NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • **Governor**

MANDY COHEN, MD, MPH • **Secretary**

MARK PAYNE • **Director, Division of Health Service Regulation**

VIA EMAIL ONLY

March 26, 2021

Robert A. Hamill
rhamill@hallrender.com

No Review

Record #:	**3505**
Date of Request:	March 19, 2021
Business Name:	North Carolina Radiation Therapy Management Services, LLC
Business #:	2124
Project Description:	Acquire the BrainLab ExacTrac system to support operation of a linear accelerator
County:	Buncombe

Dear Mr. Hamill:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne
Project Analyst

Lisa Pittman
Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
        Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Hall, Render, Killian, Heath & Lyman, LLP
Perimeter Three
3015 Carrington Mill Blvd.
Suite 450
Morrisville, North Carolina 27560

HALL RENDER
KILLIAN HEATH & LYMAN

Robert A. Hamill
(919) 447-4970
rhamill@hallrender.com

March 19, 2021

VIA EMAIL

Martha Frisone
Chief
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
Martha.Frisone@dhhs.nc.gov

Ena Lightbourne
Project Analyst
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
Ena.Lightbourne@dhhs.nc.gov

RE: **Acquisition of BrainLab ExacTrac at 20 Medical Park, Asheville, North Carolina 28803**

Dear Ms. Frisone and Ms. Lightbourne:

We represent North Carolina Radiation Therapy Management Services, LLC ("**NCRTMS**"). We are submitting this no review letter to seek confirmation from the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Planning and Certificate of Need Section ("**Agency**") that a certificate of need ("**CON**") is not required for NCRTMS to acquire a BrainLab ExacTrac system ("**Equipment**") to support the operation of a linear accelerator currently in use at 20 Medical Park, Asheville, North Carolina 28803.

The total cost of the Equipment including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities necessary to make the Equipment operational is expected to be approximately $454,750.00, which is well below the threshold for major medical equipment set forth in N.C. Gen. Stat. § 131E-176(14o). A quote for these costs is attached hereto as Exhibit A. Because the acquisition of the Equipment and related costs will not exceed the $750,000.00 threshold for major medical equipment, NCRTMS believes the acquisition of the Equipment does not require a CON.

We would appreciate your written confirmation that NCRTMS's acquisition of the Equipment is not subject to, and is except from, CON review. Please do not hesitate to contact me if you have any questions or require additional information. Thank you for your review and consideration of this matter.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, LLP

Robert A. Hamill

Exhibit A

Equipment Quote

(See attached)

BRAINLAB

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

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

Radiation Therapy Associates of Western North
Carolina - Asheville
20 Medical Park Drive
Asheville, North Carolina, 28803-2493
United States

Westchester, August 31, 2020
Quotation QN-COAARR-KER-6

Brainlab ExacTrac for Elekta
Delivery: DDP (Incoterms 2010)
Payment Terms: 8% Order Confirmation, 70% Delivery, 22% Acceptance
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.

ExacTrac Dynamic for Elekta
Project-20200707-001470
QN-COICOF-ICH-54

Pos.	Art.No.	Description	Qty.
		E X A C T R A C	
1	48501	EXACTRAC DYNAMIC 4D THERMAL CAMERA*	1
		this article is export controlled*	
2	48502	EXACTRAC DYNAMIC X-RAY SYSTEM	1
3	48503	EXACTRAC DYNAMIC CONTROL SYSTEM	1
4	48504	EXACTRAC DYNAMIC CEILING-MOUNTED MONITOR SYSTEM	1
5	48514	EXACTRAC DYNAMIC SYSTEM CALIBRATION PHANTOMS (SET OF 2)	1
6	48513	EXACTRAC DYNAMIC PRE-INSTALLATION CABLING AND MOUNTING PACKAGE	1
7	45525	EXACTRAC DYNAMIC CRANIAL VERIFICATION PHANTOM	1
8	43420	CRANIAL 4PI CT IMMOBILIZATION OVERLAY	1
9	43422	CRANIAL 4PI TREATMENT IMMOBILIZATION OVERLAY ELEKTA IBEAM EVO	1
10	43440	CRANIAL 4PI HEADREST STANDARD	2
11	43441	CRANIAL 4PI HEADREST LOW-NECK	2
12	43445	CRANIAL 4PI HEADREST INLAYS (3 SETS OF 2)	1
13	43435	CRANIAL 4PI ADJUSTABLE TARGET PHANTOM	1
		S O F T W A R E E X A C T R A C	
14	25760	SURFACE GUIDED PRE-POSITIONING SOFTWARE	1
15	25765	INTRA-FRACTION 4D THERMAL MONITORING SOFTWARE	1
16	25770	INTRA-FRACTION X-RAY MONITORING SOFTWARE	1
17	25775	PATIENT SETTINGS SOFTWARE	1
18	30038	ORIGIN DATA MANAGEMENT	2

BRAINLAB

Pos.	Art.No.	Description	Qty.
		S O F T W A R E F O R P L A T F O R M	
19	10959	CUSTOMER HARDWARE ID	1
		D I S P O S A B L E S R A D I O S U R G E R Y	
20	43450	CRANIAL 4PI STEREOTACTIC MASK (5 PCS)	1
21	43451	CRANIAL 4PI BASIC MASK (5 PCS)	1
22	43452	CRANIAL 4PI OPEN-FACE MASK (5 PCS)	1
		O N E - T I M E S E R V I C E S R A D I O S U R G E R Y	
23	82020-08	INSTALLATION EXACTRAC	1
24	82993-12	PROJECT CONSULTING AND MANAGEMENT EXACTRAC (NEW SYSTEM)	1
25	89109-04	INSTALLATION AND CONFIGURATION IHELP REMOTE SERVICE	1
		O N S I T E A P P L I C A T I O N T R A I N I N G - R A D I O S U R G E R Y	
26	82022-25	USER TRAINING EXACTRAC DYNAMIC (3 DAYS)	1
		F R E I G H T , I N S U R A N C E A N D F E E S	
27	50780	FREIGHT, INSURANCE AND FEES	1

USD

TOTAL EXCL. TAX　　　　　　　　　　　　　　　　　　　　　　**425,000.00**

* This quote contains a component that is - as per today – listed as 'dual use' good under the EU Dual Use Regulation 428/2009/EC and U.S. Export Administration Regulations (US EAR) and therefore export controlled and subject to potential export restrictions.
Brainlab will notify you if any restrictions apply to your order or if your support for the completion of your order is required (for example submission of an end user declaration).
Please note that export control regulations are subject to change without prior notice to Brainlab. In this case, Brainlab may have to cancel your purchase contract. Brainlab shall not be liable for any delay in delivery, any inability to deliver and/or any cancellation of your purchase contract due to export restrictions.

