



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

County of Ventura, owner/operator of
 Ventura County Medical Center
 300 Hillmont Ave
 Ventura, 300 Hillmont Ave, 93003-1651
 United States

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

Westchester, July 20, 2023
Quotation QN-VCMCVC-MXW-180

The prices and conditions set forth in this quotation are valid for a period of 77 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.

Delivery: DDP (Incoterms 2020)
 Payment Terms: 0% Order Confirmation, 90% Delivery, 10% Acceptance
 Payment terms periodic billing: annually upon acceptance

Loop X

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
LOOP - X						
1	19680	LOOP-X MOBILE IMAGING ROBOT	1			
2	19682	LOOP-X QUALITY CHECK PHANTOM	1			
3	19683	LOOP-X NAVIGATION INTERFACE	1			
4	19687	LOOP-X LASER PROJECTED SPINE LEVEL DEFINITION	1			
5	19684	LOOP-X EXTRA-LARGE AND ADAPTIVE FIELD OF VIEW	1			
6	19686	LOOP-X NAVIGATION GUIDED 2D IMAGING	1			
7	19681	LOOP-X WIRELESS FOOTSWITCH	1			
8	19220-27	LOOP-X MIZUHO INSITE TABLE PACKAGE STANDARD	1			
9	19144	ADHESIVE FLAT MARKERS (10 PCS)	2			
		SUB-TOTAL				756,025.00

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
IMPLEMENTATION SERVICES SURGERY						
10	B14297	PLANNING AND INSTALLATION LOOP-X	1			
		SUB-TOTAL				15,000.00
EDUCATION AND TRAINING						
11	83992-06	USER TRAINING LOOP-X MOBILE IMAGING ROBOT (ON-SITE)	1			
12	83053-10	CLINICAL LAUNCH PACKAGE LOOP-X (1 CONSECUTIVE WEEK)	1			
		SUB-TOTAL				19,100.00
FREIGHT, INSURANCE AND FEES						
13	50780	FREIGHT, INSURANCE AND FEES	1			
14	50798	LOOP-X FREIGHT, INSURANCE, FEES	1			
		SUB-TOTAL				22,350.00

Curve with Elements

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
LOOP - X						
15	B13236	CALIBRATION PACKAGE LOOP-X	1			
16	26760	AUTO-REGISTRATION SOFTWARE LOOP-X SPINE SUBSCRIPTION	1	48		
17	26764	AUTO-REGISTRATION SOFTWARE LOOP-X CRANIAL SUBSCRIPTION	1	48		
		SUB-TOTAL			3,450.00	13,375.00
PLATFORM						
18	17730	CURVE NAVIGATION SYSTEM	1			
		SUB-TOTAL				135,500.00

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
ELEMENTS SUBSCRIPTION						
19	26415	ELEMENTS VIEWER SMART LAYOUT SPINE SUBSCRIPTION	1	48		
20	26200	ELEMENTS SMARTBRUSH SUBSCRIPTION	1	48		
21	26217	ELEMENTS IMAGE FUSION SUBSCRIPTION	1	48		
22	26388	ELEMENTS VIEWER 3D SUBSCRIPTION	1	48		
23	26711	ELEMENTS SCREW PLANNING SPINE SUBSCRIPTION	1	48		
24	26201	ORIGIN DATA MANAGEMENT SUBSCRIPTION	1	48		
25	26250	ELEMENTS TRAJECTORY PLANNING CRANIAL SUBSCRIPTION	1	48		
		SUB-TOTAL				2,188.00
NAVIGATION CRANIAL						
26	26650	NAVIGATION SOFTWARE CRANIAL SUBSCRIPTION	1	48		
27	26645	REGISTRATION SOFTWARE CRANIAL SUBSCRIPTION	1	48		
28	26648	NAVIGATION SOFTWARE CRANIAL - EXTENSION SURFACE MATCHING REGISTRATION SUBSCRIPTION	1	48		
29	22228	INSTRUMENT SETUP SOFTWARE CRANIAL/ENT SUBSCRIPTION	1	48		
30	26529	ALIGNMENT SOFTWARE VARIOGUIDE SUBSCRIPTION	1	48		
		SUB-TOTAL				2,022.00
NAVIGATION SPINE & TRAUMA						
31	26509	NAVIGATION SOFTWARE SPINE & TRAUMA 3D SUBSCRIPTION	1	48		
32	22271	INSTRUMENT SETUP SOFTWARE SPINE SUBSCRIPTION	1	48		
33	26513	REGISTRATION SOFTWARE - EXTENSION SURFACE MATCHING SPINE SUBSCRIPTION	1	48		
34	26781	REGISTRATION SOFTWARE SPINE SUBSCRIPTION	1	48		
		SUB-TOTAL				1,157.00

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
AUTOMATIC PATIENT REGISTRATION						
35	19153	DRAPELINK ADAPTER KIT	1			
36	19152	CRANIAL REFERENCE UNIT DRAPELINK	1			
		SUB-TOTAL				26,450.00
ACCESSORIES CRANIAL						
37	55758-30	SCREWDRIVER	1			
		SUB-TOTAL				260.00
ACCESSORIES SPINE & TRAUMA						
38	55758	SPINE REFERENCE CLAMP CARBON WITH SLIDER	1			
39	55761	SPINE REFERENCE ARRAY FOR REFERENCE CLAMP CARBON (4-SPHERE GEOMETRY)	1			
		SUB-TOTAL				13,475.00
IMPLEMENTATION SERVICES SURGERY						
40	89109-04	INSTALLATION AND CONFIGURATION BRAINLAB CONNECTED CARE	1			
41	81001-11	INSTALLATION CURVE NAVIGATION SYSTEM	1			
		SUB-TOTAL				4,376.00
FREIGHT, INSURANCE AND FEES						
42	50780	FREIGHT, INSURANCE AND FEES	1			
		SUB-TOTAL				1,975.00

Clinical Support

Pos.	Art.No.	Description	Qty.	Period in months	USD/month	USD
SERVICE AGREEMENT SURGERY						
43	83053-01	CLINICAL CONSULTATION INTRAOPERATIVE IMAGING (12 CONSECUTIVE MONTHS)	1			
		SUB-TOTAL				168,500.00

	USD/year	USD
TOTAL EXCL. TAX	105,804.00	1,176,386.00
30.97% Blended Discounts		-364,283.84
20.61% Blended Discounts	-21,804.48	
DISCOUNTED PRICE (EXCL. TAX)*	83,999.52	812,102.16
*Year 1: Discounted Price (excl. Tax)	83,999.52	812,102.16
Year 2: Discounted Price (excl. Tax)	83,999.52	
Year 3: Discounted Price (excl. Tax)	83,999.52	
Year 4: Discounted Price (excl. Tax)	83,999.52	
Total (all annual payments)	335,998.08	
Total Capital Investment		812,102.16
Total Operating Expenses		335,998.08
Total Capital Investment + Total Operating Expenses		1,148,100.24

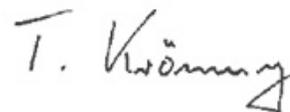
This quote expires on September 29th, 2023.

