DR. B.R.A.INSTITUTE ROTARY CANCER HOSPITAL ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI -110029. (STORES SECTION)

Dated: 12/11/2015

Ref. No.- 06/Stores (DR. B.R.A.I.R.C.H.)/R.T. & ANESTH/Proprietary Equipment/2015-16/FSC

Subject: Purchase of Image guided Treatment Planning and Robotic Needle placementn system with accessories -1 No. on proprietary basis.

The Institute is in the process to purchase of Image guided Treatment Planning and Robotic Needle placementn system with accessories -1 No. on proprietary basis.

The proposal submitted by M/s. Perfint Healthcare Pvt. Ltd. with PAC & Patent certification.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the item within issue of 15 days giving reference **06/Stores** (**DR. B.R.A.I.R.C.H.)/R.T. & ANESTH/Proprietary Equipment/2015-16/FSC** The comments should be received by office of Stores Officer (Dr. B.R.A.I.R.C.H.), Store Section, Room No. 18, G.F. (Dr. B.R.A.I.R.C.H. Building, AIIMS) on or before 01/12/15 upto 12.30 p.m., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Stores Officer Dr. B.R.A.I.R.C.H. A.I.I.M.S.

Encl.: Related documents enclosed

- 1. Proforma Invoice of M/s. Perfint Healthcare Pvt. Ltd.
- 2. Proprietary & Patent Certificate
- 3. Technical detail of the equipment



| S No | Item | Quantity | Price |
|-------------------|---|----------------------------|-------|
| 1 | MAXIO® with All new Ver 2.5 with 1.1 Electromechanical axis of stereotactic device with planning station including InstaRegMat , power and communication cables with specifications as mentioned in the technical bid. 1.2 All new latest Ver 2.5 Software features | 1 no | |
| 2 | Accessories | | |
| а | Breath Hold Monitor System (BHMS) | 1 no | |
| b | Patient Immobilizer (PI) | 1 no | |
| С | RF Ablation Generator for Pain Management | 1 no | |
| 3. | Disposables | | |
| Α | Sterile Drapes(Sterile) | 5nos | |
| В | Needle Bushes/guides in gauge sizes: 11,13,14,16,17,18,19,20,21,22,23–(Sterile) | 10 noseach size | |
| С | Cannulas/Needles for Pain Management RF ablation procedures | 50 nos | |
| 4. | Other items | | |
| | User Manual hardcopy/CD | 1 no | |
| | Comprehensive warranty(Software upgrade included) | 5 yrs | |
| | Start – up training at site | Upto 5 days | |
| Includes parts an | chensive Annual Maintenance Contract periodic preventive maintenance and breakdown maintenance a d labor) following warranty period offered at additional price from an 10% per annum from the previous year for every subsequent | n the 6 th Year | |

For Perfint Healthcare Pvt Ltd

Guruswamy K Director - Sales



PROPRIETARY CERTFICATE

This is to confirm that MAXIO™ is a proprietary product of M/s Perfint Healthcare Pvt. Ltd., 3rd Floor, No.16, South West Boag Road, T.Nagar, Chennai – 600 017, TN, India.

We, M/s Perfint Healthcare Pvt. Ltd, declare that MAXIO™ is an image-guided, physician controlled stereotactic accessory to a Computed Tomography (CT) system. MAXIO™ is intended for stereotactic accessory spatial positioning and orientation of an end effector and instrument guide to assist in manual advancement of one or more (up to 6) instruments for CT guided procedures such as Ablation, Biopsy, Drainage, FNAC, Etc.

We hold the following patents issued by the United States Patent and Trademark office.

- 1. US 8,401,620 B2 NEEDLE POSITIONING APPARATUS AND METHOD (Positioning system for all products)
- 2. US 8,613,748 B2 APPARATUS AND METHOD FOR STABILIZING THE NEEDLE (2 Disposables one for holding the needle after placement and the other for assisting in holding the needle guide for insertion)
- 3. US 8,774,901 B2 NEEDLE POSITIONING APPARATUS AND METHOD (Workflow and method for using a mobile positioning system for intervention outside the CT imaging field)
- 4. US 8,958,913 B2 ELECTRONIC DOCKING SYSTEM AND METHOD FOR ROBOTIC POSITIONING SYSTEM (Motorized docking and use of sensors for docking - no obstruction in the floor)

