BRAINLAB

BUZZ™–DIGITAL O.R.

An overview of components and features of modern O.R. integration

White Paper

Modern operating rooms (O.R.s) are equipped with a variety of technical systems. Ever-increasing pre-operative diagnostic data as well as safety and documentation requirements of O.R. procedures have significantly raised the amount and complexity of information and devices in the O.R.
Furthermore, the implementation of device integration in the O.R. is undergoing a radical transition to a modern, future-proof IP-networked infrastructure.

Users need to access medically relevant data (e.g. pre-operative CT images) and control the O.R. infrastructure. In order to increase their efficiency, and because they will be utilized by a variety of users, the complexity of the underlying integration systems must be reduced to an intuitive, uniform interface using clear and simplified operational controls to streamline the O.R. workflow.

Ideally, everything in the O.R. will relate to the patient being treated, with patient information automatically stored in a computer system so that multiple, recurring steps can be semi-automated throughout the O.R. process. Surgeons or care personnel must be able to access the following information and functions during a procedure:

- Data from the hospital information system (HIS): patient metadata, planned interventions, etc.
- Access to and presentation of radiological image data from the radiological image archive system (PACS)
- Intelligent software algorithms providing support for information analysis and enriching raw medical data
- Central control of video signals and displays of live video data (endoscope, microscope, navigation, etc.) on all screens in the O.R.
- Situation-dependent control of O.R. infrastructure (light, audio, etc.)
- Use of communication resources (streaming, video-conferencing, telephony)
- Tools for documenting procedures (video recordings, screenshots) and archiving records

The challenge is to intelligently combine both the strictly regulated medical needs of the O.R. with additional infrastructure functions, which are often adjusted to particular customer requirements, into an easy-to-use, uniform interface.

WHAT IS PART OF O.R. INTEGRATION?

Following features are part of a modern O.R. integration:

I. User interface
II. Video integration
  - Video sources (microscope, endoscope, etc.)
  - Displays (wall- and ceiling-mounted (touch-) displays)
III. Data exchange and data sharing
  - PACS access
  - HIS access
  - Cloud access
  - Concept for redundancy, data safety and maintenance
  - Access streams, screenshots and recordings
IV. Control concept
  - Touch displays
  - Nurse PC integration
  - Tablet integration
V. Documentation
  - Screenshots
  - Recordings
VI. Communication
  - Conferencing (video, audio)
  - Streaming
  - Telephone
VII. DICOM Viewing
  - Viewing of data (O.R. usable DICOM Viewer)
  - Data enrichment (Image Fusion, 3D, planning)
VIII. Workflow support
  - Checklist integration
  - Pre-fetching
IX. Audio
  - Music
  - Microphones
  - Speakers
X. Medical approval and conformance of components

