays the music with a media player and transmits it to the matrix.

Plug Module for Earphones

Making an additional output signal of the matrix accessible in the operating room allows the use of the connected music players for the patient. By connecting earphones the music can be heard. Volume control is only possible through the touch screen.

For the patient very special safety regulations occur. It is important to advise the hospital to fulfill these (see Section 2.4.1). The system can provide galvanic isolation, but all further demands have to be considered by the hospital.

6.5.3 Communication and Documentation System

The communication system consists of the following devices:

In the equipment room:	Audio Processor
	Telephone Hybrid
	BrainSUITE NET Server
In the operating room:	A microphone and active speaker at the boom touch screen
	A microphone and active speaker at the wall touch screen
	The DVD-recorder of BrainSUITE NET
	An XLR-plug for the connection of an additional microphone

As for the music system, all connections between the equipment room and the operating room are transmitted via E/O-converter.

The system implements an additional microphone input for the connection of, e.g., a tie-tack microphone. Furthermore the microphone output signal is provided, so that hospitals can distribute it, e.g., to an auditorium.

The following functionalities can be controlled from the touch screen:

- Calls can be made
- A pager call can be sent
- The microphone can be switched on/off

- Voice Recording can be switched on/off

In the following the components of the system are closer explained.

Microphone

All particularities of the microphone have been discussed in detail in Chapter 6.4. With positioning the microphone at the touch screen it is possibly within the patient environment (see Chapter 2.4). The safety within the patient environment was investigated in the risk analysis in Section 6.2. The electrical safety has to be ensured by the system, which is done by galvanic isolation. The power supply will have to be carried out by a medical power supply. The microphone should tolerate the cleaning with disinfectants.

Additional Microphone XLR-plug

A plug-in possibility definitely has to be standardized in order to foresee the signal that will be connected to the system. Thus, problems can be avoided. It is proposed to provide a plug for a digital audio signal according to AES3. This would comply with an overall digital system and could be easily converted to an optical signal. An AES3 signal can be obtained by connecting a digital microphone. Also an analog microphone can be used. However, it would have to be converted first. As an additional microphone probably would be a wireless one, a receiver could be used that also provides an AES3 output.

Speaker

The speaker has to be an active speaker with 12 V power supply or 24 V at the most as these voltages can be easily provided by the BrainSUITE NET system. Safety regulations restrict the maximum voltage that may be applied to 60 V (SELV). The position has to be chosen well as the positions of speaker and microphone strongly influence the quality of the hands-free talking unit. The speaker should be positioned in a way that as few sound as possible arrives at the microphone. The ideal position has to be found out through testing.

Audio Processor

The audio processor is the core piece of the system. It routes the signals to the desired outputs, converts them if necessary, and can apply digital signal processing. Thus, noise reduction measures can be taken. With an equalizer the microphone signals can be adapted in frequency to the behavior of the room and frequencies over 4 kHz can be attenuated. With a low cut frequencies below the needed ones can be cut off. The processor should work digitally and has to be able to process AES3.

Telephone Hybrid

The telephone hybrid enables to make calls and receive calls with a connected microphone and speaker. It is possible that the Audio processor includes the functionality of a telephone hybrid. In the schematic drawing two telephone hybrids are displayed. This is not absolutely necessary. With the restriction that calls can only be made from one touch screen at the same time, one telephone hybrid would be sufficient. The signals would then have to be routed dynamically from the microphone and to the speaker that is currently used. When two hybrids are used, the signals can be connected statically. It is possible that one hybrid includes the functionality to connect two phone lines. Thus, a second hybrid would be redundant.

The telephone hybrid needs to be able to process AES3 signals and to be remote controlled. Active echo canceling must be included.

The hybrid also should be able to signal an incoming call without sound. Thus, the incoming call can be interpreted visually and it can be made sure that the surgeon is not interrupted by incoming calls.

The final solution, how incoming calls are indicated, still has to be found. One idea is that the call can never be heard, but is saved in a kind of call list with the indication of the phone number of the caller. As indication that a phone call has been registered a small sign appears at the touch screen. When time is available the surgeon can have a look at the phone list and call back when regarded necessary. This functionality would be useful for the case that the surgeon is waiting for the pathology to finish a tissue sampling. The pathology can signal the finish and the surgeon can call back to discuss the result.

Pager Send

The functionality to send a pager call is added symbolically at the schematic diagram. The exact realization form still has to be determined. It strongly depends on the pager system the hospital is using.

DVD-Recorder

The DVD-recorder is part of BrainSUITE NET for documenting video signals during the surgery. It can be controlled via the touch screen and is usually situated within the operating room to allow an easy change of DVDs. With audio connected, the video can be commented. The recorder has two Cinch Inputs for Stereo Audio. As the signal coming from the processor is mono, an adapter to stereo is needed. Thus, on both channels the same signal is recorded. The DVD-recorder has a setting to switch the audio recording on or off, which cannot be controlled remotely. Therefore, the DVD-recorder has to be preset with audio recording on. The control whether audio shall be recorded or not has to be done via the audio processor by muting the microphone signal. This can be done by commands via the touch screen.

