



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

August 19, 2016

Ms. Dee Jay Zerman
Hedrick Building
211 Friday Center Drive, Suite G015
Chapel Hill, NC 27517

No Review

Record #: 2032
Facility Name: UNC Hospitals
FID #: 923517
Business Name: UNC Hospitals
Project Description: Acquire an Airo Mobile Intraoperative CT scanner
County: Orange

Dear Ms. Zerman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of July 14, 2016, regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Acute and Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Bernetta Thorne-Williams
Project Analyst

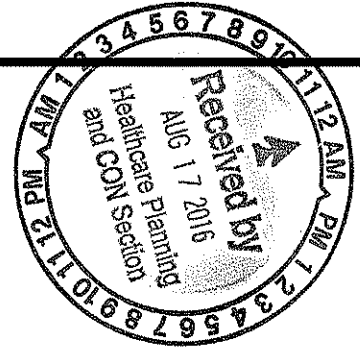


Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

Zerman, DJ

From: Zerman, DJ
Sent: Thursday, July 14, 2016 3:06 PM
To: Williams, Bernetta
Subject: UNCH ~ Request for No Review Determination
Attachments: QN-UNCHCH-GUT-79_Airo_Final.pdf



Ms Thorne-Williams,

UNC Hospitals is planning to acquire an Airo Mobile Intraoperative CT scanner for use in the operating rooms and other locations throughout the hospital where a patient's condition hinders movement to a fixed CT scanner for imaging. The CT scanner is mobile in the sense that it can be moved in and out of operating rooms and patient rooms within the hospital. The portable CT Scanner requires no construction or upfit for use. The Airo is a helical CT scanner with 32 slice detector, extra-large bore size, and with a small footprint and slim gantry that allows it to be transported easily through standard doorways. The cost is less than \$750,000 and a valid vendor quote is attached. We are asking for confirmation that this purchase does not require CON review as the equipment is not considered Major Medical Equipment as defined in NCGS § 131E-176(14o).

Please let me know if you require any additional information. Thank you for your prompt consideration of this matter.

Sincerely,

DJ
Direct line 984-974-1243

Dee Jay Zerman, MBA | System Director of Regulatory Planning
Strategic Planning and Network Development
UNC Health Care
Hedrick Building, 211 Friday Center Drive, Suite G015, Chapel Hill, NC 27517
p (984)974-1210 | f (984)974-1312
DJ.Zerman@unchealth.unc.edu

8/12/16

Bernetta,

*am sending you a hard copy of this request
I email on 7/14/16 because I noticed it did
not show upon the recent correspondence log-
also attached.*

Thanks,

Dee Jay

*984-974-1243
direct line*

Agency	Name	Date letter Received	Type of Letter	Name of Facility	Brief Description	County	Staff Assigned	NOTES
Five Star Senior Living	Katherine E. Potter	27-Jun-16	Exemption	Morningside, Concord, Gastonia & Raleigh	Change of Real Property owner	Cabarrus, Gaston, Wake	Greg Yakaboski	
Retirement Living Associates, Inc.	David J Coster	30-Jun-16	Exemption	Mars Hill Retirement Community	Intent to change license	Madison	Julie Halatek	
Carolinas HealthCare System	Elizabeth Kirkman	1-Jul-16	Exemption	Cleveland Pines Nursing Center	Aesthetic and Infrastructure Renovation	Cleveland	Julie Halatek	
Carolinas HealthCare System	Elizabeth Kirkman	1-Jul-16	Exemption	Carolinas HealthCare System Cleveland	Upgrade of Emergency Generator	Cleveland	Julie Halatek	
Carolinas HealthCare System	Elizabeth Kirkman	1-Jul-16	Exemption	Carolinas HealthCare System Union	Replacement of 2 emergency power generators	Union	Greg Yakaboski	
HDJN	Jonathan Sumrell	1-Jul-16	Exemption	Triangle Orthopaedic Associates	Services agreement/ lease of fixed and mobile magnetic resonance imaging programs	HSA1 and 5	Julie Halatek	Per analyst(JH), this is a response to previous exemption letters issued 6/13/16 (This document does not change the outcome of original request.
Cape Fear Valley Health	Sandy T. Goodwin	1-Jul-16	No Review	Cape Fear Valley Cancer Treatment & CyberKnife Center	Replace existing linear accelerator	Cumberland	Tanya Rupp	
Carolinas HealthCare System	Elizabeth Kirkman	1-Jul-16	Exemption	Physicians Office (No name listed)	Construct a physician Office Building	Mecklenburg	Gloria Hale	
SumrellSugg Smith Moore Leatherwood	David B. Baxter, Jr. Justin Puleo	1-Jul-16 1-Jul-16	Exemption Declaratory Ruling	Pungo District Hospital Columbus Regional Diagnostics	Intent to sell hospital Add one new site to the route for the mobile MRI scanner	Beaufort Columbus	Jane Rhoe-Jones Tanya Rupp	
UNC Rex Healthcare	Steve Burriss	5-Jul-16	Acquisition	The Prostate Health Center	Acquire existing prostate health center	Wake	Mike McClip	
UNC Hospitals Nelson Mullins	Dee Jay Zerman Denise M. Gunter	6-Jul-16 7-Jul-16	Exemption Exemption	UNC Hospitals Atlantic Surgicenter, LLC	Renovate and expansion of space Acquisition of the Physicians' Membership interests	Orange New Hanover	Bernetta Thorne-Williams Tanya Rupp	
Carolinas HealthCare System	Elizabeth Kirkman	12-Jul-16	Exemption	Carolinas HealthCare System Stanly	Replacement of Air Handling Equipment/Generators/Upgrade Electrical System	Stanly	Greg Yakaboski	
Sentra Healthcare	Monica Hullinger	13-Jul-16	No Review	Sentra Albemarle Hospital Healthy at Home- Albemarle	Provision of home health services to NC residents	Pasquotank	Jane Rhoe-Jones	
K & L Gates	Gary Qualls	11-Jul-16	No Review	Regency Retirement Village	Relocation of its HHA offices	Stanly	Greg Yakaboski	
Regency at Pineville	Paul Buethe	15-Jul-16	Exemption	Regency Retirement Village	Minor remodeling project for conversion of single occupancy to	Mecklenburg	Gloria Hale	