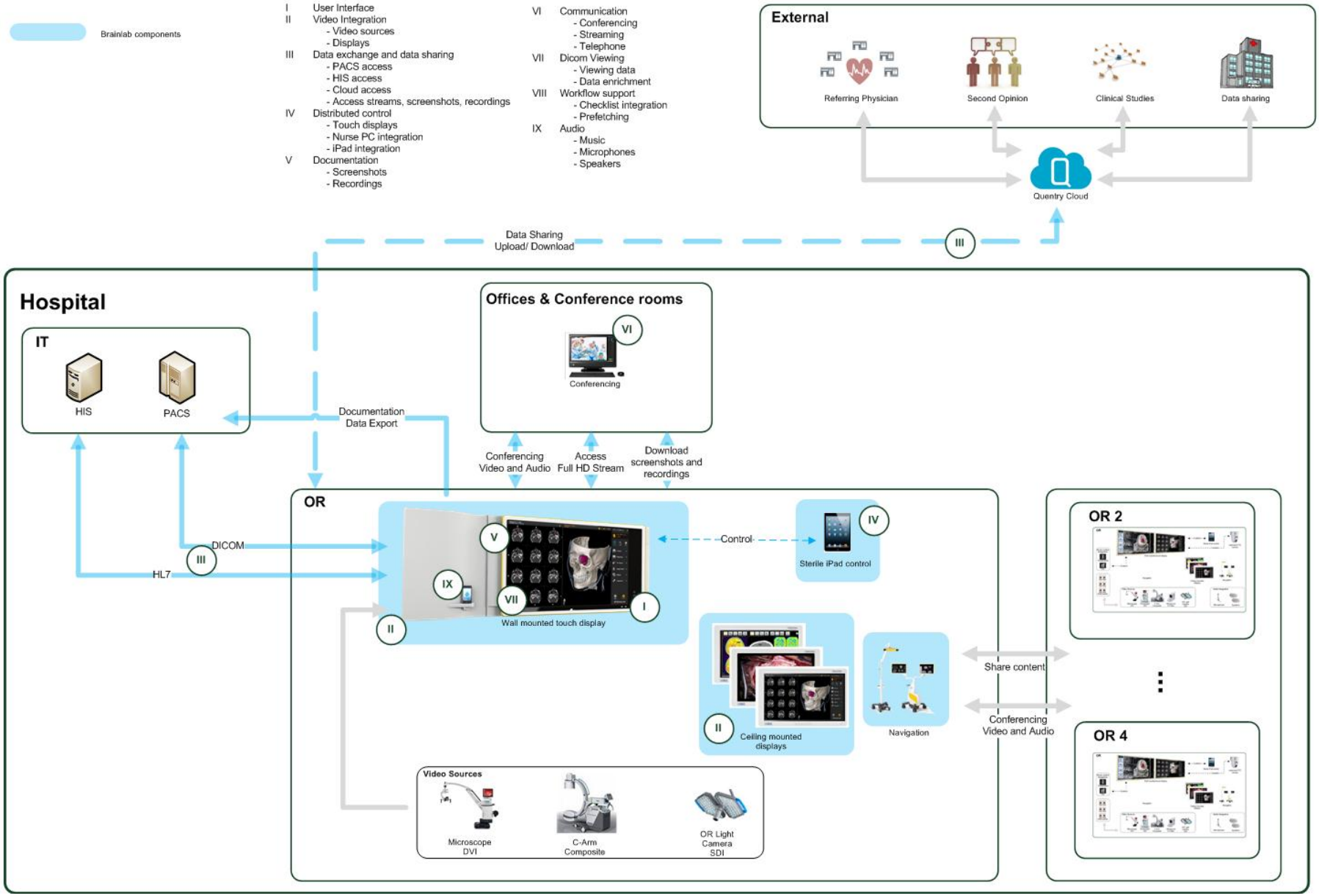


Figure 1: Brainlab standard digital O.R. integration

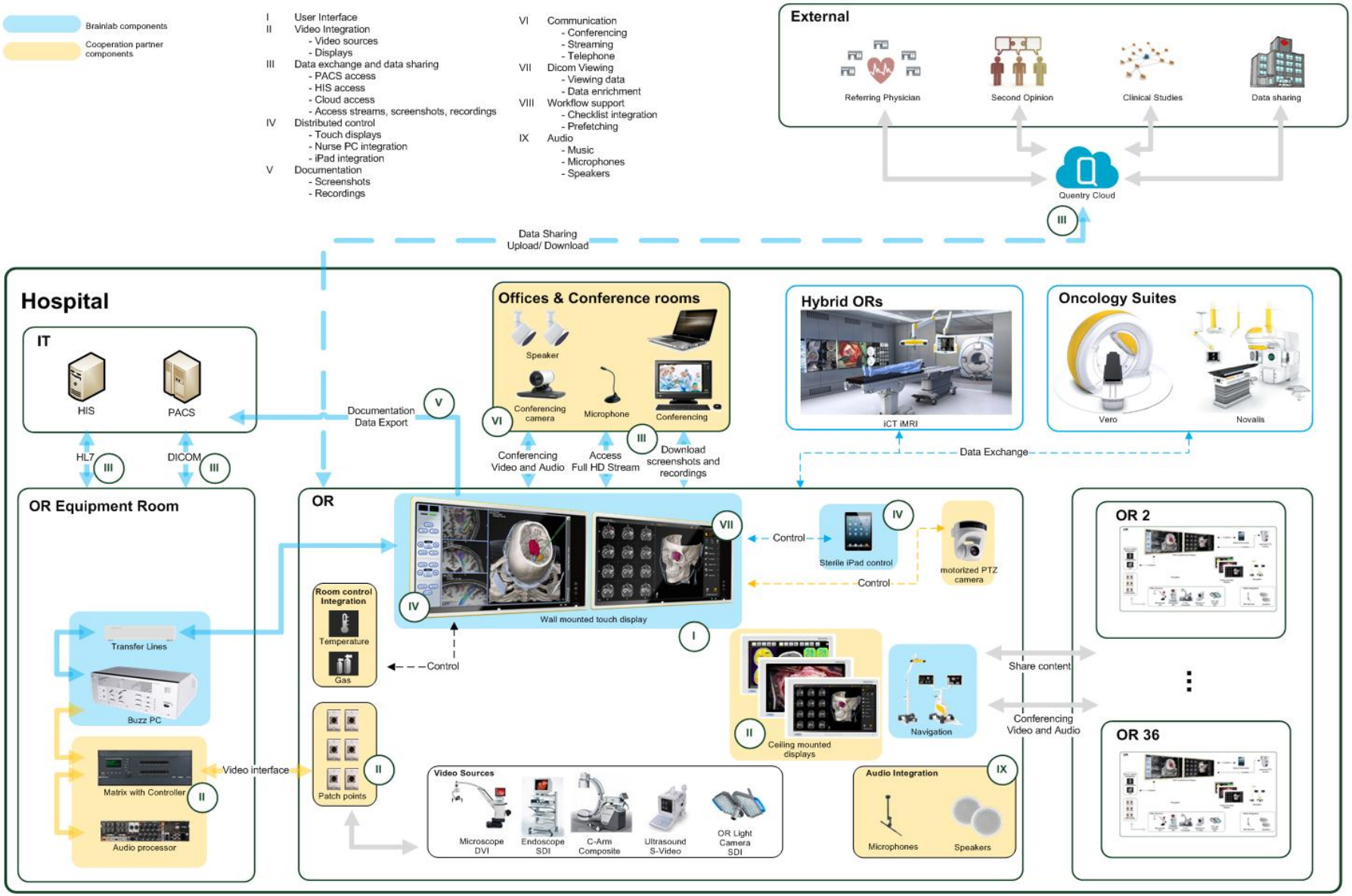


Figure 2: Brainlab advanced digital O.R. integration

BRAINLAB

I. USER INTERFACE

O.R. integration means giving the user access to all required information and controls. The most important part of O.R. integration is the user interface. A system with a complicated unstructured interface is not helpful and hinders clinical routine. Ideally, the user interface masks the technical interfaces and systems but still enables the user to access all information and control.