Customer is also purchasing a twelve-month post-warranty service and support package, as set forth in Quote No. QN-VCMCVC-JWA-177 totaling \$121,000 ("Service Quote"). Customer will issue a separate purchase order for the Service Quote on or before expiration of the warranty period for the products set forth herein or within three (3) months of such expiration date.



Brian Maxwell
Area Account Manager
brian.maxwell@brainlab.com

Technical Quote Review done by



Thomas Kroenung
Technical Quote Review Specialist

Medical devices included

Please see below a table showing the relation between quoted articles and medical devices (UDI-DI).

UDI-DI is the medical device Unique Device Identifier – Device Identifier.

Pos.	Art.No.	Quoted Item Name	UDI-DI	EU Declaration of Conformity Name
1	19680	LOOP-X MOBILE IMAGING ROBOT	19120075320075	medPhoton Loop-X (3rd party, MDR)
2	19682	LOOP-X QUALITY CHECK PHANTOM	N/A	medPhoton Loop-X (3rd party, MDR)
3	19683	LOOP-X NAVIGATION INTERFACE		medPhoton Loop-X (3rd party, MDR)
4	19687	LOOP-X LASER PROJECTED SPINE LEVEL DEFINITION		medPhoton Loop-X (3rd party, MDR)
5	19684	LOOP-X EXTRA-LARGE AND ADAPTIVE FIELD OF VIEW		medPhoton Loop-X (3rd party, MDR)
6	19686	LOOP-X NAVIGATION GUIDED 2D IMAGING		medPhoton Loop-X (3rd party, MDR)
7	19681	LOOP-X WIRELESS FOOTSWITCH	85371098	medPhoton Loop-X (3rd party, MDR)
9	19144A	ADHESIVE FLAT MARKERS (10 PCS)		Cranial ENT 3.1
15	B13236	CALIBRATION PACKAGE LOOP-X		
	19142-06	DRAPELINK INTERFACE FOR ICT CALIBRATION PHANTOM	04056481004637	Cranial ENT 3.1
	19144A	ADHESIVE FLAT MARKERS (10 PCS)		Cranial ENT 3.1
	19148-01A	CALIBRATION PHANTOM ICT		Cranial ENT 3.1
	19152-02	DRAPELINK REFERENCE ARRAY CRANIAL	04056481004545	Cranial ENT 3.1
18	17730	CURVE NAVIGATION SYSTEM		Curve Navigation 17700 (#17701) (MDR)
36	19152	CRANIAL REFERENCE UNIT DRAPELINK	04056481132200	
37	55758-30	SCREWDRIVER	04056481139285	Spine and Trauma 3D 2.6
38	55758	SPINE REFERENCE CLAMP CARBON WITH SLIDER	04056481139278	Spine and Trauma 3D 2.6
39	55761A	SPINE REFERENCE ARRAY FOR REFERENCE CLAMP CARBON (4-SPHERE GEOMETRY)	04056481142728	Spine and Trauma 3D 2.6

Loop X

LOOP-X

1 | 19680 | LOOP-X MOBILE IMAGING ROBOT

Loop-X Mobile Imaging Robot is a brand new kind of intraoperative 2D and 3D imaging device that redefines how scanner and navigation work together by incorporating automatic robotic movement.

- Slim, light weight design (520 kg / 1146 lbs)
- Small footprint (0.88 x 1.90 m / 35 x 75 in)
- Extra-large gantry opening (up to 121 cm / 47 in)
- Large flat panel detector (43 x 43 cm / 16.9 x 16.9 in)
- Robotic movement in 6 axes
- Wireless control tablet with intuitive user interface
- Wireless foot switch
- Large field of view D 25 cm x 25 cm / D9.8 x 9.8 in)
- X-Ray source 40 - 120 kV
- Battery-powered maneuvering
- Pre-defined scanner protocols (including pediatric indications)
- Laser sensors for collision prevention
- Dicom Viewer integrated into control tablet
- Dicom Interface: Storage and Worklist
- Dicom Radiation Report

REQUIREMENTS

- 360° radiolucent surgical table
- Loop-X Quality Check Phantom

REQUIREMENTS FOR COMBINED USE WITH NAVIGATION

- Navigation Software Spine and Trauma 3D (min. Version 1.5) or Cranial Navigation (min. Version 4.0)
- Automatic Image Registration (min. Version 2.5)

2 | 19682 | LOOP-X QUALITY CHECK PHANTOM

Loop-X quality check phantom verifies imaging system's accuracy and allows recalibration (by Brainlab service)

- Customized cylinder phantom for geometrical calibration
- Allows highest possible spatial resolution
- Includes specific phantomholder to be mounted on the scanner for positioning within gantry isocenter

3 | 19683 | LOOP-X NAVIGATION INTERFACE

Loop-X navigation interface connects the scanner with Automatic Image Registration software on Brainlab navigation systems.

- Continuous bidirectional communication of Brainlab navigation software and Loop-X
- Avoids unintended scanning in case Loop-X and the navigation system get disconnected

4 | 19687 | LOOP-X LASER PROJECTED SPINE LEVEL DEFINITION

With this functionality, Loop-X facilitates spine level definition and incision planning.

- Any point selected on 2D images can be represented by movable crosshair lasers on the patient skin
- Points marked on a lateral 2D image are visualized on the patient's back from AP direction for incision marking

5 | 19684 | LOOP-X EXTRA-LARGE AND ADAPTIVE FIELD OF VIEW

Loop-X Extra-Large and Adaptive Field of View can further increase the scan diameter up to 48 cm and shape the radiation beam

- Can cover extra-large structures as pelvis, chest or stereotactic localizers in 3D
- Reduces scan area to the current region of interest
- Collimation may reduce radiation dose
- Collimation may avoid radiating anatomical structures prone to scatter in order to improve image quality
- allows high resolution imaging up to 0,25mm voxel size

6 | 19686 | LOOP-X NAVIGATION GUIDED 2D IMAGING

Loop-X navigation guided 2D imaging adjusts all degrees of freedom for 2D imaging and stores its position with every image.

- The navigation pointer can define and plan X-Ray trajectories intraoperatively. Loop-X provides the option to move and adjust in all degrees of freedom automatically by pressing a footswitch
- Automated system positioning for 2D imaging according to pre-planned trajectories or pre-planned objects
- Every image stores position of Loop-X and its X-Ray components
- Scanner can be automatically repositioned according to recent images of the same patient

7 | 19681 | LOOP-X WIRELESS FOOTSWITCH

Loop-X wireless footswitch controls 2D X-Rays, 3D scans and can select predefined features.