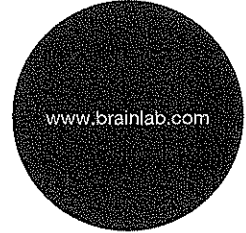
Agency	Name	Date letter Received	Type of Letter	Name of Facility	Brief Description	County	Staff Assigned	NOTES
Alliance Healthcare Services	David French	18-Jul-16	Exemption	Alliance Imaging Inc.	Temporary replacement for PET/CT equipment for the Eastern Mobile scanner	IV, V, & VI	Jane Rhoe-Jones	
Strategic Healthcare Consultants	David French	18-Jul-16	Material Compliance	Alliance Imaging Inc.	Additional host site Project ID #G-6271-00	Guilford	Celia Inman	
Pacifica	Marlene Nelson	19-Jul-16	Exemption	Brookdale Henderson North	Purchase of assisted living property	Henderson	Julie Halatek	
Liberty Healthcare Management, Inc.	Hunter Diefes	20-Jul-16	Exemption	Warren Hills Nursing Center, LLC	Acquire a combination NF/AACH facility	Warren	Bernetta Thorne-Williams	
Nelson Mullins	Denise Gunter	21-Jul-16	Exemption	Triad Imaging, LLC	in the process of forming a joint venture called Southern Pines	Moore	Tanya Rupp	
Duke University Health System	Catharine Cummer	28-Jul-16	Exemption	Southern Pines Facility	Diagnostic Imaging, LLC			
Novant Health	Lisa Griffin	28-Jul-16	Exemption	Duke Raleigh Hospital	Pharmacy/renovations	Wake	Mike McKilip	
Parker Poe	Robert Leandro	29-Jul-16	No Review	Novant Health Forsyth Medical Center	Replacement equipment (Linear Accelerator)	Forsyth	Celia Inman	
Fresenius Kidney Care	Jim Swann	29-Jul-16	Material Compliance	(NHFMC) Community CarePartners, Inc.	Acquire a Medicare certified hospice agency	McDowell	Julie Halatek	
Four Oaks Propco Holdings, LLC	J. Melvin Deaton	1-Aug-16	Exemption	Fresenius Medical Care Morrisville	Material Compliance for Project ID #J-11133-16	Wake	Mike McKilip	
Four Oaks Propco Holdings, LLC	J. Melvin Deaton	1-Aug-16	Exemption	Oakview Commons	Acquire an adult care home in Wake County	Wake	Mike McKilip	
Consulate Health Care	Tracey C. Cosby	2-Aug-16	Exemption	East Towne	Acquire an adult care home in Mecklenburg County	Mecklenburg	Gloria Hale	
Consulate Health Care	Tracey C. Cosby	2-Aug-16	Exemption	Forrest Oaks Healthcare Center	Reduce total licensed beds for conversion to SNF beds	Stanly	Greg Yakoboski	
Fresenius Kidney Care	Jim Swann	3-Aug-16	Material Compliance	Westwood Health and Rehabilitation Center	Reduce total licensed beds for conversion to SNF beds	Randolph	Celia Inman	
UNC Hospitals	Dee Jay Zermer	5-Aug-16	Exemption	Greenville Dialysis Center	Material compliance for Project ID #Q-11141-16	Pitt	Jane Rhoe-Jones	
Strategic Healthcare Consultants	David French	8-Aug-16	Exemption	Anderson Pavilion Acute & Intermediate Coronary Care unit	Renovate and refurbish the 3rd floor unit	Orange	Bernetta Thorne-Williams	
NC Flowers LLC	John Kolleng	8-Aug-16	No Review	Alliance Imaging Inc.	Temporary replacement for MRI scanner	Guilford	Celia Inman	
				Edenton Prime,	Acquire adult care home facilities	Multi-Counties	Jane Rhoe-Jones	



Brainlab, Inc.
 5 Westbrook Corporate Center · Suite 1000
 Westchester · IL 60154 · USA

phone: +1 708 409 1343
 fax: +1 708 409 1619

University of North Carolina Hospital
 101 Manning Drive
 Chapel Hill, North Carolina, 27599-7512
 United States



Westchester, June 8, 2016
Quotation QN-UNCHCH-GUT-79

Shipment: DDP (Incoterms 2010)
 Terms of Payment: See Brainlab Standard Terms and Conditions

The prices and conditions set forth in this quotation are valid for a period of 90 days from the date of its issue. The attached terms with the title 'Standard Terms and Conditions-Brainlab, Inc.' are hereby incorporated and form an integral part of this quotation.

Pos.	Art.No.	Description	Qty.
AIRO			
1	19650	AIRO MOBILE INTRAOPERATIVE CT	1
2	B13229	AIRO CALIBRATION PACKAGE	1
INTEGRATED OR 3RD PARTY PRODUCTS			
3	19225	AIRO TRUMPF PATIENT POSITIONING SYSTEM TOTAL SPINE & CRANIAL - USA	1
ONSITE APPLICATION TRAINING - IGS			
4	83992-03	AIRO TRAINING (5 CONSECUTIVE DAYS)	1
AIRO SERVICES			
5	83991-01	AIRO INSTALLATION	1
6	50788	AIRO FREIGHT, INSURANCE AND FEES	1
INTEGRATED OR PLANNING AND IMPLEMENTATION SERVICES			
7	B14278	CONSULTING AND COORDINATION OF AIRO	1
TOTAL EXCL. TAX			749,999.00 USD



A handwritten signature in black ink that reads "Nuttrell".

Natalie Luttrell
Area Account Manager Mid Atlantic
natalie.luttrell@brainlab.com

Technical Quote Review done by

A handwritten signature in black ink that reads "T. Kroenung".

Thomas Kroenung
Technical Quote Review Specialist IGS
thomas.kroenung@brainlab.com



1 | 19650 | AIRO MOBILE INTRAOPERATIVE CT

A cohesive imaging and patient positioning solution, Airo is ideal for cranial, spine and trauma procedures. Designed to function inside existing OR suites, Airo eliminates the need for construction or custom build-outs (depending on local standards, expected utilization and structural conditions of the building).

- Helical CT scanner with 32 slice detector array for high-resolution and full Hounsfield soft tissue imaging
- Extra-large bore size of 107cm expands intraoperative value
- Extra-small footprint allows for transport through standard doorways
- Extra-slim gantry houses patented custom components, increasing system flexibility
- Scan volume of D50x100cm allows to image entire spine
- Integration of TRUMPF TruSystem7500 OR column for reproducible imaging results
- Single touchscreen handheld enables efficient control of imaging, transport and calibration
- Patented air cooling system
- Electrical (battery powered) drive system and front-view camera ensure easy single-operator maneuverability
- Standard power connection

INCLUDES:

Remote control (incl. charger) for Trumpf Medical TruSystem 7500 patient positioning system.

REQUIREMENTS FOR COMBINED USE WITH NAVIGATION:

- Latest generation Brainlab navigation platform: Curve 1.1, Curve Dual Display or Curve Ceiling-Mounted Single Display.
- Minimum software versions Navigation Software Cranial 3.0 (art. 22216) and/or Navigation Software Spine & Trauma 3D 2.1 (art. 22268)
- Airo Automatic Image Transfer & Registration (art. 19651)
- Origin Data Management (art. 30038)
- Elements Image Fusion (art. 26217)
- Elements Dicom Viewer (art. 26210)
- Elements Dicom Viewer 3D (art. 26211)
- Elements Trajectory Planning (art. 26250) Elements Smartbrush (art. 25200)

NOTE:

- Additional third-party PACS license and integration fees might apply if Airo is intended to write DICOM data to a local PACS.
- It is the customer's responsibility to ensure that the requirements as stated in the Airo Pre-Installation Guide are fulfilled by the mutually agreed installation date in order to ensure a successful installation of Airo. The Airo Pre-Installation Guide is attached to this quote. For any questions please contact your Brainlab sales representative or consultant.

2 | B13229 | AIRO CALIBRATION PACKAGE

Hardware for calibration of Airo Mobile Intraoperative CT.

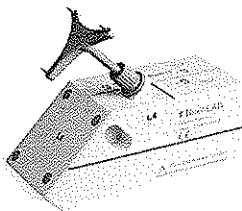
19652 | GAMMEX PHANTOM W CASE AND STAND

19144 | ADHESIVE FLAT MARKERS (10 PCS)

Adhesive markers attached to selected intra-operative imaging devices enable integration with Brainlab navigation systems.

- Reflective surface for visibility to infrared navigation camera
- For calibration and registration of imaging device (additional hardware required)

- Enables Automatic Image Registration with Brainlab navigation (additional software required)
Suitable for following imaging hardware:
- Airo
- Siemens CT scanners (iCT)
- Siemens Artis zeego (iAngio 3D)



19148 | CT SCANNER CALIBRATION PHANTOM

Calibration phantom to calibrate a CT scanner for Automatic Image Registration and verify the accuracy on a routine basis by Brainlab service engineer.