The Brainlab standard for intuitive and simplified device control in the operating room is touch control. With modern touch screen technology, multi-touch gestures like zooming or panning can simplify usage and the graphical user interface (GUI).
The Brainlab system offers an intuitive GUI with a neatly arranged, central start screen, which can be accessed at any time by pressing the home button. Various applications developed for multi-touch gestures provide intuitive and simplified usage.

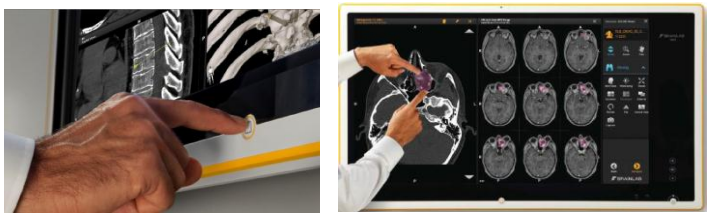


Figure 3: Home button concept and multi touch control and viewing display for intuitive interaction

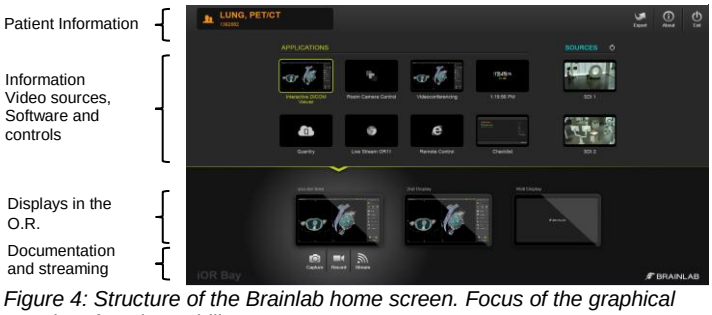


Figure 4: Structure of the Brainlab home screen. Focus of the graphical user interface is usability

Buzz uses a 42” optical touch display with full HD resolution. With a color depth of 10bit, a luminance of 450cd/m² and a viewing angle of 178° horizontal and vertical, Buzz guarantees brilliant image quality. One Buzz workstation can be equipped with two Buzz 42” touch displays and several additional viewing displays.

Features:

- 42” Full HD dual touch display
- Full functionality through touchscreen interface, no keyboard or mouse
- Home button for improved user interaction and workflows
- Intuitive and optimized touch-screen user interface

II. VIDEO INTEGRATION AND ROUTING INSIDE THE O.R.

An essential part of O.R. integration is the handling of real time video sources. The user is able to adapt the setup and to document content.

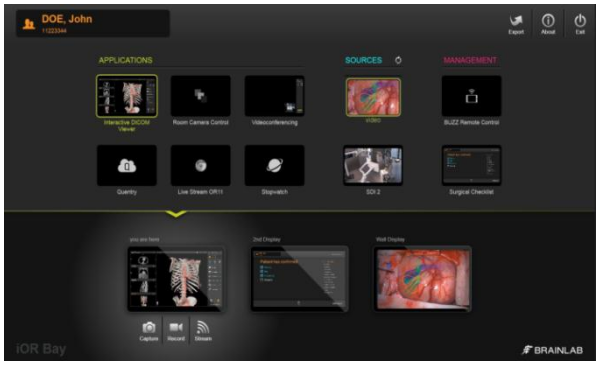


Figure 5: User interface of Brainlab Buzz. Connected video sources are detected automatically and appear with preview image.

Use Cases:

- User wants to view a video source on a particular display, for example, the endoscope image on a ceiling mounted display in the sterile field and on the wall mounted 42” display.
- User wants to change the setup in an intuitive and easy way with a single finger gesture.
- User wants to take a screenshot and/or a recording of the endoscope signal.

Features:

- Intuitive content management of available displays via "drag & drop" functionality
- Software and user interface tailored to surgeons needs
- User specific presets can be defined

III. DATA ACCESS AND SHARING

A. DATA ACCESS

As the access of patient data and information is an essential part of the O.R. integration feature set, the systems need to access the hospitals image data (Patient Archive Communication System - PACS) and the Hospital Information System (HIS). To access the PACS server, an intermediate layer (DICOM handling server) between a hospital PACS system and OR integration system enables communication. For smaller installations, a direct PACS access can be established. Depending on the hospitals requirements following additional features might considered:

- Intelligent pre-fetching of data: To decrease the time needed to load large data sets, a pre-fetching can be established. The pre-fetcher can either work with DICOM modality work lists or can create its own work list by listening to the HL7 messages distributed by the hospitals scheduling system (HL7 ORM and ADT). The system can thus load data before the procedure.
- Limiting the access of data: Depending on the hospitals privacy policy, the access of data can be limited in various ways. A common approach is to limit access to specific patients to a particular O.R. on a particular day. Emergency cases are handled separately with additional emergency access logging.