8 | 19220-27 | LOOP-X MIZUHO INSITE TABLE PACKAGE STANDARD

Brainlab's Mizuho Insite Table Standard Package consists of Mizuho components designed specifically for use with the Loop-X Imaging System. The package consists of the following articles & quantities:

- Insite Surgery Table 1x
- Insite Hand Pendant 1x
- Insite Tempur-Pedic Chest Pad only 1x
- Insite Chest Pad Support Plate 1x
- Insite Contoured Combination Hip Pad, Right 1x
- Insite Contoured Combination Hip Pad, Left 1x
- Buttocks Strap 1x
- ASSY, Armboard, Mount 2x
- Insite Legboard w/Pad 1x
- 5 way Adjustable Armboard w/Pad 2x
- Insite Cervical Crossbar 1x
- Restraint Straps 1x
- Insite Crossbar Mounts 1 pr. 1x
- Retractor Adaptor for the Prone Frame 1x
- Insite Supine Top w/Pad 1x
- Universal Side Rail Adaptor (6 inch) 2x
- Re-usable Proneview Adjustable Protective Helmet 1x
- Re-usable Proneview Mirror Platform with Post Holes 1x
- Pedestal End Arm Board Mounting Bracket, ea. 2x
- Insite Proneview, Chest Pad Pillow, Contoured Hip Pad Covers, Arm Cradles, Positioning Straps (single kit) 3x
- Cover, 6844 Insite Table Cover 1x
- Insite® Leg Board Extension 1x
- Pivoting Arm Board with 2" Tempur-Pedic® Medical Pad 2x
- Coupler II 1x
- Tempur-Pedic® Medical 2" (5cm) Table Pad 86" (cm) L x 21" (cm) W 1x
- Insite® ProneView®, Chest Pad Pillow, Contoured Hip Pad Covers, Arm Cradles, Positioning Straps 6/cs 2x
- Retractor Adaptor for the Prone Frame 3x

19220-28 RADIOLUCENT HEAD POSITIONING is offered as a compatible cranial positioning option with to 19220-27 LOOP-X MIZUHO INSITE TABLE PACKAGE STANDARD.

9 | 19144 | ADHESIVE FLAT MARKERS (10 PCS)

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

- Reflective surface for visibility to infrared navigation camera
- For calibration and registration of imaging device (additional hardware required)
- Enables Automatic Image Registration with Brainlab navigation (additional software required)

Suitable for following imaging hardware:

- Airo
- Siemens CT scanners (iCT)
- Siemens Artis zeego (iAngio 3D)

IMPLEMENTATION SERVICES SURGERY

10 | B14297 | PLANNING AND INSTALLATION LOOP-X

Article includes the following planning and installation services for one (1) Loop-X Mobile Imaging Robot. To guide the discussion and implementation, Brainlab will provide a pre-installation data package upon order confirmation, stating all specifications and requirements for a Loop-X Mobile Imaging Robot installation.

NOTE: In case a planned project management or installation visit is delayed or cancelled due to a reason attributable to the customer, Brainlab may charge for additionally incurred service hours and travel expenses for extra onsite visits. Subsequent changes to the project specifications at request of the customer may result in additional consulting and project management costs. Accordingly supplemental claims may be invoiced separately as part of a change management process.

81001-51 | INSTALLATION LOOP-X

- Coordination of installation schedule with key hospital stakeholders
- Unpacking and inspection of delivered material
- System adjustment and calibration
- Hospital network integration, including test and verification of data transfer
- If used in combination with a Brainlab Navigation Platform:
 - Navigation platform integration
 - DICOM access point installation with existing navigation platform
 - Calibration test and accuracy verification with navigation platform
 - Verification of remote support connectivity with Brainlab Connected Care
 - Function and precision check of all software and hardware components
 - System Acceptance according to Brainlab Quality System test procedure
 - Installation work during business hours

89009-33 | PROJECT MANAGEMENT LOOP-X

- Evaluation of project feasibility and documentation of site specific requirements and special requests (if applicable)
- Planning of logistics, location, integration, connection of the system into the customer environment and compatibility with third party products (if applicable)
- Consulting and clarification of project specific special requirements, e.g. site induction, work safety, regulatory requirements and logistics (if applicable)
- Project Management including time, quality and cost planning, installation scheduling, communication and alignment with involved stakeholders (hospital, third party companies and Brainlab).
- Planning, conducting and documentation of in- and external project meetings
- Off-site supervision of site and work progress related to the scope of work
- Continuous management of project adaptations including change request communication and documentation incl. supplemental claim management

EDUCATION AND TRAINING

11 | 83992-06 | USER TRAINING LOOP-X MOBILE IMAGING ROBOT (ON-SITE)

On-site User Training for Loop-X mobile Imaging Robot including:

- Loop-X features and functionalities
- Transportation and storage
- Daily putting into operation and calibration
- Clinical OR Setups
- Acquisition of 2D and 3D X-ray images
- Automatic image transfer between Loop-X and hospital network or other devices
- Navigation platform integration workflows and registration software (if applicable)

NOTE: The training will be delivered on consecutive days (max.5). Travel and accommodation for the trainer is included.

12 | 83053-10 | CLINICAL LAUNCH PACKAGE LOOP-X (1 CONSECUTIVE WEEK)

The Clinical Launch Package Loop-X provides onsite expertise in support of a successful clinical program launch. Accelerating time-to-proficiency in clinical application and ensuring fast, seamless integration of Brainlab technology in existing clinical environments beyond the principles learnt during initial user training, this package is recommended for hospitals with a user team of 1-2 surgeons.

Included in this package are the following items:

- One (1) consecutive week on-site clinical launch by specialized surgery services expert team
- Support in depth clinical application of principles learnt during initial user training
- On-site guidance and assistance to surgeons and clinical staff during first surgeries and clinical use of Brainlab systems
- Together with the user team, optimize existing and design new, surgeon-specific clinical workflows for various indications of use
- Provision of Clinical Launch follow-up report at conclusion of launch phase

NOTE:

This service is to be provided Monday through Friday, excluding Weekends & Holidays.

For larger user teams (3+ surgeons), Brainlab recommends a two (2) week launch program (2x Art-No. 83053-10)

FREIGHT, INSURANCE AND FEES

13 | 50780 | FREIGHT, INSURANCE AND FEES

14 | 50798 | LOOP-X FREIGHT, INSURANCE, FEES

Includes temperature- and humidity-controlled shipment, shipment insurance and fees if applicable.

Curve with Elements

LOOP-X

15 | B13236 | CALIBRATION PACKAGE LOOP-X

Hardware for calibration of Loop-X for Automatic Image Registration and integration with navigation.