6.5.4 Common Devices of Both Systems

E/O-Converter

As the signal transmission from the operating room to other rooms is performed via optical transmission, E/O-converters are needed. Usually they consist of pairs of one transmitter and one receiver. A very small solution for converting a digital AES3 signal to optical is the „OptoXLer" from the company Wagnertools[40]. The sender and receiver look like a small plug. To convert an analog audio signal several converters are available. Some video converters used in the BrainSUITE NET system are also capable of transmitting audio. This should be considered.

BrainSUITE NET Server

The BrainSUITE Net Server is in charge of all control of both the music system and the communication and documentation system. Through the Graphic User Interface the user gives commands. The server has to regulate the following functionalities by his commands:

- The reduction of the music's volume when a call is made
- The playing of music and calling up of play-lists of a connected MP3-player through a media player
- The control of the volume of the music
- The choice of the track
- The choice of the device, from which the music shall be played
- The control of the change between devices
- The activation and deactivation of the microphone

[40] www.wagnertools.com

7 Conclusion and Outlook

7.1 Conclusion

This thesis established a basis for the implementation of audio functionalities as an extension of the image data management system, BrainSUITE NET.

A market research showed in Chapter 1 that audio functionalities have already entered the market of integrated operating room systems. The offers of the market players are diverse and cannot be ignored.

In Chapter 4 voice control was found to be still unreliable, only working with many safety mechanisms restricting user friendliness.

An analysis of installed BrainSUITE systems showed the customers' demand for audio and communication functionalities in Chapter 5. The detailed requirements and desires of the surgeons were analyzed by performing a survey among 65 surgeons. It showed that a great demand for sound and video transmission exists. A telephone function is required in unison. The surgeons want to communicate from the sterile field and to have both sterile and unsterile control possibilities. They demand a communication possibility not only for themselves, but also for the assistant and the anesthetist. Microphones that are attached to the head of the surgeons are evaluated as not acceptable. Voice recording is desired. Music is preferably played from a CD and/or an MP3-Player.

According to the surgeons' requirements, functionalities with a high priority, like a telephone function, background music, and voice recording, have been defined. For these functionalities a conceptual design has been performed in Chapter 6 as described in the following.

In a risk analysis potential hazards for the patient and user have been identified and measures avoiding or diminishing those hazards were defined. An important measure is the signal transmission via optical fiber to guarantee galvanic isolation.

The acoustical consideration of the operating room yielded valuable information for the conceptual design. The reverberation time has been calculated approximately at $RT_{60/500}$=2.1 s. This is considered to be a long reverberation time. The reason can be found in the hard surfaced environment hardly absorbing sound. The background noise was considered in relation to speech intelligibility. It was found that the existing signal-to-noise-ratio is a minimum value and noise reduction measures must be taken. Due to the long reverberation time the calculation of the critical distance resulted in a short distance of $D_{c/500}$=53 cm (for an omni-directional microphone), which strongly influenced the decision for the microphone position. After consideration and comparison, the microphone position was determined to be on the touch screen. The directivities of an omni-directional and a cardioid microphone were compared and discussed. A final decision requires tests, which were not carried out at the time of this thesis and, therefore, could not be reached. A digital microphone was proposed as it provides a good solution on system requirements.

All results have been implemented in a final concept- for one touch screen and for two touch screens. Schematic diagrams and a description of the necessary devices show this concept.

7.2 Outlook

Specification and Implementation of the Concept

For a final determination of the microphone characteristic, tests have to be performed within an operating room. Additionally the microphone position should first be tested in an operating room without personnel, and then its practical use should be confirmed during a clinical trial. The maximum sound level of the background music has to be determined.

The schematic diagram and its components do not describe specific products. Some products that fulfill the requirements are mentioned, but most still have to be determined. The system will have to be adapted to specific abilities of these products. The final MR compatibility of the system has to be tested.

Integration of Additional Functionalities

Voice Recording should be carried out independent of the DVD-recorder and video recording. The recording on an USB-stick is possible. For this purpose more information has to be gathered about the exact purpose of the recording. If the voice quality is sufficient, the implementation of voice recognition for the dictation of reports should be taken into account. Additionally the connection of audio files with patient data and a linked storage should be considered, e.g., audio integration into HL7 (Health Level 7, a standard for the exchange of data in health care).

As the survey showed a high demand for videoconferencing capabilities, implementation of this feature is strongly recommended.

For regular communication the integration of intercom is reasonable.