Use cases:

- User wants to access patients data without delay
- User wants to select patient data just by clicking on a shortlist. The user only wants to see patients who are being operated in a certain O.R.
- User doesn't want to enter a patient name to avoid duplication of records
- User wants to save data

Features:

- Automatic identification of patients scheduled for surgery based on HL7 messages or DICOM work list provided by the hospital
- Patient list is created accordingly and displayed on the user interface of the Brainlab platform. Eliminates search for patient name or ID
- Automatic synchronization of patient image data with hospital server. Pre-loading (e.g. overnight) of image data of the scheduled patients
- Hospital-specific customization of HIS integration
- Receive queries via the DICOM Q/R protocol and answer them using the cache or forward them to one or more other DICOM Q/R servers
- Receive retrieve request via the DICOM Q/R protocol and answer them using the cache or retrieve the data from one or more other DICOM Q/R servers
- Receive pushed DICOM data and store it in the cache
- Fully HIPAA compliant

B. DATA SHARING

The requirements for data sharing strongly depend on the point of access. Inside the O.R., data needs to be available in full quality in real-time. Figure 6 shows the areas from which O.R. data can be accessed.

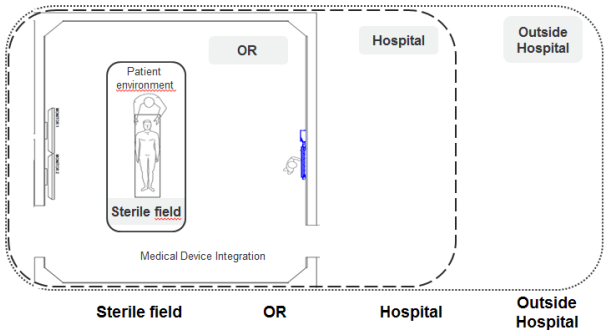


Figure 6: Data access from different locations within and outside the O.R.

Table 1: Dependency between area of access and requirements regarding quality, latency and reliability

	Access point	Data	Quality	Real-time	Reliability	Technology
Video routing	Sterile field	Video signals	full, no compression	high	High	Controlled cabling via video matrices or high speed 10 GBit network
		DICOM data	full, no compression	N/A as static	High	Standard network 1 GBit
	O.R.	Video signals	full, no compression	medium	High / medium	Controlled cabling via video matrices or high speed 10 GBit network
		DICOM data	full, no compression	N/A as static	High	Standard network 1 GBit
Data sharing	Hospital	Video signals	Full HD H.264	Low	Low	Standard LAN 1 GBit
		DICOM data	full, no compression	N/A as static	High	Standard LAN1 GBit
	Outside Hospital	Video signals	Full HD H.264	Low	Low	Standard WAN 10 MBit
		DICOM data	full, no compression	N/A as static	High	Standard WAN 10 MBit

While inside the OR (including the sterile field) data distribution has high requirements regarding real time, quality and reliability, which must be done with technologies which have limited access range.
For data sharing outside the O.R. (hospital environment, offices, etc.) or even to other hospitals/locations, different technologies are used to increase access distance.

Sterile field / O.R.:
The requirements and use cases for data and video distribution inside the O.R. are described in section *II. (Video Integration and Routing inside the O.R).*

Hospital:
Use Cases:

- Surgeon in the O.R. wants to share an endoscope image with a colleague outside (e.g. office) the O.R. Streaming is described in section *V.B (Streaming)*.
- Surgeon wants to download screenshots and recordings to the office computer

Outside Hospital:
Quentry is the cloud-based clinical network by Brainlab which allows physicians to access, control and share diagnostic images.
Use Cases:

- Referring Physician: Hospital uses a cloud service to improve integration and response time for referring hospitals and physicians. Traditionally, CDs with patient images have been sent via taxi, mail or even courier. Brainlab Quentry offers multiple tools to easily upload data from local workstations or PACS and send this data to other Quentry users. Integrated commenting and messaging functions allow quick and easy collaboration.

- Second Opinion: A Stroke Network is using Quentry to provide second opinions on CT images. The physician in charge of the potential stroke patient uploads the CT scans to Quentry and shares this data with Neurologists and Neurosurgeons specialized in stroke recognition and treatment. Feedback and advice on appropriate treatments can be provided quickly and in a user friendly manner.

- Clinical Studies: They pose two major challenges:
  - Collecting data from different sites
  - Storage of collected data

  Quentry offers multiple uploading tools to easily upload data from local workstations or PACS and store it in Quentry. Quentry CareTeams make it easy to work together in groups, share images with colleagues from different countries and review data together using the same online tools.

- Background Service: During weekends and night shifts there are usually less experienced physicians available in the hospital. The expertise of veteran physicians is often needed to review image data and, historically, these physicians had to appear on site. With Brainlab Quentry, these images are uploaded and shared to these experts at any time, allowing them the opportunity to provide feedback more quickly in less time.