Yours Faithfully,

For Perfint Healthcare Pvt. Ltd

Authorized Signatory

Dated: 01-10-2015

CHENNA

Lr. HNM. GAMI, B.Com., B.L. Advocate & Commissioner of OATHS Office: Law Association, Saidapet Court, Little Mount Chennai-600 015. Ceii: 9380903886

Perfint Healthcare Pvt Ltd

CIN No. U51507TN2005PTC065950

Registered Office: 3rd Floor, No.16, South West Boag Road, T Nagar, Chennai - 600 017, India
Tel: +91-44-45506412, Fax: +91-44-24345911, email: info@perfinttech.com, www.perfinthealthcare.com



(12) United States Patent

Velusamy et al.

(10) Patent No.: (45) Date of Patent:

US 8,401,620 B2

Mar. 19, 2013

NEEDLE POSITIONING APPARATUS AND METHOD

(75) Inventors: Gnanasekar Velusamy, TamilNadu (IN); Kannan Neelakanta Sarma,

TamilNadu (IN); Kasi Viswanathan Agilandam, Karnataka (IN); Roy Santosham, TamilNadu (IN)

(73) Assignee: Perfint Healthcare Private Limited

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35 U.S.C. 154(b) by 954 days.

(21) Appl. No.: 11/682,375

Mar. 6, 2007 (22) Filed:

(30)

Prior Publication Data

US 2008/0091101 A1 Apr. 17, 2008

Foreign Application Priority Data

Oct. 16, 2006 (IN) 1903/CHE/2006

(51) Int. Cl. A61B 5/055 (2006.01) A61B 19/00 (2006.01)

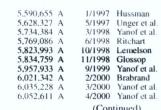
(52) U.S. Cl. ... 600/427; 600/424; 606/130

(58) Field of Classification Search None See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

| 4,583,538 | A | | 4/1986 | Onik et al. | |
|-----------|---|---|---------|--------------|---------|
| 4,883,053 | A | | 11/1989 | Simon | |
| 5,078,140 | A | * | 1/1992 | Kwoh | 600/417 |
| 5,201,742 | A | | 4/1993 | Hasson | |
| 5,371,778 | A | | 12/1994 | Yanof et al. | |



(Continued)

FOREIGN PATENT DOCUMENTS

| EP | 1524626 A2 4/2005 | 5 |
|----|---------------------|---|
| EP | 1 791 070 A2 5/2001 | 7 |
| | (Continued) | |

OTHER PUBLICATIONS

Joachim Kettenbach, Robot-Assisted Biopsy Using Computed Tomography-Guidance, Investigative Radiology, Apr. 2005, p. 219. vol. 40, No. 4, Lippincott Williams & Wilkins, Philadelphia.

(Continued)

Primary Examiner — Long V. Le Assistant Examiner - Angela M Hoffa

ABSTRACT

Apparatus for accurate positioning of a needle guide is disclosed. The apparatus provides a means for taking as input the position vector for the point of insertion of the needle into the body. This point of insertion can be selected from images produced by a Computer Tomography system. Similarly, the apparatus has a means for taking as input the point of target. A controller determines the directional vector between point of insertion and point of target. A guide manipulator accurately positions the needle guide in line with the directional vector, such that the needle can easily be inserted through the guide to the point of target. The positioning of the guide manipulator in accordance with the directional vector is done with the help of motors.

26 Claims, 13 Drawing Sheets







(12) United States Patent

Velusamy et al.

(10) Patent No.:

US 8,613,748 B2

(45) Date of Patent:

Dec. 24, 2013

| (54) | APPARATUS AND METHOD FOR |
|------|--------------------------|
| | STABILIZING A NEEDLE |

- (75) Inventors: Gnanasekar Velusamy, Tamilnadu (IN); Alan Bachman, Milford, CT (US)
- (73) Assignce: Perfint Healthcare Private Limited
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 23 days.
- (21) Appl. No.: 13/435,963
- (22) Filed: Mar. 30, 2012
- Prior Publication Data (65)

US 2012/0184956 A1 Jul. 19, 2012

Related U.S. Application Data

- (63) Continuation of application No. 13/292,186, filed on Nov. 9, 2011.
- (30)Foreign Application Priority Data

(51) Int. Cl.

A61B 19/00

(2006.01)

(52) U.S. Cl.