- Reference lines to align with CT laser
- Notches for verification of registration accuracy
- Includes the "Reference Array Intraop Imaging Cranial" interfacing with the phantom
- Also includes the DrapeLink interface for cranial customers

3 | 19225 | AIRO TRUMPF PATIENT POSITIONING SYSTEM TOTAL SPINE & CRANIAL - USA

OR TABLE X-RAY

2x Shuttle 3.6 360

1x Operating table top Carbon X-TRA 7500 U

1x Operating table top U24 U

1x Table top segment carbon 600 U

1x Leg section one part short U

GENERAL PATIENT POSITIONING

1x Clamp pair for joint plate carbon

1x Joint plate carbon 520

2x Side rail U

2x Armboard snaplock trigger

2x Armboard pad 3"

SPINE STABILIZATION

1x T3 Advance System

1x Ultra Comfort Covers, Medium, case/6

1x Ultra Comfort Covers, Large, case/6

CRANIAL STABILIZATION

1x Adapter X-ray triple joint wide

1x Retainer X-ray

1x Swivel adapter X-ray

1x Skull clamp X-ray (PMI DORO)

ADAPTERS

1x Interface Skull Clamp AL (DBS Adapter) LP

1x Interface Skull Clamp (Biopsy Arm/Varioguide) LP

SHIPPING, INSTALLATION AND TRAINING

4 | 83992-03 | AIRO TRAINING (5 CONSECUTIVE DAYS)

On-site training for Airo® mobile intraoperative CT including:

- Airo features and functionalities
- Calibration and operational procedures
- Airo specific automatic image transfer to hospital network or other devices
- Navigation platform integration workflows and registration software for cranial and spine (if applicable)
- Eligible for IACET CEUs with completion of training.

5 | 83991-01 | AIRO INSTALLATION

Installation and commissioning of Airo mobile intraoperative CT (art. No. 19650) including following tasks:

- Inspection and setup of delivered material
- Setup and test of TRUMPF column and table top
- Customization of software configuration (Pendant, Gimbal + Ring PC's)
- Warm-up and testing of X-ray tube (stability test)
- Hospital network integration, including test and verification of data transfer
- Perform complete system calibration (running gantry, ring rotation, table rotation)
- Verification of completeness, functioning and precision of all soft-and hardware components

If applicable:

- Integration of all hardware & computer components with the navigation platform
- DICOM access point installation with existing navigation platform
- Calibration test and accuracy verification with navigation platform

NOTE: Customer should provide needed installation requirements available and serviceable before the installation day (i.e. power, network data and mounting space). Radiation dose and image quality checkup is available separately depending on local regulations.

6 | 50788 | AIRO FREIGHT, INSURANCE AND FEES

Includes temperature- and humidity-controlled shipment of Airo mobile intraoperative CT.

7 | B14278 | CONSULTING AND COORDINATION OF AIRO

This quote article includes all services (including travel expenses) for consulting and coordination of AIRO integrations. Training is not included in this article. The services are provided by one Project Consultant of the Customer Consulting Team, who is responsible until release for clinical use. The Project Consultant may involve other Brainlab specialists, e.g. Application Consultants, if necessary.

CONSULTING

To implement AIRO with the clinical setup and workflow, it is important to create a joint understanding of the broad spectrum of capabilities and options. Project Consultants may provide layouts/drawings, created with AutoCAD (ready for inclusion in customer identified architect's project documentation), containing color coding and showing the area of responsibility / scope of work of all involved parties. When combined with further Brainlab devices the concept includes network and routing diagrams as well.

Brainlab consults regarding the following topics:

- General guidance regarding image modality and room concept
- Conceptual layout of operating theatre
- Technical and clinical workflow analysis
- Compatibility of other medical devices with Brainlab products

COORDINATION:

In order to enable a smooth implementation of AIRO in time, the Project Consultant coordinates all parties and project stakeholders from transport to final destination. Furthermore the Project Consultant performs a site readiness check to ensure that all prerequisites are fulfilled by the customer and by Brainlab, according to the AIRO Pre-Installation Guide.

- Room construction (Radiation safety & shielding, floor finishes, statics, laminar air flow etc.)
- Room size (min. dimension, height, access, on-site storage etc.)
- Room conditions (Temperature, humidity etc.)



- Electrics (Power & network requirement etc.)
- Last mile (Shipping logistics, transport in hospital, elevators, etc.)

Standard Terms and Conditions-Brainlab, Inc.

1. DEFINITIONS AND APPLICATION

- 1.1. "Delivery" means (i) with respect to hardware, delivery of the Product, and (ii) with respect to Software, either remote delivery, delivery at Customer's site, or delivery via download. A Software activation key will be provided if applicable.
- 1.2. "Products" means all Software and hardware products set out in the Quote.
- 1.3. "Quote" means the quotation to which these Standard Terms and Conditions are attached.
- 1.4. "Services" means the services specifically set out in the Quote or performed as part of or in connection with a Product purchase, rental, or lease or an acquired Software license, such as, for example, installation and warranty services.
- 1.5. "Software" means software to be delivered or made otherwise available by Brainlab and set out in the Quote.
- 1.6. "Term" means the time period set out in the Quote for either the provision of Operating Products or a Software license or for the provision of Services.
- 1.7. "Third Party Products" means Products manufactured by a third party and provided to Customer by Brainlab.
- 1.8. All Products and Services are furnished only on these terms and conditions and any exhibits hereto.
- 1.9. These standard terms and conditions are deemed to be accepted at the latest upon Delivery of the Products and/or performance of the Services.

2. QUOTE / ORDER CONFIRMATION

- 2.1. Brainlab's quotations are non-binding and constitute solicitations for offers to purchase, rent, lease or license only. Brainlab agrees to be bound by the quoted prices for a period of ninety (90) days.
- 2.2. A Quote may contain Software, hardware Products and/or Services. Hardware Products listed in a Setup Proposal Section of the Quote are offered for sale. Hardware Products listed in an Operating Proposal Section of a Quote are offered on a term basis ("Operating Products") for the identified Term. Software is always licensed, subject to the license conditions set out in Section 14 below and further license conditions set out in the Quote, if any.
- 2.3. After receipt of Customer's purchase order, Brainlab may conduct a technical contract review in order to review compatibility of the Products and Services with Customer's existing equipment. Subsequently, Brainlab may send Customer a final order confirmation or provide Customer with a new amended quotation according to clause 2.1 above.
- 2.4. A final and binding contract comes into force no sooner than upon receipt by Customer of Brainlab's final order confirmation.
- 2.5. If Customer requests any changes to the configuration covered by the contract after receipt of Brainlab's order confirmation, Brainlab shall reasonably consider such request, however additional costs incurred due to the changes shall be borne by Customer.
- 2.6. Brainlab shall be entitled to appoint subcontractors to perform any Services.

3. THIRD PARTY PRODUCTS

- 3.1. If Customer enters into any contracts with third parties that are technically related to the Products, Brainlab assumes no responsibility for such contracts with third parties or the products covered thereunder.
- 3.2. Brainlab warrants compatibility with Third Party Products or other third party products explicitly listed in the Product manual or other technical documentation only in the version which is current on the date of the order confirmation.
- 3.3. Brainlab shall not be liable for any damages whatsoever occurred due to or in connection with any future changes of any third party products. This applies, for example, to orthopedic or other implants, microscopes, magnetic resonance units, and CT scanners.
- 3.4. Customer shall make reasonable efforts to make third party products available during installation for any required acceptance or compatibility testing as reasonably required by Brainlab.
- 3.5. Unless otherwise agreed to by Brainlab, Customer shall be solely responsible for the installation and maintenance of Software that is indicated for use on third party computer hardware.

4. PRICING / PRICE INCREASES

- 4.1. Unless otherwise indicated in the Quote, prices as set forth in Brainlab's quotations are DDP (delivered duty paid). Insurance, freight, taxes and other charges are included in the total Quote price.
- 4.2. Unless otherwise stated in the Quote, Brainlab reserves the right to adjust any periodic fees, including but not limited to monthly, quarterly or yearly Software subscription or Service fees or fees set out under the Operating or Setup Proposal Section of the Quote, if any ("Periodic Fees"). Such price changes become effective in the contract year following the price adjustment, provided that Brainlab has notified Customer of these changes at least four (4) months in advance.