Features:

- Seamless integration into Brainlab devices
- Integrated and web-based diagnostic DICOM viewer supporting modalities like MR, CT, PET, CR, DX, ECHO, US, VL, SC, OT, etc.
- Three different upload tools, reaching from a web-based uploader of a desktop software to a server based component for an automated high volume transfer
- Free to download mobile application for iPhone and iPad

IV. CONTROL CONCEPT

Due to its modern technology, contemporary O.R. integration allows for powerful and flexible control concept. Brainlab Buzz can control other devices (Nurse PC, Navigation system, etc.) but can also be controlled by other devices (Nurse PC, Navigation system, Tablet, etc.)

A. Nurse. PC

By installing specific software on the computer inside the operating room (nurse PC) this computer can also be seamlessly integrated via the hospital network. As a result, that PC is available from the Buzz start screen. Content from the nurse PC can be shared and controlled on Buzz and vice versa.

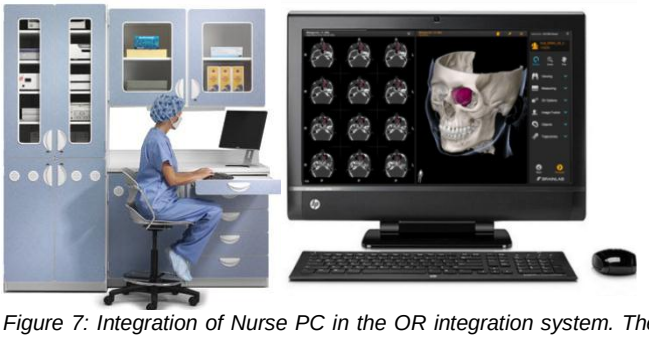


Figure 7: Integration of Nurse PC in the OR integration system. The Nurse can take over control but can also push content to the workstation (e.g. DICOM Viewer). Documentation functionality can be controlled from nurse PC.

B. TABLET

For very flexible and even mobile control, a sterilely draped tablet (e.g. iPad) can be used for controlling the system. The tablet can also be used as an additional display or to complete the first steps of the checklist from outside the O.R.

Figure 8: Integration of an iPad

Features:

- Remote control of Buzz software from tablet: touch display can be viewed and controlled from tablet
- Content management of all displays
- Control of treatment documentation features (screenshots, streaming and recording)
- Applications available on Buzz platform (e.g. interactive DICOM viewer, etc.) can be opened, viewed and controlled from tablet

C. INTEGRATION OF NAVIGATION SYSTEM

Operating rooms that are equipped with Brainlab navigation systems can benefit from seamless integration between Buzz and the navigation system. Linked via network, the two systems continuously exchange information: All information available on Buzz is also available on the navigation system such as the patient name, available applications or video sources.

Use case:

Buzz can display the content of the navigation screen and control the software running on the system. Full control over all available displays and applications is available on both systems.

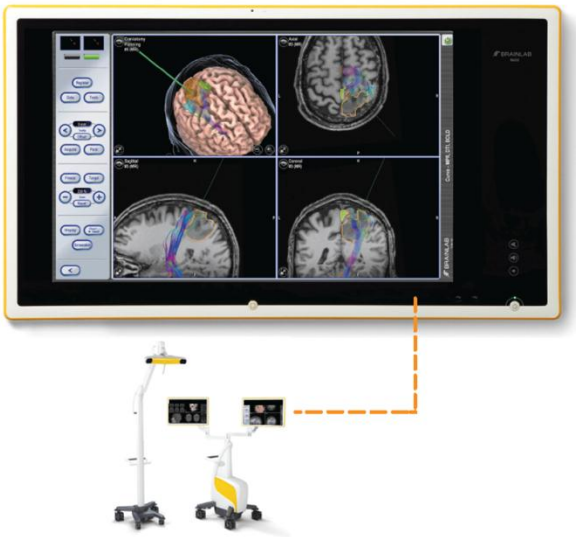


Figure 9: Integration of Navigation system. The intelligent network-based pairing functionality allows for sharing content and application as well as bi-directional control

V. COMMUNICATION

For communication outside the OR, the user has several options. According to the use case, the user can:

- Initiate a video conference
- Enable a video stream
- Use the integrated hospital telephone system

A. CONFERENCING

For communication with colleagues outside the OR, audio and visual contact is possible. Video conferencing enables the user to call colleagues in offices or other O.R.s.

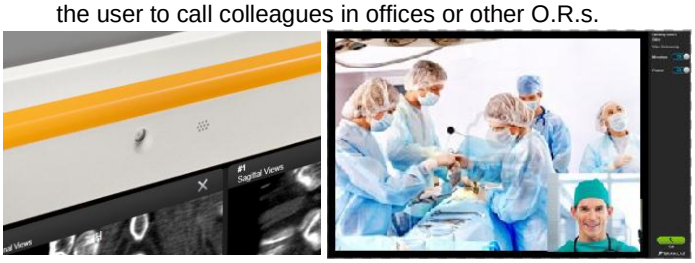


Figure 10: Brainlab Buzz video conferencing. The video conferencing camera and microphone are integrated into the touch display frame

Use case:

- User wants to communicate with colleagues with visual contact
- User wants to interact with colleagues in another O.R. or office

Features:

- Allows for audio and video communication between (i) Buzz and office PC, or (ii) between two Buzz systems
- Purely web-based, therefore requires no installation of hardware or additional software on client side besides web browser
- Conferencing application available for office use on a wide range of operating systems: Apple OS, Windows 8/7/Vista/XP
- Buzz equipped with built-in web camera and microphone
- Optional use of external microphone connected to Buzz (e.g. Bluetooth headset) for audio communication from sterile field
- When viewing a live stream from the O.R. (e.g. displaying live microscope video) a single-click in the web portal allows remote consulting

B. STREAMING

Streaming can be a helpful feature to share high quality content (video sources, DICOM images, planning and navigation information) with colleagues and staff outside the O.R.

