DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

March 20, 2017

Jeffrey Shovelin
P.O. Box 6028
Greenville, NC 27835-6028

No Review

Record #:	**2195**
Facility Name:	Vidant Medical Center
FID #:	933410
Business Name:	Vidant Health
Business #:	2131
Project Description:	Acquire an Airo mobile intraoperative CT scanner
County:	Pitt

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of February 27, 2017 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

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

Sincerely,

Jane Rhoe-Jones
Project Analyst

Martha J. Frisone
Assistant Chief, Certificate of Need

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV
TELEPHONE 919-855-3873
LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603
MAILING ADDRESS: 2704 MAIL SERVICE CENTER •RALEIGH, NC 27699-2704
AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER

VIDANT HEALTH™

February 27, 2017

Ms. Jane Rhoe-Jones
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Request for "No Review" for an AIRO mobile intraoperative CT scanner

Dear Ms. Rhoe-Jones:

Pitt County Memorial Hospital, Incorporated d/b/a/ Vidant Medical Center (VMC) is planning to purchase an AIRO mobile intraoperative CT scanner to be operated in the hospital's existing operating rooms. This medical equipment is typically used to support cranial, spine and trauma invasive and minimally invasive surgery, but can also be used anytime a CT image is needed during surgery. Today, VMC uses fluoroscopy to support imaging needs in the operating room, however, the intraoperative CT scanner can produce far better image quality, especially for cranial, spine and trauma surgery patients.

VMC believes the proposed project is not subject to review under North Carolina's Certificate of Need laws. Pursuant to N.C.G.S. 131E-176(14o), the proposed project does not meet the definition of "major medical equipment" as defined below.

> *"Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars ($750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars ($750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.*

Specifically,

1. According to the manufacturer's itemized quote (attached), the total capital cost of the equipment is $749,999. This includes the equipment and all accessories, on-site training, installation, delivery, insurance and fees. Since the equipment is not fixed and can be moved, there are no studies, surveys, designs, plans, working drawings, specifications, construction, and other activities essential to acquiring and making the equipment operational. In fact, according to the manufacturer's pre-installation guide (attached), the system is designed "to fit through a standard doorway and plug into a standard wall electrical outlet."

2. VMC believes the manufacturer's quoted price represents the fair market value for the equipment. This is based on comparing the price other hospitals in North Carolina recently paid for the same system, all of which were granted CON exemption from the Certificate of Need Section (attached). Specifically,

    a. Duke University Health System: No Review granted October 11, 2013 with a purchase price of "less than $750,000" (exact amount not available).

    b. North Carolina Baptist Hospital: No Review granted May 3, 2016 with a purchase price of $749,999.

    c. UNC Hospital: No Review granted August 19, 2016 with a purchase price of $749,999.

Since the manufacturer's quote and the assumed fair market value of the system is less than $750,000, the proposed project does not meet the definition of major medical equipment. Because the proposed project does not meet the definition of major medical equipment, VMC requests a "no review" approval. If you need additional information or clarification, please do not hesitate to contact me at (252) 847-3631.

Sincerely,

Jeffrey Shovelin
Director of Corporate Planning
Vidant Health
PO Box 6028
Greenville, NC 27835-6028
Phone: (252)-714-5156
Email: jshoveli@vidanthealth.com

BRAINLAB

Brainlab, Inc.
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Westchester · IL 60154 · USA

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

Vidant Medical Center.
2100 Stantonsburg Road
Greenville, North Carolina, 27834-2818
United States

www.brainlab.com

Westchester, January 25, 2017
Quotation QN-PCMHGN-GUT-129

Shipment: DDP (Incoterms 2010)
Terms of Payment: See Brainlab Standard Terms and Conditions
The prices and conditions set forth in this quotation are valid for a period of 90 days from the date of its issue. The attached terms with the title 'Standard Terms and Conditions-Brainlab, Inc.' are hereby incorporated and form an integral part of this quotation.

Pos.	Art.No.	Description	Qty.
		AIRO	
1	19650	AIRO MOBILE INTRAOPERATIVE CT	1
2	B13229	AIRO CALIBRATION PACKAGE	1
		INTEGRATED OR 3RD PARTY PRODUCTS	
3	19225	AIRO TRUMPF PATIENT POSITIONING SYSTEM TOTAL SPINE & CRANIAL - USA	1
		ONSITE APPLICATION TRAINING - IGS	
4	83992-03	AIRO TRAINING (5 DAYS)	1
		AIRO SERVICES	
5	83051-01	AIRO INSTALLATION AND FIRST PMI VISIT	1
6	50788	AIRO FREIGHT, INSURANCE AND FEES	1

	Sum USD
TOTAL EXCL. TAX	**749,999.00**

Vidant agress to keep all pricing and terms contained in this quote confidential from all third parties. This includes, but is not limited to, third party buying services like MD Buyline, ECRI and similar services.

Natalie Luttrell
Regional Manager Mid Atlantic
natalie.luttrell@brainlab.com

Technical Quote Review done by

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

(quote automatically reviewed)

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1 | 19650 | AIRO MOBILE INTRAOPERATIVE CT

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

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

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

REQUIREMENTS FOR COMBINED USE WITH NAVIGATION:

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

NOTE:

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

2 | B13229 | AIRO CALIBRATION PACKAGE

Hardware for calibration of Airo Mobile Intraoperative CT.

19652 | GAMMEX PHANTOM W CASE AND STAND

19144 | ADHESIVE FLAT MARKERS (10 PCS)
Adhesive markers attached to selected intra-operative imaging devices enable integration with Brainlab navigation systems.

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

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

19148 | CT SCANNER CALIBRATION PHANTOM
Calibration phantom to calibrate a CT scanner for Automatic Image Registration and verify the accuracy on a routine basis by Brainlab service engineer.

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

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

OR TABLE X-RAY
2x Shuttle 3.6 360
1x Operating table top Carbon X-TRA 7500 U
1x Operating table top U24 U
1x Table top segment carbon 600 U
1x Leg section one part short U

GENERAL PATIENT POSITIONING
2x Clamp pair for joint plate carbon
2x Joint plate carbon 520
4x Side rail U
2x Armboard snaplock trigger
2x Armboard pad 3"
2x Universal Arm Support 450

SPINE STABILIZATION
1x T3 Advance System
1x Ultra Comfort Covers, Medium, case/6
1x Ultra Comfort Covers, Large, case/6

CRANIAL STABILIZATION
1x Adapter X-ray triple joint wide
1x Retainer X-ray
1x Swivel adapter X-ray
1x Skull clamp X-ray (PMI DORO)

ADAPTERS
1x Interface Skull Clamp AL (DBS Adapter) LP
1x Interface Skull Clamp (Biopsy Arm/Varioguide) LP

SHIPPING, INSTALLATION AND TRAINING

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

On-site training for Airo® mobile intraoperative CT including:
- Airo features and functionalities
- Calibration and operational procedures
- Airo specific automatic image transfer to hospital network or other devices
- Navigation platform integration workflows and registration software for cranial and spine (if applicable)

-Eligible for IACET CEUs with completion of training.
This training shall be delivered on 5 consecutive days

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5 | 83051-01 | AIRO INSTALLATION AND FIRST PMI VISIT

Includes the installation of one Airo mobile intraoperative CT system and one site visit to cover one preventive maintenance inspection (PMI) to be done during first year after system acceptance. Provided as described on each article below.

83991-01 | AIRO INSTALLATION

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

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

If applicable:

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

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

83054-04 | AIRO SCANNER - SYSTEM INSPECTION & SAFETY CHECK

This articles provide one visit to perform a preventive maintenance inspection for AIRO portable intraoperative CT scanner, including the examination of the proper functioning of the system modules and products components according to Brainlab quality standards. It will include:

- System inspection
- Filters replacements:
  - Gimbal Filter
  - DMS Filter
- Lubrication:
  - Main Bearing
  - Main Drive
  - Main Drive Chain
  - Main Drive Carriage Rails
  - Z Rails Carriages
  - Caster Lead Screws
- Laser Aligment Check
- High Voltage gasket replacement
- X-Ray Tube / Heater Exchanger Air Purging
- Constancy test (according to Norm (61223-2-6). Note that only one test is provided. Additional tests, not included in this article, may be needed during one year.
  - CDTI Measurements
  - Image Quality Check
- Trumpf column inspection and verification of correct operation.
  A safety check of mechanical and electric devices is also performed.
  Are included the scheduled parts replacement according to AIRO maintenance program and the following material needed for PMI:
  Filter Gimbal Air, DMS Filter (Qty 3), Grease Cartridge Dow Corning 3451, Dupont Chain Saver Lubricant (DCS614101), Nook E-100 Spray Lubricant, THK Grease, AFB-LF

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Notice that the biannual Airo PMI is performed in 2 visits, covering the Airo Scanner and the column. This article include the tasks done during one visit to perform a PMI on Airo Scanner side only.
Performed during regular working hours: Monday through Friday from 8:00am till 5:00pm.

6 | 50788 | AIRO FREIGHT, INSURANCE AND FEES

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

Standard Terms and Conditions-Brainlab, Inc.

1. Definitions and Application

1.1. "Delivery" means (i) with respect to hardware, delivery of the Product, and (ii) with respect to Software, either remote delivery, delivery at Customer's site, or delivery via download. A Software activation key will be provided if applicable.

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

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

1.4. "Services" means the services specifically set out in the Quote or performed as part of or in connection with a Product purchase, rental, or lease or an acquired Software license, such as, for example, installation and warranty services.

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

1.6. "Term" means the time period set out in the Quote for either the provision of Operating Products or a Software license or for the provision of Services.

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

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

1.9. These standard terms and conditions are deemed to be accepted at the latest upon Delivery of the Products and/or performance of the Services.

2. Quote / Order Confirmation

2.1. Brainlab's quotations are non-binding and constitute solicitations for offers to purchase, rent, lease or license only. Brainlab agrees to be bound by the quoted prices for a period of ninety (90) days.

2.2. A Quote may contain Software, hardware Products and/or Services. Hardware Products listed in a Setup Proposal Section of the Quote are offered for sale. Hardware Products listed in an Operating Proposal Section of a Quote are offered on a term basis ("Operating Products") for the identified Term. Software is always licensed, subject to the license conditions set out in Section 14 below and further license conditions set out in the Quote, if any.

2.3. After receipt of Customer's purchase order, Brainlab may conduct a technical contract review in order to review compatibility of the Products and Services with Customer's existing equipment. Subsequently, Brainlab may send Customer a final order confirmation or provide Customer with a new amended quotation according to clause 2.1 above.

2.4. A final and binding contract comes into force no sooner than upon receipt by Customer of Brainlab's final order confirmation.

2.5. If Customer requests any changes to the configuration covered by the contract after receipt of Brainlab's order confirmation, Brainlab shall reasonably consider such request, however additional costs incurred due to the changes shall be borne by Customer.

2.6. Brainlab shall be entitled to appoint subcontractors to perform any Services.

3. Third Party Products

3.1. If Customer enters into any contracts with third parties that are technically related to the Products, Brainlab assumes no responsibility for such contracts with third parties or the products covered thereunder.

3.2. Brainlab warrants compatibility with Third Party Products or other third party products explicitly listed in the Product manual or other technical documentation only in the version which is current on the date of the order confirmation.

3.3. Brainlab shall not be liable for any damages whatsoever occurred due to or in connection with any future changes of any third party products. This applies, for example, to orthopedic or other implants, microscopes, magnetic resonance units, and CT scanners.

3.4. Customer shall make reasonable efforts to make third party products available during installation for any required acceptance or compatibility testing as reasonably required by Brainlab.

3.5. Unless otherwise agreed to by Brainlab, Customer shall be solely responsible for the installation and maintenance of Software that is indicated for use on third party computer hardware.

4. Pricing / Price Increases

4.1. Unless otherwise indicated in the Quote, prices as set forth in Brainlab's quotations are DDP (delivered duty paid). Insurance, freight, taxes and other charges are included in the total Quote price.

4.2. Unless otherwise stated in the Quote, Brainlab reserves the right to adjust any periodic fees, including but not limited to monthly, quarterly or yearly Software subscription or Service fees or fees set out under the Operating or Setup Proposal Section of the Quote, if any ("Periodic Fees"). Such price changes become effective in the contract year following the price adjustment, provided that Brainlab has notified Customer of these changes at least four (4) months in advance.

5. Payment Terms

5.1. Payment terms and/or letter of credit requirements are set out in the Quote.

5.2. If no payment terms are set out in the Quote, the following shall apply:
For total amounts exceeding $15,000.00 USD (or an equivalent amount in any other currency) incl. sales tax, terms of payment are as follows:

- 30% net of total within 3 days from receipt by customer of Brainlab's final order confirmation
- 60% net of total within 10 days from date of Delivery
- 10% net of total within 10 days from date of acceptance of the Product.