5. PAYMENT TERMS

- 5.1. Payment terms and/or letter of credit requirements are set out in the Quote.
- 5.2. If no payment terms are set out in the Quote, the following shall apply: For total amounts exceeding \$15,000.00 USD (or an equivalent amount in any other currency) incl. sales tax, terms of payment are as follows:
 - 30% net of total within 3 days from receipt by customer of Brainlab's final order confirmation
 - 60% net of total within 10 days from date of Delivery
 - 10% net of total within 10 days from date of acceptance of the Product.

For purposes of this Section, for Products, particularly but not limited to Software, where no acceptance procedure is performed, acceptance shall be deemed to have occurred simultaneously with Delivery.

Payments of up to \$15,000.00 USD (or an equivalent amount in any other currency) incl. sales tax shall be due and payable in full within 14 days from date of invoice.

- 5.3. In the event Customer desires to pay the aggregate amount of the Periodic Fees (such amount being the Periodic Fee multiplied by the number of months in the Term) ("Aggregate Fee") in one lump-sum, Customer shall notify Brainlab of such intention and the Aggregate Fee shall be due according to the payment terms set forth in Section 5.2.
 - 5.4. In case shipment or Delivery is delayed due to circumstances caused by or within the responsibility of Customer, Delivery shall be deemed performed, and the payment due upon Delivery shall be due and payable, 30 days after Brainlab reports ability to deliver. Customer shall bear and indemnify Brainlab for any and all additional costs caused by the delay.
 - 5.5. In case of delay of execution of the acceptance protocol due to circumstances caused by or within the responsibility of Customer, payment due upon acceptance of the Product shall be due and payable in full upon the earlier of six months after Delivery or acceptance. Customer shall bear and indemnify Brainlab for any and all additional costs caused by the delay.
 - 5.6. For Services, if no payment terms are set out in the Quote, payments shall be made annually in advance. The first payment shall be due within 10 days from receipt by Customer of the order confirmation.
 - 5.7. If a security deposit is set out in the Quote ("Security Deposit"), it shall be payable within ten (10) days of the date of the related invoice. The Security Deposit may be commingled by Brainlab with other funds and shall not bear interest. If Brainlab applies the Security Deposit to Customer's obligations, Customer shall immediately restore the same. Upon Customer's full performance of all of Customer's obligations, Brainlab shall, at the request of Customer, return any remaining Security Deposit to Customer.
 - 5.8. The first of any applicable Periodic Fees shall be due and payable within ten (10) days of execution of the acceptance protocol or first patient treatment, whichever occurs earlier. Thereafter, the Periodic Fee shall be due and payable before the third day of the respective payment periods indicated in the Quote.
 - 5.9. Customer shall pay as directed by Brainlab or reimburse Brainlab upon demand for all taxes, including but not limited to sales, use, or property taxes (exclusive of federal and state taxes based on or measured solely by Brainlab's net income), fees, charges or assessments, of whatsoever kind, whether based on the fee, rent or levied, assessed or imposed upon the Products or upon or in respect of the manufacture, purchase, delivery, ownership, leasing, use, return or other disposition of the Products, now or hereafter levied, assessed or imposed under the authority of a federal, state or local taxing jurisdiction, regardless of when and by whom payable. In the event Customer is a tax exempt entity, Customer shall notify Brainlab in writing and provide written evidence of such status.
 - 5.10. All payments not made when due pursuant to this agreement shall be subject to late charges of the lesser of (i) one and one-half percent (1.5%) per month of the overdue amount or (ii) the maximum amount permitted under applicable law.
 - 5.11. In case of partial Delivery by Brainlab, Customer shall pay an appropriate part of the amount due, e.g. if one or more separable components remain to be delivered, Customer shall pay the amount due for all components that have been delivered. The amount due shall be paid in full if the components that have not been delivered are only of minor value and do not affect the Product's suitability for safe clinical use.
 - 5.12. Customer shall not be entitled to offset claims without the prior written consent of Brainlab.
 - 5.13. Customer agrees to provide all information reasonably requested by Brainlab to carry out credit approval.
- ### 6. SITE PLANNING/ CUSTOMIZATION
- 6.1. The Customer is responsible for the site and technical setup and for meeting any regulatory, structural, or radiation prerequisites as they may be required by Brainlab, or any applicable law. Validation or assessment of such prerequisites shall be at Customer's expense. The readiness for installation, which may require formal validation 10 days prior to installation, may be a condition for beginning the installation at Brainlab's reasonable discretion.
 - 6.2. Customer shall obtain any permits, approvals, licenses, certifications, local or otherwise, that may be required for installation or operation of the Products. If any such requirement is expected to impact Customer's readiness for taking delivery or installation or require changes to the contract, Customer shall notify Brainlab without delay.
 - 6.3. If applicable and included with the Products, Services may include site planning with a design phase for, including but not limited to, layout, electrical wiring, network integration, and routing.
 - 6.4. The formal end of the design phase, if any, is defined as the project milestone "Design Freeze". The Design Freeze document sets out the layout of the Product installation. It is decisive, for example and without limitation, for network specifications, power, grounding, required wiring etc. In the event that Customer requires changes to any item set out in the Design Freeze document, Brainlab and Customer will review the impact of such changes. If Brainlab, in its sole discretion, decides to initiate a change request process, any additional costs that are caused by such changes will be borne by Customer and the project schedule

shall be adjusted to reflect any additional time necessary to make such changes. For the sake of clarity, Brainlab shall in no case be obligated to make any changes to the items specified in the Design Freeze document.

- 6.5. Customer must approve the Design Freeze in writing.
- 6.6. In the event of a conflict between the signed Design Freeze and any other previous drawings, tender specifications or other specifications, the Design Freeze shall prevail.

7. DELIVERY

- 7.1. Brainlab shall use commercially reasonable efforts to deliver the Products within three (3) months from receipt by Customer of Brainlab's final order confirmation or at an agreed date.
- 7.2. If Delivery is delayed due to Act of God, strike, regulatory difficulties, or due to unforeseen circumstances, Brainlab shall be entitled to postpone performance for the duration of the obstruction and an additional appropriate time to resume performance and/or to make partial shipments or provide partial Services.
- 7.3. Meeting the scheduled Delivery dates is contingent upon Customer providing proper and reasonable cooperation in a timely manner, including but not limited to the provision of technical support, precise and complete data and information on all aspects related to the Delivery and installation of the Products.
- 7.4. If the date of Delivery is postponed by Customer or if Delivery is delayed for reasons within the responsibility of Customer, Brainlab may, at its reasonable discretion, ship the Products to storage or, if shipment is already in progress, also revert shipment to Brainlab's premises. Section 5.4. above applies. Any additional costs caused thereby will be borne by Customer, including but not limited to transport and/or storage related costs and insurance. At the reasonable discretion of Brainlab, the Customer shall provide an adequate warehouse with appropriate storage environment (e.g. climate controlled and insured). Brainlab reserves the right to claim further damages.
- 7.5. Customer shall arrange for barrier-free transportation of Brainlab shipping crates as reasonably required from the Customer's receiving area (including adequate parking space for transportation vehicle) to the installation site or to the storage room, and, if applicable, from the storage room to the installation site. Unless otherwise agreed between the parties, Customer shall provide a loading dock with capabilities for non-power tailgate delivery. Costs for necessary traffic control, rigging and transportation equipment or labor, any adjustments made to doorframes, hallways, ceilings, or other facility structures, as well as dust and noise protection related to existing equipment shall be borne by the Customer.