For an Elekta Versa HD Linac purchase the following items should be considered as they are required to integrate the systems:
-iBEAM® evo Couch Adapter
-Set of five (5) Elekta SRS Cones (if necessary)
-Elekta "Goal Posts & Installation kit
-iGuide camera swivel joint
-Frameless extension, MI Part# 10105-414
-XVI 5.0
-MOSAIQ v2.5
-iGuide v 2.2
-Integrity 1.2 for Beam Modulator, MLCi, MLCi2
-Integrity 3.2. for Agility
-NSS (Network Security System)
-CITB interface
-Hexapod 6DOF couch (for 6D functionality)

Technical Quote Review done by

Kurt Erler
Area Sales Manager
kurt.erler@brainlab.com

Christian Haberkorn
Technical Quote Review Specialist
christian.haberkorn@brainlab.com

ExacTrac Dynamic for Elekta
Project-20200707-001470
QN-COICOF-ICH-54

EXACTRAC

1 | 48501 | EXACTRAC DYNAMIC 4D THERMAL CAMERA*
Integrated 4D Thermal Camera for patient pre-positioning and patient monitoring. This hybrid camera combines 3D surface imaging with thermal imaging allowing for accurate patient tracking.
- 3D camera unit including structured light projector and stereoscopic cameras scan the patient's surface
- Thermal camera enriches surface information with patient's heat signature
- Camera device holder for attachment to central ceiling mount
- Camera covers
- Power supplies and data cables

REQUIREMENTS
- ExacTrac Dynamic System and Software

2 | 48502 | EXACTRAC DYNAMIC X-RAY SYSTEM
This article comprises the core X-Ray hardware enabling accurate patient positioning via stereoscopic kV imaging.
- 2 X-Ray generators for simultaneous stereoscopic X-Ray acquisition
- 2 X-Ray tubes including tube covers
- 2 X-Ray collimators
- 2 flat panel detectors with an imaging area of 300 x 300 mm (768 x 768 pixel resolution) including tungsten shielding for electronics
- 2 device mounts and covers for ceiling mounting of flat panel detectors
- Power supplies and data cables

REQUIREMENTS
- ExacTrac Dynamic System and Software
- Please note that the responsibility of conducting or verifying bunker shielding calculations lies with the customer

3 | 48503 | EXACTRAC DYNAMIC CONTROL SYSTEM
This package comprises the hardware components needed for system control.
- System computer cabinet including system electronics with all necessary interfaces, inserts and cablings. The computer cabinet also holds the user workstation.
- User workstation for running ExacTrac Dynamic software
  - CPU Intel Xeon Processor (3.6 GHz, 6x CPU cores)
  - RAM 16GB DDR4
  - 2x NVIDIA Quadro RTX4000 Graphics Card
  - SSD 1TB
  - Microsoft Windows 10 IoT 64bit
- 24 Monitor (16:10), mouse and keyboard for the control room user workspace
- Operator console for the X-Ray system
- Power supplies and cables

REQUIREMENTS
- ExacTrac Dynamic System and Software
- ExacTrac Dynamic Pre-Installation Package
- Varian linac: TrueBeam, VitalBeam (machines with MMI), or Edge
  - Interface: MMI (ADI 3.0)

- TrueBeam console version: 2.7MR2 or higher (customers with TrueBeam version 2.5MR2 or 2.7MR1 will receive a free upgrade to the latest TrueBeam version that is available in their market and validated with ExacTrac Dynamic)
  - ARIA version 13.7 or higher / MOSAIQ v2.64 or higher
  - Couch: PerfectPitch for 6DoF / TrueBeam couch without PerfectPitch for 4DoF
- Elekta linac: VersaHD or all digital linacs (except Compact) satisfying these specifications
  - Integrity 4.0 Control System or higher, supporting Agility, MLCi2, and Beam Modulator
  - XVI 5.0 or higher
  - Couch: HexaPOD, iGuide v2.2.3 or higher for 6DoF / Precise table only for 3DoF
  - R&V: MOSAIQ v2.64 or higher
  - Interface: Response Gating Interface, iCom Vx (Read) Interface, MOSAIQ Patient Positioning Systems Interface (PPS WebIF), Elekta Linac HW signal Interface (CITB box)
  - NSS (Network Security System) or CCP (Consolidated Computer Platform)
  - Linac serial number higher than 152784
  - Pre Installation Floor Boxes or installed 12'' floor boxes (in case of replacement)
  - Elekta wide fascia cover set. ETD is not compatible with the narrow fascia cover set. Consult the Brainlab Project Site Manager in case narrow covers are installed.
- Room and construction requirements as specified in the site planning manual must be met.
- The customer is responsible for site and technical setup meeting regulatory, structural, and 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. Brainlab will support planning of pre-installation construction measures.
- Frequently applying high energy beams (10MV or higher) during treatments can lead to neutron radiation in the treatment room. If the computer cabinet is installed inside the treatment room, neutron radiation may cause severe damage to the system electronics and the user workstation. Neutron radiation shielding hardware (not included in this article) is required if the computer cabinet is installed inside the treatment room.

4 | 48504 | EXACTRAC DYNAMIC CEILING-MOUNTED MONITOR SYSTEM

In-room touch screen monitor for system control from within the treatment room. Flexible ceiling arm for simple adjustment of the monitor position.
- 24" in-room touch screen for system control from within the treatment room
- Rigid mounting on treatment room ceiling
- Flexible rotation arm
- Spring arm with integrated friction break to adjust height

REQUIREMENTS
- ExacTrac Dynamic System and Software

5 | 48514 | EXACTRAC DYNAMIC SYSTEM CALIBRATION PHANTOMS (SET OF 2)

Two phantoms for system calibration and daily QA.
- Thermal to 3D Calibration Phantom for calibrating thermal camera to 3D camera, including power supply unit
- System Calibration Phantom to calibrate X-Ray system and surface camera to isocenter. Also used for daily QA check.
    - Precise form for calibration of surface camera
    - 16 ring markers for calibration of the X-Ray system
    - 4 internal marker spheres for MV and X-Ray calibration

REQUIREMENTS
- ExacTrac Dynamic System and Software

6 | 48513 | EXACTRAC DYNAMIC PRE-INSTALLATION CABLING AND MOUNTING PACKAGE

Complete set of all components required for pre-installation of ExacTrac Dynamic System.
- Ceiling mount for 4D Thermal Camera
- 2x ceiling mount for flat panel detectors
- X-Ray signal light (optional)
- Ceiling mount for in-room touch screen
- Pre-installation package for cooling system
- Power, grounding and data cables for pre-installation
- Step ladder for ceiling work

REQUIREMENTS
- ExacTrac Dynamic System and Software
- Room and construction requirements as specified in the site planning manual must be met

7 | 45525 | EXACTRAC DYNAMIC CRANIAL VERIFICATION PHANTOM

Head phantom for quality assurance and training.
- Bone equivalent skull and upper cervical vertebrae visible in CT and X-Ray images
- Tissue equivalent outer material
- Includes three 5mm tungsten carbide spheres for ExacTrac Dynamic calibration consistency

REQUIREMENTS
- ExacTrac Dynamic System and Software
- Cranial 4Pi Immobilization System

8 | 43420 | CRANIAL 4PI CT IMMOBILIZATION OVERLAY

Overlay board for CT table tops for patient immobilization.
- Low density carbon fiber overlay board with integrated mask and headrest interface
- Dose optimized design
- Light weight of 4 kg / 8.8 lbs supports easy mounting and removal of overlay board
- Simple attachment to large range of CT table tops or dedicated bracket set compatible with Varian or Elekta indexing systems
- Interface for simple headrest attachment
- Rapid click-in fixation for easy mounting and removal of masks
- Integrated height adjustment unit to adjust upper mask by ± 2 mm (no additional accessories such as spacers or clips required)
- Rubber-edged foot end allows storage in upright position
- Maximum load: 195 kg / 429 lbs (may be lower if restricted by maximum load of supporting table top)