19142-06 | DRAPELINK INTERFACE FOR ICT CALIBRATION PHANTOM

19144 | ADHESIVE FLAT MARKERS (10 PCS) (x2)

For a detailed product description please refer to position 9 on page 11.

19148-01 | CALIBRATION PHANTOM ICT

Calibration phantom to calibrate a CT, 3D Angio, Conebeam-CT scanner for Automatic Image Registration and verify the accuracy.

- Reference lines to align with CT laser
- Notches for verification of registration accuracy

19148-02 | CALIBRATION PHANTOM ICT CASE

Case for save storage of Calibration Phantom iCT.

19152-02 | DRAPELINK REFERENCE ARRAY CRANIAL

Radiolucent cranial reference array with 4 marker spheres. Spare part of Cranial Reference Unit Drapelink (art. 19152). MR conditional up to 3T. Sterilizable.

16 | 26760 | AUTO-REGISTRATION SOFTWARE LOOP-X SPINE SUBSCRIPTION

Software module for Brainlab navigation systems enabling automatic receipt and registration of spinal image data from Loop-X. Intraoperative images are made available for navigation immediately after the scanning process for optimized surgical workflows.

- Option to start navigation without preoperative image set
- Direct and automatic receipt and conversion of DICOM data
- Eliminates the need for manual registration in spinal procedures
- Marker detection algorithm for automatic calibration of Loop-X
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

REQUIREMENTS

- Latest generation Brainlab navigation platform
- Loop-X Calibration Package
- Latest Generation Navigation Software Spine & Trauma 3D (1.5)

17 | 26764 | AUTO-REGISTRATION SOFTWARE LOOP-X CRANIAL SUBSCRIPTION

Software module for Brainlab navigation systems enabling automatic receipt and registration of cranial bony structures image data from Loop-X. Intraoperative images are made available for navigation immediately after the scanning process for optimized surgical workflows.

- Option to start navigation without preoperative image set
- Direct and automatic receipt and conversion of DICOM data
- Eliminates the need for manual registration in cranial procedures
- Marker detection algorithm for automatic calibration of Loop-X
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

REQUIREMENTS

- Compatible platform: Kick 1 with Performance Upgrade Kit, Curve (all versions), Curve CM, Buzz IGS
- Calibration Package Loop-X
- Latest Generation Cranial Navigation Software

PLATFORM

18 | 17730 | CURVE NAVIGATION SYSTEM

High-performance system for passive, optical navigation including a mobile touch display cart and a separate infrared camera cart for flexible positioning in the O.R.

- Large 32" capacitive touch display for clear viewing and easy control
- 4K resolution (3840 x 2160 pixels) for brilliant visualization of clinical data
- Display drape allows operation within sterile field
- Mobile camera cart with telescopic stand
- Infrared camera with a large tracking volume for flexible positioning
- Integrated laser pointer for fast and intuitive camera alignment
- Motorized joints for remote-controlled camera alignment
- Integrated HD video camera for O.R. streaming or documentation of the surgical field
- WiFi module for wireless communication to hospital network access points (WiFi 5, up to 867 Mbps) - available in specific countries
- High-performance computer with Intel® Core™ i9-10900X X-series 10-core Processor 3.7/4.7 GHz, 32 GB RAM memory and 1 TB SSD
- Easily accessible connection panel for integration of intraoperative devices
- Digital and analog video interfaces including 4 x 3G-SDI Video-In, DVI Video-In, 2 x DP Video-out
- Simultaneous access to PACS and network based devices with 4 x LAN (up to 1 Gbit/s each)
- Fast data transfer with 4 x USB 3.0

Option to add electromagnetic tracking with the Curve® Navigation - Extension EM Tracking

Option to add a second Curve Navigation display cart

Option to combine Curve Navigation System with Buzz® Digital O.R., existing displays and tablets
Supports Brainlab Mixed Reality application
Requires Brainlab Origin Data Management

ELEMENTS SUBSCRIPTION

19 | 26415 | ELEMENTS VIEWER SMART LAYOUT SPINE SUBSCRIPTION

Intelligent, indication-specific Smart Views for spinal indications exploiting anatomical information from Anatomical Mapping

- Automatic, anatomically aligned multi-planar reconstructions along the spinal cord
- Effortless assessment of pedicle anatomy
- Quick and easy estimation of screw dimensions
- Intraoperative or postoperative verification of screw placement
- Optimize workflow by preparing views in the office and access them later in the O.R.

PLATFORM COMPATIBILITY

- Brainlab and 3rd party Planning Workstations and Servers (which meet minimum technical requirements)
- Buzz 2.0
- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2
- Curve Navigation 2.0
- Kick 2.0

LIMITED PLATFORM COMPATIBILITY

- Buzz 1.0 (requires Performance Upgrade Kit for Buzz)
- Curve 1.0 (requires Performance Upgrade Kit for Curve)
- Additionally required: Remote Processing for Elements (Client) combined with a Brainlab Node or 3rd party Server with Remote Processing for Elements (Server)

REQUIREMENTS:

- Elements Viewer 3D
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

20 | 26200 | ELEMENTS SMARTBRUSH SUBSCRIPTION

Quick and easy interactive 3D contouring tool for outlining of pathologies and anatomical structures in medical images.

- Instant volume generation by outlining on just two orthogonal slices using multi-modal "Side by Side" or axial, coronal and sagittal view configurations
- Intelligent contour propagation with ambient edge detection supporting various CT, MR, CBCT or PET sequence
- Point coordinates and multi-line distance measurement support approach-planning
- Fast contour adaptation using "SimpleBrush" or "SmartBrush" modes
- Threshold segmentation based on user-defined intensity values e.g. for vessels, burned-in objects or fractures
- Intuitive user interface with both mouse and touch control compatibility
- Automatic creation of "Volumetric Report" PDF files per object with representative screenshots and details on geometrical measurements like volume, RECIST and MacDonal criteria
- Smooth creation of additional organs at risk or objects, based on ELEMENTS SEGMENTATION (optional)
- Expandable with SmartBrush Angio for neurovascular indications

INCLUDED SERVICES:

- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

INSTALLATION REQUIREMENTS:

Elements can be installed on the supported Brainlab hardware, 3rd party platforms or virtual machines, as long as the software and hardware requirements are fulfilled. For details please refer to the attached document:

PLF TS EN Elements Installation Requirements.pdf

21 | 26217 | ELEMENTS IMAGE FUSION SUBSCRIPTION

- Fast and precise fusion, based on mutual information algorithm enables to exploit all anatomical & functional data sets simultaneously
- Automatic fusion of numerous modalities including CT, MRI (T1, T2, FLAIR, MRA), PET, SPECT
- Automatic pair selection with instantaneous pre-alignment and fusion
- Possibility of manual fine-adjustments in all dimensions
- Definition of a "Region of Interest" in all dimensions to exclude areas from fusion
- Color overlay in amber-blue and Spyglass functionality for reviews
- Ability to fuse a series of image datasets from different modalities and points of time
- Compatible with datasets of various body regions
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