For purposes of this Section, for Products, particularly but not limited to Software, where no acceptance procedure is performed, acceptance shall be deemed to have occurred simultaneously with Delivery.
Payments of up to $15,000.00 USD (or an equivalent amount in any other currency) incl. sales tax shall be due and payable in full within 14 days from date of invoice.

5.3. In the event Customer desires to pay the aggregate amount of the Periodic Fees (such amount being the Periodic Fee multiplied by the number of months in the Term) ("Aggregate Fee") in one lump-sum, Customer shall notify Brainlab of such intention and the Aggregate Fee shall be due according to the payment terms set forth in Section 5.2.

5.4. In case shipment or Delivery is delayed due to circumstances caused by or within the responsibility of Customer, Delivery shall be deemed performed, and the payment due upon Delivery shall be due and payable, 30 days after Brainlab reports ability to deliver. Customer shall bear and indemnify Brainlab for any and all additional costs caused by the delay.

5.5. In case of delay of execution of the acceptance protocol due to circumstances caused by or within the responsibility of Customer, payment due upon acceptance of the Product shall be due and payable in full upon the earlier of six months after Delivery or acceptance. Customer shall bear and indemnify Brainlab for any and all additional costs caused by the delay.

5.6. For Services, if no payment terms are set out in the Quote, payments shall be made annually in advance. The first payment shall be due within 10 days from receipt by Customer of the order confirmation.

5.7. If a security deposit is set out in the Quote ("Security Deposit"), it shall be payable within ten (10) days of the date of the related invoice. The Security Deposit may be commingled by Brainlab with other funds and shall not bear interest. If Brainlab applies the Security Deposit to Customer's obligations, Customer shall immediately restore the same. Upon Customer's full performance of all of Customer's obligations, Brainlab shall, at the request of Customer, return any remaining Security Deposit to Customer.

5.8. The first of any applicable Periodic Fees shall be due and payable within ten (10) days of execution of the acceptance protocol or first patient treatment, whichever occurs earlier. Thereafter, the Periodic Fee shall be due and payable before the third day of the respective payment periods indicated in the Quote.

5.9. Customer shall pay as directed by Brainlab or reimburse Brainlab upon demand for all taxes, including but not limited to sales, use, or property taxes (exclusive of federal and state taxes based on or measured solely by Brainlab's net income), fees, charges or assessments, of whatsoever kind, whether based on the fee, rent or levied, assessed or imposed upon the Products or upon or in respect of the manufacture, purchase, delivery, ownership, leasing, use, return or other disposition of the Products, now or hereafter levied, assessed or imposed under the authority of a federal, state or local taxing jurisdiction, regardless of when and by whom payable. In the event Customer is a tax exempt entity, Customer shall notify Brainlab in writing and provide written evidence of such status

5.10. All payments not made when due pursuant to this agreement shall be subject to late charges of the lesser of (i) one and one-half percent (1.5%) per month of the overdue amount or (ii) the maximum amount permitted under applicable law.

5.11. In case of partial Delivery by Brainlab, Customer shall pay an appropriate part of the amount due, e.g. if one or more separable components remain to be delivered, Customer shall pay the amount due for all components that have been delivered. The amount due shall be paid in full if the components that have not been delivered are only of minor value and do not affect the Product's suitability for safe clinical use.

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

5.13. Customer agrees to provide all information reasonably requested by Brainlab to carry out credit approval.

6. Site Planning/ Customization

6.1. The Customer is responsible for the site and technical setup and for meeting any regulatory, structural, or radiation prerequisites as they may be required by Brainlab, or any applicable law. Validation or assessment of such prerequisites shall be at Customer's expense. The readiness for installation, which may require formal validation 10 days prior to installation, may be a condition for beginning the installation at Brainlab's reasonable discretion.

6.2. Customer shall obtain any permits, approvals, licenses, certifications, local or otherwise, that may be required for installation or operation of the Products. If any such requirement is expected to impact Customer's readiness for taking delivery or installation or require changes to the contract, Customer shall notify Brainlab without delay.

6.3. If applicable and included with the Products, Services may include site planning with a design phase for, including but not limited to, layout, electrical wiring, network integration, and routing.

6.4. The formal end of the design phase, if any, is defined as the project milestone "Design Freeze". The Design Freeze document sets out the layout of the Product installation. It is decisive, for example and without limitation, for network specifications, power, grounding, required wiring etc. In the event that Customer requires changes to any item set out in the Design Freeze document, Brainlab and Customer will review the impact of such changes. If Brainlab, in its sole discretion, decides to initiate a change request process, any additional costs that are caused by such changes will be borne by Customer and the project schedule

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

6.5. Customer must approve the Design Freeze in writing.

6.6. In the event of a conflict between the signed Design Freeze and any other previous drawings, tender specifications or other specifications, the Design Freeze shall prevail.

7. DELIVERY

7.1. Brainlab shall use commercially reasonable efforts to deliver the Products within three (3) months from receipt by Customer of Brainlab's final order confirmation or at an agreed date.

7.2. If Delivery is delayed due to Act of God, strike, regulatory difficulties, or due to unforeseen circumstances, Brainlab shall be entitled to postpone performance for the duration of the obstruction and an additional appropriate time to resume performance and/or to make partial shipments or provide partial Services.

7.3. Meeting the scheduled Delivery dates is contingent upon Customer providing proper and reasonable cooperation in a timely manner, including but not limited to the provision of technical support, precise and complete data and information on all aspects related to the Delivery and installation of the Products.

7.4. If the date of Delivery is postponed by Customer or if Delivery is delayed for reasons within the responsibility of Customer, Brainlab may, at its reasonable discretion, ship the Products to storage or, if shipment is already in progress, also revert shipment to Brainlab's premises. Section 5.4. above applies. Any additional costs caused thereby will be borne by Customer, including but not limited to transport and/or storage related costs and insurance. At the reasonable discretion of Brainlab, the Customer shall provide an adequate warehouse with appropriate storage environment (e.g. climate controlled and insured). Brainlab reserves the right to claim further damages.

7.5. Customer shall arrange for barrier-free transportation of Brainlab shipping crates as reasonably required from the Customer's receiving area (including adequate parking space for transportation vehicle) to the installation site or to the storage room, and, if applicable, from the storage room to the installation site. Unless otherwise agreed between the parties, Customer shall provide a loading dock with capabilities for non-power tailgate delivery. Costs for necessary traffic control, rigging and transportation equipment or labor, any adjustments made to doorframes, hallways, ceilings, or other facility structures, as well as dust and noise protection related to existing equipment shall be borne by the Customer.

8. TRANSPORTATION AND RISK OF LOSS

8.1. Brainlab shall be entitled to insure the Products for transportation at Customer's expense. Appropriate means of transportation to Customer's site will be chosen by Brainlab.

8.2. Upon Delivery of the Products to Customer's premises, or, if Delivery is delayed due to circumstances caused by or within the responsibility of the Customer, upon Brainlab's reporting ability to deliver, Customer hereby assumes and shall bear the entire risk of loss of, theft of, damage to, or destruction of the Products from any cause whatsoever ("Casualty Occurrence"). No Casualty Occurrence to the Operating Products shall relieve Customer from its obligation to pay Periodic Fees or to perform any other of its obligations hereunder. Customer shall promptly notify Brainlab in writing of any Casualty Occurrence to Operating Products and shall, at its sole cost and expense, within twenty (20) days cause the repair of any Operating Products to first class condition. Notwithstanding the foregoing, if Brainlab deems repair unfeasible, then, at Brainlab's option, Customer, at its sole cost and expense shall (i) procure from Brainlab the replacement of damaged or stolen Operating Products, or (ii) pay to Brainlab the sum of the following: 1) all sums then due to Brainlab under this agreement 2) the unpaid balance of the Fees attributable to the remainder of the applicable Term and 3) twenty percent (20%) of the total of all costs to Brainlab of and relating to purchasing and making available the Operating Products, plus taxes and other charges.

8.3. For Operating Products, Customer shall, at its sole cost and expense, obtain and maintain commercial general liability insurance and property insurance (including coverage against a Casualty Occurrence in an amount equal to at least the full replacement value of the hardware included in the Operating Products, based on the then current list price) satisfactory to Brainlab covering both personal injury and property damage arising out of or in connection with the use or operation of the Operating Products with limits of at least $1,000,000 USD per occurrence and $3,000,000 USD in the aggregate. Customer shall name Brainlab or Brainlab's assignee as additional insured on the commercial general liability and as loss payee on the property insurance. In addition, the policies shall grant a waiver of subrogation on behalf of Brainlab. Customer shall provide to Brainlab a certificate of insurance evidencing such insurance coverage. Customer hereby irrevocably appoints Brainlab as Customer's attorney-in-fact to make claims for, receive payment of, and execute and endorse all documents, drafts or checks for a Casualty Occurrence or returned premiums under any insurance policy required herein.

9. INSTALLATION / ACCEPTANCE / ACCEPTANCE PROTOCOL

9.1. Installation will be performed (i) remotely or (ii) by a Brainlab Service Engineer or other party designated by Brainlab within three (3) months after Delivery or within a period otherwise agreed upon or set out in the Quote. On-site installation will generally require no more than two visits of a Brainlab engineer, unless otherwise specified by Brainlab. If one visit is sufficient, or if more than two visits will be required, Brainlab will notify Customer in advance.

9.2. If completion of the installation is delayed for more than six (6) months after Delivery due to circumstances caused by or within the responsibility of Customer, including but not limited to false or incomplete technical information regarding Customer's equipment or premises, or incorrect or missing data, Customer shall be charged any and all additional costs resulting from such delay. In addition, Brainlab shall no longer be obligated to perform the installation.

9.3. If more than the specified number of visits of a Service Engineer are required due to circumstances caused by or in the responsibility of Customer, Customer shall bear the additional costs.

9.4. Up to ten (10) man hours of engineer's overtime work , i.e. work outside Brainlab's normal working hours (Mo-Fri, 8 a.m. – 5 p.m.), during installation are included in the price indicated in the Quote. Any additional working hour or fraction thereof outside normal working hours requested by Customer will be charged to Customer according to Brainlab's then current price list.

9.5. After complete installation and prior to final acceptance, one of Brainlab's Service Engineers will test the Products, either at Customer's premises or remotely, to evaluate its capability of functioning according to the specifications. At least one representative of Customer shall be present during this procedure. The acceptance may also have an extended scope covering use of Products in conjunction with third party products.

9.6. After successful performance of the acceptance test, Customer shall accept the Product and sign Brainlab's acceptance protocol to verify acceptance. Customer agrees that signature of a present healthcare professional shall be legally binding on Customer. The acceptance protocol shall become part of the contract. It shall be provided to the Customer prior to installation upon request.

9.7. Acceptance shall not be refused because of minor problems that do not affect the suitability for safe clinical use. Acceptance shall be deemed to have occurred, and the final payment shall be due and payable, if Customer refuses acceptance due to such minor problems.

9.8. The Product may not be used for patient treatment before the applicable acceptance test has been performed successfully and the acceptance protocol has been signed.

9.9. If Customer performs any kind of patient treatment before signing the applicable acceptance protocol, the Product shall be deemed accepted and payment of the last installment shall be due.

9.10. Customer shall be solely responsible for effectiveness, correctness, cost and timely implementation of any clinical and physics setup-procedures, including but not limited to sterilization of non-sterile surgical instruments or acquisition and documentation of radiation beam data, as applicable.

10. EXAMINATION AND NOTIFICATION OF DEFECTS

10.1. Customer shall inspect the packaging and the Products immediately upon Delivery and shall report any damage to the shipping agent without delay.

10.2. During the acceptance test, Customer shall examine the Product in the presence of a Brainlab Service Engineer. Any defect or missing part shall be listed in the acceptance protocol.

10.3. Brainlab will not accept complaints relating to malfunctions or missing items that have not been reported as set out above, unless the defect was indiscernible at the time of the examination.

10.4. In case such defect occurs later, Customer will notify Brainlab within 14 days after occurrence. Otherwise, the Products shall also be deemed accepted regarding this defect.

11. TRAININGS / OR ASSISTANCE

11.1. The contract may also include a specified number of trainings / OR assistance sessions. If the Quote contains Operating Products, all training and OR assistances included as part the description of such Products shall occur within the Term, unless otherwise agreed to by Brainlab. Upon expiration or termination of the Term, Customer shall no longer be entitled to such training and OR assistances. If the Term is for less than one (1) year and Customer renews the Term for any additional period, Customer shall not be entitled to the additional training and OR assistance which is automatically included in the description of the Brainlab Product being renewed. Customer may purchase additional training and/or OR assistance.