REQUIREMENTS
- ExacTrac Dynamic System and Software
- Flat CT table top with a width of 530 mm to 550 mm or Elekta or Varian indexing system on CT table top

BRAINLAB

9 | 43422 | CRANIAL 4PI TREATMENT IMMOBILIZATION OVERLAY ELEKTA IBEAM EVO

Overlay Board for patient immobilization compatible with Elekta iBEAM evo table tops.
- Low density carbon fiber overlay board with integrated mask and headrest interface
- Dose optimized design
- Light weight of 4kg / 8.8 lbs supports easy mounting and removal of overlay board
- Simple mounting to a range of treatment table tops with a table top-specific bracket set and single lock
- Extends beyond the table top by maximum 480 mm
- Interface for simple headrest attachment
- Rapid click-in fixation for easy mounting and removal of masks
- Integrated height adjustment unit to adjust upper mask by ± 2 mm (no additional accessories such as spacers or clips required)
- Rubber-edged foot end allows storage in upright position
- Maximum load: 195 kg / 429 lb (may be lower if restricted by maximum load of supporting table top)

REQUIREMENTS
- ExacTrac Dynamic System and Software
- Compatible with iBEAM evo table top

10 | 43440 | CRANIAL 4PI HEADREST STANDARD

Carbon headrest for mask molding support. Used in combination with headrest inlays.
- Radio-translucent, low density and biocompatible carbon material
- Dose optimized design
- Simple clip fixation to Cranial 4Pi CT or Treatment Overlay board

REQUIREMENTS
- ExacTrac Dynamic System and Software

11 | 43441 | CRANIAL 4PI HEADREST LOW-NECK

Carbon headrest for mask molding support. Used in combination with headrest inlays. This headrest is optimized for patients with short necks allowing for a more caudal fixation of the patient's head.
- Radio-translucent, low density and biocompatible carbon material
- Dose optimized design
- Simple clip fixation to Cranial 4Pi CT or Treatment Overlay board

REQUIREMENTS
- ExacTrac Dynamic System and Software

12 | 43445 | CRANIAL 4PI HEADREST INLAYS (3 SETS OF 2)

Set of low density foam inlay cushions for headrest to support head during mask molding and treatment. Three different inlay types enable adaptation to treatment indication and method. Inlay types come in sets of two.
- 2x Cranial 4Pi Headrest Inlay 1 Standard
- 2x Cranial 4Pi Headrest Inlay 2 Open Face for treatment with open face mask
- 2x Cranial 4Pi Headrest Inlay 3 Head and Neck for treatment of neck indications
- Low density foam material

REQUIREMENTS
- ExacTrac Dynamic System and Software

13 | 43435 | CRANIAL 4PI ADJUSTABLE TARGET PHANTOM

QA test equipment (Winston Lutz) that allows for radiation isocenter calibration of ExacTrac Dynamic.
- Allows for verification of lasers and isocenter consistency
- Integrated 5 mm tungsten sphere for center marking of radiation field
- Embossed lines for center marking of laser isocenter
- Simple fixation to the Cranial 4Pi Treatment Immobilization Overlay
- Carriages for high-precision translational adjustment in three degrees of freedom
- High-precision pitch adjustment (4th degree of freedom)

REQUIREMENTS
- ExacTrac Dynamic System and Software

SOFTWARE EXACTRAC

14 | 25760 | SURFACE GUIDED PRE-POSITIONING SOFTWARE

Treatment Preparation
- Template Editor to customize treatment templates for standardized clinical workflows
- DICOM RT Plan import from R&V system (ARIA, MOSAIQ)
- Patient settings application to import plan, select treatment template and configure all treatment relevant settings including workflow type, automatic X-Ray triggers, tolerances, highlighted objects, and CT volume of interest restriction

Surface Guided Patient Pre-Positioning
- Automatic surface guided pre-positioning by matching the patient surface to the CT outer contour
- Intuitive area of interest selection for thermal-surface tracking

SOFTWARE UPDATES & UPGRADES
- For the first year after initial installation, software-related updates and upgrades within terms of use are included. If not installed remotely via iHelp additional service costs will be incurred
- From the second year on, software-related updates and upgrades as well as 24/7 hotline support are covered by a separate license support contract for each individual software which must be purchased separately

REQUIREMENTS
- ExacTrac Dynamic System

15 | 25765 | INTRA-FRACTION 4D THERMAL MONITORING SOFTWARE

Real-time patient monitoring using the 4D Thermal Camera.
- The selected area of interest on patient is tracked by thermal-surface technology with
  - translation accuracy better than 1.0 mm, and
  - rotational accuracy better than 1.0° in each dimension
- Monitoring helps to detect intra-fraction movements and reduces delivery uncertainty for stereotactic radiosurgery and radiotherapy

4D Thermal Monitoring Features and Workflows
- Integrated gating interface to linac enables automatic beam hold when patient moves out of defined tolerances
- Enables surface-triggered automatic X-Ray acquisition
- Dedicated workflow for surface monitoring of Cone Beam CT position
- Dedicated workflow for surface monitoring of implanted marker position

Calibration Application
- Thermal-to-Surface Camera Calibration application

SOFTWARE UPDATES & UPGRADES

- For the first year after initial installation, software-related updates and upgrades within terms of use are included. If not installed remotely via iHelp additional service costs will be incurred
- From the second year on, software-related updates and upgrades as well as 24/7 hotline support are covered by a separate license support contract for each individual software which must be purchased separately

REQUIREMENTS
- ExacTrac Dynamic System

16 | 25770 | INTRA-FRACTION X-RAY MONITORING SOFTWARE

Accurate X-Ray positioning and monitoring at coplanar and non-coplanar table angles.
- DRR to stereoscopic X-Ray fusion calculates precise patient position in 6 degrees of freedom
- X-ray visible anatomical structures and implanted markers of a rigid body can be positioned and monitored with
  - translational accuracy better than 1.0 mm or better than half CT slice thickness (whatever value is larger), and
  - angular accuracy better than 1° in each dimension
- IGRT imaging dose delivered to the patient is kept as low as reasonably possible and significantly lower than the imaging dose required for Cone Beam CT imaging

X-Ray Positioning and Monitoring Features and Workflows
- Intuitive fusion verification tools: Blending, Spyglass, Crosshair, Rubberband, and A/B Switching
- Restrict X-Ray and/or CT data to account for anatomical changes between scan and treatment time
- Adjust DDR soft-tissue contrast to optimize fusion
- Integrated gating interface to linac enables automatic beam hold when patient moves out of defined tolerances
- Automatic X-Ray can be trigger based on gantry position, monitor units delivered, or surface movement
- Accurate X-Ray repositioning to correct for patient movement at any table angle
- Gantry widget to show real-time gantry position and trigger automatic X-Rays
- Dedicated workflow for monitoring of Cone Beam CT position
- Dedicated workflow for monitoring implanted markers
- Export of DICOM RT Image to R&V system
- Treatment report export of all treatment relevant data including patient motion