Use cases:

- Surgeon requires intraoperative feedback regarding a structure in the endoscope image
- Surgeon needs feedback from the histology laboratory
- Surgeon wants to share image on DICOM viewer with a colleague

To ensure HIPAA compliant O.R. streaming, two requirements must be fulfilled to enable a video stream:

- The stream must be enabled from inside the O.R.
- The second party user must authenticate the stream (login, password)
-

Features:

- Streaming of any display content in Full HD quality
- Streaming of two displays in HD quality simultaneously
- One-click control interface for streaming, recording and screenshot
- Direct web-access to live stream, recordings and screenshots via web portal accessible from any web-browsing enabled computer

C. INTEGRATION OF HOSPITAL TELEPHONE SYSTEM

The telephone system, which includes all contact information, is usually the standard communication medium. The integration of the hospital telephone system enables the user to access and control all functionality from the Buzz control interfaces in the O.R.

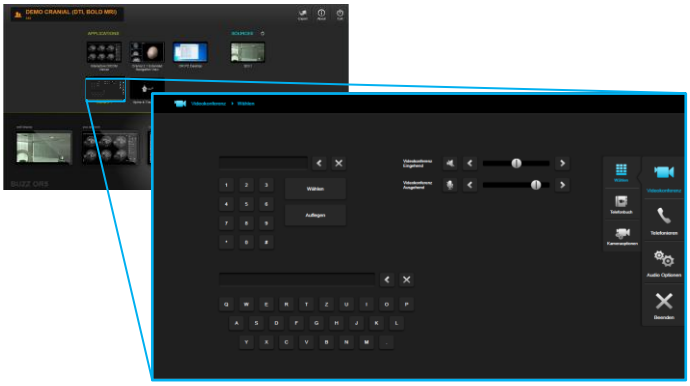


Figure 11: Integration of hospital telephone system into Buzz digital O.R. Integration enables the user to control the telephone system from all touch displays (e.g. access contact list and favorites, etc.)

The telephone system is integrated as an additional application into the Buzz home screen (Figure 11). The user interface language can be adapted to customers' local language.

Use cases:

- User wants to call a colleague outside the hospital
- User wants to call a colleague on their mobile phone

VI. DOCUMENTATION

Documentation is becoming more and more important in daily surgical routine. Modern O.R. integration offers a variety of documentation functionalities. Screenshots or recordings can be exported to CD/DVD, USB, a network folder and/or to the hospital's PACS.

Figure 12: Documentation features (screenshot, recording) can be controlled from all interfaces in the O.R.

Features:

- Documentation anytime
- Recording of any display content in Full HD
- Recording of two displays contents in HD quality simultaneously
- Recordings encoded in MPEG4/H.264 format
- One-click control interface for streaming, recording and screenshots
- Direct web-access to live stream, recordings and screenshots via web portal accessible from any web-browsing enabled computer
- Download of documentation data via web portal
- Export documentation (screenshots, recordings) to USB, CD/DVD, a network folder, PACS

VII. DICOM VIEWING AND HANDLING

The DICOM support is available for all disciplines and fulfills requirements for e.g. Orthopedics, Spine, Trauma, Neuro and Cardio. The interactive DICOM viewer has been specially developed for the needs of surgeons in the O.R.

Figure 13: Brainlab Buzz with interactive DICOM viewer. The display shows images from a CT scan: a series of single layers on the left and an on-the-fly calculated 3D visualization of the data on the right. Objects can be highlighted for further planning. In this example, an object (a tumor in red) has already been defined and displayed in a 3D view.

Intelligent software algorithms are used to generate additional information from raw medical image data. For example, it is possible to calculate "live" 3D renderings or merge different image datasets such as CT and MRI. Thus, static raw image data is enriched and dynamic views are available, which can provide important additional insights for patient treatment.

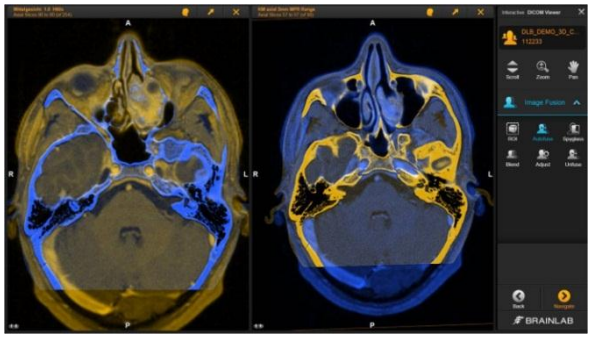


Figure 14: Automatic Image Fusion: when different diagnostic image datasets are available, MRI and CT in this case, the images can be merged using an automated intelligent software algorithm. This provides the surgeon with an enriched view of anatomical details

Features:

- DICOM viewer interface optimized for use in the O.R.
- Loading data from PACS, CD/DVD, USB, Cloud (image sharing through Quentry)
- Access to 3D multi-planar reconstructions (live calculation)
- 3D volume rendering of data sets (specific views for CT (e.g. Bone), MR (e.g. Vessels))
- 3D visualization with crop and threshold functionalities
- Quick Surgical Planning of Objects and Trajectories
- Automatic image fusion of e.g. CT / MR / PET scans
- Basic measuring functionalities (distance, angle, diameter)
- Orthopaedic Planning (Digital Templating with TraumaCad)
- Unified search and load of patient data from various sources: PACS ("Query/Retrieve" and "Push"), USB, CD/DVD and network.