USPC

USPC 606/130 (58) Field of Classification Search

See application file for complete search history.

(56)References Cited

U.S. PATENT DOCUMENTS

4,583,538 A 4,883,053 A 5,078,140 A 4/1986 Onik et al. 11/1989 Simon 1/1992 Kwoh

> CHE AR



. 606/130

| 5,201,742 | A | | 4/1993 | Hasson | |
|-----------|---|---|---------|--------------|---------|
| 5,263,939 | A | * | 11/1993 | Wortrich | 604/174 |
| 5,269,305 | A | * | 12/1993 | Corol | 600/429 |
| 5,371,778 | Α | | 12/1994 | Yanof et al. | |
| 5,590,655 | Α | | 1/1997 | Hussman | |

(Continued)

FOREIGN PATENT DOCUMENTS

1103223 A2 5/2001 1524626 A2 4/2005 EP EP

(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion for PCT/IN08/ 00507, mailed on Mar. 23, 2009; 7 pages

(Continued)

Primary Examiner — Gary Jackson Assistant Examiner — Eric Blatt (74) Attorney, Agent, or Firm - Cooley LLP

ABSTRACT

Apparatus and methods for use in an image-guided interventional procedure are described herein. In one embodiment, an apparatus includes a base configured to be releasably coupled to a patient's skin. A support portion extends from the base at an angle transverse to a longitudinal axis defined by the base. The support portion has a first end portion and a second end portion. The first end portion is disposed adjacent the base. A holder portion extends from the second end portion of the support portion. The holder portion defines an opening and is configured to be moved between a first configuration in which the opening defined by the holder portion has a first size and is configured to movably receive an interventional tool therethrough, and a second configuration in which the opening defined by the holder portion has a second size different than the first size.

21 Claims, 25 Drawing Sheets



(12) United States Patent Velusamy et al.

(54)NEEDLE POSITIONING APPARATUS AND METHOD

(71) Applicant: Perfint Healthcare Private Limited, Chennai (IN)

Gnanasekar Velusamy, TamilNadu

(IN); Kannan Neelakanta Sarma, TamilNadu (IN); Kasi Viswanathan Agilandam, Karnataka (IN); Roy Santosham, TamilNadu (IN)

(73) Assignee: Perfint Healthcare Private Limited, T'Nagar, Chennai (IN)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-

(21) Appl. No.: 13/743,960

(22) Filed: Jan. 17, 2013

Prior Publication Data US 2013/0184572 A1 Jul. 18, 2013

Related U.S. Application Data

(62) Division of application No. 11/682,375, filed on Mar. 6, 2007, now Pat. No. 8,401,620.

(30) Foreign Application Priority Data

Oct. 16, 2006 (IN) 1903/CHE/2006

(51) Int. Cl. A61B 6/03

(2006.01) (2006.01)

(52) U.S. Cl.

A61B 19/00

CPC . A61B 6/032 (2013.01); A61B 6/03 (2013.01); A61B 19/201 (2013.01); A61B 6/03 (2013.01);

(10) Patent No.:

US 8,774,901 B2 *Jul. 8, 2014

(45) Date of Patent:

(2013.01); A61B 2019/507 (2013.01); A61B 2019/5238 (2013.01); A61B 2019/467 (2013.01)600/427: 600/424

USPC (58) Field of Classification Search

See application file for complete search history.

References Cited

U.S. PATENT DOCUMENTS

4/1986 Onik et al 11/1989 Simon

(Continued)

FOREIGN PATENT DOCUMENTS

1524626 A2 4/2005 1791 070 A2 5/2007

(Continued)

OTHER PUBLICATIONS

Barrett, S. et al., "A Remote Needle Guidance System for Percutaneous Biopsies," Proceedings of IDETC/CIE 2005, Sep. 2005, 9 pages

(Continued)

Primary Examiner — Long V. Le Assistant Examiner — Angela M Hoffa

ABSTRACT

Apparatus for accurate positioning of a needle guide is disclosed. The apparatus provides a means for taking as input the position vector for the point of insertion of the needle into the body. This point of insertion can be selected from images produced by a Computer Tomography system. Similarly, the apparatus has a means for taking as input the point of target. A controller determines the directional vector between point of insertion and point of target. A guide manipulator accurately positions the needle guide in line with the directional vector, such that the needle can easily be inserted through the guide to the point of target. The positioning of the guide manipulator in accordance with the directional vector is done with the help of motors.