8. TRANSPORTATION AND RISK OF LOSS

- 8.1. Brainlab shall be entitled to insure the Products for transportation at Customer's expense. Appropriate means of transportation to Customer's site will be chosen by Brainlab.
- 8.2. Upon Delivery of the Products to Customer's premises, or, if Delivery is delayed due to circumstances caused by or within the responsibility of the Customer, upon Brainlab's reporting ability to deliver, Customer hereby assumes and shall bear the entire risk of loss of, theft of, damage to, or destruction of the Products from any cause whatsoever ("Casualty Occurrence"). No Casualty Occurrence to the Operating Products shall relieve Customer from its obligation to pay Periodic Fees or to perform any other of its obligations hereunder. Customer shall promptly notify Brainlab in writing of any Casualty Occurrence to Operating Products and shall, at its sole cost and expense, within twenty (20) days cause the repair of any Operating Products to first class condition. Notwithstanding the foregoing, if Brainlab deems repair unfeasible, then, at Brainlab's option, Customer, at its sole cost and expense shall (i) procure from Brainlab the replacement of damaged or stolen Operating Products, or (ii) pay to Brainlab the sum of the following: 1) all sums then due to Brainlab under this agreement 2) the unpaid balance of the Fees attributable to the remainder of the applicable Term and 3) twenty percent (20%) of the total of all costs to Brainlab of and relating to purchasing and making available the Operating Products, plus taxes and other charges.
- 8.3. For Operating Products, Customer shall, at its sole cost and expense, obtain and maintain commercial general liability insurance and property insurance (including coverage against a Casualty Occurrence in an amount equal to at least the full replacement value of the hardware included in the Operating Products, based on the then current list price) satisfactory to Brainlab covering both personal injury and property damage arising out of or in connection with the use or operation of the Operating Products with limits of at least \$1,000,000 USD per occurrence and \$3,000,000 USD in the aggregate. Customer shall name Brainlab or Brainlab's assignee as additional insured on the commercial general liability and as loss payee on the property insurance. In addition, the policies shall grant a waiver of subrogation on behalf of Brainlab. Customer shall provide to Brainlab a certificate of insurance evidencing such insurance coverage. Customer hereby irrevocably appoints Brainlab as Customer's attorney-in-fact to make claims for, receive payment of, and execute and endorse all documents, drafts or checks for a Casualty Occurrence or returned premiums under any insurance policy required herein.

9. INSTALLATION / ACCEPTANCE / ACCEPTANCE PROTOCOL

- 9.1. Installation will be performed (i) remotely or (ii) by a Brainlab Service Engineer or other party designated by Brainlab within three (3) months after Delivery or within a period otherwise agreed upon or set out in the Quote. On-site installation will generally require no more than two visits

of a Brainlab engineer, unless otherwise specified by Brainlab. If one visit is sufficient, or if more than two visits will be required, Brainlab will notify Customer in advance.

- 9.2. If completion of the installation is delayed for more than six (6) months after Delivery due to circumstances caused by or within the responsibility of Customer, including but not limited to false or incomplete technical information regarding Customer's equipment or premises, or incorrect or missing data, Customer shall be charged any and all additional costs resulting from such delay. In addition, Brainlab shall no longer be obligated to perform the installation.
 - 9.3. If more than the specified number of visits of a Service Engineer are required due to circumstances caused by or in the responsibility of Customer, Customer shall bear the additional costs.
 - 9.4. Up to ten (10) man hours of engineer's overtime work, i.e. work outside Brainlab's normal working hours (Mo-Fri, 8 a.m. - 5 p.m.), during installation are included in the price indicated in the Quote. Any additional working hour or fraction thereof outside normal working hours requested by Customer will be charged to Customer according to Brainlab's then current price list.
 - 9.5. After complete installation and prior to final acceptance, one of Brainlab's Service Engineers will test the Products, either at Customer's premises or remotely, to evaluate its capability of functioning according to the specifications. At least one representative of Customer shall be present during this procedure. The acceptance may also have an extended scope covering use of Products in conjunction with third party products.
 - 9.6. After successful performance of the acceptance test, Customer shall accept the Product and sign Brainlab's acceptance protocol to verify acceptance. Customer agrees that signature of a present healthcare professional shall be legally binding on Customer. The acceptance protocol shall become part of the contract. It shall be provided to the Customer prior to installation upon request.
 - 9.7. Acceptance shall not be refused because of minor problems that do not affect the suitability for safe clinical use. Acceptance shall be deemed to have occurred, and the final payment shall be due and payable, if Customer refuses acceptance due to such minor problems.
 - 9.8. The Product may not be used for patient treatment before the applicable acceptance test has been performed successfully and the acceptance protocol has been signed.
 - 9.9. If Customer performs any kind of patient treatment before signing the applicable acceptance protocol, the Product shall be deemed accepted and payment of the last installment shall be due.
 - 9.10. Customer shall be solely responsible for effectiveness, correctness, cost and timely implementation of any clinical and physics setup-procedures, including but not limited to sterilization of non-sterile surgical instruments or acquisition and documentation of radiation beam data, as applicable.
- #### **10. EXAMINATION AND NOTIFICATION OF DEFECTS**
- 10.1. Customer shall inspect the packaging and the Products immediately upon Delivery and shall report any damage to the shipping agent without delay.
 - 10.2. During the acceptance test, Customer shall examine the Product in the presence of a Brainlab Service Engineer. Any defect or missing part shall be listed in the acceptance protocol.
 - 10.3. Brainlab will not accept complaints relating to malfunctions or missing items that have not been reported as set out above, unless the defect was indiscernible at the time of the examination.
 - 10.4. In case such defect occurs later, Customer will notify Brainlab within 14 days after occurrence. Otherwise, the Products shall also be deemed accepted regarding this defect.
- #### **11. TRAININGS / OR ASSISTANCE**
- 11.1. The contract may also include a specified number of trainings / OR assistance sessions. If the Quote contains Operating Products, all training and OR assistances included as part of the description of such Products shall occur within the Term, unless otherwise agreed to by Brainlab. Upon expiration or termination of the Term, Customer shall no longer be entitled to such training and OR assistances. If the Term is for less than one (1) year and Customer renews the Term for any additional period, Customer shall not be entitled to the additional training and OR assistance which is automatically included in the description of the Brainlab Product being renewed. Customer may purchase additional training and/or OR assistance.
 - 11.2. After successful performance of training for Brainlab Products, the training acceptance protocol must be signed by an authorized representative of the Customer, if applicable.
 - 11.3. No Products may be used before the applicable training has been performed and any applicable training acceptance protocol has been signed.
 - 11.4. Customer warrants that the Products will be operated only by trained personnel.
- #### **12. WARRANTY**
- 12.1. Brainlab warrants that the Products are free from defects in material and workmanship under normal use and in substantial compliance with operational features of Brainlab's published specifications at the time of sale. The warranty period shall be one (1) year beginning (i) 6 months after delivery, (ii) 3 months after installation, (iii) acceptance of the purchased goods, or (iv) treatment of the first patient, whichever occurs first.
 - 12.2. In the event that any malfunctions occur, Customer shall immediately cease using the Product and inform Brainlab hereof without delay.