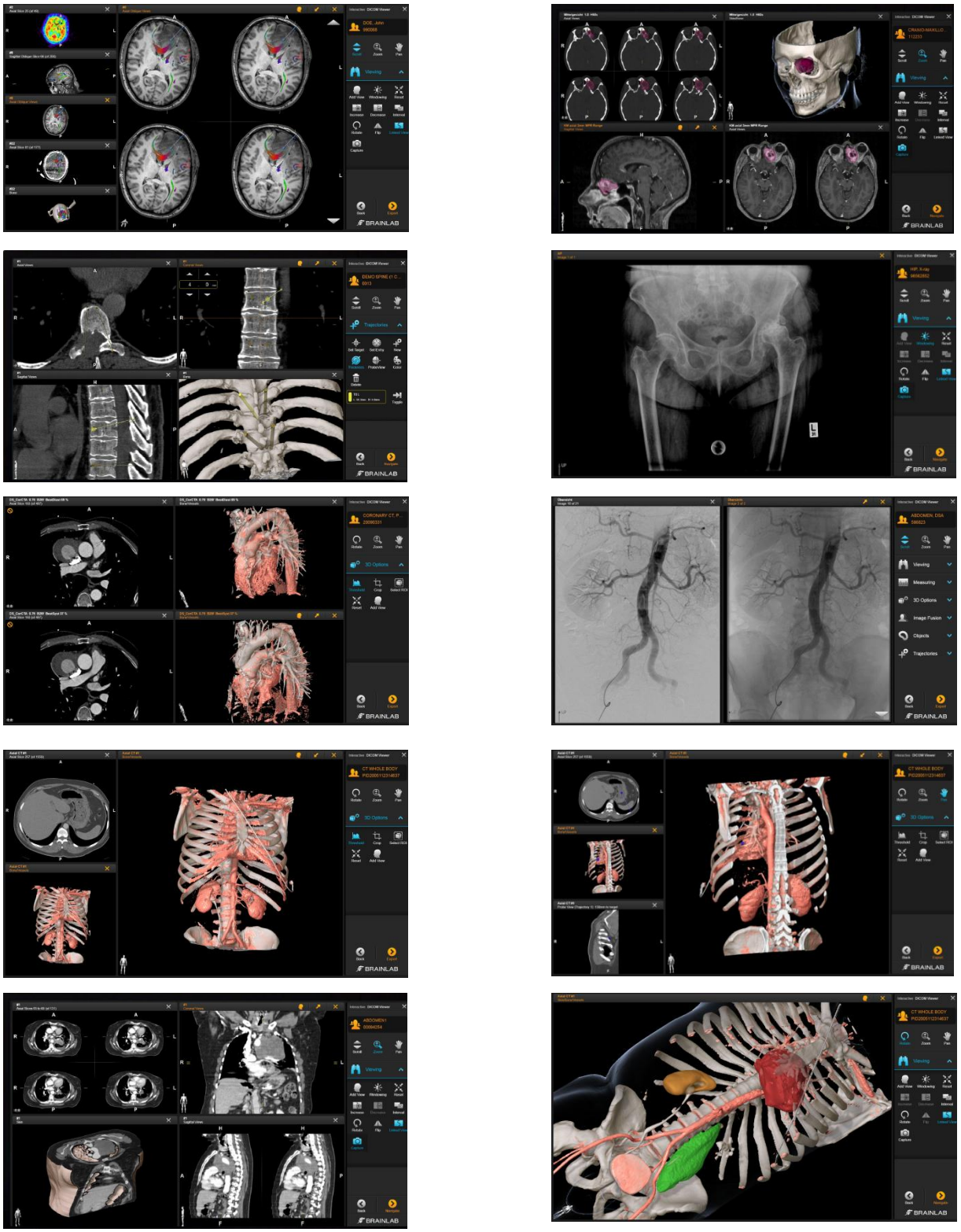


Figure 15: Further examples of the interactive DICOM viewer with data from different disciplines

VIII. WORKFLOW SUPPORT

Modern O.R. integration also offers several features dedicated to support workflows within the O.R. that can help to save time and provide relevant information to the O.R. team.

A. IMAGE DATA PRE-FETCHING

Based on HL7 messages from the Hospital Information System (HIS) or a DICOM work list provided by the hospital, the system can automatically identify which patients are scheduled for surgery in the O.R. This list is provided to the O.R. team on the touch display, eliminating the need to search for patient name or ID.