11.2. After successful performance of training for Brainlab Products, the training acceptance protocol must be signed by an authorized representative of the Customer, if applicable.

11.3. No Products may be used before the applicable training has been performed and any applicable training acceptance protocol has been signed.

11.4. Customer warrants that the Products will be operated only by trained personnel.

12. WARRANTY

12.1. Brainlab warrants that the Products are free from defects in material and workmanship under normal use and in substantial compliance with operational features of Brainlab's published specifications at the time of sale. The warranty period shall be one (1) year beginning (i) 6 months after delivery, (ii) 3 months after installation, (iii) acceptance of the purchased goods, or (iv) treatment of the first patient, whichever occurs first

12.2. In the event that any malfunctions occur, Customer shall immediately cease using the Product and inform Brainlab hereof without delay.

Customer shall not resume use of the Product before Brainlab has given notice that the malfunction has been eliminated.

12.3. Brainlab will, at its own discretion, repair or replace defective parts or Products.

12.4. During the warranty period, Customer may request up to ten (10) hours of engineer's overtime work for Service visits. Any additional working hour or fraction thereof outside normal working hours requested by Customer will be charged to Customer according to Brainlab's then current price list.

12.5. The quality of Products is to be measured exclusively by the given specifications which are hereby incorporated in the contract. The specifications are subject to change without notice as far as such change is not material and the suitability for the intended use is not reduced.

12.6. In the interest of conservation of scarce materials, Products, including repair or replacement parts or components, may contain remanufactured parts. Such parts are subject to the same high standards of quality control applied to other parts and are covered by this warranty.

12.7. THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF AND EXPRESSLY EXCLUDES ALL OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL PRACTICE, USE, OR APPLICATION.

12.8. Notwithstanding anything to the contrary contained herein, Brainlab does not warrant that the Software will be error-free or bug-free or that the use of the Software will be uninterrupted. In addition, except as otherwise stated herein, the Software is provided without any additional warranties.

12.9. Notwithstanding the one (1) year warranty period referenced in Section 12.1, repair or replacement parts ("Spare Parts") provided during the warranty carry the same warranty set forth in Section 12.1 for the unexpired portion of the original warranty period. Spare Parts provided by Brainlab under a purchased service contract are covered for the unexpired portion of the service contract period.

12.10. Any original parts removed and/or replaced during any repair process shall become the property of Brainlab.

12.11. Customer's claims are only valid when made in writing.

12.12. Customer shall bear the costs for any disposable parts needed for use of the Products, as well as any further costs of operation.

12.13. No representation is made as to the accounting validity, adequacy or compliance with the standards set forth in the criteria found within, but not limited to, the industry accounting standards as defined by the Financial Accounting Standards Board (FASB), Generally Accepted Accounting Principles (GAAP), the International Accounting Standards Board (IASB), or any other accounting standard defined by an independent third party or government agency. If desired, Customer should consult a Certified Public Accountant (CPA) and/or attorney before entering into this Agreement.

13. Warranty exclusions and Performance of Service

13.1. Any warranty is excluded and, further, Brainlab shall not be obligated to perform any Services in case of:

- general wear;
- accident;
- lack of proper care;
- use of Products that is not in compliance with Brainlab's manuals, instructions for use and a reasonable degree of care or failure to use Brainlab systems under normal or specified operating conditions and environment;
- use of Products in combination with devices, parts of devices, or accessories that have not been expressly cleared by Brainlab for use with such Products;
- maintenance or repair of Products that have not been authorized by Brainlab;
- unauthorized modification or alteration of Products;
- failure of Customer to immediately report any malfunction of a Product or continuous use of the Product after occurance of any such malfunction;
- faults, failures or damages caused by intentional or negligent behaviour; or
- circumstances beyond Brainlab's control, including but not limited to force majeure, acts of God, power and/or environmental failures.

13.2. Customer shall allow Brainlab free access to the Products, including online access if remote service is performed. This shall, in particular, not be made contingent on the limitation of Customer's liability. Customer shall offer a suitable workplace, including access to a telephone if needed. Brainlab shall use this telephone line exclusively to perform the Services

13.3. Customer shall ensure safe conditions at the location of the Products. Particularly, Customer shall inform Brainlab of existing safety regulations that are relevant for Brainlab personnel.

13.4. Customer and Brainlab shall mutually agree on dates and times for Service visits at least 48 hours in advance. This shall not apply to Service provided on a time and material basis, where more advance notice may be required.

13.5. Brainlab will provide Services Monday through Friday from 8.00 am untill 5.00 pm. Services provided at other times will be charged to the Customer as overtime unless otherwise agreed.

13.6. In the event that a Service, installation or other appointment is cancelled due to reasons within Customer's responsibility, Customer shall inform Brainlab at least 24 hours in advance.

13.7. In the event that Customer fails to notify Brainlab in due time, Brainlab shall be entitled to charge Customer for all costs reasonably incurred with regard to the appointment.

13.8. Brainlab shall respond to Customer reports of malfunctioning Products by phone, fax or email within no more than 24 hours by phone call. If the malfunction cannot be eliminated by phone call, the dispatch of spare parts as well as maintenance and repair will normally be initiated within one working day after the problem analysis by phone, pending availability of personnel and material. Notwithstanding the foregoing, in the event the defective Product is the Brainlab Dash System, or any component or accessory thereto, Customer shall ship such defective Product to Brainlab for replacement or repair. Customer shall properly package the Dash Product so as to avoid damage during transit and shall ship the Dash Product with a reputable carrier and shall provide to Brainlab the applicable tracking information upon shipment.

14. Intellectual Property, Software Licenses

14.1. All rights to patents, trademarks, and any other intellectual property shall remain the property of Brainlab, its affiliates and/or its licensors, as applicable. Brainlab and/or its affiliates, suppliers and/or licensors presently owns and will continue to own all right, title, and interest in and to the Software and its source code, and any and all copyrights, trademarks, trade names, logos and other proprietary rights in and to the Software and any other materials provided to or otherwise made available to Customer hereunder, and all worldwide intellectual property rights embodied herein

14.2. Brainlab grants Customer a limited, non-exclusive, non-transferable license to use any Software. Software available for download from a Brainlab website may be used solely in accordance with the respective intended use. Software delivered with or integrated in hardware products may solely be used in conjunction with such hardware products and for its intended use. Software is provided for the Term (if provided on a leased, rented or subscription basis), solely for use at the location indicated in the Quote for such Software, or the hardware with which such Software is integrated, and for such number of concurrent users as indicated in the Quote. If no Term is indicated in the Quote for either the Software or the hardware product that it is integrated with, then the Software license is perpetual, subject to end of life provisions. If no geographic limitation is made, then Software may be accessed and used worldwide in accordance with applicable law and export regulations. If the Quote does not indicate a permitted number of concurrent users, then the Software may be used by one user at a time.

14.3. Customer hereby accepts any further license conditions for Software that may be required by third party manufacturers or licensors in so far as such conditions are commonly used or reasonably acceptable to Customer. Brainlab will make such additional license conditions available to Customer upon request.

14.4. All title and interest to any Software provided to Customer shall remain with Brainlab, its affiliates and/or its licensors, as applicable. Customer shall not copy, modify or reverse engineer Software and shall prevent third party access to the Software.

14.5. The Software under this Agreement is commercial computer software as that term is defined in 48 C.F.R. 252-227-7014(a)(1). If acquired by or on behalf of a civilian agency, the U.S. Government acquires this commercial computer software and/or commercial computer software documentation and other technical data subject to these terms as specified in 48 C.F.R. 12.212 (Computer Software) and 12.211 (Technical Data) of the Federal Acquisition Regulations ("FAR") and its successors. If acquired by or on behalf of any agency within the Department of Defense ("DOD"), the U.S. Government acquires this commercial computer software and/or commercial computer software documentation subject to the terms of this Agreement as specified in 48 C.F.R. 227.7202-3 of the DOD FAR Supplement ("DFAR") and its successors. This U.S. Government Rights clause is in lieu of, and supersedes, any other FAR, DFAR, or other clause or provision that addresses Government rights in computer software or technical data under this Agreement.

15. Ownership and Retention of Title

15.1. Brainlab shall retain title to any Products that are sold until payment is made in full and all claims are settled.

15.2. In the event that the Setup Proposal Section of a Quote provides for the payment of Periodic Fees, then title to the Products set out in such Setup Proposal Section shall pass to Customer upon payment of no less than all of the Periodic Fees.

15.3. If third parties take up steps to levy execution upon or otherwise dispose of the Products, Customer shall immediately notify Brainlab. If Customer fails to do so in due time Customer will be held liable for any damages caused.

15.4. The Operating Products shall at all times be and remain the sole and exclusive property of Brainlab notwithstanding that the Operating Products may now be, or hereafter become, in any manner affixed or attached to, or embedded in, or permanently resting upon real property. Customer shall have no right, title or interest therein or thereto except as to the use thereof according to their intended use. Customer shall not permit its rights or interests hereunder to be subject to any lien, charge or encumbrance and shall keep the Operating Products free and clear of any and all liens, charges and encumbrances which may be levied against or imposed upon Customer for whatever reason.

15.5. Customer shall not remove any labeling affixed to the Products.

15.6. Customer, at its sole cost and expense, shall maintain the Operating Products in first class condition, normal wear and tear excepted.

Customer shall keep the Operating Products safe and secure in Customer's possession and control at Customer's premises. At any reasonable time Brainlab or its agents may inspect the Operating Products.

15.7. Without the prior written consent of Brainlab, Customer shall not make any alterations, additions or improvements to any Products, whether provided on a term basis or sold. In any event, Customer shall, at its cost and expense, reverse any alterations, additions or improvements made before returning the Operating Products. If not done, all alterations, additions or improvements shall be deemed accessions thereto, shall belong to and immediately become the property of Brainlab and Customer shall remain liable and responsible for the costs to bring the Operating Products back into compliance with its original condition. Brainlab shall invoice the Customer accordingly. For Operating Products which consist of a dedicated computer workstation provided by Brainlab, or which reside on a dedicated computer workstation provided by Brainlab, Customer shall not install any third party software or programs on the dedicated computer workstation.

15.8. In the event any transaction with respect to any Product sold or provided hereunder is qualified or deemed to be a secured loan, Customer hereby grants to Brainlab a security interest in such Products which shall secure the performance of all of Customer's obligations of any kind whatsoever, whenever originated, to Brainlab. Customer authorizes Brainlab or its designee, and Brainlab reserves its right, to file a Uniform Commercial Code financing statement without Customer's signature, in form and content and from time to time as Brainlab deems proper, listing Customer as a lessee or debtor. Customer represents that it has identified or will correctly identify to Brainlab its exact legal name, state of incorporation, and location of its chief executive office

15.9. Upon termination or expiration of the Term or this Agreement, Customer shall return the Operating Products to Brainlab and the license for any Software included with the Operating Products shall expire. Customer shall remove all protected health information from the Operating Products prior to returning to Brainlab. Brainlab shall be entitled to deduct from the Security Deposit, if applicable, any amounts due for any damage to the Operating Products. In the event the damages exceed the Security Deposit, Customer shall pay to Brainlab the exceeding amount of such damage within ten (10) days of receipt of written notice thereof. Customer will be liable and responsible for any damages incurred by Brainlab due to a delay by Customer in returning the Operating Products to Brainlab. In the event Customer does not immediately return the Operating Products upon termination or expiration of this agreement, Customer shall continue to incur and be liable and responsible for any and all Periodic Fees (or pro-rations thereof, if applicable) and taxes until the Operating Product is returned to Brainlab. Customer shall be liable and responsible for all costs associated with the removal and disposal of the Operating Products, such amounts to be due net ten (10) days of the date of invoice issued to Customer after removal and disposal of the Operating Products.

16. Term and Termination

16.1. The Term for the provision of Operating Products shall commence after acceptance or sixty (60) days after Delivery of the Operating Products, whichever occurs first. At least sixty (60) days prior to the expiration of the Term, Customer shall provide Brainlab with written notice of its intent regarding the end of term options, Customer shall indicate in its notice of intent whether Customer desires to (i) allow the Agreement to expire and return the Operating Products and allow the license for any Software included to expire; (ii) extend or renew this Agreement; or (iii) purchase the Operating Products and procure an ongoing license to any associated Software. If Customer desires to renew or extend this Agreement or purchase the Operating Products, if available for purchase, the parties will meet together to negotiate the renewal term and renewal fees or the purchase price, as applicable. If the parties are able to reach an agreement, (a) these terms and conditions shall continue to apply; (b) Term shall mean the initial Term plus the extension or renewal time period; and/or (c) with respect to a purchase, no warranty will be provided. If the parties are unable to come to an agreement, this Agreement will not be renewed.