Calibration and Daily Check Applications
- Isocenter Calibration application calibrates the X-Ray system and the surface tracking system to the linac coordinate system and isocenter
- Radiation Isocenter Calibration application fine-tunes the calibration to the radiation isocenter of the linac
- Daily Check application verifies the cross-calibration of X-Ray and surface tracking system and performs the tube warm-up
- X-Ray Test Acquisition application

SOFTWARE UPDATES & UPGRADES
- For the first year after initial installation, software-related updates and upgrades within terms of use are included. If not installed remotely via iHelp additional service costs will be incurred
- From the second year on, software-related updates and upgrades as well as 24/7 hotline support are covered by a separate license support contract for each individual software which must be purchased separately

REQUIREMENTS
- ExacTrac Dynamic System

17 | 25775 | PATIENT SETTINGS SOFTWARE

Template Editor and Patient Preparation application for an independent workstation or for a server.
- Template Editor to customize treatment templates to standardize clinical workflows
- DICOM RT Plan import from R&V system (ARIA, MOSAIQ)
- Patient Preparation application to import plan, select treatment template and configure all treatment relevant settings including workflow type, automatic X-Ray triggers, tolerances, highlighted objects, and CT volume of interest restriction

SOFTWARE UPDATES & UPGRADES
- For the first year after initial installation, software-related updates and upgrades within terms of use are included. If not installed remotely via iHelp additional service costs will be incurred
- From the second year on, software-related updates and upgrades as well as 24/7 hotline support are covered by a separate license support contract for each individual software which must be purchased separately

REQUIREMENTS
- ExacTrac Dynamic System

18 | 30038 | ORIGIN DATA MANAGEMENT

Brainlab Origin Operating System facilitates intelligent and automatic synchronization of data between platforms and offers easy access to all new software capabilities. Universal patient data management software, that allows for import of patient data in DICOM format on Brainlab- and 3rd Party systems. Easy and intuitive user interface for streamlined access to patient data and applications.

1. GENERIC ORIGIN FEATURES
- Full control with support of touch gesture interaction, as well as mouse and keyboard support
- Advanced data import & export features (PACS, USB, CD/DVD, Quentry and network folder)
- Support of various modalities including CT, MR, PET/SPECT, X-ray
- PACS access via DICOM "Query/Retrieve" and "Push" (compatible to all standard conform PACS systems)
- Receipt of data via DICOM "Push" and support of DICOM worklists
- Automatic content configuration of OR displays based on user pre-defined setups
- Optional HIS integration via HL7 interface (message types: SIU, ADT, ORM - requires Origin Integration of HIS)
- Intelligent export of screenshots (.png or DICOM) and video recordings (.mp4 or DICOM) via DICOM "C-Store"
- Advanced patient data management tools including new patient creation, merging and editing
- HIPAA-compliant feature set including authentication, accountability log and automatic log-off
- Easy to service through link to Brainlab remote support (iHelp)____

2. ORIGIN SERVER SOFTWARE FEATURES

When installed on Brainlab Node Server or compatible 3rd party servers, Origin Data Management includes Origin Server Software either for full planning or for image viewing workflows. It enables access to Brainlab applications from any desktop PC, laptop or tablet connected to the hospital network (LAN/ WLAN / Internet) either from inside or outside the hospital.
- Mac OS and iOS devices compatible
- Full SSL encryption through HTTPS for higher security
- Scalability through Server Clustering with Load Balancing (e.g. Monte Carlo advanced dose calculation)
- Session Sharing and team planning functionality
- Fully web based image viewing workflow - no client installation or configuration required
- Single Sign On (SSO) and support for Invoke Image Display IHE profile
- Software License valid for users within one clinical institution, concurrent users licensing model
- Each license contains 1 concurrent session
- Available on Brainlab Node Server or Customer Server
- Allows remote access to all treatment planning applications

INCLUDED SERVICES
- Includes for the first year after initial installation related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via iHelp
- From the second year on software related updates and upgrades as well as 24/7 hotline support are covered by a separate license support contract for each individual software and needs to be purchased separately for each software in the portfolio.

SOFTWARE FOR PLATFORM

19 | 10959 | CUSTOMER HARDWARE ID

For the proper creation of the license and functioning of the software for the use on a platform provided by the customer Brainlab requires the host-ID information of the respective platform. Brainlab (Sales Operations) will contact and instruct the customer how to retrieve and forward the host-ID information for smooth order processing.
If you have further questions please contact your Brainlab service engineer.

DISPOSABLES RADIOSURGERY

20 | 43450 | CRANIAL 4PI STEREOTACTIC MASK (5 PCS)

Thermoplastic masks for patient immobilization during delivery of single-fraction or multi-fraction SRS treatments, enabling non-invasive patient fixation and reproducible position.
- Moldable patient-specific mask consisting of a single sheet rear mask and a rigid upper mask with two sheets and a customized nose bridge
- Integrated rails for rapid click-in fixation for simple mounting and dismounting of mask
- Mask height can be adjusted by ± 2 mm
- Includes 5 complete mask sets, each containing
  - Perforated rear mask sheet
  - First non-perforated upper sheet with large eye and mouth opening
  - Pellets for molding the nose bridge to minimize rotational movements of patient head
  - Perforated second upper sheet with eye opening and five-point fixation to the rail

REQUIREMENTS
- ExacTrac Dynamic System and Software

21 | 43451 | CRANIAL 4PI BASIC MASK (5 PCS)

Thermoplastic immobilization masks for enhanced patient comfort.
- Moldable patient-specific mask with single layer
- Integrated rails for rapid click-in fixation for simple mounting and dismounting of mask
- Mask height can be adjusted by ± 2 mm
- Includes 5 perforated mask sheets

REQUIREMENTS
- ExacTrac Dynamic System and Software

22 | 43452 | CRANIAL 4PI OPEN-FACE MASK (5 PCS)

Thermoplastic immobilization masks with large facial opening for enhanced comfort for claustrophobic patients and for surface tracking during treatment delivery.
- Moldable patient-specific mask consisting of a rear mask and upper open- face mask
- Integrated rails for rapid click-in fixation for simple mounting and dismounting of mask
- Mask height can be adjusted by ±2 mm
- Includes 5 complete mask sets, each consisting of
  - Perforated rear mask sheet
  - Non-perforated upper sheet with large facial opening

REQUIREMENTS
- ExacTrac Dynamic System and Software

ONE-TIME SERVICES RADIOSURGERY

23 | 82020-08 | INSTALLATION EXACTRAC

Set-up of ExacTrac X-ray system and pre-Installation Kit on-site with following scope of work:
- Preparation of installation plan and installation kick-off meeting on-site
- Installation of ExacTrac ceiling mounts on concrete ceiling (maximum height of 4250 mm)
- Setting of ExacTrac Floor boxes
- Workstation hardware assembly and software pre-installation in Brainlab production facility
- Assembly of all system & computer hardware components onsite and adjustment to the LINAC
- Adjustment and calibration of the x-ray system
- Testing & verification of data transfer by scanning a test- phantom and simulation of the data processing chain
- Acceptance protocol according to the Quality System Phantom test procedure
- Verification of completeness, function, precision and operational condition of all software and hardware components
- Installation work during normal business hours. Additional costs for a no-downtime installation outside normal business hours apply (Article 82021-01)
- Not included: ExacTrac System Pre-Installation including but not limited to digging work, concrete pouring, finished floor and cable ducts, modification of false ceiling (Article No 82021-10 or 82021-04 required).