PLATFORM SUPPORT

- Buzz, Curve, Kick
- Brainlab- and customer planning stations or servers which meet Minimum Technical Requirements

22 | 26388 | ELEMENTS VIEWER 3D SUBSCRIPTION

- Intuitive image viewing, manipulation and data enrichment software specifically developed for surgeons
- Instantaneous, high-quality 3D visualization for analysis by and increased diagnostic confidence of the surgeon.
- 3D volume rendering of CT, MR, PET, SPECT datasets, with presets for visualization of skin, bone, vessel, DRR and MIP
- Toggle functionality to select between default and anatomical-specific textures and view anatomical data based on personal preferences
- Manual or automatical alignment of ACS and 3D views along the Frankfurter horizontal plane
- Superimposition of 3D dataset visualization and surgical planning data (volume objects, trajectories and labeled points)
- 3D multi-planar reconstructions in multiple planes (axial, coronal, sagittal, oblique)
- Concurrent display of multiple medical image series with flexible hanging protocols
- Image annotations and measurement functions for distance, angles and circles
- Selection of region of interest to cut and zoom onto the relevant anatomical volume
- Crop functionality to cut viewing plane into 3D visualization along any freely definable direction
- Equipment removal functionality from 2D and 3D reconstructions for better anatomical viewing
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might

change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

23 | 26711 | ELEMENTS SCREW PLANNING SPINE SUBSCRIPTION

Planning Software to enable planning of screws and trajectories for Spine & Trauma procedures.

- Manual planning of any type of screws on CT, XT and MR
- Automatic planning of thoracic and lumbar pedicle screws on CT
- Automatic rod visualization and rod length estimation on CT
- Different screw visualization options
- Runs on all Brainlab navigation platforms as well as PC/Server

PLATFORM COMPATIBILITY

- Brainlab and 3rd party Planning Workstations and Servers (which meet minimum technical requirements)
- Buzz 2.0
- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2
- Curve Navigation 2.0
- Kick 2.0

LIMITED PLATFORM COMPATIBILITY

- Buzz 1.0 (requires Performance Upgrade Kit for Buzz)
- Curve 1.0 (requires Performance Upgrade Kit for Curve)
- Additionally recommended: Remote Processing for Elements (Client) combined with a Brainlab Node or 3rd party Server with Remote Processing for Elements (Server)
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

24 | 26201 | ORIGIN DATA MANAGEMENT SUBSCRIPTION

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 (Brainlab Connected Care)

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 related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met
Minimum Screen Resolution also for Client Monitors (Radiotherapy) : 1920 x 1200

25 | 26250 | ELEMENTS TRAJECTORY PLANNING CRANIAL SUBSCRIPTION

Features

- Planning of multiple trajectories for neurosurgical approaches
- Flexible 3D shapes for case-specific trajectory visualization (e.g. DBS leads, sEEG electrodes, shunts, biopsy needles etc.)
- Automatically estimate and adjust the orientation of Boston Scientific directional leads
- Apply pre-defined Boston Scientific 3D lead templates
- Apply safety margin around trajectories e.g. for BenGun approaches
- Verification of trajectories in Axial, Coronal, Sagittal, Probe's Eye and Inline reconstructions
- Fully integrated with Elements Cranial Distortion Correction, Basal Ganglia Segmentation, Fibertracking and Smartbrush
- Combined visualization of supplemental information such as Fibertracks, Nuclei and Leads
- Precise multiline, point, and angle measurement tools
- Multiple view layouts for optimal interactive target, entry and trajectory planning

New in Version 2.6:

- Visualise multimodal information simultaneously with Blending Mode
- Set your windowing setting with the Windowing Histogram
- Extended Measurement Toolset with multiline, point, and angle measurements
- Change your target point with a single click
- Create an increased variety of lead, electrode, and probe models
- Use an extended set of 3D Views to get an overview of the procedure plan
- Secure your plan from unintended changes with the Locked Mode

PLATFORM COMPATIBILITY

- Minimum version of Patient Data Manager: 2.7
- Buzz Digital OR
- Curve and Kick navigation systems
- Brainlab planning workstations which meet minimum technical requirements
- Non-Brainlab customer workstations which meet minimum technical requirements. Quotation of article 10959 - CUSTOMER HARDWARE ID is mandatory
- Brainlab Node server or customer server which meet minimum technical requirements

MINIMUM SYSTEM REQUIREMENTS

- Operating System: Windows 8.1 (64-bit)
- Processor: 4 logical cores
- RAM: 6 GB
- Graphics: DirectX 12 compatible
- Display resolution: 1920x1080

MINIMUM SERVER REQUIREMENTS

- Windows Server 2012 R2 64 Bit with minimum RAM of 16 GB

SERVICE REMARKS

- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals

- Software subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

NAVIGATION CRANIAL

26 | 26650 | NAVIGATION SOFTWARE CRANIAL SUBSCRIPTION

Navigation software for image-guided neurosurgery.

- Smart composition of view layouts provides optimal data selection based on available patient data
- Navigation on multiple fused data sets (e.g. CT, MR, FLAIR, MRA, DSA, PET, SPECT)
- Intuitive customization and population of 3, 4 or 6 views layouts via “drag-and-drop”
- Individually configurable navigation views (selection between multiple 2D reconstructions and 3D visualizations)
- Overlay of fused CT and ultrasound image sets consolidates relevant anatomical details of different modalities in one view
- Adjustment of overlay threshold and transparency for direct comparison with underlying dataset
- 3D Smart Approach view simulates path from incision to defined target structure with dynamic zoom, optimizing spatial orientation
- Dynamic 3D view visualizes patient data with a cut perpendicular to the instrument plane to visualize the structures surrounding the instrument
- Display of fibers in true red-green-blue color code for detailed functional information
- Real-time tracking and visualization of navigated instruments (e.g. Cranial Pointer, Microscope, Ultrasound, etc.) in 2D and 3D navigation views
- In-plane distance measurement between navigated instrument tip and anatomical landmark
- Smart, virtual extension of navigated instrument to the center of the defined target structure visualizes deep-seated anatomy supporting approach planning
- Definition of view center to adjust the data seen in a view, e.g. both the navigated instrument tip and a deep-seated lesion
- Digitizing of anatomical landmarks for later reference and documentation
- Acquisition of instrument offset defines a trajectory and supports biopsy planning
- Screenshot feature for documentation purposes