16.2. A Software license Term shall commence upon Delivery of the Software according to Section 1.6 above; in the event that Software is installed on corresponding Brainlab Product hardware, then the Term shall commence upon acceptance of such hardware, or sixty (60) days after Delivery of the Software and hardware, whichever occurs first.

16.3. Service shall be provided for a minimum Term of one (1) year, unless a longer Term is specified in the Quote, in which case such longer Term shall apply. This shall not apply to service provided on a time and material basis.

16.4. In case of permanent obstructions to Delivery of a Product, Brainlab shall have the right to terminate the underlying contract or license in part or in whole. Brainlab will promptly inform Customer about the obstructions and, in the event of termination of the contract or license, will reimburse Customer any payments already made for unavailable parts.

16.5. If Delivery obstructions last for a period of more than six months, Customer may terminate the underlying contract with respect to the unavailable parts. Customer may terminate the entire contract only if Customer cannot be reasonably expected to have an interest in partial Delivery without the unavailable parts.

16.6. Brainlab may terminate the provision of Operating Products, Term-based Software licenses or any other ongoing contractual relationships if Customer's property becomes subject to levy of execution, seizure, or the like, or if Customer is in default of payment for more than one month.

16.7. Notwithstanding the foregoing, either party shall have the right to terminate the agreement before its fulfillment in its entirety and with immediate effect a) for the provision of Operating Products, Term-based Software licenses or any other ongoing contractual relationships, if there is a material breach by the other party not remedied within thirty (30) days of notice thereof; and b) for all Products: (i) if the other party becomes subject to voluntary or involuntary bankruptcy, receivership, or related proceedings; or (ii) at a party's dissolution.
Statutory provisions regarding termination without notice shall not be restricted by the foregoing.

16.8. If Brainlab terminates this Agreement under Sections 16.6. or 16.7, Brainlab shall have the right, to the extent permitted by applicable law, to do any one or more of the following: (i) declare the Agreement in default, whereupon an amount equal to the present value of the entire unpaid balance of the Periodic Fees (the Periodic Fee multiplied by the remaining periods) plus any other sums and or damages, is immediately due and payable, (ii) pursue any remedy at law, in bankruptcy or in equity, proceeding by court action or otherwise; (iii) repossess or take possession of the Operating Products or financed Products, together with all additions, replacements and attachments, wherever such Operating Products or financed Products may be located, and for such purposes Brainlab and/or its agents may enter upon any premises of or under the control or jurisdiction of Customer or any agent of Customer, without any liability for doing so, and take the Products therefrom. Customer hereby expressly waives any and all rights to any form of notice, demand, legal process and/or judicial hearing prior to any such taking or repossession. Customer also expressly waives, and indemnifies Brainlab against, any damages, costs and expenses specifically including reasonable attorney's fees in any way relating to or caused any such entry and/or repossession. Customer agrees to make such Products available to Brainlab at such location as Brainlab may reasonably specify. Upon such repossession by or return to Brainlab of the affected Products, all rights of Customer in such Products shall terminate; (iv) deactivate any Software licenses; and/or (v) hold, scrap or use any such repossessed or returned Products for any purpose whatsoever, or sell same at a public or private sale, or re-finance the same for such a term and payment as shall be solely determined by Brainlab, or hold the Products for future sale or re-leasing, solely for the account of Brainlab. In the event the provision of the Operating Products is terminated, such termination shall not affect any financing of any Products and such amounts shall remain due and payable by Customer.

16.9. Customer hereby waives any right to require Brainlab to sell, lease, rent or otherwise use any repossessed or returned Products in mitigation of damages.

16.10. Notwithstanding anything to the contrary contained herein and/or in the Quote, Brainlab shall have the right to terminate an ongoing agreement, in whole or in part, in the event that one or more of the Products that are covered under such agreement reach the Brainlab or original equipment manufacturer designated "end of life" or otherwise are no longer offered commercially by Brainlab or the original equipment manufacturer. Upon the effective date of termination under this subsection, Brainlab shall refund to Customer a pro-rated amount of the paid amount, reflecting the amount due for the unused portion of the agreement. Brainlab shall have no obligation to perform Services or deliver parts for Products declared "end of life" beyond the end of life date, which will be communicated well in advance to the Customer.

16.11. Should Customer not agree to a price increase as set out in Section 4.2 above, then Customer may terminate its ongoing agreement with Brainlab by giving at least three (3) months written notice before the end of the then current contract period.

16.12. Customer shall not be released from its obligations under this Agreement until the payment of all unpaid amounts, which would include but not be limited to all amounts due for delivered Products and all Periodic Fees incurred prior to termination. All of the foregoing applies notwithstanding any remedies which Brainlab may have under applicable law.

16.13. In the event that an automatic renewal of the Term is set forth in the Quote, then all conditions shall continue to apply for any renewal period. Should the Customer wish to prevent an automatic renewal, then the underlying agreement must be terminated by giving Brainlab written notice at least sixty (60) days before the expiration of the then current Term.

16.14. In addition to any sums due hereunder, CUSTOMER AGREES TO PAY BRAINLAB'S COLLECTION AND LEGAL EXPENSES AND REASONABLE ATTORNEYS' FEES AS DAMAGES, NOT AS COSTS, in all proceedings arising under this Agreement, including without limitation in, exercising any of Brainlab's rights or remedies hereunder, protecting any of Brainlab's interests hereunder, in arbitration, and in counterclaims on which Brainlab prevails.

16.15. All rights and remedies of Brainlab hereunder shall be cumulative and not alternative.

17. Limitations of Liability and Indemnification

17.1. Brainlab shall not be liable for delays in performance due to Acts of God, strike, regulatory difficulties, or due to unforeseen circumstances. The same applies if the delay occurs at Brainlab's suppliers, their sub suppliers, or other sub-contractors.

17.2. The total liability of Brainlab shall not exceed any payment received for the respective Brainlab Product contributing to the loss or damage

claimed. The foregoing shall apply to any and all claims, including but not limited to tort claims.

17.3. Brainlab (and its affiliates) shall not be liable for any loss of use, revenue or anticipated profits, loss of business, loss of stored or transmitted data, interruption of service, or for indirect, incidental, unforeseen, special, punitive or consequential damages arising out of or in connection with this agreement or the sale or use of Brainlab's products, whether in any action in warranty, contract, tort (including without limitation, negligence or strict liability) arising out of or in any connection with the use of, of the inability to use, the products.

17.4. In no event shall Brainlab's liability hereunder exceed the actual loss or damage sustained by Customer.

17.5. Brainlab shall not be liable for any damage caused by (i) the use of purchased goods before performance of the acceptance test according to Section 9 above; (ii) the use, operation, service, modification of Brainlab products contrary to relevant manuals, written warnings, automated warnings, or instructions of Brainlab personnel; (iii) the use of Brainlab products in conjunction with third party products, unless this use has been expressly authorized in writing by Brainlab; and (iv) the use of any product supplied by Brainlab as a convenience to the Customer that is not manufactured by Brainlab and is not generally offered by Brainlab.

17.6. With respect to bodily injury or death to third parties, Brainlab's liability shall be restricted to an equitable proportion as reflects its relative fault in relation to Customer's contribution to the injury or death of the third party.

17.7. Customer agrees to defend, indemnify and hold harmless Brainlab from and against any and all liabilities, judgments, awards, settlements, losses, damages and expenses in connection with any third party claim, suit, or other action arising from (i) the negligence and willful misconduct of the Customer or its directors, officers, or employees; (ii) use of the Brainlab products prior to completion of the applicable acceptance by anyone other than Brainlab personnel; (iii) use, operation, service, modification of the Brainlab products contrary to relevant manuals, written warnings, automated warnings, or instructions by Brainlab personnel; (iv) use of the Brainlab products in conjunction with third party products, unless the use has been expressly authorized in writing by Brainlab; (v) use of any product supplied by Brainlab as a convenience to Customer and that is not manufactured by Brainlab and is not generally offered by Brainlab; or (vi) an infringement of third party rights by any actions or omissions of Customer, including but not limited to the disclosure of user data or patient data, by way of example, when using Quentry. All other rights, including but not limited to damage claims by Brainlab, shall remain unaffected.

18. EXPORT CONTROL

18.1. Brainlab shall not be liable for any delay in Delivery or any inability to deliver due to export restrictions. In this case, Brainlab may cancel the contract and shall not be liable for any damages arising of or in connection with such cancellation.

18.2. Brainlab advises all customers that export regulations may apply to the resale of the delivered Products. In addition, Products delivered by Brainlab may contain US components (including but not limited to hardware, software, technology) in which case compliance with US regulations may be required. Customer shall ensure compliance with all export regulations applicable to the re-export of the delivered Products.

19. CONFIDENTIALITY, REGISTRATION, DATA PROTECTION

19.1. Customer shall keep in confidence all information, including but not limited to technical data, product descriptions, and any other information which is readily and reasonably identifiable as confidential based on its nature and/or the circumstances of its disclosure. For clarification only, this shall include but not be limited to information provided verbally. Such information shall not be disclosed to any third parties or employees, except for employees who are directly involved in the operation of the Products on a need to know basis.

19.2. For the improvement of Products and customer support Brainlab shall be entitled to collect statistical data stored on the Products. This data will be stored anonymously and used exclusively for internal purposes.

19.3. Brainlab and Customer undertake to observe the applicable data protection regulations.

19.4. Customer agrees that Brainlab may remotely access the Products at Customer's site within the scope of this agreement, and may process and store data in order to perform the remote Services. Customer shall prevent accidental access to patient data and other protected data and/or, as applicable, obtain the written approval of patients regarding the possibility of access to their data by Brainlab in the course of the performance of Services.

19.5. Certain Brainlab Products require a single personal registration of each authorized health care professional or administrator using the Product, including the user's location. Customer warrants the correctness of the information entered and Brainlab shall grant access to the technology subject to validation of such information. This registration information is deemed confidential information and governed by the terms of this Section 19.

19.6. Brainlab is entitled to disable or otherwise restrict the access to Brainlab Products, including but not limited to deletion of data, whenever Brainlab has reasonable evidence that Customer is in violation of Sections 14 or 19.1.

20. PROTECTION OF ENVIRONMENT

20.1. Brainlab shall dispose of any Product packing free of charge and in compliance with applicable regulations.

20.2. Upon end of use, Customer shall dispose of the Products (other than Products which are returned to Brainlab) at its own costs pursuant to any applicable regulations. Brainlab shall not be required to take back the Products or Third Party Products for disposal.

21. APPLICABLE LAW / ARBITRATION / PARTIAL INVALIDITY/ASSIGNMENT

21.1. Customer shall comply with all applicable local, state, national and foreign laws, treaties, regulations and third-party rights, including, without limitation, those related to data privacy (e.g. HIPAA), international communications, the transmission of technical or personal information, and government regulations.

21.2. These terms and conditions as well as all contractual and other legal relationships between the parties shall be governed by the laws of the State of Illinois, USA. Any claim or controversy arising out of or relating to these standard terms and/or any other legal relationship between the parties shall be settled by arbitration in Chicago, Illinois in accordance with the arbitration rules of the American Arbitration Association. The dispute shall be heard and determined by one arbitrator, unless any party's claim exceeds USD 1 million, exclusive of interest and attorneys' fees, in which case the dispute shall be heard and determined by three arbitrators. Language of the arbitration shall be English. The arbitration tribunal shall not award punitive damages. The arbitration shall be final and binding, shall be the sole and exclusive remedy regarding any and all claims and counterclaims presented, and may not be reviewed by or appealed to any court except for enforcement.

21.3. Nothing in this agreement shall prevent Brainlab from seeking injunctive relief or other legal remedy to prevent unauthorized copying, disclosure, use, retention, or distribution of Brainlab's intellectual property or confidential information.

21.4. Brainlab shall have the exclusive right to bring legal action for failure to pay for Products and Services furnished in the courts of Brainlab's headquarters.

21.5. If any part of the terms and conditions is held void or unenforceable, such part will be treated as separable, leaving valid the remainder of these terms and conditions. The invalid clause will be replaced by the valid clause that comes closest to the commercial intention of the invalid clause.

21.6. Brainlab may freely assign this Agreement or its right or obligations under this Agreement to any affiliate, successor-in-interest, or third party. Customer may not assign this Agreement or its rights or obligations thereunder without the prior written consent of Brainlab.