24 Claims, 13 Drawing Sheets





(12) United States Patent Velusamy et al.

- (54) ELECTRONIC DOCKING SYSTEM AND METHOD FOR ROBOTIC POSITIONING SYSTEM
- (71) Applicant: Perfint Healthcare Private Limited, Chennai, TamilNadu (IN)
- (72) Inventors: Gnanasekar Velusamy, Chennai (IN); Cregg K. Cowan, Mountain View, CA (US); Thomas P. Low, Belmont, CA (US); Annjoe Wong-Foy, Pacifica, CA (US)
- (73) Assignce: Perfint Healthcare Private Limited, T'Nagar (IN)
- Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 145 days. Notice:
- (21) Appl. No.: 13/834,751
- (22) Filed: Mar. 15, 2013
- Prior Publication Data US 2014/0222205 A1 Aug. 7, 2014
- (30) Foreign Application Priority Data

Feb. 2, 2013 (IN) 458/CHE/2013

- (51) Int. Cl. A61B 5/05 (2006.01) A61B 8/00 A61B 19/00 (2006.01) (2006.01)A61B 6/03 (2006.01)
- U.S. Cl. USPC 700/259; 600/424; 702/150; 702/94;





(10) Patent No.: US 8,958,913 B2 (45) Date of Patent: Feb. 17, 2015

(58) Field of Classification Search USPC700/259; 600/424; 702/95, 150, 94; See application file for complete search history.

U.S. PATENT DOCUMENTS

(56)References Cited

| 7,182,083 | | 2/2007 | Yanof et al | 28/204 23 |
|--------------|------|---------|-----------------|-----------|
| 7,660,623 | B2 * | 2/2010 | Hunter et al. | 600/424 |
| 7,742,801 | B2 * | 6/2010 | Neubauer et al. | |
| 7,751,868 | B2 * | 7/2010 | Glossop | |
| 7,871,406 | B2 * | | Nields et al. | 606/22 |
| 7,962,193 | B2 * | 6/2011 | Edwards et al. | 600/407 |
| 8,150,495 | | 4/2012 | Edwards et al | 600/407 |
| 8,774,901 | | 7/2014 | Velusamy et al | 600/424 |
| 2002/0156376 | | 10/2002 | Wang et al. | 600/42/ |
| 2004/0152970 | A1 * | 8/2004 | Hunter et al. | 600/434 |
| 2011/0251815 | | 10/2011 | Bar-Tal et al. | 702/05 |
| 2013/0096575 | | 4/2013 | Olson | /02/93 |
| | | 72013 | Olson | . 000/130 |

* cited by examiner

Primary Examiner — Ronnie Mancho (74) Attorney, Agent, or Firm — Cooley LLP

(57)ABSTRACT

An apparatus includes a robotic positioning device and a locating mat. The locating mat includes a location pattern and can be disposed on a floor at a desired position relative to a movable cradle of an imaging system. The robotic positioning device is configured to be disposed, at least partially, above the locating mat. The robotic positioning device includes a docking device that includes an optical device and a guide manipulator supported on the docking device. The guide manipulator can be positioned relative to the movable cradle based, at least partially, on image data associated with the optical device and the location pattern of the locating mat. The guide manipulator can position an instrument guide relative to a patient disposed on the movable cradle.

29 Claims, 14 Drawing Sheets

Lr. HNM. GANI, B Com Advocate & Commissioner of OATHS Office: Law Association, Saidapet Court, Little Mount, Chennai-600,015. Cell: 9380903886







TECHNICAL BID

Image guided Treatment Planning and Robotic Needle placement system with Accessories

Submitted To

Chief, DR. BRAIRCH AIIMS, New Delhi

29th September 2015

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The contents of this document are confidential and are meant for the review of only the person who is
the recipient of the same. All logos are trademarks of their respective owners and have been used in this
proposal for representational purposes only.





Dear Doctor,

SUB: Technical Proposal for Image guided Treatment Planning Robotic Needle placement system with Accessories- MAXIO®

Reference: Discussion during the meeting held on 18 September 2015

In reference to the discussion that we had with you, we are pleased to present to you the technical proposal for the MAXIO $\mbox{\tt @}$ – Planning and Targeting for CT guided procedures.