Additional Applications for an Audio System

If a hospital performs many awake-surgeries, an overall patient music system might be found to be desirable. Several music channels could be offered for several operating rooms giving the patient the choice of listening to his favorite music.

It should be investigated whether other audio functionalities are of use during awake-surgeries. For brain mapping (see IV Glossary) during neurosurgery cases, e.g., possible applications might be documentation purposes or the measuring of reaction times.

Future Trends

Voice control has a high potential for the control of devices during two-handed tasks. Therefore, the development of voice control, especially connected with voice entry by microphone arrays, should be observed.

III Abbreviations

AES	Audio Engineering Society
ALARP	As low as reasonable possible
CE	Communauté Européenne / Europäische Gemeinschaft
CT	Computer Tomography
DC	Direct Current
D_c	Critical Distance
DICOM	Digital Imaging and Communication in Medicine
DSF	Distance Factor
DSP	Digital Signal Processing
EBU	European Broadcasting Union
EMC	Electromagnetic Compatibility
EN	Europäische Norm / European Standard
FCC	Federal Communications Commission
FDA	Food and Drug Administration
GUI	Graphical User Interface
HL7	Health Level 7
iCT	Integrated Computer Tomography
IDMS	Image Data Management System
IEC	International Electro Technical Commission
IGS	Image Guided Surgery
iMRI	Integrated Magnetic Resonance Imaging
iOR	Integrated Operating Room
iORS	Integrated Operating Room Solutions
ISO	International Organization for Standardization
MDD	Medical Device Directive
ME system	Medical Electrical System

MIS	Minimally Invasive Surgery
MPG	Medizinproduktegesetz
MRI	Magnetic Resonance Imaging
OR	Operating Room
PACS	Picture Archiving and Communication System
RT	Reverberation time
SELV	Safety Extra-Low Voltage
SNR	Signal-to-Noise-Ratio
TÜV	Technischer Überwachungsverein
UL	Underwriters Laboratories
UPS	Unique Power Supply

IV Glossary

Ambulatory surgery	Ambulante Chirurgie
Anesthesia, Anesthesist	Anästhesie, Narkosearzt
Brain Mapping	Das Identifizieren verschiedener Hirnareale durch Tests mit dem wachen Patienten
Cardiovascular	Kardiovaskulär, das Herz und die Gefäße betreffend
Cholecystectomy	Cholezystektomie, Entfernung der Gallenblase
Computer tomography scanner	Computertomograph
sterile Drape	Sterile Plastikhülle zur Bedeckung von unsterilen Gegenständen
General anesthesia	Vollnarkose
Insufflation	Das Einblasen von Luft oder Gas
Laparoscopy, Laparoscope	Laparoskopie (Bauchspiegelung), Laparoskop (optisches Instrument mit Lichtquelle zur Bauchspiegelung)
Metabolic	Den Stoffwechsel betreffend
Pelvi	Das Becken betreffend
Radiology, radiologist	Radiologie, Radiologe
Rotating nurse	Unsterile OP-Schwester
Scrub Nurse	Sterile OP-Schwester
Sedative treatment	Behandlung mit Beruhigungsmitteln
Spinal	Zur Wirbelsäure gehörig
Sterilizable	Sterilisierbar
Unsterile	unsteril
Minimally Invasive Surgery	Minimal-invasive Chirurgie (operative Eingriffe mit kleinster Verletzung)

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Standards

DIN EN ISO 9001 Quality Management Systems- Requirements, Geneva 2000

IEC 60601-1 Medical electrical equipment –Part 1:General requirements for basic safety and essential performance, Geneva 2000

IEC 60601-1-1 Medical electrical equipment - General requirements for safety - 1-Safety requirements for medical electrical systems, Geneva 2000

ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes, Geneva 2003

ISO 14971 Medical Devices- Application of risk management to medical devices, Geneva 2000

MDD 93/42/EWG Medical Device Directive COUNCIL DIRECTIVE 93/42/EWG concerning medical devices, 1993

MPG Medizinproduktegesetz, http://bundesrecht.juris.de/bundesrecht/mpg

Other Sources

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Berchtold http://www.berchtold.de

Carino, P. Sales Manager North America, BrainLAB, personal email

Cohn & Wolfe Public Relations “Factsheet Stryker Op-Funktionen“, www.cwnewsroom.ch