24 | 82993-12 | PROJECT CONSULTING AND MANAGEMENT EXACTRAC (NEW SYSTEM)

On- and Off-site project consulting and management for one ExacTrac System Upgrade or 2nd System project, performed by a Brainlab team of Project Managers and Technical Consulting Specialists, including the following scope of services.
Technical Planning:
- Project feasibility of the Brainlab device according to the Pre-installation manual specification based on hospital AutoCAD 2D drawings.
- Implementation of the Brainlab components within the submitted drawings.
- Creation of scope of work document and schedules related to the Brainlab equipment
Project Management:
- Project management throughout the project cycle from sales consulting to acceptance
- Creation and maintenance of a project schedule including dependencies, project steps and milestones of Brainlab and stakeholder tasks required to execute the agreed upon scope of work
- Cooperation with the customer key project stakeholders and coordination of Brainlab resources.
- Upon system installation completion and system acceptance, project handover to Brainlab field service
- Up to five (5) onsite visits included

NOTE: In case a planned site visit is delayed or cancelled and rescheduled, Brainlab may invoice for additionally incurred working hours and travel expenses.

25 | 89109-04 | INSTALLATION AND CONFIGURATION IHELP REMOTE SERVICE

iHelp remote service is an integral part of most Brainlab software and hardware solutions to optimize system availability and lower overall system lifetime cost, and is therefore installed and configured by default with every Brainlab system installation to facilitate:

- faster system defect diagnosis through remote monitoring
- instant downloading of log files for faster troubleshooting
- remote management of software/firmware versions
- remote deployment of new software and software updates
- generating historic performance data documentation reports helping to improve products throughout their lifecycle

  Brainlab iHelp® technology is based on PTC Axeda. Axeda provides services under the highest security and performance standards to all of its infrastructure users. Furthermore, Axeda cloud services have undergone independent testing and validation, are security certified by VeriSign and is ISO 27001 certified and accredited base for our iHelp® remote support platform. Furthermore, the platform is continuously developed further to comply with medical standards and regulations, such as HIPAA and GDPR.

ONSITE APPLICATION TRAINING - RADIOSURGERY

26 | 82022-25 | USER TRAINING EXACTRAC DYNAMIC (3 DAYS)

Three-day (4 hours per day) on-site clinical course for new users and other members of a clinical team who utilize ExacTrac Dynamic taught by skilled Brainlab Application Consultant:

- Designed to develop proficiency in Brainlab Radiation Oncology technology including general hardware and room set-up, software and system calibration, patient transfer, patient pre-positioning, patient positioning and patient monitoring , as well as common troubleshooting techniques.
- Eligible for IACET CEUs with completion of training. ASRT credit provided with completion of training.
- Includes tuition, course materials and supplies, including applicable supplemental materials, travel & accommodation for the Brainlab Consultant. Course or supplemental materials can change without notice.
- Requires minimum four weeks prior notice to enable scheduling

BRAINLAB

FREIGHT, INSURANCE AND FEES

27 | 50780 | FREIGHT, INSURANCE AND FEES

Standard Terms and Conditions-Brainlab, Inc.

1. DEFINITIONS AND APPLICATION

1.1. "Affiliate" of a party means a person or entity which controls, is controlled by, or is under common control with, a party, for as long as such control exists. "Control" for purposes of this definition means (i) in the case of corporate entities, direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of fifty percent (50%) or more of the equity or income interest therein.

1.2. "Brainlab" means Brainlab, Inc.

1.3. "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.

1.4. "Products" means all Software and hardware products set out in the Quote.

1.5. "Quote" means the quotation to which these Standard Terms and Conditions are attached.

1.6. "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.

1.7. "Software" means software to be delivered or made otherwise available by Brainlab and set out in the Quote.

1.8. "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.

1.9. "Third Party Products" means Products manufactured by a third party and provided to Customer by Brainlab.

1.10. All Products and Services are furnished only on these terms and conditions and any exhibits hereto.

1.11. 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. Brainlab shall be entitled to assign or transfer any of its rights and/or payment claims against the Customer or other persons or entities to any of its Affiliates or to a third party at Brainlab's sole discretion at any time.

5.7. 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.

5.8. 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.

5.9. 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.

5.10. 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

5.11. 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.

5.12. 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.

5.13. Customer shall not be entitled to offset claims without the prior written consent of Brainlab.

5.14. 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 or hindered due to Act of God, strike, regulatory difficulties, a pandemic, epidemic, serious viral outbreak or due to any other unforeseen circumstances (whether similar to the preceding events or not), 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 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 occurance 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 untill 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 Software acquired hereunder subject to the restrictions set forth in these terms. Software may only be accessed and/or used (a) in accordance with its intended use; (b) on the Brainlab hardware on which it is delivered or on which it is installed; (c) for the Term, if provided on a subscription basis, or perpetually, if not provided on a subscription basis; (d) by Customer and/or its Affiliate; (e) at the Customer location indicated in the Quote, and/or, solely with respect to Software installed on a Customer or Affiliate owned server, at an Affiliate co-located in the same geographic setting; and (f) by the number of permitted concurrent users indicated in the Quote, or if no number of concurrent users is indicated in the Quote, by one (1) authorized 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.

14.6. If a Product contains a Microsoft product ("Embedded System"), Customer shall not use internet browsing functionality with the Embedded System to connect to and access cloud hosted applications, such as Microsoft Office 365. This section is a requirement that Brainlab must comply with based on its Microsoft OEM Customer License Agreement for Embedded Systems

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 Brainlab still holds title of the Products. 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 of, or the inability to peform, its contractual obligations which are due to, or hindered by, an Acts of God, strike, regulatory difficulties, a pandemic, epidemic, serious viral outbreak or any other unforeseen circumstances, whether similar to the foregoing or not. 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.

BRAINLAB

ExacTrac Dynamic

Technical Hardware Specifications

ExacTrac Dynamic* Hardware Specifications

X-Ray Generators

Weight	500 kg // 1100 lbs (both generators)
Height	1510 mm // 59.4"
Width	1100 mm // 43.3" (both generators)
Depth	550 mm // 21.7"
Main input voltage	Y400 V
Main input voltages with optional integrated pre-transformers	Y208 V Y420/440/480 V D200/210/220 V
Max output power	65 kW
Max cable length between two generator units	20 m // 65'
Max cable length to X-Ray tube	18 m // 59'

X-Ray Tube

Weight	31 kg // 68.3 lb (each)
Height	300 mm // 11.8"
Width	500 mm // 19.7"
Depth	289 mm // 11.4"
Max tube voltage	150 kV
Max tube current	800 mA
Exposure time	100 ms

X-Ray Tube Casing
Option A: In-Floor Casing and Cover

|	
Weight	53.6 kg // 118 lb (each)
Height	312 mm // 12.3"
Width	3750 mm // 147.6"
Depth	1026 mm // 40.4"
Required depth of floor recess	330 mm (±20 mm) // 13" (±0.75")

Option B: On-Floor Cover

Weight	20 kg // 44 lb
Height	342 mm // 13.5"
Width	~3000 mm // 118"
Depth	1250 mm // 50"