- Customer shall not resume use of the Product before Brainlab has given notice that the malfunction has been eliminated.
- 12.3. Brainlab will, at its own discretion, repair or replace defective parts or Products.
 - 12.4. During the warranty period, Customer may request up to ten (10) hours of engineer's overtime work for Service visits. Any additional working hour or fraction thereof outside normal working hours requested by Customer will be charged to Customer according to Brainlab's then current price list.
 - 12.5. The quality of Products is to be measured exclusively by the given specifications which are hereby incorporated in the contract. The specifications are subject to change without notice as far as such change is not material and the suitability for the intended use is not reduced.
 - 12.6. In the interest of conservation of scarce materials, Products, including repair or replacement parts or components, may contain remanufactured parts. Such parts are subject to the same high standards of quality control applied to other parts and are covered by this warranty.
 - 12.7. THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF AND EXPRESSLY EXCLUDES ALL OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL PRACTICE, USE, OR APPLICATION.
 - 12.8. Notwithstanding anything to the contrary contained herein, Brainlab does not warrant that the Software will be error-free or bug-free or that the use of the Software will be uninterrupted. In addition, except as otherwise stated herein, the Software is provided without any additional warranties.
 - 12.9. Notwithstanding the one (1) year warranty period referenced in Section 12.1, repair or replacement parts ("Spare Parts") provided during the warranty carry the same warranty set forth in Section 12.1 for the unexpired portion of the original warranty period. Spare Parts provided by Brainlab under a purchased service contract are covered for the unexpired portion of the service contract period.
 - 12.10. Any original parts removed and/or replaced during any repair process shall become the property of Brainlab.
 - 12.11. Customer's claims are only valid when made in writing.
 - 12.12. Customer shall bear the costs for any disposable parts needed for use of the Products, as well as any further costs of operation.
 - 12.13. No representation is made as to the accounting validity, adequacy or compliance with the standards set forth in the criteria found within, but not limited to, the industry accounting standards as defined by the Financial Accounting Standards Board (FASB), Generally Accepted Accounting Principles (GAAP), the International Accounting Standards Board (IASB), or any other accounting standard defined by an independent third party or government agency. If desired, Customer should consult a Certified Public Accountant (CPA) and/or attorney before entering into this Agreement.
- 13. WARRANTY EXCLUSIONS AND PERFORMANCE OF SERVICE**
- 13.1. Any warranty is excluded and, further, Brainlab shall not be obligated to perform any Services in case of:
 - general wear;
 - accident;
 - lack of proper care;
 - use of Products that is not in compliance with Brainlab's manuals, instructions for use and a reasonable degree of care or failure to use Brainlab systems under normal or specified operating conditions and environment;
 - use of Products in combination with devices, parts of devices, or accessories that have not been expressly cleared by Brainlab for use with such Products;
 - maintenance or repair of Products that have not been authorized by Brainlab;
 - unauthorized modification or alteration of Products;
 - failure of Customer to immediately report any malfunction of a Product or continuous use of the Product after occurrence of any such malfunction;
 - faults, failures or damages caused by intentional or negligent behaviour; or
 - circumstances beyond Brainlab's control, including but not limited to force majeure, acts of God, power and/or environmental failures.
 - 13.2. Customer shall allow Brainlab free access to the Products, including online access if remote service is performed. This shall, in particular, not be made contingent on the limitation of Customer's liability. Customer shall offer a suitable workplace, including access to a telephone if needed. Brainlab shall use this telephone line exclusively to perform the Services
 - 13.3. Customer shall ensure safe conditions at the location of the Products. Particularly, Customer shall inform Brainlab of existing safety regulations that are relevant for Brainlab personnel.
 - 13.4. Customer and Brainlab shall mutually agree on dates and times for Service visits at least 48 hours in advance. This shall not apply to Service provided on a time and material basis, where more advance notice may be required.
 - 13.5. Brainlab will provide Services Monday through Friday from 8.00 am until 5.00 pm. Services provided at other times will be charged to the Customer as overtime unless otherwise agreed.
 - 13.6. In the event that a Service, installation or other appointment is cancelled due to reasons within Customer's responsibility, Customer shall inform Brainlab at least 24 hours in advance.
 - 13.7. In the event that Customer fails to notify Brainlab in due time, Brainlab shall be entitled to charge Customer for all costs reasonably incurred with regard to the appointment.
 - 13.8. Brainlab shall respond to Customer reports of malfunctioning Products by phone, fax or email within no more than 24 hours by phone call. If the malfunction cannot be eliminated by phone call, the dispatch of spare parts as well as maintenance and repair will normally be initiated within one working day after the problem analysis by phone, pending availability of personnel and material. Notwithstanding the foregoing, in the event the defective Product is the Brainlab Dash System, or any component or accessory thereto, Customer shall ship such defective Product to Brainlab for replacement or repair. Customer shall properly package the Dash Product so as to avoid damage during transit and shall ship the Dash Product with a reputable carrier and shall provide to Brainlab the applicable tracking information upon shipment.
- 14. INTELLECTUAL PROPERTY, SOFTWARE LICENSES**
- 14.1. All rights to patents, trademarks, and any other intellectual property shall remain the property of Brainlab, its affiliates and/or its licensors, as applicable. Brainlab and/or its affiliates, suppliers and/or licensors presently owns and will continue to own all right, title, and interest in and to the Software and its source code, and any and all copyrights, trademarks, trade names, logos and other proprietary rights in and to the Software and any other materials provided to or otherwise made available to Customer hereunder, and all worldwide intellectual property rights embodied herein
 - 14.2. Brainlab grants Customer a limited, non-exclusive, non-transferable license to use any Software. Software available for download from a Brainlab website may be used solely in accordance with the respective intended use. Software delivered with or integrated in hardware products may solely be used in conjunction with such hardware products and for its intended use. Software is provided for the Term (if provided on a leased, rented or subscription basis), solely for use at the location indicated in the Quote for such Software, or the hardware with which such Software is integrated, and for such number of concurrent users as indicated in the Quote. If no Term is indicated in the Quote for either the Software or the hardware product that it is integrated with, then the Software license is perpetual, subject to end of life provisions. If no geographic limitation is made, then Software may be accessed and used worldwide in accordance with applicable law and export regulations. If the Quote does not indicate a permitted number of concurrent users, then the Software may be used by one user at a time.
 - 14.3. Customer hereby accepts any further license conditions for Software that may be required by third party manufacturers or licensors in so far as such conditions are commonly used or reasonably acceptable to Customer. Brainlab will make such additional license conditions available to Customer upon request.
 - 14.4. All title and interest to any Software provided to Customer shall remain with Brainlab, its affiliates and/or its licensors, as applicable. Customer shall not copy, modify or reverse engineer Software and shall prevent third party access to the Software.
 - 14.5. The Software under this Agreement is commercial computer software as that term is defined in 48 C.F.R. 252-227-7014(a)(1). If acquired by or on behalf of a civilian agency, the U.S. Government acquires this commercial computer software and/or commercial computer software documentation and other technical data subject to these terms as specified in 48 C.F.R. 12.212 (Computer Software) and 12.211 (Technical Data) of the Federal Acquisition Regulations ("FAR") and its successors. If acquired by or on behalf of any agency within the Department of Defense ("DOD"), the U.S. Government acquires this commercial computer software and/or commercial computer software documentation subject to the terms of this Agreement as specified in 48 C.F.R. 227.7202-3 of the DOD FAR Supplement ("DFAR") and its successors. This U.S. Government Rights clause is in lieu of, and supersedes, any other FAR, DFAR, or other clause or provision that addresses Government rights in computer software or technical data under this Agreement.
- 15. OWNERSHIP AND RETENTION OF TITLE**
- 15.1. Brainlab shall retain title to any Products that are sold until payment is made in full and all claims are settled.
 - 15.2. In the event that the Setup Proposal Section of a Quote provides for the payment of Periodic Fees, then title to the Products set out in such Setup Proposal Section shall pass to Customer upon payment of no less than all of the Periodic Fees.
 - 15.3. If third parties take up steps to levy execution upon or otherwise dispose of the Products, Customer shall immediately notify Brainlab. If Customer fails to do so in due time Customer will be held liable for any damages caused.
 - 15.4. The Operating Products shall at all times be and remain the sole and exclusive property of Brainlab notwithstanding that the Operating Products may now be, or hereafter become, in any manner affixed or attached to, or embedded in, or permanently resting upon real property. Customer shall have no right, title or interest therein or thereto except as to the use thereof according to their intended use. Customer shall not permit its rights or interests hereunder to be subject to any lien, charge or encumbrance and shall keep the Operating Products free and clear of any and all liens, charges and encumbrances which may be levied against or imposed upon Customer for whatever reason.
 - 15.5. Customer shall not remove any labeling affixed to the Products.
 - 15.6. Customer, at its sole cost and expense, shall maintain the Operating Products in first class condition, normal wear and tear excepted.

