LAW OFFICES
CUNLIFFE & COOK
210 Archbishop F.C. Flores Street
Hagåtña, Guam 96910
Telephone: (671) 472-1824
Telecopier: (671) 472-2422

Attorneys for: Interested Party MedPharm

BEFORE THE PUBLIC AUDITOR
PROCUREMENT APPEAL

IN THE APPEAL OF JMI – EDISON , Appellant.	DOCKET NO. OPA-PA-11-001 **INTERESTED PARTY MEDPHARM'S COMMENT ON AGENCY REPORT**

Pursuant to 2 GAR §12104(c)(4) Interested Party MedPharm Guam aka MedPharm Group of Companies (hereafter referred to as "MedPharm") files these comments on the Agency Report filed with the Office of Public Accountability (hereafter referred to as "the OPA") on January 19, 2011.

The Notice of Appeal filed by Appellant on January 4, 2011, sets forth three (3) basis for the appeal. Those three (3) basis of appeal were part of six (6) issues raised by Appellant in its protest to General Services Agency (hereafter referred to as "GSA") filed August 6, 2010. (Procurement Record No. 1). The three (3) issues raised by Appellant, as well as the other three (3) issues initially raised in the protest to GSA, were rejected by GSA in its rejection letter dated December 16, 2010. (Procurement Record No. 2). MedPharm files these comments to support the rejection of the initial protest by GSA and to support the dismissal of this appeal as lacking any merit on the issues raised in the appeal.

Appellant's first basis of appeal is that MedPharm's bid was non-responsive and that it did not meet the specifications of the solicitation requiring "optional stretcher".

Under §1A System Configuration of the Invitation For Bid GSA-105-10 (hereafter referred to as "the IFB"), it states: "Standard or extended arm digital wall stand ONLY with single portable detector and optional stretcher." (Procurement No. 5). Attached and marked as Exhibit "1" is a page from the brochure submitted as part of MedPharm's bid. (Procurement Record No. 4). It states in pertinent part: "A single button pressed automatically moves the ceiling mounded x-ray tube support to the imaging position, relative to the wall stand, x-ray table and, if used, stretcher." The system configuration request in the IFB is that the equipment can be used with a patient on a stretcher. That is what the IFB requested. That is what the brochure provided by MedPharm as part of its bid states. That is what was relied on by GSA to approve MedPharm's bid as noted by GSA in its letter to Appellant dated December 16, 2010, rejecting that issue in Appellant's protest to GSA.

The second issued raised in the Notice of Appeal is the contention by Appellant that MedParm's bid did not respond to the specifications that there be two (2) LCD monitors. On Page No. 2 of MedPharm's bid under Section F, Acquisition Work Station "Two (2)-19 in. (48)CM LCD Color Monitor (1280x1024 pixels)", MedPharm put in the "Bidding On or Remarks" column "Two (2)-19 in. LCD color monitor (1280x1204 pixels)". See, Exhibit "2". Therefore, MedPharm clearly stated in its bid response that it would comply with this specification by listing two (2) color monitors in its bid proposal. Also, attached as Exhibit "3" is a page from the brochure submitted with MedPharm's bid in which it states:

"Superior quality imaging using Cannon's amorphous silicon back panel detector known as LANMIT, VCXDI-60C produces high resolution, high contrast diaganostic images. The sensors multi-objective frequency processing can be optimately calibrated

to view captured images on *LCD monitors*." (Emphasis added). Therefore, it is clear from the brochure submitted with the bid that the equipment can handle more than one (1) monitor.

In GSA's rejection of the protest, it again referenced that its review of the bid and brochure satisfied its investigation that MedPharm's bid met the specifications set forth in the IFB.

The third basis for the appeal filed by Appellant is that Medpharm's bid does not provide documentation showing compliance with necessary regulatory agencies as it claims is required in the bid. GSA made a finding that Medpharm's bid was compliant because the IFB did not specify what regulatory agencies specifications had to be met. In its appeal, Appellant admits that the brochure submitted with MedPharm's bid references that the equipment is in compliance with ISO9001:2000 Quality Management Systems and ISO13485:2003 Medical Equipment Quality Management Systems. Attached hereto as Exhibit "4" are pages from the brochures where this compliance is noted.