*CE cleared, FDA clearance pending

Flat Panel Detector

Weight	9 kg // 19.8 lb
Height	330 mm // 12.9"
Width	340 mm // 13.4"
Depth	60 mm // 2.4"
Pixel area	298 x 298 mm // 11.7 x 11.7"
A/D conversion	16-bit
Pixel pitch	194 µm
Data interface	Gigabit Ethernet
Pixel matrix – total	1536 x 1536
Pixel matrix – used	768 x 768 (software 2x2 binned)
Quantum efficiency	55% @ 1 lp/mm
Energy range	40 – 150 KVp
Speed	15 fps
Dynamic range	94 dB
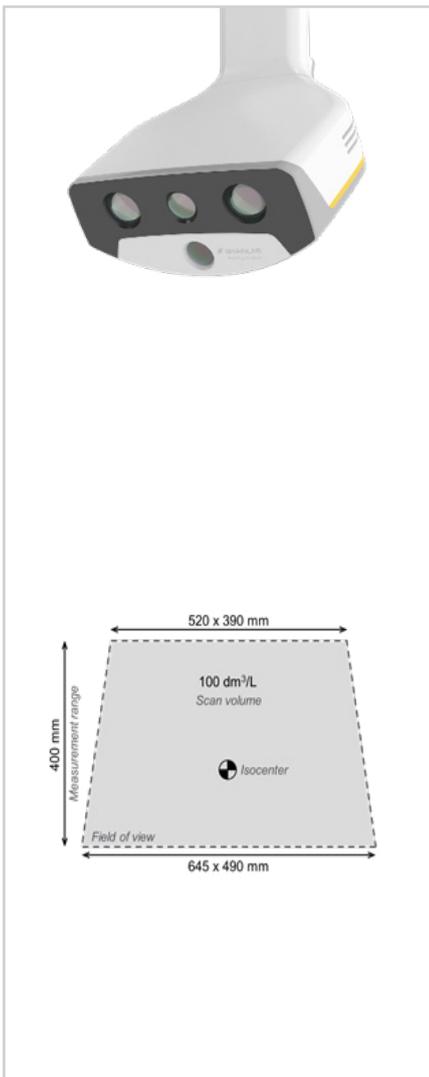
4D Thermal Camera

Weight	9.7 kg // 21.4 lb
Height	200 mm // 7.9"
Width	370 mm // 14.6"
Depth	310 mm // 12.2"
Registration frame rate	15 – 20 fps
Far field of view	645 x 490 mm
Measurement range	400 mm
Scan volume	100 dm^3/L

3D Structured Light Camera

Power	Voltage: +24 VDC Current: 6.0 A max
Image acquisition	Stereoscopic 3D cameras
Scan rate	500 images per second
Resolution	300,000 points
Ethernet	10 Gigabit Ethernet interface
Projection	Rotating structured light pattern, blue light with wavelength 459 nm

Thermal Camera

Thermal sensitivity	< 0.05° C // 50mK @ +30° C // +86° F
F-number	1.25
Image frequency	30 Hz
Image resolution	640 x 512
Field of view	25 x 20°
Temperature range	-40 – +550° C // -40 – +1022° F
Image acquisition	Patient's thermal radiation captured by camera

System Computer Cabinet

Weight	180 kg // 397 lb
Height	1770 mm // 70"
Width	610 mm // 24"
Depth	890 mm // 35"
Max cable length to X-Ray generator	40 m // 131'
Max cable length to distribution box treatment room	40 m // 131'
Max cable length to distribution box control room	40 m // 131'
Main input voltage	100V/240V, 50/60HZ

User Workstation

Weight	9 kg // 19.8 lb
Height	180 mm // 7"
Width	480 mm // 19"
Depth	560 mm // 22"
OS	MS Windows 10 IoT 64bit
SSD	1 TB
Primary Graphic	2 x NVIDIA Quadro RTX4000
Processor	Xeon family (3.6 Ghz, 6 x CPU cores)
RAM	16GB DDR4

Control Room Monitor

Weight	5.7 kg // 12.6 lb
Height	341.9 mm // 13.5"
Width	531 mm // 20.9"
Depth	45.5 mm // 1.8"
Screen size	24.1"
Resolution	1920 x 1200

In-Room Touchscreen Monitor

Weight	7 kg // 15 lb
Height	402.7 mm // 15.9"
Width	578.1 mm // 22.8"
Depth	68 mm // 2.7"
Screen size	24"
Resolution	1920 x 1200

Ceiling-Mounted Monitor Arm

Weight	42 kg // 93 lb
Height	800 mm // 31.5" or 400 mm // 15.7"
Max extension	1900 mm // 74.8"
Arm width	100 mm // 3.9"
Length	900 mm // 35.4"
Max payload	26 kg // 57.3 lb
Positions	360° with stop

User Console

Weight	0.8 kg // 1.8 lb
Height	185 mm // 7.3"
Width	116 mm // 4.6"
Depth	28 mm // 1.1"

X-Ray Signal Light

Weight	0.3 kg // 0.7 lb
Height	170 mm // 6.7"
Width	90 mm // 3.5"
Depth	50 mm // 2"

Ceiling Mount

Weight	38 kg // 84 lb
Height	1150 mm // 45.3"
Width	500 mm // 19.7"
Depth	500 mm // 19.7"

Device Mount

Weight	5 kg // 11 lb
Height	170 mm // 6.7"
Width	280 mm // 11"
Depth	1150 mm // 45.3"

Interface Plate

Weight	5.7 kg // 12.6"
Diameter	460 mm // 18.1"
Depth	8 mm // 0.3"

ExacTrac Dynamic Phantoms* Specifications

System Calibration Phantom

Weight	5 kg // 11 lb
Height	216.5 mm // 8.5"
Width	173.0 mm // 6.7"
Depth	212.175 mm // 8.4"
X-Ray marker number	16
MV markers	4
IR markers	4

Thermal-to-3D Calibration Phantom

Weight	9.5 kg // 20.9 lb
Height	40.6 mm // 1.6"
Width	550.0 mm // 21.6"
Depth	520.0 mm // 20.5"
Thermal marker number	7
Main input voltage	80 V – 264 V, 47 – 63 Hz

Cranial Verification Phantom

Weight	5 kg // 11.0 lb
Height	250 mm // 9.8"
Width	180 mm // 7.1"
Depth	230 mm // 9.1"
X-Ray marker number	Three 5 mm // 0.2" diameter tungsten carbide spheres

Pelvic Verification Phantom

Weight	17 kg // 37.5 lb
Height	290 mm // 11.4"
Width	220 mm // 8.7"
Depth	280 mm // 11"
X-Ray marker number	One 5 mm // 0.2" diameter tungsten carbide sphere

*CE cleared, FDA clearance pending

Cranial 4Pi Immobilization* Specifications

Cranial 4Pi Headrest A Standard

Weight	99 g // 0.2 lb
Height	238 mm // 9.4"
Width	215 mm // 8.5"
Depth	75 mm // 3"
Material	0.8 mm CFRP (carbon fiber reinforced plastic)
Aluminum equivalent	0.22 mm Al @ 100 kV (shell with cushion)
Identification Letter	A