- Customer shall keep the Operating Products safe and secure in Customer's possession and control at Customer's premises. At any reasonable time Brainlab or its agents may inspect the Operating Products.
- 15.7. Without the prior written consent of Brainlab, Customer shall not make any alterations, additions or improvements to any Products, whether provided on a term basis or sold. In any event, Customer shall, at its cost and expense, reverse any alterations, additions or improvements made before returning the Operating Products. If not done, all alterations, additions or improvements shall be deemed accessions thereto, shall belong to and immediately become the property of Brainlab and Customer shall remain liable and responsible for the costs to bring the Operating Products back into compliance with its original condition. Brainlab shall invoice the Customer accordingly. For Operating Products which consist of a dedicated computer workstation provided by Brainlab, or which reside on a dedicated computer workstation provided by Brainlab, Customer shall not install any third party software or programs on the dedicated computer workstation.
- 15.8. In the event any transaction with respect to any Product sold or provided hereunder is qualified or deemed to be a secured loan, Customer hereby grants to Brainlab a security interest in such Products which shall secure the performance of all of Customer's obligations of any kind whatsoever, whenever originated, to Brainlab. Customer authorizes Brainlab or its designee, and Brainlab reserves its right, to file a Uniform Commercial Code financing statement without Customer's signature, in form and content and from time to time as Brainlab deems proper, listing Customer as a lessee or debtor. Customer represents that it has identified or will correctly identify to Brainlab its exact legal name, state of incorporation, and location of its chief executive office.
- 15.9. Upon termination or expiration of the Term or this Agreement, Customer shall return the Operating Products to Brainlab and the license for any Software included with the Operating Products shall expire. Customer shall remove all protected health information from the Operating Products prior to returning to Brainlab. Brainlab shall be entitled to deduct from the Security Deposit, if applicable, any amounts due for any damage to the Operating Products. In the event the damages exceed the Security Deposit, Customer shall pay to Brainlab the exceeding amount of such damage within ten (10) days of receipt of written notice thereof. Customer will be liable and responsible for any damages incurred by Brainlab due to a delay by Customer in returning the Operating Products to Brainlab. In the event Customer does not immediately return the Operating Products upon termination or expiration of this agreement, Customer shall continue to incur and be liable and responsible for any and all Periodic Fees (or pro-rations thereof, if applicable) and taxes until the Operating Product is returned to Brainlab. Customer shall be liable and responsible for all costs associated with the removal and disposal of the Operating Products, such amounts to be due net ten (10) days of the date of invoice issued to Customer after removal and disposal of the Operating Products.
- 16. TERM AND TERMINATION**
- 16.1. The Term for the provision of Operating Products shall commence after acceptance or sixty (60) days after Delivery of the Operating Products, whichever occurs first. At least sixty (60) days prior to the expiration of the Term, Customer shall provide Brainlab with written notice of its intent regarding the end of term options. Customer shall indicate in its notice of intent whether Customer desires to (i) allow the Agreement to expire and return the Operating Products and allow the license for any Software included to expire; (ii) extend or renew this Agreement; or (iii) purchase the Operating Products and procure an ongoing license to any associated Software. If Customer desires to renew or extend this Agreement or purchase the Operating Products, if available for purchase, the parties will meet together to negotiate the renewal term and renewal fees or the purchase price, as applicable. If the parties are able to reach an agreement, (a) these terms and conditions shall continue to apply; (b) Term shall mean the initial Term plus the extension or renewal time period; and/or (c) with respect to a purchase, no warranty will be provided. If the parties are unable to come to an agreement, this Agreement will not be renewed.
- 16.2. A Software license Term shall commence upon Delivery of the Software according to Section 1.6 above; in the event that Software is installed on corresponding Brainlab Product hardware, then the Term shall commence upon acceptance of such hardware, or sixty (60) days after Delivery of the Software and hardware, whichever occurs first.
- 16.3. Service shall be provided for a minimum Term of one (1) year, unless a longer Term is specified in the Quote, in which case such longer Term shall apply. This shall not apply to service provided on a time and material basis.
- 16.4. In case of permanent obstructions to Delivery of a Product, Brainlab shall have the right to terminate the underlying contract or license in part or in whole. Brainlab will promptly inform Customer about the obstructions and, in the event of termination of the contract or license, will reimburse Customer any payments already made for unavailable parts.
- 16.5. If Delivery obstructions last for a period of more than six months, Customer may terminate the underlying contract with respect to the unavailable parts. Customer may terminate the entire contract only if Customer cannot be reasonably expected to have an interest in partial Delivery without the unavailable parts.
- 16.6. Brainlab may terminate the provision of Operating Products, Term-based Software licenses or any other ongoing contractual relationships if Customer's property becomes subject to levy of execution, seizure, or the like, or if Customer is in default of payment for more than one month.
- 16.7. Notwithstanding the foregoing, either party shall have the right to terminate the agreement before its fulfillment in its entirety and with immediate effect a) for the provision of Operating Products, Term-based Software licenses or any other ongoing contractual relationships, if there is a material breach by the other party not remedied within thirty (30) days of notice thereof; and b) for all Products: (i) if the other party becomes subject to voluntary or involuntary bankruptcy, receivership, or related proceedings; or (ii) at a party's dissolution. Statutory provisions regarding termination without notice shall not be restricted by the foregoing.
- 16.8. If Brainlab terminates this Agreement under Sections 16.6. or 16.7, Brainlab shall have the right, to the extent permitted by applicable law, to do any one or more of the following: (i) declare the Agreement in default, whereupon an amount equal to the present value of the entire unpaid balance of the Periodic Fees (the Periodic Fee multiplied by the remaining periods) plus any other sums and or damages, is immediately due and payable, (ii) pursue any remedy at law, in bankruptcy or in equity, proceeding by court action or otherwise; (iii) repossess or take possession of the Operating Products or financed Products, together with all additions, replacements and attachments, wherever such Operating Products or financed Products may be located, and for such purposes Brainlab and/or its agents may enter upon any premises of or under the control or jurisdiction of Customer or any agent of Customer, without any liability for doing so, and take the Products therefrom. Customer hereby expressly waives any and all rights to any form of notice, demand, legal process and/or judicial hearing prior to any such taking or repossession. Customer also expressly waives, and indemnifies Brainlab against, any damages, costs and expenses specifically including reasonable attorney's fees in any way relating to or caused any such entry and/or repossession. Customer agrees to make such Products available to Brainlab at such location as Brainlab may reasonably specify. Upon such repossession by or return to Brainlab of the affected Products, all rights of Customer in such Products shall terminate; (iv) deactivate any Software licenses; and/or (v) hold, scrap or use any such repossessed or returned Products for any purpose whatsoever, or sell same at a public or private sale, or re-finance the same for such a term and payment as shall be solely determined by Brainlab, or hold the Products for future sale or re-leasing, solely for the account of Brainlab. In the event the provision of the Operating Products is terminated, such termination shall not affect any financing of any Products and such amounts shall remain due and payable by Customer.
- 16.9. Customer hereby waives any right to require Brainlab to sell, lease, rent or otherwise use any repossessed or returned Products in mitigation of damages.
- 16.10. Notwithstanding anything to the contrary contained herein and/or in the Quote, Brainlab shall have the right to terminate an ongoing agreement, in whole or in part, in the event that one or more of the Products that are covered under such agreement reach the Brainlab or original equipment manufacturer designated "end of life" or otherwise are no longer offered commercially by Brainlab or the original equipment manufacturer. Upon the effective date of termination under this subsection, Brainlab shall refund to Customer a pro-rated amount of the paid amount, reflecting the amount due for the unused portion of the agreement. Brainlab shall have no obligation to perform Services or deliver parts for Products declared "end of life" beyond the end of life date, which will be communicated well in advance to the Customer.
- 16.11. Should Customer not agree to a price increase as set out in Section 4.2 above, then Customer may terminate its ongoing agreement with Brainlab by giving at least three (3) months written notice before the end of the then current contract period.
- 16.12. Customer shall not be released from its obligations under this Agreement until the payment of all unpaid amounts, which would include but not be limited to all amounts due for delivered Products and all Periodic Fees incurred prior to termination. All of the foregoing applies notwithstanding any remedies which Brainlab may have under applicable law.
- 16.13. In the event that an automatic renewal of the Term is set forth in the Quote, then all conditions shall continue to apply for any renewal period. Should the Customer wish to prevent an automatic renewal, then the underlying agreement must be terminated by giving Brainlab written notice at least sixty (60) days before the expiration of the then current Term.
- 16.14. In addition to any sums due hereunder, CUSTOMER AGREES TO PAY BRAINLAB'S COLLECTION AND LEGAL EXPENSES AND REASONABLE ATTORNEYS' FEES AS DAMAGES, NOT AS COSTS, in all proceedings arising under this Agreement, including without limitation in, exercising any of Brainlab's rights or remedies hereunder, protecting any of Brainlab's interests hereunder, in arbitration, and in counterclaims on which Brainlab prevails.
- 16.15. All rights and remedies of Brainlab hereunder shall be cumulative and not alternative.
- 17. LIMITATIONS OF LIABILITY AND INDEMNIFICATION**
- 17.1. Brainlab shall not be liable for delays in performance due to Acts of God, strike, regulatory difficulties, or due to unforeseen circumstances. The same applies if the delay occurs at Brainlab's suppliers, their sub-suppliers, or other sub-contractors.
- 17.2. The total liability of Brainlab shall not exceed any payment received for the respective Brainlab Product contributing to the loss or damage