APPROACH PLANNING SUPPORT

- 3D Smart Approach view: Automatic 3D visualization of bone (MR-based when no CT available), cortex, cerebrum and cortical vessels (based on MRI T1 with contrast agent) summarizes relevant information
- Virtual scrolling through 3D patient plan reveals underlying anatomy and planned objects providing guidance during approach planning
- Virtual scalpel simulates craniotomy and creates a “bone flap” object that can be exported and saved for documentation purposes
- Choice of Approach Planes (relative to instrument, patient position and setup), Inline reconstructions and Axial, Coronal and Sagittal views

REQUIREMENTS

- Registration Software Cranial
- Navigation Pointer Cranial/ENT
- Patient Reference Array Cranial (2 pcs)
- Patient Reference Attachment Arm

OPTIONAL

- Navigation Software Cranial – Extension Angio
- Instrument Setup Software Cranial/ENT
- Alignment Software VarioGuide
- Patient Reference Attachment Universal
- Patient Reference Package Skull Mounted

PLATFORM COMPATIBILITY

- Buzz Navigation (Ceiling-Mounted)
- Curve Ceiling-Mounted
- Curve 1.1
- Curve 1.2
- Curve Navigation
- Kick 2.0

LIMITED PLATFORM COMPATIBILITY

- Curve 1.0 (requires Performance Upgrade Kit for Curve)
- Kick 1.0 (requires Performance Upgrade Kit for Kick)
- Additionally required: Remote Processing for Elements (Client) combined with a Brainlab Node or 3rd party Server with Remote Processing for Elements (Server)
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

27 | 26645 | REGISTRATION SOFTWARE CRANIAL SUBSCRIPTION

Software for registration of cranial patient data for image-guided neurosurgery.

- Paired points matching technique to correlate image set to patient anatomy
- Anatomical landmarks or marker-based patient registration
- Semiautomatic Multi-Modality Donut Marker detection
- Registration based on pre-operative CT or MRI data sets
- Planning of anatomical landmarks for "Rescue Registration" in case of registration loss

REQUIREMENTS

- Navigation Software Cranial
- Softtouch Registration Pointer

OPTIONAL

- Registration Software – Extension Surface Matching Cranial
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

28 | 26648 | NAVIGATION SOFTWARE CRANIAL - EXTENSION SURFACE MATCHING REGISTRATION SUBSCRIPTION

Extension of Registration Software Cranial to support surface matching registration of cranial patient data for image-guided neurosurgery.

- Registration based on available CT or MRI patient data
- Minimizes skin-shift inaccuracies compared to marker-based registration methods
- Pre-registration based on guide points acquisition for a more robust registration result
- 3D display of patient data for registration area identification
- 3D threshold adjustment for optimized registration results
- Animated registration 'guide' for set-up and tool specific support with continual feedback
- Contactless acquisition of surface registration points on patients' skin with Z-touch Laser Registration Pointer
- Selective acquisition of registration points with the Softtouch Registration Pointer anywhere on the patients' skin to support challenging patient positioning, i.e. prone position
- Acoustic and visual registration status information
- Automatic correlation of acquired surface points with anatomical data
- Easy verification of registration result through display of acquired points in the 3D patient data view

REQUIREMENTS

- Registration Software Cranial
- Z-touch Laser Registration Pointer

- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

29 | 22228 | INSTRUMENT SETUP SOFTWARE CRANIAL/ENT SUBSCRIPTION

Software to integrate instruments for image-guided neuro- and ENT surgery.

- Surgical instrument integration with diameter, length and instrument trajectory using instrument adapters (S, M, L, XL clamps and M, ML, L, XL arrays) and Instrument Calibration Matrix
- Pathway control of instruments through pre- or user-defined Inline and Probe's Eye navigation views
- Visualization of patient data and instrument shapes in 3D for comprising overviews and improved spatial orientation

REQUIREMENTS

- Navigation Software Cranial or Navigation Software Cranial/ENT
- Instrument Calibration Matrix
- Instrument Integration Accessory Package (2 Sizes)

OPTIONAL

- Instrument Integration Accessory Package (4 Sizes)
- Instrument Adapter Clamp (Cylindrical Instruments)
- Instrument Adapter Clamp (Rectangular Instruments)
- Instrument Adapter Offset 45°
- Multiple Tip Pointer Package
- Instrument Set ENT (5 Tips)
- Instrument Set ENT – Extension Structure Acquisition (2 Tips)
- Instrument Suctions Package (Set of 4)
- Instrument Suctions Package (Set of 7)
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

30 | 26529 | ALIGNMENT SOFTWARE VARIOGUIDE SUBSCRIPTION

Software for precise alignment of the VarioGuide to a defined trajectory.

- Dialog box guided step-by-step adjustment of VarioGuide joints
- Dialog box auto-proceed function minimizes user interaction during alignment process
- Alignment summary with quantitative deviation measurement for result verification

REQUIREMENTS

- VarioGuide Alignment System
- T-Adapter Headholder
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

NAVIGATION SPINE & TRAUMA

31 | 26509 | NAVIGATION SOFTWARE SPINE & TRAUMA 3D SUBSCRIPTION

Image-guided surgery software for Spine and Trauma navigation:

- Real-time tracking and 2D/3D visualization of a pointer and of up to 4 instruments simultaneously in various views
- Compatibility to multiple pre- and intraoperative imaging and registration options (CT, CBCT and MR), including navigation of 2D Loop-X images
- Large variety of navigation view options (Inline and Probe's eye views, 3D view, MIS view, DRR view, Cropped DRR view, Autopilot view)
- Simultaneous navigation on multiple fused datasets (e.g. MR, CT, CBCT; in combination with Elements Image Fusion)
- Overlay of preplanned objects into navigation views (e.g. tumor volume, screws; in combination with Planning Elements)
- Automatic, anatomy-based centering of navigation view to eliminate manual adjustments and simplify MIS procedure workflows
- Automatic selection of navigation views based on the approach and orientation of the instrument (e.g. for pedicle screws or SI screws)
- Smart View for scrolling through the scan slices, following the curvature of the spine.
- Quick adjustment of navigation views to the curvature of the spine to see both pedicles in a locally aligned axial view in deformity cases
- Enhanced ruler view for optimized screw estimation
- Instrument based intraoperative screw planning and including update of planned screws
- MIS-Skin-Bone view for incision and access navigation already on skin level.
- Support of navigated disc preparation instruments and navigated interbody cages of various shapes.*

- Special, calculated view that provides an intuitive overview in the interbody space during navigation in respect to cranial and caudal endplates
- Smart app switching between Navigation and Cirq creates a more streamlined user feel and eliminates the need for screen interaction.**

PLATFORM COMPATIBILITY

- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2
- Curve Navigation 2.0
- Kick 2.0

REQUIREMENTS

- Accessory Package Spine Basic
- Registration Software Spine
- Instrument Setup Software Spine
- Alignment Software 2.0
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