Cranial 4Pi Headrest B Low Neck

Weight	99 g // 0.2 lb
Height	238 mm // 9.4"
Width	215 mm // 8.5"
Depth	75 mm // 3"
Material	0.8 mm CFRP (carbon fiber reinforced plastic)
Aluminum equivalent	0.22 mm Al @ 100 kV (shell with cushion)
Identification Letter	B

Cranial 4Pi Headrest Inlay 1 Standard

Weight	50 g // 0.1 lb
Height	227 mm // 8.9"
Width	178 mm // 7"
Depth	60 mm // 2.4"
Material	PU & PE foam
Thickness	12 mm // 0.5"
Identification	1 Standard

Cranial 4Pi Headrest Inlay 2 Open-Face

Weight	50 g // 0.1 lb
Height	227 mm // 8.9"
Width	178 mm // 7"
Depth	60 mm // 2.4"
Material	PU & PE foam
Thickness	11 – 30 mm // 0.4 – 1.2"
Identification	2 Open-Face

Cranial 4Pi Headrest Inlay 3 Head & Neck

Weight	53 g // 0.1 lb
Height	227 mm // 8.9"
Width	178 mm // 7"
Depth	60 mm // 2.4"
Material	PU & PE foam
Thickness	5 – 21 mm // 0.2 – 0.8"
Identification	3 Head & Neck

*CE cleared, FDA clearance pending

Cranial 4Pi CT Immobilization Overlay

Weight	4 kg // 8.8 lb
Height	1210 mm // 47.6"
Width	530 mm // 20.9"
Depth	113 mm // 4.4"
Overlay thickness	23 mm // 0.9"
Aluminum equivalent	0.56 mm Al @100kV

Cranial 4Pi Treatment Immobilization Overlay Varian IGRT

Weight	4 kg // 8.8 lb
Height	1210 mm // 47.6"
Width	530 mm // 20.9"
Depth	113 mm // 4.4"
Overlay thickness	23 mm // 0.9"
Aluminum equivalent	0.56 mm Al @100kV
Compatibility	Varian IGRT table top

Cranial 4Pi Treatment Immobilization Overlay Elekta iBeam Evo

Weight	4 kg // 8.8 lb
Height	1210 mm // 47.6"
Width	530 mm // 20.9"
Depth	113 mm // 4.4"
Overlay thickness	23 mm // 0.9"
Aluminum equivalent	0.56 mm Al @100kV
Compatibility	Elekta iBEAM Evo table top

Cranial 4Pi Treatment Immobilization Overlay Qfix kVue

Weight	4 kg // 8.8 lb
Height	1210 mm // 47.6"
Width	530 mm // 20.9"
Depth	113 mm // 4.4"
Overlay thickness	23 mm // 0.9"
Aluminum equivalent	0.56 mm Al @100kV
Compatibility	Qfix kVue table top (RT-4551KV) + kVue Short Insert (RT-4551KV2)
	kVue Calypso table top (RT-4551KVCL-M) and (RT-4551KVCL-V) + kVue Short Insert (RT-4551KV2)
	All-in-one kVue table top (RT-4551KVP) + kVue Short Insert (RT-4551KV2)

Cranial 4Pi Stereotactic Mask

Weight	440 g // 1.0 lb
Height	290 mm // 11.4"
Width	225 mm // 8.9"
Depth	40 mm // 1.6"
Number of thermoplastic sheets	3
Recommended hardening time	20 min
Material properties	Rear mask: Maxi perforated Middle mask: Non-perforated Top mask: Maxi perforated
Material	Rails: Polycarbonate Mask: Low temperature thermoplastic
Layer thickness	Rear mask: 2.4 mm // 0.09" Middle mask: 2 mm // 0.08" Top mask: 2 mm // 0.08"
Softening temperature	65 – 70 °C // 149 – 158 °F
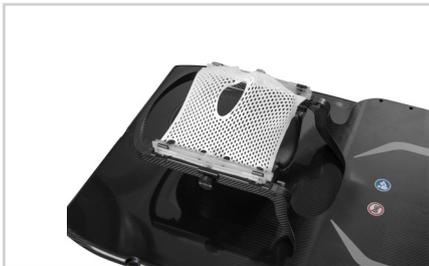
Cranial 4Pi Basic Mask

Weight	140 g // 0.3 lb
Height	220 mm // 8.7"
Width	260 mm // 10.2"
Depth	30 mm // 1.2"
Number of thermoplastic sheets	1
Recommended hardening time	15 min
Material properties	Maxi perforated
Material	Rails: Polycarbonate Mask: Low temperature thermoplastic
Layer thickness	1.6 mm // 0.06"
Softening temperature	65 – 70 °C // 149 – 158 °F

Cranial 4Pi Open-Face Mask

Weight	290 g // 0.6 lb
Height	240 mm // 9.5"
Width	255 mm // 10"
Depth	31 mm // 1.2"
Number of thermoplastic sheets	2
Recommended hardening time	20 min
Material properties	Rear mask: Maxi perforated Open-Face mask: Non-perforated
Material	Rails: Polycarbonate Mask: Low temperature thermoplastic
Layer thickness	Rear mask : 2.4 mm // 0.09" Open-Face mask: 2 mm // 0.08"
Softening temperature	65 – 70° C // 149 – 158° F

Cranial 4Pi Adjustable Target Phantom

Target Pointer

Weight	500 g // 1.1 lb
Height	180 mm // 7.1"
Width	265 mm // 10.4"
Depth	118 mm // 4.6"
Size of metal sphere	Ø 5 mm // 0.2"

Case

Weight	2160 g // 4.8 lbs
Height	320 mm // 12.6"
Width	390 mm // 15.4"
Depth	160 mm // 6.3"

Disclaimer

The information in this brochure contains general technical descriptions of specifications and options as well as physical and performance characteristics that do not always have to be present in individual cases. Technical specifications, availability and packaging may vary and may be subject to change without prior notice.

Brainlab reserves the right to modify the design, packaging, specifications and options described in this brochure without prior notice.

Due to certain regional limitations of sales rights and service availability Brainlab does not guarantee availability of all products included in this brochure through the Brainlab sales organization worldwide.

Please contact your local service or sales representative for the most current information.

BRAINLAB

Technical Hardware Requirements for Elements installation

Elements can be installed on the supported Brainlab hardware, 3rd party platforms or virtual machines, as long as the software and hardware requirements listed in this document are fulfilled. For further questions or assistance please contact Brainlab support

SUPPORTED BRAINLAB HARDWARE PLATFORMS

Radiotherapy
Advanced Planning Computer 9 and newer
Planning Station 8.0 RT
(Planning Workstation for RT)
Planning Station 7 Workstation
(Planning Workstation Premium)
Node Server Hardware 4.0
Node Server Advanced 5.1 and newer
Node Server Essential 5.1 and newer

Surgery
Planning Workstation Premium
Node Server Hardware 4.0 & newer
Buzz In / On-Wall
Kick Navigation Station
Curve Navigation Station

RECOMMENDED HARDWARE SPECIFICATIONS*

*For 3rd party planning workstation or single session server

CPU:	Intel XEON CPU with Skylake Microarchitecture (released August 2017) or newer
	Radiotherapy: 12 physical cores **Surgery:** 6 physical cores Example: Intel Xeon W 2195 Intel Xeon Gold 6148
Memory:	**Radiotherapy:** 64 GB **Surgery**: 16 GB Server Environment: see section "Concurrent user sessions"
Graphics:	DirectX 12 compatible NVIDIA workstation graphics card with at least 4 GB graphics memory and hardware feature level 11 High memory bandwidth between accelerator memory and accelerator and at least 640 GPU cores

Examples for supported NVIDIA Quadro GPUs with the respective recommended minimum driver version:

GPU	Recommended Minimum Driver Version
K2200	361.91
M2000	377.11
P4000	385.41, 411.63
RTX4000	426.32

Note: GPU is required for all Radiotherapy workflows.