MAXIO® will enable physicians to offer a wide variety of CT guided Interventional procedures like

- Tumor Ablation : MAXIO supports ablation with all energy sources viz, RF, Microwave, Cryo and IRE (Irreversible Electroporation)
- Biopsy,FNAC & Drainage procedures
- Pain management procedures Facet joint/Nerve root/Various Ganglion injections and RF ablation procedures
- Fiducial Marker placement for targeted radiation therapy
- lodine I125 Seeds placement

We thank you once again for the interest that you have shown in our technology and we now look forward to your valuable PO

With best regards,

Guruswamy K

Director - Sales



ITEM 1

MAXIO® - Planning and Targeting for CT guided procedures

MAXIO® is an image-guided, physician controlled stereotactic accessory to a Computed Tomography (CT) system, intended for the stereotactic spatial positioning and orientation of an end effector and instrument guide (Patents-US 8,401,620 B2, US 8,774,901 B2) to assist in manual advancement of one or more instruments such as rigid straight needles and probes during CT guided percutaneous procedures on organs and anatomical structures in the thorax, abdomen and pelvis.



MAXIO® System provides pre-operative planning assistance to the physician by creating a reconstructed 3D image model of received CT data and by visually representing the planned instrument path and position(s) (Patents-US 8,401,620 B2, US 8,774,901 B2) of one or more instruments on the model, along with performance data provided by the instrument manufacturer or as specified by the

MAXIO® permits physician verification of patient position prior to needle advancement and monitoring of respiratory for levels during the procedure. Image registration and overlay tools available in MAXIO® are intended to provide guidance to the user

during planning and instrument placement.

MAXIO® consists of a stereotactic device and its accessories, software loaded on a computer, and a respiratory gating system. The accessories include a patient immobilizer and skin-markers. MAXIO® System uses single use sterile disposables viz, end effector, instrument guide and drapes.

MAXIO® is intended to be used by physicians trained for CT procedures.





Key features of the MAXIO®

- Pre-operative image registration
- Tools for volumetric visualization and segmentation of multiple VOI
- Multi-probe placement plan on one or more targets
- Tools to verify patient position and respiratory levels
- Stereotactic assistance for multi-probe placement, without fluoroscopic radiation (Patents-US 8,401,620 B2, US 8,774,901 B2)
- Ability to perform compound angle probe placement (Patents-US 8,401,620 B2, US 8,774,901 B2)
- Tools for post procedure verification

New features in the Latest Version V2.5

- Intuitive User interface, Faster & Optimised Workflow for faster procedures
- New & Faster Trajectory planning for IRE (Irreversible Electrophoresis)
 Procedures
- Platform for Offline Planning
- New Procedure workflow for faster Single needle procedures
- Patient movement Detection
- User controlled Robotic Arm positioning for Simultaneous Multi needle placement
- Ablation Volume Edit facility for high accurate estimation
- RoHS Compliance
- Device Self Check- Single click Device readiness



4

Perfint Healthcare Pvt Ltd





Key benefits of the MAXIO®

Today, physicians plan interventional procedures by combining 2D images with their understanding of human anatomy. Physicians are then expected to manually advance one or more instruments to reach the target, without causing damage to vital structures, while accounting for organ and patient movement. It is, therefore, not surprising that these procedures are limited to the most skilled and experienced physicians.

- Now, MAXIO® assists physicians to visualize and plan an interventional procedure, in 3D.
 Multiple VOI, Multiple instruments, Placement sequencing can all be planned before advancing a single instrument.
- Once the plan, patient position and respiratory levels are confirmed, MAXIO's stereotactic arm, combined with intra-operative registration, assists the physician to carefully advance one or more instruments to reach the target.
- MAXIO's post-operative image registration helps physicians verify and extend the treatment if needed. MAXIO's reporting tool then helps generate required reports.