Conmed	Marketing brochure “Innovation for the medical environment"
	http://www.conmedis.com
Etacon	http://www.etacon.de
	Product Brochure „OP-Steuerung und Dokumentation“
Glimmann, J.	Product Manager BrainSUITE NET, BrainLAB, personal interview
Maquet	http://www.maquet.com
McGuinn, B.	Product Manager BrainSUITE, BrainLAB, personal interview
Meppelink, A.	Sales iORS, BrainLAB, personal email
Noeth, E.	PD Dr.-Ing, Academic Director, Computer Science Department, University of Erlangen, personal email
Olympus	http://www.olympus-europa.com
	“ENDOBASE- das interdisziplinäre Dokumentationssystem”
Personal visit	Hospital “Rechts der Isar”, Munich, where the SIOS system and the Berchtold ORICS system was clinically proved
Richard Wolf	http://www.richard-wolf.com
	“Core- Das integrierte OP-Konzept”
Schneider, A.	Engineer MITI Group, Hospital Rechts der Isar, Munich, personal email and interview
Seifert, U.	Area Support Specialist IGS/BrainSUITE, BrainLAB, personal email
Smith & Nephew	http://www.endo.smith-nephew.com, Product Catalog A
Storz	Product brochure „Der integrierte OP“
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Stryker	http://www.stryker.com
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VI Appendix

A. Questionnaire

On the following three pages the questionnaire is presented the way it was shown in the Internet. In question No 4 the additional questions popped up when a communication partner was selected. This is shown exemplary for the communication partner "Radiology". The questionnaire was available in English and German. By clicking "submit" a Perl script was started which saved the entered data in a text file.

Please mark the check box of the corresponding answer for each question or fill out the text field.

If you have any annotations or suggestions, I would be pleased if you noted them in the text field at the end of the questionnaire.
Of course you can also contact me: <claudia.mattes@brainlab.com>.

Your position ______

In which surgical field do you work (neurosurgery, orthopaedics...)? ______

1 How important would it be for you to play music in the operating room from the following media?

	very important	desirable	no preference	unnecessary
CD	○	○	○	○
Radio	○	○	○	○
iPod/MP3-player	○	○	○	○
MP3-files	○	○	○	○
other ______	○	○	○	○

2 Who should be able to operate the play back of music? (check as many as apply)

- ☐ surgeon
- ☐ anaesthetist
- ☐ surgical assistant
- ☐ rotating nurse
- ☐ scrub nurse

3 How would you evaluate the possibility of transmitting:

	very important	desirable	no preference	unnecessary
sound out of the operating room?	○	○	○	○
video out of the operating room?	○	○	○	○

4 With whom of the listed partners (located outside the operating room) would you like to communicate with in the OR and how often do you need the given functionalities for this communication?

Please mark the partners you would like to communicate with and indicate in the opening window where this partner is located and how often you would like to use the specified functionalities.

☐ PATHOLOGY

☑ RADIOLOGY

	inhouse	extern
Where is this partner located? (check as many as apply)	☐	☐

I would like to:	regularly	sometimes	rarely	never
talk to him/her	○	○	○	○
see the partner on a screen	○	○	○	○
send him any video signal (e.g. microscope)	○	○	○	○
receive any video signal from him/her	○	○	○	○
send him/her data (e.g. DICOM) and receive data	○	○	○	○
edit data together with him/her	○	○	○	○

The partner should:

be able to initiate the conversation	○	○	○	○
see me on a screen	○	○	○	○
-after asking for permission- be able to select and see any video source in the OR autonomously	○	○	○	○
be able to select and see any video source in the OR without asking for permission	○	○	○	○

☐ AUDITORIUM/ CONFERENCE ROOM

☐ OFFICE OF PHYSICIAN (e.g. chief physician)

☐ ANOTHER OR (e.g. for consulting a "sterile" colleague)

☐ EXPERT (e.g. for second opinion)

☐ OTHER ________

☐ OTHER ________

5	In the operating room, how important is it for you to:	very important	desirable	no preference	unnecessary
	communicate with several people in a conference channel?	○	○	○	○
	send a pager call to any person in the hospital?	○	○	○	○
	call any person in the hospital?	○	○	○	○
	call any person outside the hospital/ worldwide?	○	○	○	○
	be called from any person?	○	○	○	○

		very important	desirable	no preference	unnecessary
6	How do you evaluate the importance to communicate in the sterile field?	○	○	○	○

		yes	no
7	In your hospital, are you using a videoconferencing or telemedicine system in the operating room?	○	○

If yes: Which? ________

	very satisfied	satisfied to some extent	less satisfied	not at all satisfied
Are you satisfied with its functionalities?	○	○	○	○

Please describe why: ________

8 Who of the OR-personnel should be able to participate in a conversation? (check as many as apply)

☐ surgeon ☐ anaesthetist

☐ surgical assistant ☐ rotating nurse

☐ scrub nurse

9	How would you evaluate the following possibilities of microphone placements?	very annoying, not acceptable	annoying, but acceptable	acceptable	don't know
	Wearing a headset*	○	○	○	○
	Attached to the surgical mask*	○	○	○	○
	Attached to clothing*	○	○	○	○
	Integration into touch screen in the sterile field	○	○	○	○
	other ________	○	○	○	○