Mobius IMAGING Now You See

AIRO SYSTEM

PRE-INSTALLATION GUIDE

Doc.# MI-42-0002
Rev. 7

Airo Pre-Installation Guide

1. PURPOSE

This guide provides an overview of key process steps, scheduling, resources and critical items needed to prepare your site for delivery and installation of an Airo CT System.

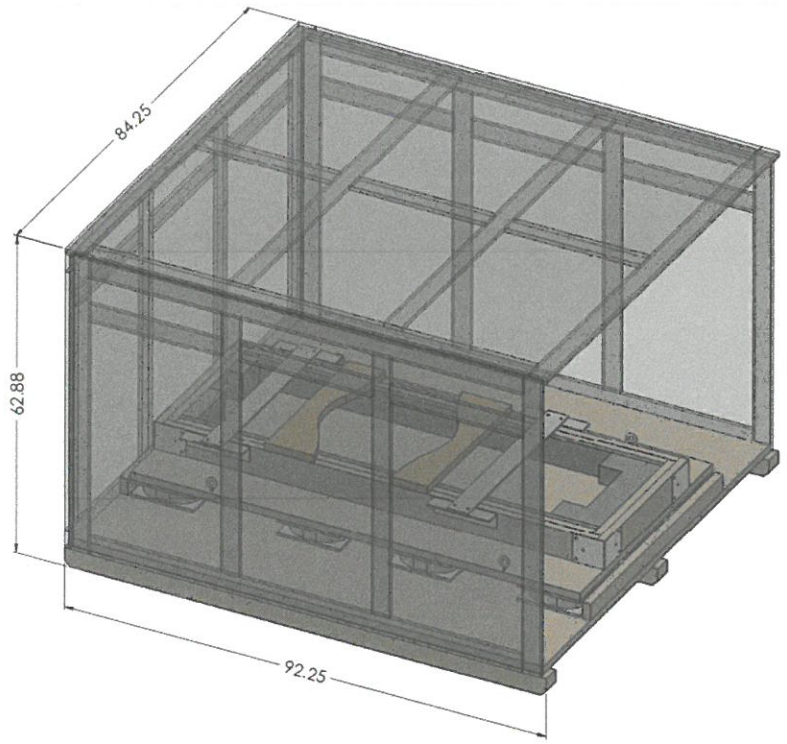
2. SYSTEM OVERVIEW

The Airo CT Scanner is a high resolution, large bore (107cm) helical CT scanner. The system was designed to fit through a standard doorway and plug into a standard wall electrical outlet. The Airo contains a self-drive system that allows a single operator to easily transport the system to wherever it is needed.

- Model Name: MobiCT-32

3. AIRO CRATE SPECIFICATIONS

- Length: 92.25 in (234 cm)
- Width: 84.25 in (214 cm)
- Height: 62.9 in (160 cm)
- Weight:
  - Crate Only: 1250 lbs. (567 kg)
  - Crated System: 3400 lbs. (1814 kg)



4. DELIVERY

Upon delivery, the Airo system requires a 12+ hour acclimation period prior to powering up the system. Adequate storage for the crated system will be required.

CAUTION

Powering on a system that has not acclimated to room temperature could result in damage due to condensation formed on internal components.

Moving of the crated Airo system will require a pallet jack with a minimum 3400 lb (1814 kg) capacity. **Only use pallet jacks or fork lifts with extended forks, 6 ft (1.8 m) or longer.**

There are 7 Lithium Iron Phosphate (LiFePO4) batteries which power the Airo.

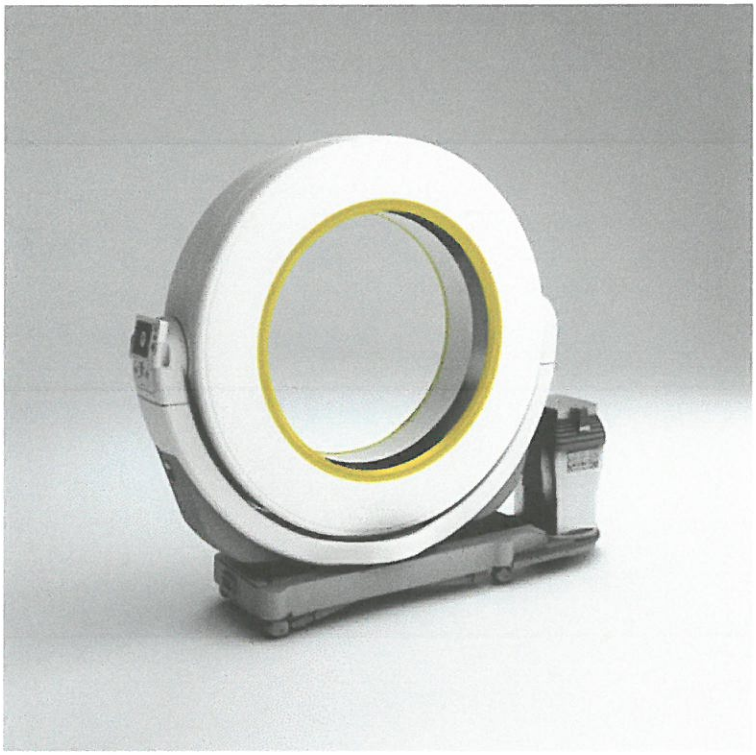
CAUTION

Only Brainlab employees trained in procedure to unpackage the batteries along with Dangerous Goods Handling should handle the batteries.

5. SYSTEM SPECIFICATIONS

Airo has two modes of operation; transport and scan, as shown below.

5.1. Transport Mode



Specifications for Transport Mode

- Length: 90.5 in (230 cm)
- Width: 23.5 in (60 cm)
- Height: 77.7 in (197 cm)
- Weight: 2150 lbs. (975 kg)

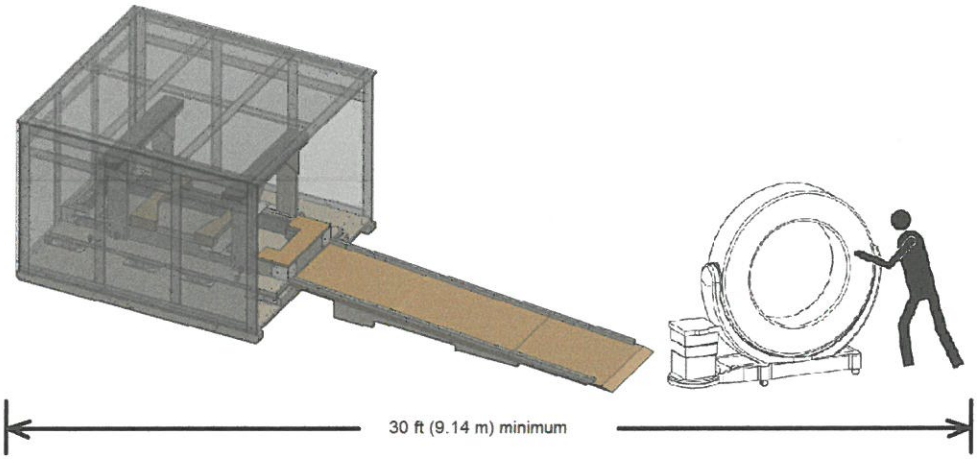
5.2. Scan Mode

Specifications for Scan Mode

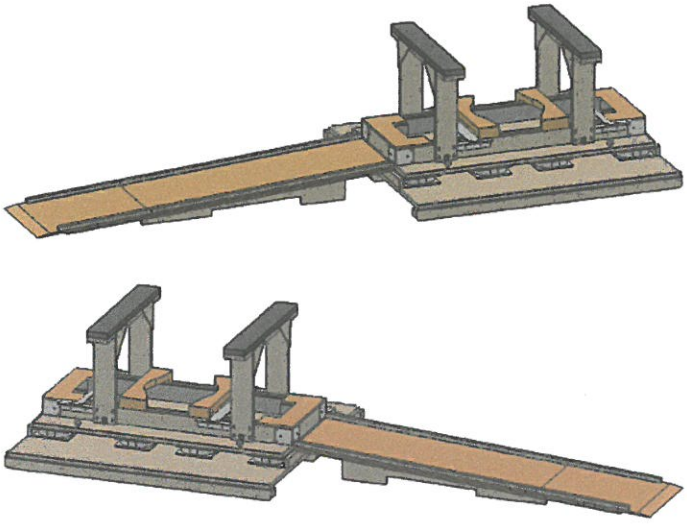
- Length: 76.0 in (193 cm)
- Width: 76.4 in (194 cm)
- Height: 74.8 in (190 cm)
- Weight: 2150 lbs. (975.2 kg)
  - Weight is without a tabletop installed
  - The weight with the tabletop will depend upon the model installed. Refer to the manufacturer's literature for specific tabletop weight.

6. UNPACKING AND INSTALLATION

Unpacking of the Airo system will require a minimum of 30 feet (9.14 m) to accommodate the crate and ramp as well as room to drive the Airo off the crate and down the ramp.



The crate is designed so the Airo can be removed from either side of the 84.25 inch end.



It will take approximately 8 hours to complete the installation of the Airo system. Some of this time will require the generation of x-rays; therefore the installation of the Airo will require the use of a room that is acceptable for x-rays.

Installation of the Airo System to be performed by Authorized Brainlab Service personnel only.

7. ENVIRONMENTAL CONDITIONS

7.1. Warehouse Storage and Transportation*

- Temperature: 0°C to 50°C (32°F to 122°F)
- Humidity: 5% to 95%, condensing
  * Airo remains in original packaging

7.2. Operating and Hospital Storage**

- Temperature: 10°C to 25°C (50°F to 77°F)
- Humidity: 20% to 70%, non-condensing
- Altitude: max. 3000 m

  ** Airo installed per appropriate installation procedure

8. POWER REQUIREMENTS

- Voltage requirement: 100 VAC – 240 VAC, single phase
- Frequency: 50/60 Hz
- Power: 1500 VA
  - 6.25 A @ 240 VAC
  - 15 A @ 100 VAC
- Peak Heat Output
  - During Scanning: 1.5 kW (21.51 kcal/min)
  - System on but not scanning: 575 W (8.2 kcal/min)
  - System off and plugged in: 200 W (2.9 kcal/min)

The Airo system can be powered from a standard wall outlet. No special electrical connections are required.

The Airo contains a 15.5 ft. (4.7 m) power cord with a hospital grade plug.

9. TRANSPORTING THE AIRO WITHIN THE HOSPITAL

The Airo contains a self-drive system that can transport the Airo at a fixed rate of approximately 1 mph (1.6 kph)

The minimum width of hallways for the safe transportation of the Airo is 4 ft. (1.2 m).

The Airo system should not be transported on inclines or declines that are greater than 5° or over thresholds greater than 0.375 in (10 mm).

The Airo should never be turned on a ramp. Always ascend and descend an incline parallel to its slope.

Wet inclines or declines can cause the Airo to lose traction and slide uncontrolled. **Do not transport the Airo up or down wet ramps.**

10. ELEVATORS

- Elevator requirements
  - Recommended Minimum Width: 48 in (122 cm)
  - Recommended Minimum Depth: 100 in (254 cm)
  - Minimum Weight capacity: 3500 lbs (1588 kg)

The Airo system can fit in most standard hospital elevators.

Certain elevator floors may flex under the weight of the Airo and could cause some vinyl tiles to crack. The conditions of the floors of the elevators that will be used in the transport of the Airo system should be assessed against the floor loading.

11. ON-SITE STORAGE REQUIREMENTS

Plug the Airo in when not in use.

The Airo contains batteries which require charging when the system is not in use. Leaving the system unplugged causes the batteries to deplete.

Prolonged discharge can permanently damage the batteries.

12. NETWORK REQUIREMENTS

The Airo system contains Ethernet ports which allow the system to push images to the hospitals PACS servers or to an image guided surgery system. Adequate length CAT -5e (or greater) cables will be needed to connect the Airo to the PACS network connection or to the image guide surgery system.

Specification for the PAC server port is 100BASE T (IEEE 802.3 Standard)

Specification for the IGS port is GbE (IEEE 802.3 Standard)

The patient data is stored on a computer located inside the Gimbal. The hard drive is partitioned into a C: drive which the operating system and user interface software is located on, and a D: drive which is used for the patient database. The D: partition is 700 GB.

13. SHIELDING GUIDELINES

The Airo System's primary x-ray beam is fully absorbed in the detector assembly. Only scatter off the objects being impacted by the primary beam contribute to the radiation that must be managed for protection of the surrounding environment.

The scatter patterns in this section were generated using a body phantom designed for CT evaluation, producing patterns similar to those seen with CT patient operations.