| S No | Parameter | Value/Specification/Description |
|------|--|--|
| 1 | Compatible Modality | СТ |
| 2 | Imaging Interface | DICOM 3.0 |
| 3 | Needle positioning accuracy at delivery point Patents(US 8,401,620 B2, US 8,774,901 B2) | *2mm radius sphere at a needle length of 120 mm on specific non-moving phantom * = RMS |
| | Electrical | |
| 4 | Mains Voltage | 100 - 240 Vac |
| 5 | Line frequency | 50 / 60 Hz |
| 6 | Length of power cable | 8 Meters maximum |
| 7 | Power usage | 300Watts |
| 8 | Max. Current Rating | 3.15 Amps |
| 9 | Mains Isolation | Power supply cord shall be plugged where both |
| 9 | External: done by the user | poles (L & N) are isolated simultaneously. |
| 10 | User Interface | Computer Monitor display |
| | Mechanical | |
| 11 | Mobility | 4 Castor wheels with Locks |
| 12 | x range | 600 +20 / - 0 mm |
| 13 | y range | 450 +20 / - 0 mm |
| 14 | z range | 180 +20 / - 0 mm |
| 15 | a range | ± 95° +10 / -0° |
| 16 | b range | ± 95° +10 / -0° |
| 17 | Positioning of the device with respect to CT system Patents(US 8,958,913 B2) | InstaReg® |
| 18 | Weight | Approx :250 Kgs |
| 19 | Mechanical Dimensions | ~H 1310 x D 850 x W 775 mm |
| 20 | Max. Allowable floor incline during mobility - during procedure - during installation Patents (US 8,958,913 B2) | 10° 5° |





| 21 | Device controls | Control panel switches and foot switch for | | | | |
|----|--|--|--|--|--|--|
| | Device controls | procedure functionality. | | | | |
| | Planning Console Patents (US 8,401,620 B2, | US 8,774,901 B2) | | | | |
| 22 | Operating system | Windows 8.1 professional | | | | |
| 23 | | Intel Core i7 or above | | | | |
| | | 8 GB RAM (min) | | | | |
| | System configuration | 320 GB Hard disk (min) | | | | |
| 23 | System comiguration | 22 inch wide monitor with 1920 x 1080 pixels | | | | |
| | | resolution (FULL HD) | | | | |
| | | Speaker – External or Built in monitor | | | | |
| | Needles supported by the Device | | | | | |
| 24 | Туре | Rigid – Straight, | | | | |
| 25 | Sizes (Gauge) | 11,13,14,16,17,18,19,20,21,22. | | | | |
| 26 | Needle Length | 60 to 250mm | | | | |
| | Needle Guide | | | | | |
| 27 | Compatible needle gauge | 11,13,14,16,17,18,19,20,21,22. | | | | |
| | Sterilization | Single use- disposable | | | | |
| | Procedure Verification | | | | | |
| 28 | Patient Position confirmation module | | | | | |
| | Operating Conditions | | | | | |
| 29 | Operating temperature range | 15 to 40°C | | | | |
| 30 | Transport and storage temperature range | 0 to 50°C | | | | |
| 31 | Relative Humidity range | 50% to 95% RH non-condensing | | | | |
| | Safety | | | | | |
| 32 | Wheels with Lock | | | | | |
| 33 | Detachable Needle bush / Needle guide | | | | | |
| 34 | Emergency Switch | | | | | |
| | Conformance to Standards | | | | | |
| 35 | MDD (93/42/EEC) | Yes | | | | |
| 26 | IEC 60601-1, IEC 60601-1-2, IEC 60601 -1- 6, IEC 60601 -1- 8, ISO 14971, IEC 62304, IEC 62366, | | | | | |
| 36 | BS EN 980, ISO 10993, ISO 14155 | | | | | |





ITEM 2

Accessories

a Breath Hold Monitor System (BHMS) - 1 no

Developed by physicians at Mayo Clinic, the device enables patients to accurately self-monitor their own breath-holds or controlled shallow breathing based on biofeedback provided by an easy-to-read display. The device provides efficient, convenient and affordable respiratory motion control that also has been shown to save time of many procedures.



b Patient Immobilizer (PI) - 1 no

A reusable vacuum cushion with small polystyrene beads inside that hardens on its held position and immobilize the patient. The device hardens around the patient when deflated and immobilize the patient.



c Sterile Drape - 1 no

Sterile drapes are used to cover the electromechanical arm to prevent contact by physicians during the procedure.

Not re-usable



d Needle Bush 11G, 13G, 14G, 16G-22G - 10 each

A single unit sterilized pack consists of "needle bush". The needle bush is held between the grippers and used to guide various sizes of needles or probes during the procedure. Each unit comes in a sterile pack and has various sizes.



e Radiofrequency Generator System for Pain Management – 1 no with 50 nos Cannulas/Needles

K. 61