32 | 22271 | INSTRUMENT SETUP SOFTWARE SPINE SUBSCRIPTION

Instrument Setup Software for Spine and Trauma Navigation:

- Enables the preparation of multiple instruments such as drill guides, pedicle access needles, taps, screwdrivers, awls, probes and chisels for the use with the Navigation Software Spine & Trauma 3D & Cirq
- Includes many predefined instruments from Brainlab, DePuy Synthes and Aesculap with assembly instructions, specific visualizations and accuracy check
- Enables calibration of disc preparation instruments and for interbody cages of various shapes
- Other 3rd party instruments can be calibrated with different visualization possibilities
- Enables a quick and remote-controlled re-calibration method for screwdrivers, when screw sizes are changed during the procedure
- Frequently used instruments can be stored as favorites for a more streamlined and efficient instrument setup workflow
- Easy possibility to re-verify instruments and to delete existing calibrations

PLATFORM COMPATIBILITY

- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2

- Curve Navigation 2.0
- Kick 2.0

REQUIREMENTS

- Accessory Package Spine Basic
- Navigation Software Spine & Trauma 3D
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
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33 | 26513 | REGISTRATION SOFTWARE - EXTENSION SURFACE MATCHING SPINE SUBSCRIPTION

Manual surface-matching registration for Spine and Trauma navigation:

- Registration of preoperative or intraoperative CT datasets
- Points are acquired with the pointer and automatically matched to the bone surface in the dataset
- Integrated video guidance supports the user during the acquisition
- Automatic monitoring of achieved registration accuracy and improvement suggestions if applicable
- Supports Disposable Clip-on Remote Control for more streamlined point acquisition

PLATFORM COMPATIBILITY

- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2
- Curve Navigation 2.0
- Kick 2.0

LIMITED PLATFORM COMPATIBILITY

- Curve 1.0 (requires Performance Upgrade Kit for Curve)
- Kick 1.0 (requires Performance Upgrade Kit for Kick)

REQUIREMENTS

- Accessory Package Spine Basic
- Navigation Software Spine & Trauma 3D
- Registration Software Spine
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

34 | 26781 | REGISTRATION SOFTWARE SPINE SUBSCRIPTION

Manual registration for Spine and Trauma navigation:

- Points are planned in the dataset and acquired with the navigation pointer ("Paired Points").
- Registration works on CT and XT datasets
- Supports Disposable Clip-on Remote Control for more streamlined point acquisition.

PLATFORM COMPATIBILITY

- Buzz Navigation (Ceiling-Mounted)
- Curve 1.1
- Curve 1.2
- Curve Navigation 2.0
- Kick 2.0

LIMITED PLATFORM COMPATIBILITY

- Curve 1.0 (requires Performance Upgrade Kit for Curve)
- Kick 1.0 (requires Performance Upgrade Kit for Kick)

REQUIREMENTS

- Accessory Package Spine Basic
- Navigation Software Spine & Trauma 3D
- Includes related software updates and upgrades within terms of use - additional service costs occur, if not installed remotely via Brainlab Connected Care
- Includes 24 hours, 7 days a week phone support hotline operated by technical professionals
- subscriptions will automatically renew with extension by 12 months, unless written notice is provided to Brainlab at least 60 days before the expiration of the then current term
- With regular updates and upgrades of the software the technical requirements for the hardware might change over the course of the subscription period and compatibility of hardware with software might be affected. Brainlab shall not be responsible and/or liable if this requirement is not met

AUTOMATIC PATIENT REGISTRATION

35 | 19153 | DRAPELINK ADAPTER KIT

Radiolucent skull clamp adapter kit for rigid and accurate attachment of Cranial Reference Unit Drapelink (art. 19152) to compatible skull clamps. All components are MR conditional up to 3T and sterilizable.

The kit consists of:

- 1x Base Long for Drapelink (art.19153-03)
- 1x Base Short for Drapelink (art.19153-04)
- 1x Adapter for Mayfield Skull Clamp (art.19153-01)
- 1x Adapter for Doro Skull Clamp (art.19153-02)

COMPATIBLE SKULL CLAMPS:

- DORO® Skull Clamp Radiolucent (item-no. 3034-00); supplied by Black Forest Medical Group (formerly PMI)
- DORO LUCENT® iMRI Skull Clamp Radiolucent (item-no. 4003); supplied by Black Forest Medical Group (formerly PMI)
- Integra MAYFIELD XR2 Radiolucent (A-2079); supplied by Integra Life Science Corp.

REQUIRES

Cranial Reference Unit Drapelink (art. 19152)

36 | 19152 | CRANIAL REFERENCE UNIT DRAPELINK

The Cranial Reference Unit Drapelink is optimized for navigation with intraoperative imaging. It allows a rigid and accurate attachment of the reference array to compatible skull clamps without compromising the sterile field. The unit consists of two pairs of radiolucent interconnectors and reference arrays with 4 marker spheres for sterile (navigation) and non-sterile (registration) use. All components are MR conditional up to 3T and sterilizable.

Includes: Steritray and Storage Case

Requires: Reflective Marker Spheres

REQUIREMENTS FOR iCT AND iANGIO WORKFLOWS:

- Cranial Navigation Software 3.x (art. 22216)
- Adapter Kit for Drapelink (art. 19153)
- The CT scanner requires an aperture of minimum 78 cm

REQUIREMENTS FOR iMRI WORKFLOWS WITH AUTOMATIC IMAGE REGISTRATION:

- Cranial Navigation Software, min. version 3.1
- for GE scanners: Revision C of iMRI REGISTRATION MATRIX FOR GE (art. 19202)
- for Siemens/Philips scanners: "Drape Link Adapter II #118521 Rev 01" with "Universal Angle Adapter # 11392" (for both parts distribution by Noras mri products GmbH)

ACCESSORIES CRANIAL

37 | 55758-30 | SCREWDRIVER

Autoclavable screwdriver for axial operation of slider locking screw (i.e. spine reference clamp carbon with slider) or secure tightening of drill depth stops.

- Reduces clamp movement during mounting
- Allows for fine adjusted tightening and firm fit of the clamp
- 2.5 MM hexagonal tip with rounded outline for tilted operation of screw

ACCESSORIES SPINE & TRAUMA

38 | 55758 | SPINE REFERENCE CLAMP CARBON WITH SLIDER

Spinous process reference clamp enabling patient tracking in combination with Spine Reference Array for Reference Clamp Carbon (4-Sphere Geometry) for use in the entire spine.