Screen Resolution: 1920 x 1200 (WUXGA)
2560 x 1140 (only for Radiotherapy)

Network connection: 1 Gbit/s

Hard Drive: Solid State Drive (SSD) recommended with 250 GB disk space for Windows installation and third party applications
At least 250 GB additional disk space on SSD for Brainlab applications and patient data

SOFTWARE REQUIREMENTS

Planning Workstation

Operating System:
Windows 10 Enterprise 1507 LTSC
Windows 10 Enterprise 1607 LTSC
Windows 10 Enterprise 1809 LTSC

Planning Server

Operating System (OS):   Windows Server 2012 R2 Standard 64bit
Windows Server 2016 Standard 64 bit
Windows Server 2019
English OS language

OS Roles & Services: The server shall be installed with the default configuration without any additional Roles or Services

Power Shell: Version 3.0 or newer

SSL Certificate: Fully Qualified Domain Name SSL certificate.

* The Windows Server license as well as the RD Client Access Licenses (RD CALs) and the SSL certificates have to be provided by the hospital IT

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SERVER VIRTUAL MACHINES

Brainlab supports virtualization environments with Citrix XenServer or VMWare ESXi as recommended technologies.
Since the virtual machine will host highly CPU and RAM demanding software, following aspects need to be considered when setting up the VM:

vCPU: the recommended hardware CPU specifications above apply for virtual machines as well (e.g. 12 physical cores for RT software)

Sockets: For optimal memory management, it is recommended to keep the number of sockets as low as possible

Oversubscription: the configured hardware resources shall be reserved for the virtual machine. In case of oversubscription it is not possible to guarantee a high session density (like for instance in bare metal installations).

Concurrent user sessions: for each additional user session the server configuration shall be expanded with 2 physical cores and 8 GB RAM (16 GB for Radiotherapy installations).

3D GRAPHICS & ALGORITHMS ACCELERATION

GPU accelerated algorithms: For physical servers see the Graphics section in the hardware specifications above.

For virtualized servers GPU sharing (vGPU) or GPU pass-through based on a dedicated physical NVIDIA graphics card in the VM Host is required.

The VM client itself must be equipped with recent graphics driver (NVIDIA driver versions 361.91 ODE branch *and GRID vGPU Manager (340.57)*" or newer).

Advanced 3D graphics views: Elements software offers advanced 3D mostly available with and without physical graphics adapter. High resource demanding data type content may require dedicated 3D graphic acceleration which is supported for server hardware and virtual machines.
The absence of physical graphics adapter on the virtual machine can be partly compensated assigning at least one additional physical core per concurrent session.

In general, Brainlab strongly recommends the adoption of a graphics adapter in order to avoid low quality user experiences.

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PERFORMANCE OPTIMIZATION

Depending on the clinical workflow and resources availability, data pre-fetching can enhance peak load performance by pre-loading and pre-processing part of the data before planning sessions.

SERVER SCALING

In order to scale the server according to your real load refer to the maximum number of concurrent sessions estimated for the peak hours. For increasing the sessions density Brainlab Load Balancing allows the distribution of user sessions across multiple servers (Microsoft cluster services are not needed).

Example server architecture tested for up to 5 concurrent sessions:
2 x Intel Xeon Gold 6146 (3.2 – 4.2 GHz)

Note: to achieve an optimal user experience for the target environment and workflow, these parameters shall be used as orientation and they shall be supported by a dedicated consulting session with Brainlab Service.

ENVIRONMENT PREREQUISITES FOR SERVER BASED PLANNING

Client Computer

Minimum		Recommended	
OS	Windows XP / SP 3 or newer MAC OS X 10.11 or newer	**OS**	Windows 7 or newer
CPU/RAM	1GHz, 512 MB	**CPU/RAM**	2 GHz, 2GB
Display resolution	1280x1024 landscape (Surgery) 1920x1200 landscape (RT)	**Display resolution**	1920x1200 landscape 2560 x 1140 (RT)
Display color depth	24 bit	**Display color depth**	32 bit
Browsers for HTML5 connection	IE version: >8 Safari version: > 9 Chrome version: > 48 Firefox version: > 45	**Browsers for RDP connection**	IE 8.x or newer, RDP client 7.0 or newer and ActiveX control enabled for Origin server URL

Tablets

- iPad with iOS 8.4 or higher
- Display resolution: 1024x768 or higher
- HTML5 compatible web browser (recommended for full screen capability: e.g. Safari)

Hospital Network

- Existing LAN with minimum 100 Mbit/s bandwidth speed and less than 50ms latency
- Static server IP address
- For wireless client connection: Wireless LAN must be provided by the hospital
- Installation required in an air-conditioned IT industrial standard environment (max 35 °C)
- Data storage solution for long term archiving

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- Recommended existing Windows Domain (mandatory only for server clusters in load balancing)

List of critical policies that should not be defined (Setting: "Not Configured") :

Value Name
Computer Configuration\Policies\Administrative Templates\Windows Components\Remote Desktop Services\Remote Desktop Session Host*
Computer Configuration\Policies\Windows Settings\Security Settings\Software Restriction Policies*

The following policies should have the following values:

Value Name	Setting
MACHINE\Software\Policies\Microsoft\Windows\Safer\CodeIdentifiers\AuthenticodeEnabled	0
Computer Configuration\Administrative Templates\Windows Components\Windows Update\Allow non-administrators to receive updates notification	Disabled

From:	Lightbourne, Ena
To:	Waller, Martha K
Subject:	Fwd: [External] No Review Request - Equipment Acquisition - BrainLab ExacTrac at 20 Medical Park Asheville - North Carolina Radiation Therapy Management Services, LLC
Date:	Tuesday, March 23, 2021 10:32:17 AM
Attachments:	Letter to CON Section re 20 Medical Park Asheville - BrainLab ExacTrac - No Review Request.pdf

Martha can you log in #4. Geez..

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From: Hamill, Robert A. <RHamill@hallrender.com>
Sent: Tuesday, March 23, 2021 10:06:02 AM
To: Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>
Cc: Martha.Frisone@dhhs.nc.gov <Martha.Frisone@dhhs.nc.gov>; Mercolino, Alec T. <AMercolino@hallrender.com>
Subject: [External] No Review Request - Equipment Acquisition - BrainLab ExacTrac at 20 Medical Park Asheville - North Carolina Radiation Therapy Management Services, LLC

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Ms. Frisone and Ms. Lightbourne –

On behalf of our client, North Carolina Radiation Therapy Management Services, LLC, please see the attached no review request related to the acquisition of a BrainLab ExacTrac at 20 Medical Park, Asheville.

Please let us know if you have any questions or if we can provide you additional information.

Best,
Bobby

Robert A. Hamill
Attorney
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