MedPharm notes that a number of the major components of the system specified in the IFB are specifically exempt from FDA Section No. 510(k) requirements. Attached as Exhibit "5" are pages from Title 21 Code of Federal Regulations ("CFR") where these exemptions are noted. Specifically, diagnostic x-ray high voltage generator is exempt. Diagnostic x-ray tube is exempt. Radiological table is exempt. Wall mounted radio graphic cassette holder is exempt. Diagnostic x-ray with housing assembly is exempt.

Additionally, the fact the equipment submitted in MedPharm's bid meets ISO9001 and ISO13485 standards demonstrates that the equipment comports to FDA requirements pertaining to medical devices. A print out of the FDA Medical Devices

Quality Systems regulation is attached hereto as Exhibit "6". MedPharm specifically cites to the second paragraph which states: "Also, the agency [FDA] believed that it would be beneficial to the public and the medical device industry for the CGMP [Current Good Manufacture Practices] regulation to be consistent, to the extent possible, with the requirements for quality systems contained in the applicable international standards, primarily, the International Organization For Standards (ISO) 9001;1994 "Quality Systems -- Model for Quality Assurance in Design Development and Production Installation, and Services" and at the time ISO Committee (CD) revision of ISO/CD 13485 "Quality Systems – Medical Devices -- Supplementary Requirements to ISO9001". Therefore, it is clear that FDA recognizes ISO standards. This is most clearly exemplified by the fact that the equipment MedPharm included in its bid for purchase by the Department of Public Health & Social Services for use in Guam's Public Health Centers, is equipment that is available and used at many medical clinics through the United States.

Therefore, MedPharm's bid met the specification requirements that the equipment meets applicable standards. This is what GSA determined upon review of the bid.

//

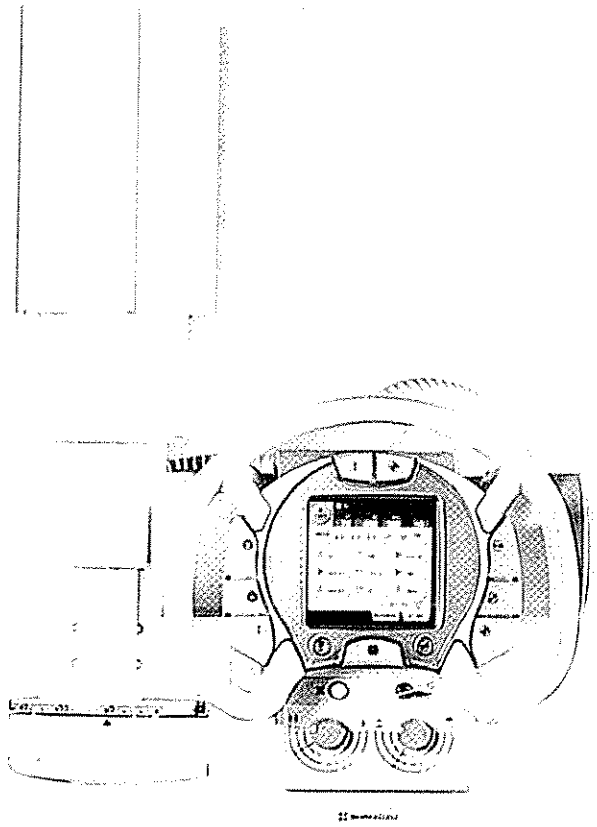
//

In closing, MedPharm would comment that it is unfortunate that there are no penalties for Appellant to be fined or otherwise punished for filing a meritless appeal which does nothing but harass a competitor, MedPharm, and more importantly, interferes with the Department of Public Health & Social Services' ability to provide appropriate medical services to the people of Guam.

Respectfully submitted this 31st day of January, 2011.

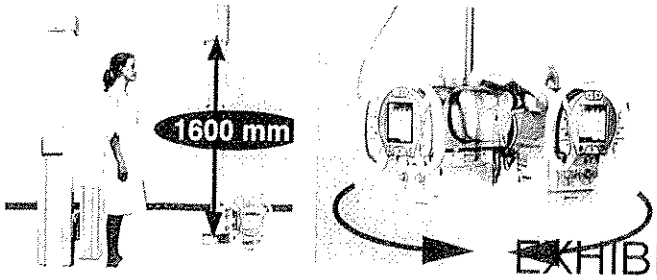
CUNLIFFE & COOK
A Professional Corporation
Attorneys for Interested Party *MedPharm*

By _____
JEFFREY A. COOK, ESQ.

