



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



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



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



Strategic and Business Planning

Medical Center Boulevard
Winston-Salem, NC 27157
p 336.716.1046
f 336.716.2879
lpitman@wakehealth.edu
www.WakeHealth.edu

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 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. 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-176 140 and therefore does not require a certificate of need. Please let me know if you have questions or need additional information.

Very Truly Yours,

A handwritten signature in cursive script, appearing to read 'Lynn S. Pitman'.

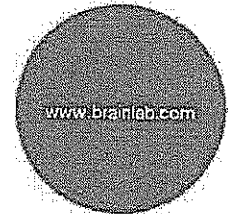
Lynn S. Pitman
Associate Vice President
Strategic and Business Planning
Wake Forest Baptist Health



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

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

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



Nuttrell

Natalie Nuttrell
Area Account Manager Mid Atlantic
natalie.nuttrell@brainlab.com

DUPLICATE



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. 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

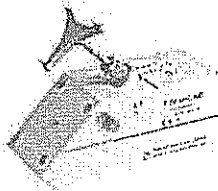
19144 | ADHESIVE FLAT MARKERS (10 PCS)

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

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



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.