- one clamp for all regions of the spine
- less x-ray artifacts by optimized material mix for intra-OP imaging
- extension provides for local adaptation
- better grip with adaptive pin plate, performing pin geometry and optimized pin material
- slim profile with axial operation of slider and screw
- fast fit with quick-lock slider and spring loaded branches
- firm fit with fine adjusted tightening amplification mechanism
- bayonet interface for quick and firm array fixation includes adaptable array rotation

REQUIREMENTS:

- Screwdriver #55758-30 (x2)

39 | 55761 | SPINE REFERENCE ARRAY FOR REFERENCE CLAMP CARBON (4-SPHERE GEOMETRY)

Enables patient tracking in combination with Spine Reference Clamp Carbon With Slider:

- Design optimized for accuracy, reliability and usability.
- Connects to Brainlab Spine Reference Clamp Carbon With Slider, to Spine Reference Clamp Extension(40mm) or to 2-pin bone fixator via x-press connector clamp
- Array may be oriented around 3 axes.
- Tool-free fixation of all axes.
- Compatible with Brainlab Reflective Marker Spheres
- Autoclavable

REQUIREMENTS:

- Spine Reference Clamp Carbon With Slider
- Reflective Marker Spheres
- Spine & Trauma 3D 2.6 software and AIR 1.3 or Navigation Software Fluoro Express 2D (minimum required versions for 4-sphere geometry)

IMPLEMENTATION SERVICES SURGERY

40 | 89109-04 | INSTALLATION AND CONFIGURATION BRAINLAB CONNECTED CARE

Brainlab Connected Care 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 Connected Care is a service built on PTC ThingWorx and hosted on Microsoft Azure servers. Combining the power of these platforms, Brainlab Connected Care uses only industry-standard security features through HTTPS, including encrypted storage and transmission of sensitive data, security logging sub-systems, and support for TLS 1.2 to ensure that all data transmitted is safely encrypted with Advanced Encryption Standard (AES) 256-bit.

41 | 81001-11 | INSTALLATION CURVE NAVIGATION SYSTEM

Installation and acceptance of one Curve Navigation System performed by certified Brainlab Service personnel, including the following services:

- Installation coordination and scheduling with involved hospital stakeholders
- System unpacking and assembly
- Installation and configuration of Brainlab software
- Basic IT integration including connection to DICOM, setup of DICOM Query Retrieve and DICOM PUSH, modality worklist and intraoperative modality integration, manual/automatic data saving to central archive, active directory integration
- Verification of completeness, functioning, precision, faultlessness of all soft-and hardware components
- System Acceptance and hand-off to customer

FREIGHT, INSURANCE AND FEES

42 | 50780 | FREIGHT, INSURANCE AND FEES

Clinical Support

SERVICE AGREEMENT SURGERY

43 | 83053-01 | CLINICAL CONSULTATION INTRAOPERATIVE IMAGING (12 CONSECUTIVE MONTHS)

A certified Brainlab Consultant will be available Monday – Friday during normal business hours for twelve (12) consecutive months. Allowing availability to provide optimal support for Brainlab intraoperative imaging and Curve navigation products, ensuring that Brainlab products are being used to their fullest potential. The following services are included:

- Educate/train physicians and hospital personnel, including Radiology, OR staff, Central Sterile Processing, Biomedical and Information Technologies staff, on the use of Brainlab intraoperative imaging and other Brainlab products and services as required.
- Provide on-site guidance and assistance to physicians and OR personnel during surgery and diagnostic use of Brainlab intraoperative imaging system, to maximize efficiency and usage of Brainlab products.
- Provide guidance to radiology staff regarding scan protocols to perform any required pre-operative MR scans that can merge with intra-operative CT data acquired with Brainlab intraoperative imaging system.
- Develop and conduct training programs for hospital staff enabling them to implement in-house training-
- Utilize expertise to contribute to the quality improvement process by recommending product modifications to in house development teams.
- Coordination of Brainlab Technical Specialists as required.
- Act as primary customer liaison maintaining contact with customers and assessing satisfaction.

NOTE: Clinical Consultation packages are sold as consecutive time frames and cannot be separated into individual days / weeks. The twelve (12) months period does not include the time, when the Consultant is off due to vacation, public holidays, approved personal days and off-site training. Technical services for system hardware and 3rd party integrations are not included.

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 occurrence of any such malfunction;
 - faults, failures or damages caused by intentional or negligent behaviour; or
 - circumstances beyond Brainlab's control, including but not limited to force majeure, acts of God, power and/or environmental failures.
- 13.2. Customer shall allow Brainlab free access to the Products, including online access if remote service is performed. This shall, in particular, not be made contingent on the limitation of Customer's liability. Customer shall offer a suitable workplace, including access to a telephone if needed. Brainlab shall use this telephone line exclusively to perform the Services.
- 13.3. Customer shall ensure safe conditions at the location of the Products. Particularly, Customer shall inform Brainlab of existing safety regulations that are relevant for Brainlab personnel.
- 13.4. Customer and Brainlab shall mutually agree on dates and times for Service visits at least 48 hours in advance. This shall not apply to Service provided on a time and material basis, where more advance notice may be required.
- 13.5. Brainlab will provide Services Monday through Friday from 8.00 am until 5.00 pm. Services provided at other times will be charged to the Customer as overtime unless otherwise agreed.
- 13.6. In the event that a Service, installation or other appointment is cancelled due to reasons within Customer's responsibility, Customer shall inform Brainlab at least 24 hours in advance.
- 13.7. In the event that Customer fails to notify Brainlab in due time, Brainlab shall be entitled to charge Customer for all costs reasonably incurred with regard to the appointment.
- 13.8. Brainlab shall respond to Customer reports of malfunctioning Products by phone, fax or email within no more than 24 hours by phone call. If the malfunction cannot be eliminated by phone call, the dispatch of spare parts as well as maintenance and repair will normally be initiated within one working day after the problem analysis by phone, pending availability of personnel and material. Notwithstanding the foregoing, in the event the defective Product is the Brainlab Dash System, or any component or accessory thereto, Customer shall ship such defective Product to Brainlab for replacement or repair. Customer shall properly package the Dash Product so as to avoid damage during transit and shall ship the Dash Product with a reputable carrier and shall provide to Brainlab the applicable tracking information upon shipment.
- 14. INTELLECTUAL PROPERTY, SOFTWARE LICENSES**
- 14.1. All rights to patents, trademarks, and any other intellectual property shall remain the property of Brainlab, its affiliates and/or its licensors, as applicable. Brainlab and/or its affiliates, suppliers and/or licensors presently owns and will continue to own all right, title, and interest in and to the Software and its source code, and any and all copyrights, trademarks, trade names, logos and other proprietary rights in and to the Software and any other materials provided to or otherwise made available to Customer hereunder, and all worldwide intellectual property rights embodied herein
- 14.2. Brainlab grants Customer a limited, non-exclusive, non-transferable license to use 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 prorations 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 perform, 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 Qentry. 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.