- claimed. The foregoing shall apply to any and all claims, including but not limited to tort claims.
- 17.3. Brainlab (and its affiliates) shall not be liable for any loss of use, revenue or anticipated profits, loss of business, loss of stored or transmitted data, interruption of service, or for indirect, incidental, unforeseen, special, punitive or consequential damages arising out of or in connection with this agreement or the sale or use of Brainlab's products, whether in any action in warranty, contract, tort (including without limitation, negligence or strict liability) arising out of or in any connection with the use of, of the inability to use, the products.
- 17.4. In no event shall Brainlab's liability hereunder exceed the actual loss or damage sustained by Customer.
- 17.5. Brainlab shall not be liable for any damage caused by (i) the use of purchased goods before performance of the acceptance test according to Section 9 above; (ii) the use, operation, service, modification of Brainlab products contrary to relevant manuals, written warnings, automated warnings, or instructions of Brainlab personnel; (iii) the use of Brainlab products in conjunction with third party products, unless this use has been expressly authorized in writing by Brainlab; and (iv) the use of any product supplied by Brainlab as a convenience to the Customer that is not manufactured by Brainlab and is not generally offered by Brainlab.
- 17.6. With respect to bodily injury or death to third parties, Brainlab's liability shall be restricted to an equitable proportion as reflects its relative fault in relation to Customer's contribution to the injury or death of the third party.
- 17.7. Customer agrees to defend, indemnify and hold harmless Brainlab from and against any and all liabilities, judgments, awards, settlements, losses, damages and expenses in connection with any third party claim, suit, or other action arising from (i) the negligence and willful misconduct of the Customer or its directors, officers, or employees; (ii) use of the Brainlab products prior to completion of the applicable acceptance by anyone other than Brainlab personnel; (iii) use, operation, service, modification of the Brainlab products contrary to relevant manuals, written warnings, automated warnings, or instructions by Brainlab personnel; (iv) use of the Brainlab products in conjunction with third party products, unless the use has been expressly authorized in writing by Brainlab; (v) use of any product supplied by Brainlab as a convenience to Customer and that is not manufactured by Brainlab and is not generally offered by Brainlab; or (vi) an infringement of third party rights by any actions or omissions of Customer, including but not limited to the disclosure of user data or patient data, by way of example, when using Quentry. All other rights, including but not limited to damage claims by Brainlab, shall remain unaffected.
- 18. EXPORT CONTROL**
- 18.1. Brainlab shall not be liable for any delay in Delivery or any inability to deliver due to export restrictions. In this case, Brainlab may cancel the contract and shall not be liable for any damages arising of or in connection with such cancellation.
- 18.2. Brainlab advises all customers that export regulations may apply to the resale of the delivered Products. In addition, Products delivered by Brainlab may contain US components (including but not limited to hardware, software, technology) in which case compliance with US regulations may be required. Customer shall ensure compliance with all export regulations applicable to the re-export of the delivered Products.
- 19. CONFIDENTIALITY, REGISTRATION, DATA PROTECTION**
- 19.1. Customer shall keep in confidence all information, including but not limited to technical data, product descriptions, and any other information which is readily and reasonably identifiable as confidential based on its nature and/or the circumstances of its disclosure. For clarification only, this shall include but not be limited to information provided verbally. Such Information shall not be disclosed to any third parties or employees, except for employees who are directly involved in the operation of the Products on a need to know basis.
- 19.2. For the improvement of Products and customer support Brainlab shall be entitled to collect statistical data stored on the Products. This data will be stored anonymously and used exclusively for internal purposes.
- 19.3. Brainlab and Customer undertake to observe the applicable data protection regulations.
- 19.4. Customer agrees that Brainlab may remotely access the Products at Customer's site within the scope of this agreement, and may process and store data in order to perform the remote Services. Customer shall prevent accidental access to patient data and other protected data and/or, as applicable, obtain the written approval of patients regarding the possibility of access to their data by Brainlab in the course of the performance of Services.
- 19.5. Certain Brainlab Products require a single personal registration of each authorized health care professional or administrator using the Product, including the user's location. Customer warrants the correctness of the information entered and Brainlab shall grant access to the technology subject to validation of such information. This registration information is deemed confidential information and governed by the terms of this Section 19.
- 19.6. Brainlab is entitled to disable or otherwise restrict the access to Brainlab Products, including but not limited to deletion of data, whenever Brainlab has reasonable evidence that Customer is in violation of Sections 14 or 19.1.
- 20. PROTECTION OF ENVIRONMENT**
- 20.1. Brainlab shall dispose of any Product packing free of charge and in compliance with applicable regulations.
- 20.2. Upon end of use, Customer shall dispose of the Products (other than Products which are returned to Brainlab) at its own costs pursuant to any applicable regulations. Brainlab shall not be required to take back the Products or Third Party Products for disposal.
- 21. APPLICABLE LAW / ARBITRATION / PARTIAL INVALIDITY/ASSIGNMENT**
- 21.1. Customer shall comply with all applicable local, state, national and foreign laws, treaties, regulations and third-party rights, including, without limitation, those related to data privacy (e.g. HIPAA), international communications, the transmission of technical or personal information, and government regulations.
- 21.2. These terms and conditions as well as all contractual and other legal relationships between the parties shall be governed by the laws of the State of Illinois, USA. Any claim or controversy arising out of or relating to these standard terms and/or any other legal relationship between the parties shall be settled by arbitration in Chicago, Illinois in accordance with the arbitration rules of the American Arbitration Association. The dispute shall be heard and determined by one arbitrator, unless any party's claim exceeds USD 1 million, exclusive of interest and attorneys' fees, in which case the dispute shall be heard and determined by three arbitrators. Language of the arbitration shall be English. The arbitration tribunal shall not award punitive damages. The arbitration shall be final and binding, shall be the sole and exclusive remedy regarding any and all claims and counterclaims presented, and may not be reviewed by or appealed to any court except for enforcement.
- 21.3. Nothing in this agreement shall prevent Brainlab from seeking injunctive relief or other legal remedy to prevent unauthorized copying, disclosure, use, retention, or distribution of Brainlab's intellectual property or confidential information.
- 21.4. Brainlab shall have the exclusive right to bring legal action for failure to pay for Products and Services furnished in the courts of Brainlab's headquarters.
- 21.5. If any part of the terms and conditions is held void or unenforceable, such part will be treated as separable, leaving valid the remainder of these terms and conditions. The invalid clause will be replaced by the valid clause that comes closest to the commercial intention of the invalid clause.
- 21.6. Brainlab may freely assign this Agreement or its right or obligations under this Agreement to any affiliate, successor-in-interest, or third party. Customer may not assign this Agreement or its rights or obligations thereunder without the prior written consent of Brainlab.