The following is a table of the scatter intensities predicted around standard GWB (Gypsum Wall Board) wall construction for the Airo for a variety of room sizes, also listing the maximum number of scans per year allowed assuming 100% occupancy with general public restrictions applied and with the Airo operating in the center of the room. Also listed is the upper number of scans recommended per year if the room surroundings are restricted to monitored radiation workers. Since the scatter pattern is symmetrical in both dimensions, all rooms listed are square.

Room Size (ft)	Dose/Scan (mR)	Dose thru sheetrock wall (mR)	Scans/year @ 100 mR limit	Scans/year @ 500 mR limit
16 x 16	0.5	0.16	625	3125
20 x 20	0.32	0.11	909	4545
24 x 24	0.22	0.07	1428	7143
30 x 30	0.14	0.05	2000	10,000
36 x 36	0.1	0.03	3333	16,666

Note: If lower surrounding room occupancy can be reliably predicted, permissible number of scans can be increased proportionally (e.g. 25% occupancy would allow 4 times as many scans per year).

The guidance provided focuses on scatter to neighbors on the same floor as the Airo. The effects on floors above and below the radiation source must also be considered. The existing floor structures in most buildings involved in modern medicine will contain adequate material to shield the areas above and below the Airo since the floors would all be more substantial than wall structures, usually sufficient to even be adequate when wall leading is needed.

The information in this section is only guidance. Assessment from locally approved experts on radiation control may be required.

13.1. Radiation profiles of the Airo System.

13.1.1. Horizontal Profile

Horizontal profile

kV	mA	sec	mAs	Values in uGy/mAs
120	25	2	50	

cm	150	100	50	0	50	100	150
150	0.02992	0.03872	0.04576	0.04576	0.04576	0.03872	0.02992
100	0.04048	0.06160	0.08800	0.08800	0.08800	0.06160	0.04048
50	0.01760	0.11616	0.24288	0.40480	0.24288	0.11616	0.01760
0	0.00528	0.00704	Gantry	Phantom	Gantry	0.00704	0.00528
50	0.06864	0.14080	0.276	0.546	0.276	0.14080	0.06864
100	0.04594	0.08448	0.111	0.123	0.111	0.08448	0.04594
150	0.03502	0.04576	0.053	0.070	0.053	0.04576	0.03502

Table

13.1.2. Vertical Profile

Vertical profile

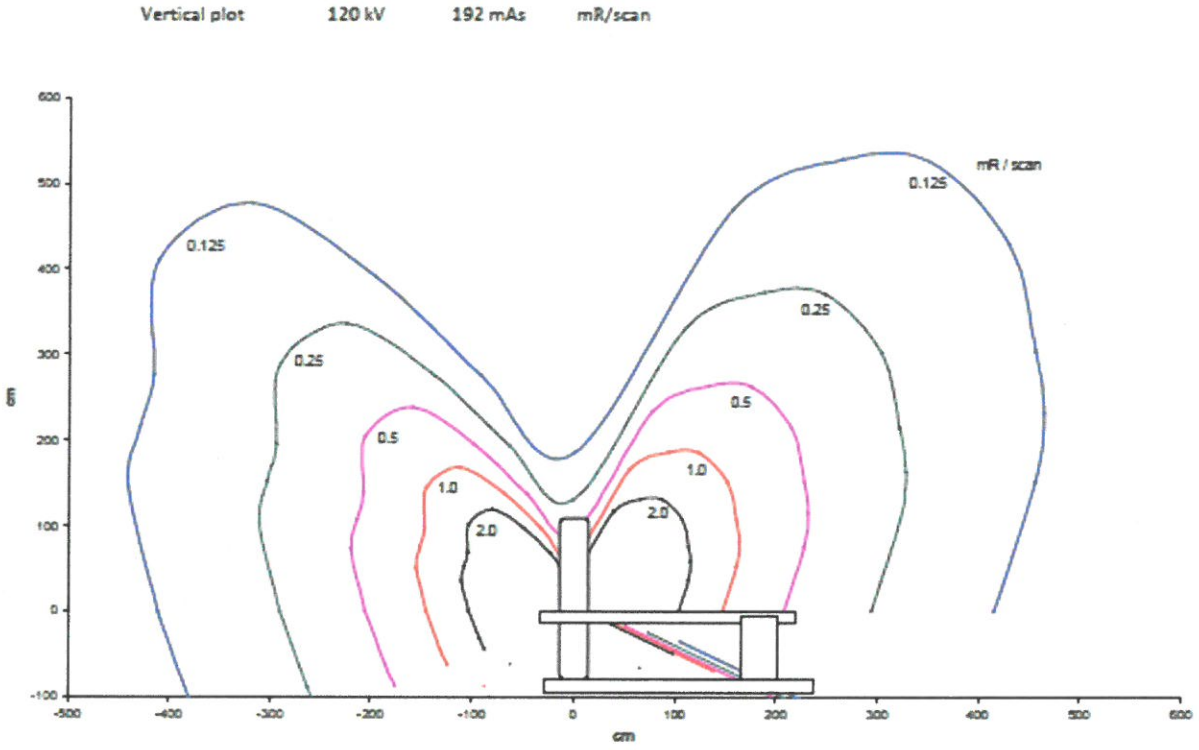
kV	mA	sec	mAs	Values in uGy/mAs
120	25	2	50	

cm	150	100	50	0	50	100	150
150	0.03696	0.05808	0.01936	0.00880	0.06688	0.03872	0.04400
100	0.04400	0.08800	0.08800	0.01584	0.16016	0.08800	0.05280
50	0.05280	0.08800	0.26400	Gantry	0.33616	0.10560	0.07040
0	0.05280	0.08800	0.44528	Phantom	0.54560	0.12320	0.07040
50	0.03520	0.07040	0.14080	Gantry	0.15840	0.08800	0.00282

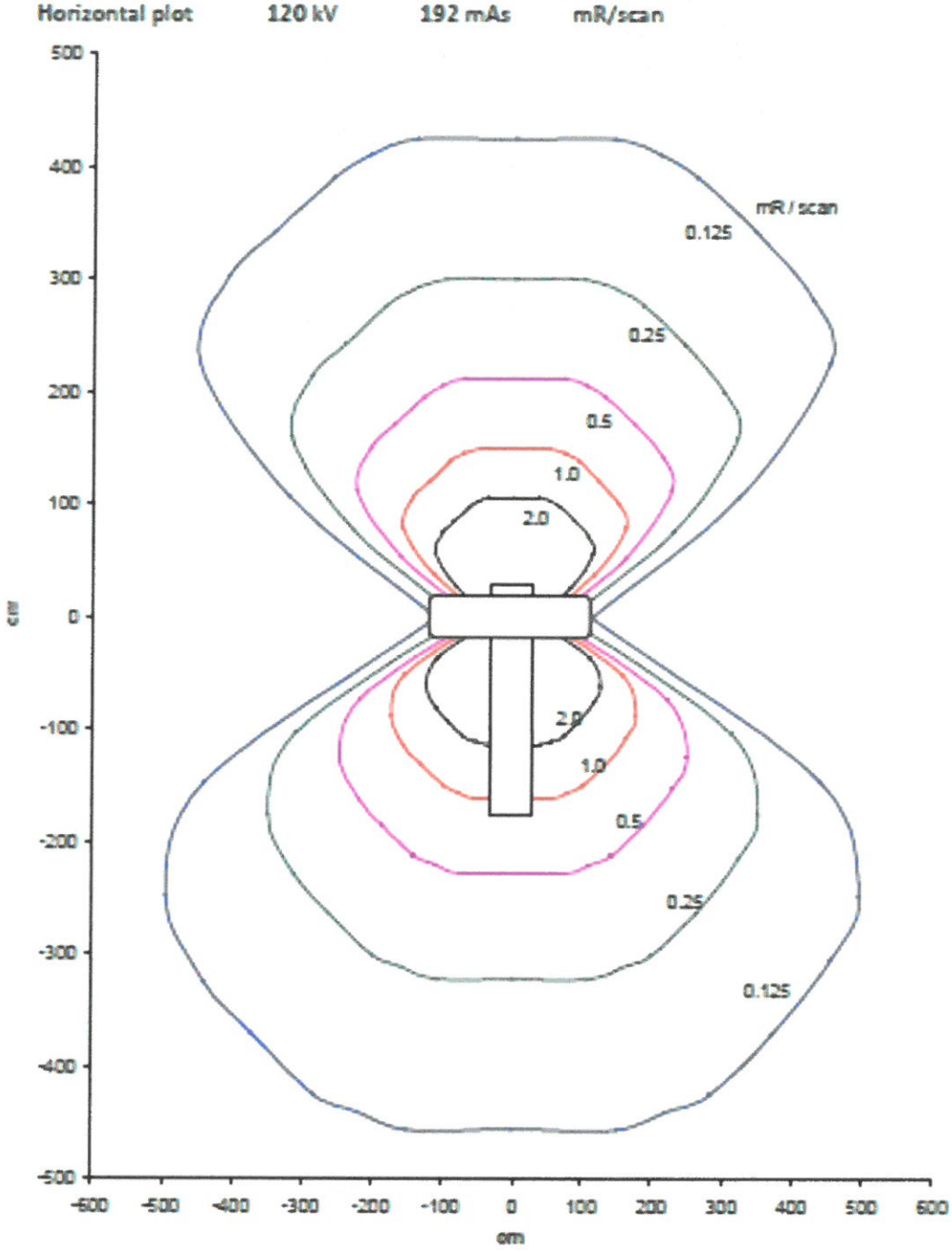
Table

13.2. Scatter Plots

13.2.1. Vertical Plot



13.2.2. Horizontal Plot



14. SCANNING PROTOCOLS AND PRINCIPLES

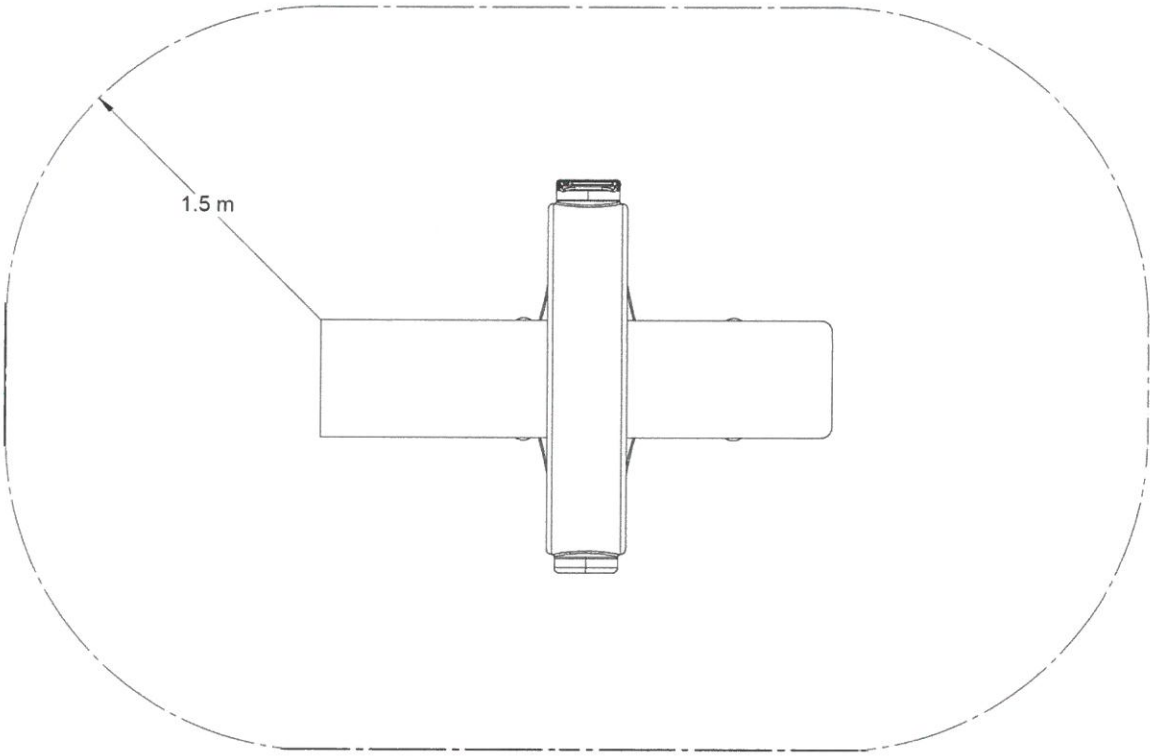
For information on the Airo's scanning protocols and principles, please refer to Mobius Imaging's Protocols and Principles Application Guide, document number MI-42-0005.