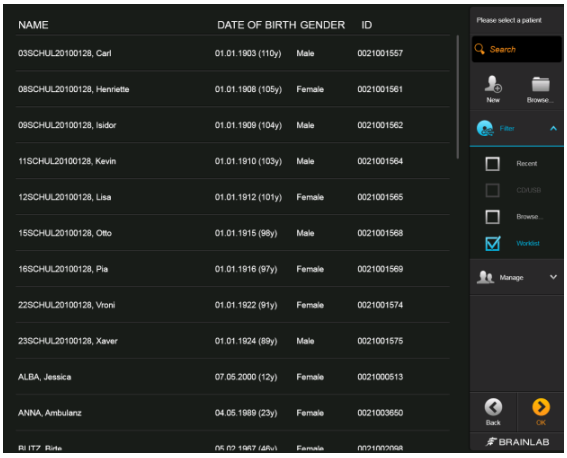


Figure 16: Work list based on hospitals scheduling system information

Additionally, image data from the PACS can be pre-fetched (e.g. overnight) so that data is already available when the team enters the O.R.

B. SURGICAL CHECKLIST

An electronic checklist (standard WHO or customer specific) guides the user through patient related questions to ensure that, for example, the correct patient is operated on the correct side or that the OR team is prepared for risk of high blood loss. The content of the checklist can be modified to match the needs of the hospital. After completing the checklist, the system creates a document providing evidence that all steps in the checklist were completed. This document is sent to HIS and embedded in the electronic medical record of the patient.

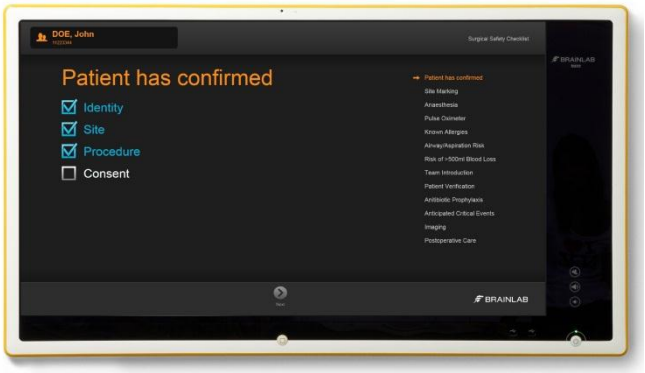


Figure 17: Integrated Checklist application on Buzz touch display

X. MEDICAL APPROVAL AND CONFORMANCE

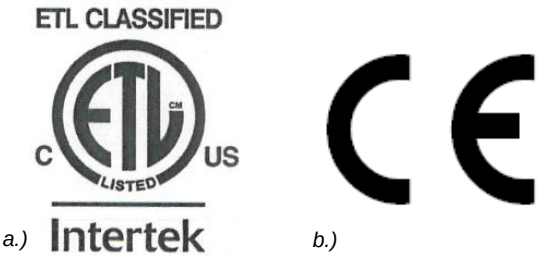
As O.R. integration components are intended to be used and installed in a medical environment they require medical approval and must conform to applicable standards.

Buzz hardware is approved as a Class I medical product according to different directives and regulations for medical devices (e.g. US FDA regulations, European Directive MDD, Health Canada). Buzz software, including DICOM viewing and planning features, is a Class II medical product.

Buzz has been designed, developed and manufactured according to international and recognized standards.

The following standards have been fulfilled by the manufacturer:

Title	Description
ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
21 Code of Federal Regulation. Part 820	Quality system Regulation
ISO 14971:2009	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01); German version EN ISO 14971:2009
IEC 60601-1: 2005+ CORR. 1 (2006)+ CORR. 2 (2007) (incl. AAMI ES60601-1 and UL for the USA market)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests



a.) *b.)*

Figure 18: Labels for a) ETL Mark is proof of product compliance to North America and Canada safety Standards and b) CE Mark proofs the compliance to the essential requirements of the Medical Device Directive in Europe.

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ADDITIONAL BUZZ INFORMATION

IT Department / Administration:

- DICOM Conformance statement
- HL7 Whitepaper
- IEC 80001 summary
- Antivirus and Windows update policy

OR planner:

- BUZZ Digital O.R. Whitepaper
- Whitepaper Brainlab Crestron Digital O.R. Integration
- Clinical Whitepaper Computer- and IP-centric concept for a truly digital operating room
- Wiring diagram examples

ABBREVIATIONS

DICOM	**D**igital **I**maging and **Co**mmunications in **M**edicine - describes a standard how to store and exchange medical images between medical devices.
PACS	**P**icture **A**rchiving and **C**ommunications **S**ystems - describes a system, which contains all the hospital's medical patient images and usually offers a DICOM conform interface for the retrieval of patient information.
Q/R	**Q**uery / **R**etrieve – part of the DICOM standard which describes in detail how to search and request patient data for retrieval from a hospital PACS via network.
HIS	**H**ospital **I**nformation **S**ystem **/**
HL7	**H**ealth **L**evel **7**
HL7 - ADT	**A**dmission **D**ischarge **T**ransfer
HL7 - ORM	**Or**der **M**essage
HIPAA	**H**ealth **I**nsurance **P**ortability and **A**ccountability **A**ct

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