*with wired connection to pocket transmitter

		very important	desirable	no preference	unnecessary
10	How would you evaluate the following functionalities of voice recording?				
	Voice recording in addition to video recording	○	○	○	○
	Voice recording independent of video recording e.g. for dictations as support of the OR-report	○	○	○	○

		yes, perfectly	reasonable	not very good	not at all
11	Do you think that voice control in the operating room works?	○	○	○	○

		very important	desirable	no preference	unnecessary
12	How important would it be for you to use an (error-free) voice control in the operating room?	○	○	○	○

		yes, personally	yes, by watching	no	
13	Do you have experience with voice control in the operating room?	○	○	○	

If yes: Which devices were controlled by voice? [ ]

	very satisfied	satisfied to some extent	less satisfied	not at all satisfied
Were you satisfied with the voice control?	○	○	○	○

If there where problems, please describe them: [ ]

		good	average	poor	don't know
14	How would you evaluate the following device controls?				
	voice control	○	○	○	○
	sterile touchscreen	○	○	○	○
	foot control	○	○	○	○
	sterile keyboard	○	○	○	○
	sterile mouse	○	○	○	○

15 Which devices would you like to control centrally? (check as many as apply)

- ☐ OR-table
- ☐ OR-light On/Off
- ☐ HF-surgery
- ☐ Dimmer OR-light
- ☐ telephone
- ☐ other [ ]

16 Which information would you like to access centrally in the operating room? (check as many as apply)

- ☐ PACS/ diagnostic imaging data
- ☐ OR schedule/ time schedule
- ☐ patient records
- ☐ other [ ]

Annotations/Feedback

[ ]

For submitting please click the button below

If I may use your data in relation to your name, please write down your name here: [ ]

[submit]

Thank you very much!

B. Additional Survey Results

In the following the additional results of the survey in the section “Communication Functionalities” (see Section 5.2.3) are presented.

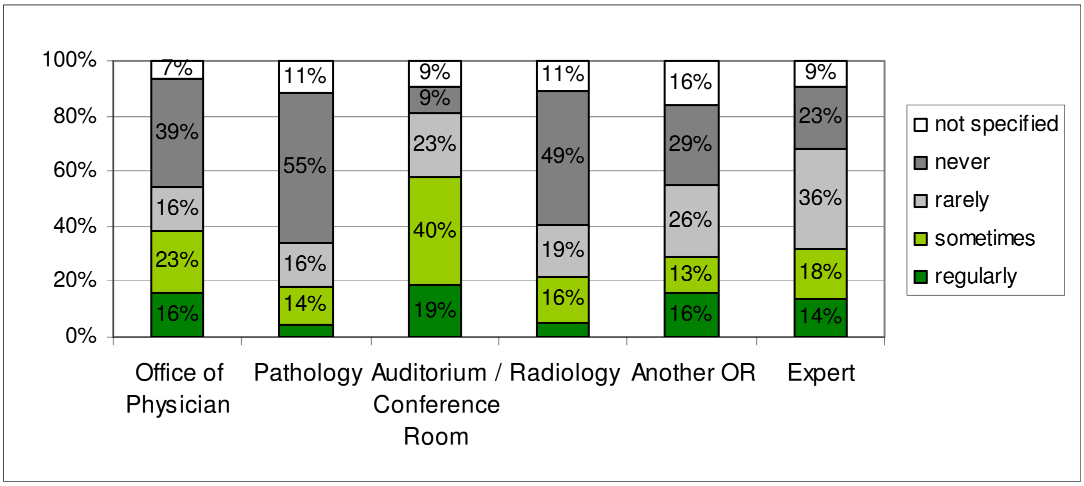

Table B-1 How often do you need the given functionalities for this communication? See the partner on a screen.

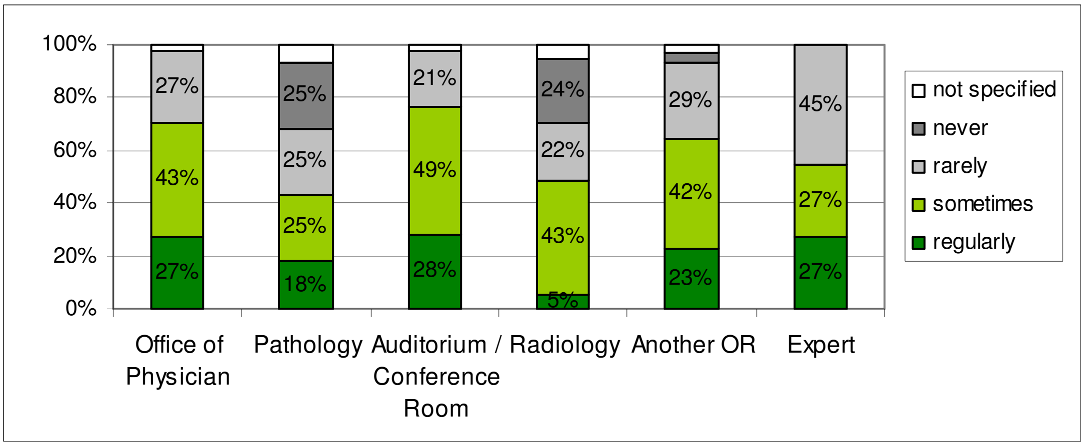

Table B-2 How often do you need the given functionalities for this communication? Send him any video signal.