15. PATIENT ENVIRONMENT

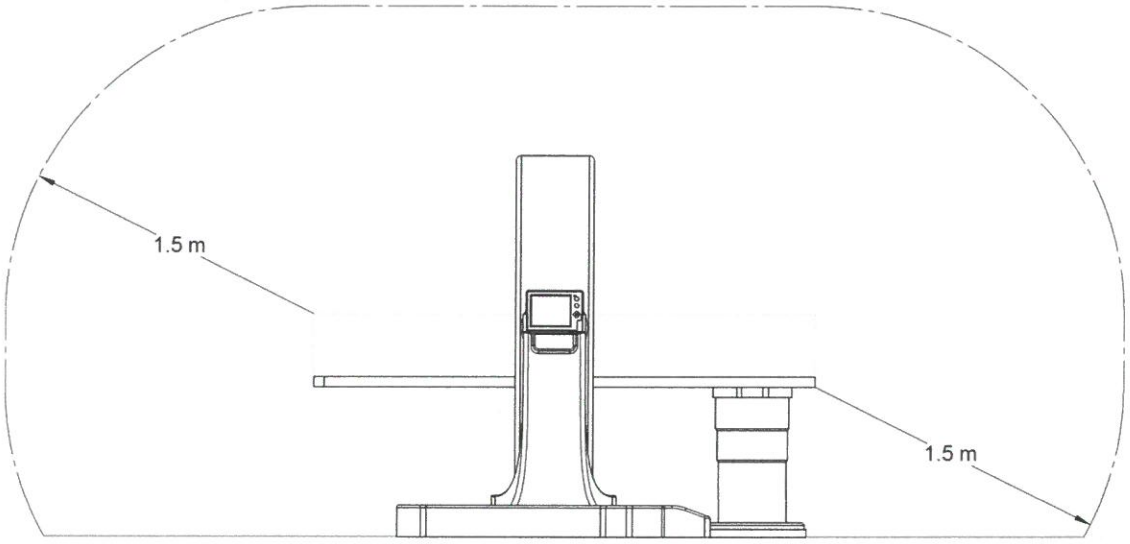
The patient environment is the space in a room where diagnosis, monitoring and treatment occurs. The dimensions provided below show where intentional or unintentional contact can occur between a patient and parts of the system, or between a patient and other persons touching the system.

The patient environment, shown in the following images, is in reference to the tabletop mounted to the system. As the tabletop translates, rotates or tilts, the patient environment moves with it.

15.1. Patient Environment - Top View



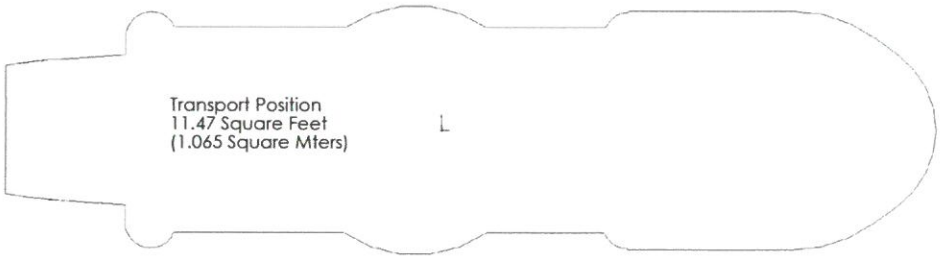
15.2. Patient Environment - Side View



16. FLOOR LOADING

16.1. Transport Mode

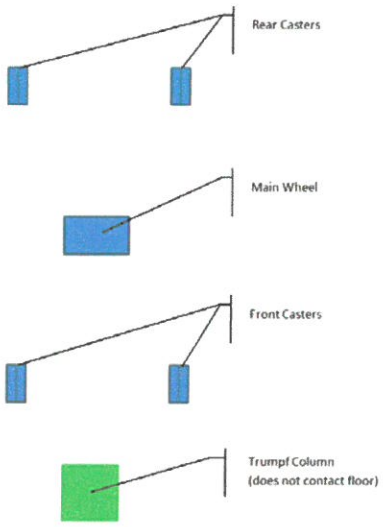
- Total System weight = 2150 lbs. (975 kg)
- Footprint area of the Airo: 11.47 ft² (1.065 m²).



Airo Footprint in Transport Mode

- System general floor loading:
  - 2150 lbs./11.47 ft² = 187.4 lbs./ft²
  - 975 kg/1.065 m = 915.5 kg/m²

- Caster load
  In Transport mode, the system Base is supported by four casters, two in the front and two in the rear. The loading for the casters is:
  - Front casters average pressure: 482 lb/in² (33.8 kg/cm²)
  - Rear casters average pressure: 120 lb/in² (8.4 kg/cm²)
  - Caster wheel hardness: A 92 Shore
- Main Wheel load
  The Airo also contains a main wheel which carries load of Gimbal and Gantry. The load on the Main Wheel is the same in Transport and Scan modes. The loading on the Main Wheel is:
  - Main Wheel average pressure: 350 lb/in² (24.6 kg/cm²)
  - Main Wheel hardness: A 95 Shore



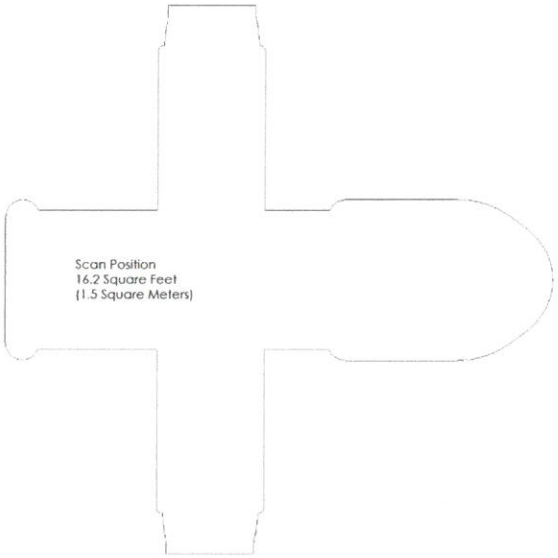
Airo Floor Loading Map

- Caster/Wheel Spacing (center to center)
  - Left Caster to Right Caster: 17.50 in (44.5 cm)
  - Rear Caster to Front Caster: 44.25 in (112.4 cm)
  - Rear Caster to Main Wheel: 21.25 in (54.0 cm)
  - Front Caster to Main Wheel: 23.00 in (58.4 cm)

16.2. Scan Mode

The total system weight will consist of the Airo at 2150 lbs. (975 kg), a table top which we will assume at 200 lbs. (90.7 kg) and a patient. For the patient, we will use the maximum patient weight allowed for the Airo which is 400 lbs. (181.4 kg). The total maximum weight in scan mode is therefore 2750 lbs. (1247.4 kg).

The footprint area in scan mode is 16.2 ft^2 (1.5 m^2).



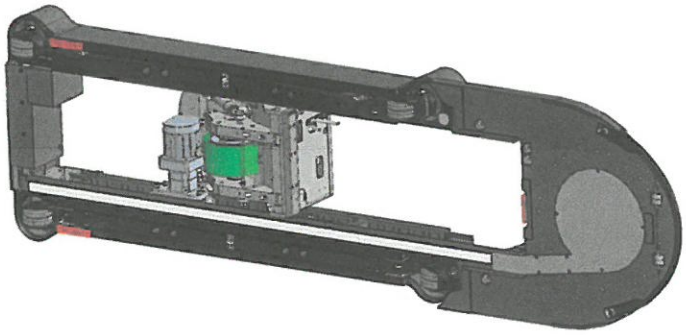
Airo Footprint in Scan Mode

- The general floor loading of the system is:
  - 2750 lbs./16.2 ft^2 = 169.8 lbs./ft^2
  - 1247.4 kg/1.5 m^2 = 831.6 kg/m^2
- In Scan mode, there are three mechanically independent parts of the system which rest on the floor; the Ring/Gimbal, the Base and the Trumpf Column plate (which is mechanically isolated from the base.
  - Ring/Gimbal

    The Ring/Gimbal load is carried by the Main Wheel. This load is the same in Scan mode as in Transport Mode. The Main Wheel average pressure is 350 lb/in^2 (24.6 kg/cm^2)

- Base

  The base rests on the floor on three pads. The front pad as an area of 0.5 in^2 (3.2 cm^2) and the two rear pads each have an area of 2 in^2 (12.9 cm^2). The total Base pad area is 4.5 in^2 (29.0 cm^2).

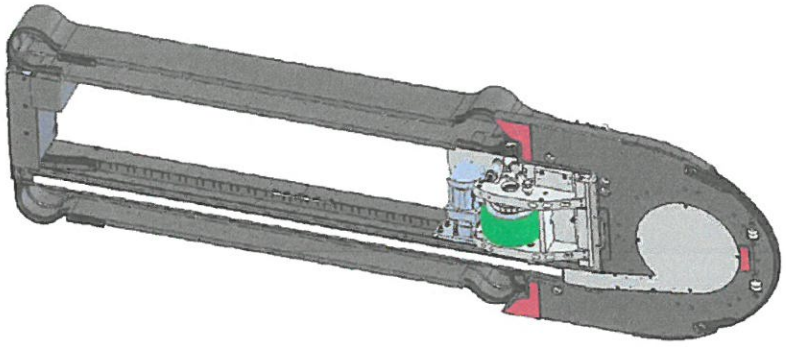


  The weight of the Base is 200 lbs. (90.7 kg). There is 200 lbs. (90.7 kg) of weight transferred from the Ring/Gimbal onto the Base. This gives a total weight of 400 lbs. (181.4 kg).

  - Load on the rear base pads:
    - 250 lbs./4 in^2 = 62.5 lb/in^2
    - 113.4 kg/25.8 cm^2 = 4.39 kg/cm^2
  - Load on the front base pad:
    - 150 lbs/0.5 in^2 = 300 lb/in^2
    - 68.0 kg/3.2 cm^2 = 21.1 kg/cm^2

- Trumpf Column plate

  The Trumpf Column is attached to a plate which is part of the Base but mechanically isolated from it. This plate has three pads which supports all of the weight of the plate and are shown below in red.



These two larger pads each have an area of 8 in^2 (51.6 cm^2) and the smaller pad has an area of 2.6 in^2 (16.8 cm^2).

The total weight supported by these pads is 1150 lbs. (431 kg)

Depending upon the rotation and translation of the tabletop, the weights on these pads can vary. Each of these pads will support some weight even if the table is translated full towards it, but for our calculations, we will assume worst case scenario with all the weight rests upon the pad the table is translated towards.

- Table rotated away from the Ring and translated fully outward.
  - In this position all of the weight would be supported by the small pad. This gives a loading of;
    - 1150 lbs. / 2.6 in^2 = 442 lb/in^2
    - 522 kg/ 16.8 cm^2 = 31 kg/cm^2
- Table rotated perpendicular to the Ring and translated fully outward.
  - In this position, all of the weight would be supported by one of the larger pads (8 in^2 / 51.6 cm^2), depending upon the orientation of the table rotation. This gives a loading of;
    - 1150 lbs./8 in^2 = 144 lb/in^2
    - 522 kg/51.6 cm^2 = 10 kg/cm^2

16.3. Emergency Transport Mode

In Emergency Transport Mode, the weight of the Airo is carried on the Main Drive, allowing the system to be transported on the drive wheel. The wheel supports a load of 2150 lbs. (975 kg) on a bearing surface of 4 in^2 (25.8 cm^2), resulting in a total loading pressure of 537.5 lb/in^2 (37.8 kg/cm^2).

17. SUPPORT

For questions or problems, please contact Brainlab customer support at the following:

Region	Telephone and Fax	Email
United States and Canada	Tel: (800) 597-5911 Fax: (708) 409-1619	us.support@brainlab.com
Europe	Tel: +49 89 991568-44 Fax: +49 89 991568-811	support@brainlab.com
France and French-speaking regions	Tel: +33 800 676 030	

18. AUTHORIZED EU REPRESENTATIVE

Brainlab AG
Kapellenstr. 12
85622 Feldkirchen
Germany
Ph: +49 89 99 15 68 0
Fx: +49 89 99 15 68 33

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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

May 3, 2016

Lynn S. Pitman
Wake Forest Baptist Health
Medical Center Boulevard
Winston-Salem, NC 27157

No Review

Record #:	**1936**
Facility Name:	North Carolina Baptist Hospital
FID #:	943495
Business Name:	North Carolina Baptist Hospital
Business #:	1324
Project Description:	Acquire an Airo Mobile Intra-Operative CT
County:	Forsyth

Dear Ms. Pitman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of May 3, 2016, regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

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

Sincerely,

Celia C. Inman
Project Analyst

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Kelli Fisk, Program Assistant, Healthcare Planning, DHSR

Wake Forest™
Baptist Health

Strategic and Business Planning

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Lynn S. Pitman
Associate Vice President

Ms. Celia C. Inman
Certificate of Need Section
Division of Health Services Regulation
North Carolina Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Request for no Review Confirmation

Dear Ms. Inman:

On behalf of the North Carolina Baptist Hospital (NCBH), I am writing to notify the CON Section of our intent to acquire a CT scanner that can be moved for use at a variety of locations within the Medical Center. NCBH has the opportunity to purchase an Airo Mobile Intra-Operative CT which will allow us to enhance patient safety by avoiding the need to transport patients undergoing surgical procedures or Critical Care inpatients requiring scans. This is a mobile 32-slice helical CT scanner with a large 107cm (42") bore and a field of view of 50cmx 100cm, ensuring flexibility of patient positioning and the ability to image the entire spine in a single acquisition. While the name of the equipment indicates its utility as intra-operative equipment due to its abilty to be moved in and out of operating rooms, it is not limited to intra-operative and operating room use. The total cost of the equipment, which requires no construction or installation as it can be moved from room to room, is less than $750,000. Based on this, it is our understanding that it does not constitute major medical equipment subject to certificate of need review. Attached please find a quote from the vendor outlining the purchase price.

NCBH respectfully requests confirmation from the Division of Health Regulation that this purchase does not constitute major medical equipment pursuant to NC General Statute 131 E-176 14O and therefore does not require a certificate of need. Please let me know if you have questions or need additional information.

Very Truly Yours,

Lynn S. Pitman
Associate Vice President
Strategic and Business Planning
Wake Forest Baptist Health

BRAINLAB

Brainlab, Inc.
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Westchester · IL 60154 · USA

phone: +1 708 409 1343
fax: +1 708 409 1519

Wake Forest Baptist Medical Center
Medical Center Boulevard
Winston-Salem, North Carolina, 27157-0001
United States

Westchester, March 29, 2016
Quotation QN-NCBHPI-GUT-139

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

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

Pos.	Art.No.	Description	Qty.
		AIRO	
1	19650	AIRO MOBILE INTRAOPERATIVE CT	1
2	B13229	AIRO CALIBRATION PACKAGE	1
		19652 GAMMEX PHANTOM W CASE AND STAND	
		19144 ADHESIVE FLAT MARKERS (10 PCS)	
		19148 CT SCANNER CALIBRATION PHANTOM	
		INTEGRATED OR 3RD PARTY PRODUCTS	
3	19225	AIRO TRUMPF PATIENT POSITIONING SYSTEM TOTAL SPINE & CRANIAL - USA	1
		ONSITE APPLICATION TRAINING - IGS	
4	83992-03	AIRO TRAINING (5 CONSECUTIVE DAYS)	1
		AIRO SERVICES	
5	83991-01	AIRO INSTALLATION	1
6	50788	AIRO FREIGHT, INSURANCE AND FEES	1

TOTAL	1,107,732.00 USD
Wake Forest Special Discount	-357,733.00 USD
TOTAL EXCL. TAX	749,999.00 USD

BRAINLAB

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

BRAINLAB

AIRO

1 | 19650 | AIRO MOBILE INTRAOPERATIVE CT

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

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

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

REQUIREMENTS FOR COMBINED USE WITH NAVIGATION:

- Latest generation Brainlab navigation platform: Curve 1.1, Curve Dual Display or Curve Ceiling-Mounted Single Display.
- Minimum software versions Navigation Software Cranial 3.0 (art. 22216) and/or Navigation Software Spine & Trauma 3D 2.1 (art. 22266)
- Airo Automatic Image Transfer & Registration (art. 19651)
- Origin Data Management (art. 30038)
- Elements Image Fusion (art. 26217)
- Elements Dicom Viewer (art. 26210)
- Elements Dicom Viewer 3D (art. 26211)
- Elements Trajectory Planning (art. 26250)Elements Smartbrush (art. 25200)

NOTE:

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

2 | B13229 | AIRO CALIBRATION PACKAGE

Hardware for calibration of Airo Mobile Intraoperative CT.

19652 | GAMMEX PHANTOM W CASE AND STAND

19144 | ADHESIVE FLAT MARKERS (10 PCS)
Adhesive markers attached to selected intra-operative imaging devices enable integration with Brainlab navigation systems.

- Reflective surface for visibility to infrared navigation camera

BRAINLAB

- 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)

19146 | CT SCANNER CALIBRATION PHANTOM
Calibration phantom to calibrate a CT scanner for Automatic Image Registration and verify the accuracy on a routine basis by Brainlab service engineer.

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

INTEGRATED OR 3RD PARTY PRODUCTS

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

OR TABLE X-RAY
2x Shuttle 3.6 360
1x Operating table top Carbon X-TRA 7500 U
1x Operating table top U24 U
1x Table top segment carbon 600 U
1x Leg section one part short U

GENERAL PATIENT POSITIONING
1x Clamp pair for joint plate carbon
1x Joint plate carbon 520
2x Side rail U
2x Armboard snaplock trigger
2x Armboard pad 3"

SPINE STABILIZATION
1x T3 Advance System
1x Ultra Comfort Covers, Medium, case/6
1x Ultra Comfort Covers, Large, case/6

CRANIAL STABILIZATION
1x Adapter X-ray triple joint wide
1x Retainer X-ray
1x Swivel adapter X-ray
1x Skull clamp X-ray (PMI DORO)

ADAPTERS
1x Interface Skull Clamp AL (DBS Adapter) LP
1x Interface Skull Clamp (Biopsy Arm/Varioguide) LP

SHIPPING, INSTALLATION AND TRAINING

BRAINLAB

ONSITE APPLICATION TRAINING - IGS

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

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

- Airo features and functionalities
- Calibration and operational procedures
- Airo specific automatic image transfer to hospital network or other devices
- Navigation platform integration workflows and registration software for cranial and spine (if applicable)

AIRO SERVICES

5 | 83991-01 | AIRO INSTALLATION

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

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

If applicable:

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

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

6 | 50788 | AIRO FREIGHT, INSURANCE AND FEES

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

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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

August 19, 2016

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

No Review

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

Dear Ms. Zerman:

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

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

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

Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

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

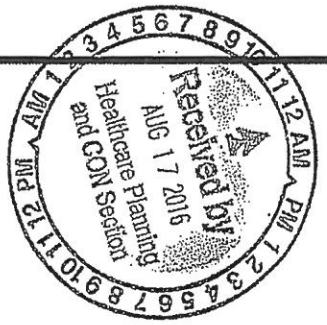
Sincerely,

Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Assistant Chief, Certificate of Need

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

FID#923517
Record# 2032



Zerman, DJ

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

Ms Thorne-Williams,

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

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

Sincerely,

DJ
Direct line 984-974-1243

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

8/12/16

Bernetta,

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

Thanks, Dee Jay 984-974-1243 direct line

BRAINLAB

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

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

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

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

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

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

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

	Sum USD
TOTAL EXCL. TAX	**749,999.00 USD**

(quote manually reviewed)

BRAINLAB

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

Technical Quote Review done by

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

BRAINLAB

1 | 19650 | AIRO MOBILE INTRAOPERATIVE CT

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

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

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

REQUIREMENTS FOR COMBINED USE WITH NAVIGATION:

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

NOTE:

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

2 | B13229 | AIRO CALIBRATION PACKAGE

Hardware for calibration of Airo Mobile Intraoperative CT.

19652 | GAMMEX PHANTOM W CASE AND STAND

19144 | ADHESIVE FLAT MARKERS (10 PCS)
Adhesive markers attached to selected intra-operative imaging devices enable integration with Brainlab navigation systems.

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

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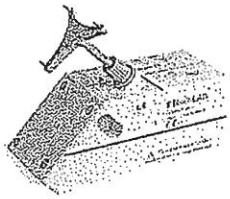
- Enables Automatic Image Registration with Brainlab navigation (additional software required)
  Suitable for following imaging hardware:
- Airo
- Siemens CT scanners (iCT)
- Siemens Artis zeego (iAngio 3D)



19148 | CT SCANNER CALIBRATION PHANTOM
Calibration phantom to calibrate a CT scanner for Automatic Image Registration and verify the accuracy on a routine basis by Brainlab service engineer.

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

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

OR TABLE X-RAY
2x Shuttle 3.6 360
1x Operating table top Carbon X-TRA 7500 U
1x Operating table top U24 U
1x Table top segment carbon 600 U
1x Leg section one part short U

GENERAL PATIENT POSITIONING
1x Clamp pair for joint plate carbon
1x Joint plate carbon 520
2x Side rail U
2x Armboard snaplock trigger
2x Armboard pad 3"

SPINE STABILIZATION
1x T3 Advance System
1x Ultra Comfort Covers, Medium, case/6
1x Ultra Comfort Covers, Large, case/6

CRANIAL STABILIZATION
1x Adapter X-ray triple joint wide
1x Retainer X-ray
1x Swivel adapter X-ray
1x Skull clamp X-ray (PMI DORO)

ADAPTERS
1x Interface Skull Clamp AL (DBS Adapter) LP
1x Interface Skull Clamp (Biopsy Arm/Varioguide) LP

SHIPPING, INSTALLATION AND TRAINING

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

On-site training for Airo® mobile intraoperative CT including:
- Airo features and functionalities
- Calibration and operational procedures
- Airo specific automatic image transfer to hospital network or other devices
- Navigation platform integration workflows and registration software for cranial and spine (if applicable)

-Eligible for IACET CEUs with completion of training.

BRAINLAB

5 | 83991-01 | AIRO INSTALLATION

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

- Inspection and setup of delivered material
- Setup and test of TRUMPF column and table top
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If applicable:

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

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

6 | 50788 | AIRO FREIGHT, INSURANCE AND FEES

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

7 | B14278 | CONSULTING AND COORDINATION OF AIRO

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

CONSULTING

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

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

COORDINATION:

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

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

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

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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 11, 2013

Catharine W. Cummer, Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707

No Review

Facility or Business:	Duke University Health System d/b/a Duke University Hospital
Project Description:	Acquisition of portable intra-operative CT scanner
County:	Durham
FID #:	943138

Dear Ms. Cummer:

The Certificate of Need Section (CON Section) received your letter of October 9, 2013 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-733-8139
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

Sincerely,

Michael J. McKillip, Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR

Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

Via Electronic Delivery

October 9, 2013

Mr. Michael McKillip
Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Duke University Hospital Project # J-8030-07
Request for Material Compliance Determination

Dear Mr. McKillip:

On behalf of the Duke University Health System, I am writing to notify the CON Section of our intent to acquire a CT scanner that can be moved for use at a variety of locations within Duke University Hospital. Duke has the opportunity to purchase a Portable Intra-Operative CT which has just received FDA 510(k) clearance. This equipment is a mobile 32-slice helical CT system with a large 107cm (42") bore and a field of view of 50cm x 100cm, ensuring flexibility of patient positioning and the ability to image the entire spine in a single acquisition. While the name of the equipment indicates its utility as intra-operative equipment due to its ability to be moved in and out of operating rooms, it is not limited to intra-operative and operating room use.

The total cost of the equipment, which requires no construction or installation as it can be moved from room to room, is less than $750,000. We have previously made the quote for this equipment available to you for your review, and the quote reflects that all costs for delivery and training are included in that cost. Because this equipment is less than $750,000, it is our understanding that it does not constitute major medical equipment subject to certificate of need review.

We would note that Duke was expressly approved for 5 additional CT scanners as part of Project J-8030-07 and has not yet purchased and installed all of the approved scanners. However, unless otherwise instructed by the CON Section, we would not consider this "mobile" CT scanner as part of the DMP project because it would not be limited to use at the DMP and in

3100 Tower Blvd Suite 1300 * Durham, NC 27707 * tel (919) 668-0857 * catharine.cummer@duke.edu

fact could be moved throughout the DMP, Duke North, Duke South, and any other contiguous areas at the Duke University Hospital. If necessary, however, Duke would be willing to consider this new CT scanner as one of the five scanners approved as part of Project J-8030-07. (This would not be the designated "intra-operative" fixed CT scanner already installed as part of the operating room suite in the DMP.)

We would appreciate your confirmation that this acquisition does not require any further certificate of need review, and furthermore that it is in compliance with Project ID J-8030-07. Please let us know if you consider this scanner as one of the approved scanners under that project, or if you have any other questions. Thank you for your attention to this request.

Very truly yours,

Catharine W. Cummer

3100 Tower Blvd Suite 1300 * Durham, NC 27707 * tel (919) 668-0857 * catharine.cummer@duke.edu