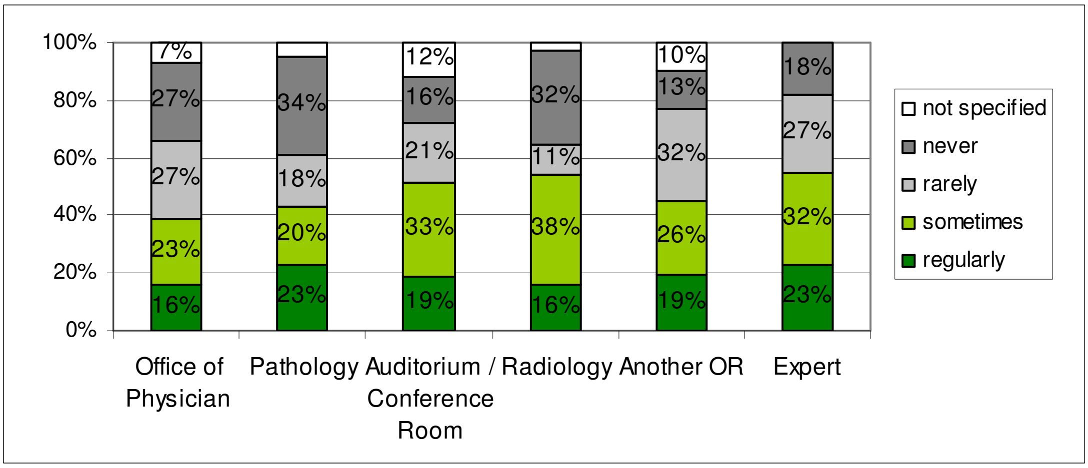

Table B-3 How often do you need the given functionalities for this communication? Receive any video signal from him/her.

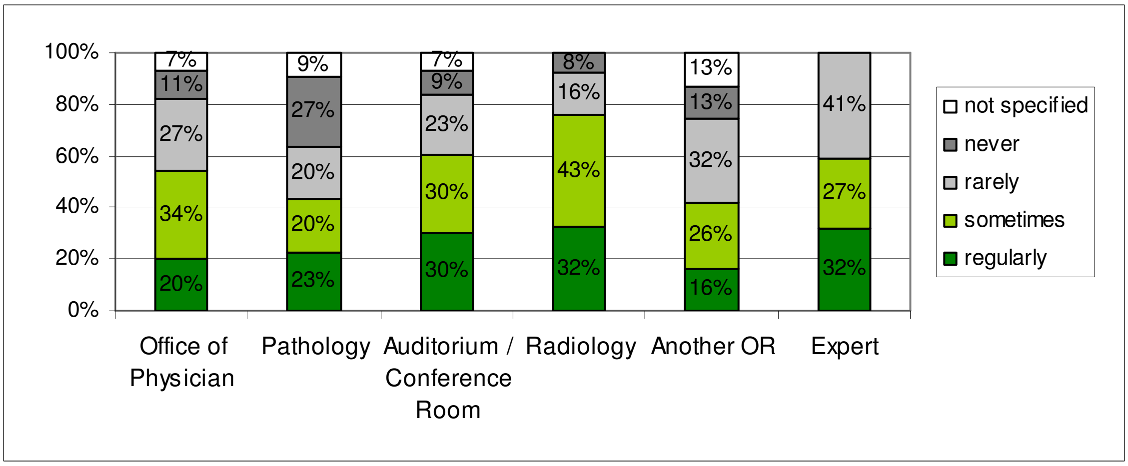

Table B-4 How often do you need the given functionalities for this communication? Send and receive data.

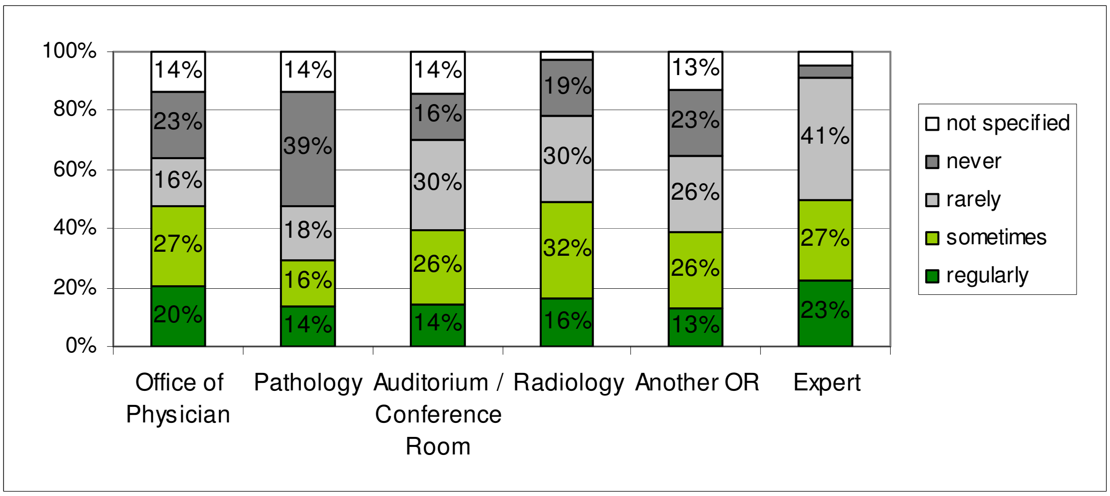

Table B-5 How often do you need the given functionalities for this communication? Edit data together with the partner.

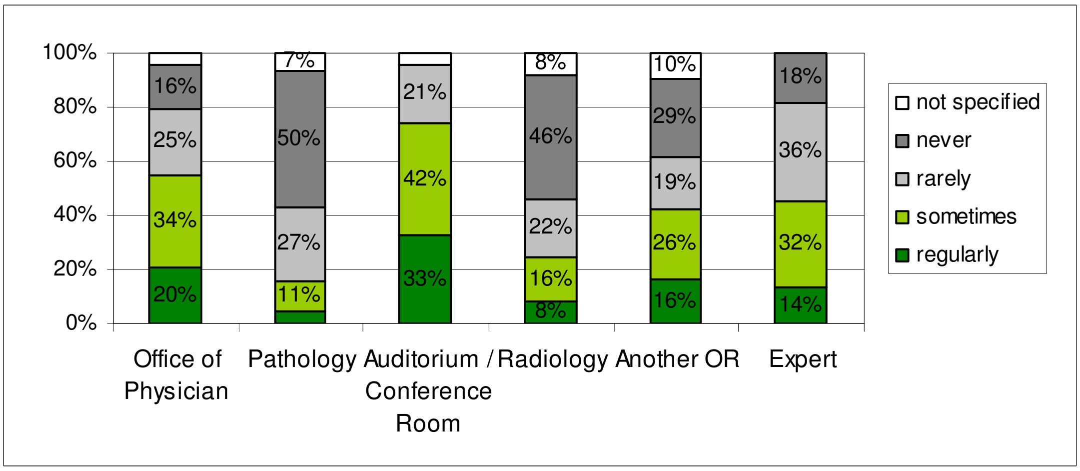

Table B-6 How often do you need the given functionalities for this communication? The partner should see me on a screen.

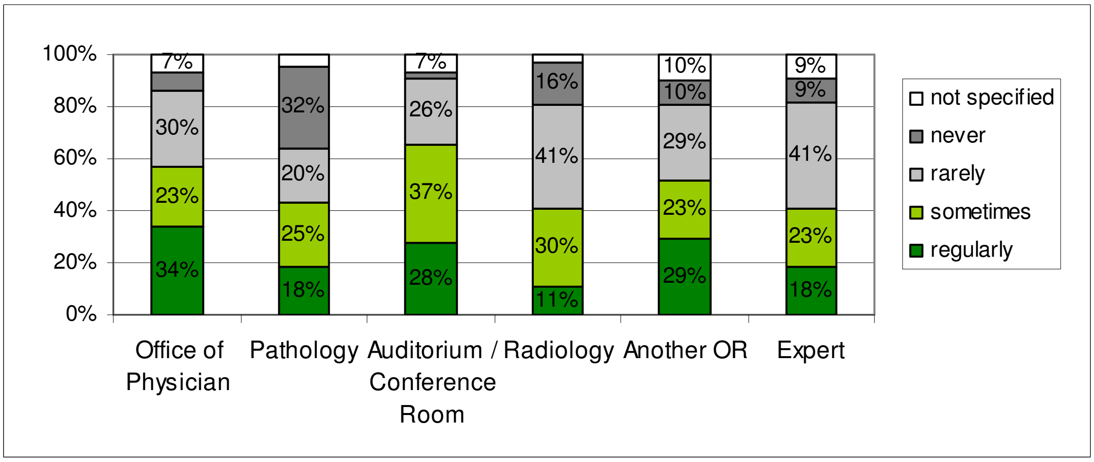

Table B-7 How often do you need the given functionalities for this communication? The partner should -after asking for permission- be able to select and see any video source in the OR autonomously.

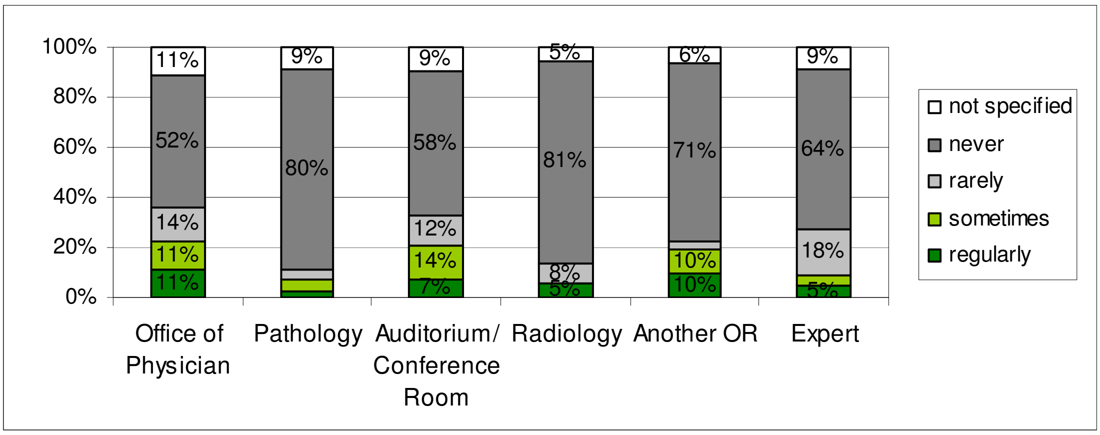

Table B-8 How often do you need the given functionalities for this communication? The partner should be able to select and see any video source in the OR without asking for permission.

C. Calculation of the Equivalent Absorption Area

	Device/Object/Person		H	W	D	Material	Surface [m2]	A.Coef. α 500Hz	A.Coef. α 1000Hz	Absorption Area [m] 500Hz	Absorption Area [m] 1000Hz	Source
	Air	Humidity 40%								0,36	0,792	[1]
Ceiling	Plain surface		6	10		Gypsum	60	0,05	0,04	3	2,4	[3]
	Microscope		0,7	0,4	0,4		1,44	0,03	0,03	0,0432	0,0432	[E]
	OR-lights						1	0,03	0,03	0,03	0,03	[E]
	Ceiling-mounted devices						1	0,03	0,03	0,03	0,03	[E]
Floor	Plain surface		6	10		Linoleum	56,54	0,03	0,03	1,6962	1,6962	[1]
	OR table	Chair with a textile Cover								0,3	0,35	[1]
		Chair with a textile Cover								0,3	0,35	[1]
		Chair with a textile Cover								0,3	0,35	[1]
	Patient	1 person sitting								0,55	0,8	[2]
	Anesthesia	1 person sitting								0,55	0,8	[2]
		Devices					1,5	0,03	0,03	0,045	0,045	[E]
	Scanner		2,3	2,05	1,2		19,545	0,03	0,03	0,58635	0,58635	[E]
	Person standing									0,6	0,95	[2]
	Person standing									0,6	0,95	[2]
	Person standing									0,6	0,95	[2]
	Person standing									0,6	0,95	[2]
	Empty chair									0,02	0,04	[1]
	Empty chair									0,02	0,04	[1]
Wall 1	Plain surface		3	6		Glass	18	0,04	0,03	0,72	0,54	[3]
Wall 2	Plain surface		3	10		Glass	30	0,04	0,03	1,2	0,9	[3]
Wall 3	Plain surface		3	6		Stainless Steel	12,67	0,03	0,03	0,3801	0,3801	[E]
	Sliding door		2,2	1,4		Stainless Steel	3,08	0,03	0,03	0,0924	0,0924	[E]
	Window to viewing room		1,5	1,5		Window	2,25	0,1	0,06	0,225	0,135	[1]
Wall 4	Plain surface		3	10		Stainless Steel	27,14	0,03	0,03	0,8142	0,8142	[E]
	Emergency exit door		2,2	1,3		Stainless Steel	2,86	0,03	0,03	0,0858	0,0858	[E]
						Total Equivalent Absorption Area*				13,7483	15,10025	

[1] Willems, W.M.: „Vorlesungsskript Bauhysik I“, Ruhr University of Bochum, accessible at http://www.ruhr-uni-bochum.de/bauko/downloads/bph1_uebung11.pdf, accessed 30 March 2007

[2] Goerne, T.: „Tontechnik“, Leipzig 2006, p. 99

[3] Sengpiel, E: "Absorption coefficient of different materials", accessible at http://www.sengpielaudio.com/Rechner-RT60Koeff.htm, accessed 04 April 2007

[E] estimated, no source has been found

* Calculation with equation 6.3 in Chapter 6.3.1

Table C-9 Calculation of Equivalent Absorption Area