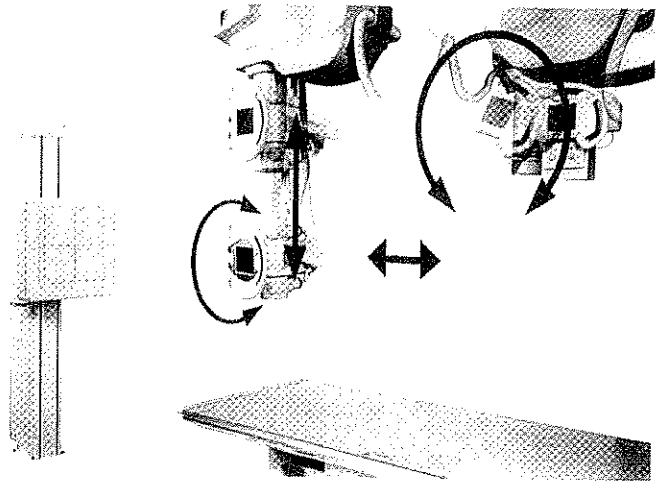


Ceiling Mounted X-ray Tube Support for Versatile Positioning

X-ray tube support vertical range of 1,600 mm ensures sufficient SID when examining supine patients and low focal point radiography of standing patients.
This support also rotates on the vertical and horizontal axis in addition to fixed positioning at any desired angle, enabling fast positioning at complex angles for orthopedic applications.



Advanced level positioning can automatically move the ceiling mounted X- ray tube support to the optimal imaging position, relative to the Wall Stand and the X-ray Table.



A single button press automatically moves the ceiling mounted X-ray tube support to the imaging position, relative to the Wall Stand, X-ray Table and, if used, stretcher. This automatically switches the SID or X-ray tube angle, allowing an operator to change position from one examination area to another, easy tube support preparation and stowage, and provides a significantly improved, trouble-free, efficient examination workflow. The X-ray tube can be manually positioned for precision alignment.

A single button press moves the ceiling-mounted X-ray tube support smoothly to the registered position. Movement stops immediately when the remote control button is released. Uses up to two remote-control units.

Auto-Positioning Via Linkage with Anatomical Programs (AFP)

EXHIBIT "1"

System Access & Authorization Control that support Health-care organization's HIPAA compliance efforts.	ISO, TUV Certified
Integrated quality procedure	Comply

C. Workflow and Networking

Auto-protocol recognition (optional)	Comply
Auto-positioning and Auto-detents	Comply
Fast preview image (quality control)	Comply
Post acquisition reprocessing for multiple "looks" From single exposure	Comply
Patient edit/auto-foldering (copy exam)	Comply
Modality Perform Procedure Step (MPPS/SPS/PPS)	Comply
Automated and Customizable image transfer and printing	Comply
DICOM 3.0 and IHE compliant	Comply

D. Image Quality and Dose

Multi-resolution image processing capability	Comply
Tissue Equalization (TE) used to correct over-penetrated And under-penetrated areas with the image	Comply
Intelligent Collimation Edge Detection (ICED) Automated image shuttering and cropping tool	Comply
Automated brightness/contrast setting (Smart Windowing)	Comply
Orthopedic magnification/print – Detector	
Exposure Index (DEI) – Dose tracking and QC Metric	Comply
Dose Area Product (DAP) – Entrance dose Metric	Comply

E. Digital Image System – Portable Digital Flat Panel Detector

Portable digital flat-panel detector, non-tiled amorphous silicon Detector with a Cesium Iodide scintillator. Delivers very high Quantum efficiency / low noise characteristics.	Portable digital flat-panel detector, non tiled silicon detector with a Cesium Iodide scintillator.Delivers very high Quantum efficiency/low noise characteristics.
390 cm (153 in.) detachable extension cable allows for table Top and cross table exams and simplifies detector placement	630 cm detachable cables allows for table top and cross exams and simplifies detector placement
To include attachable high line rate grid - * 30 cm focus and SID Range of 100-180 cm (70 lines/cm; 6:1 ratio)	To include attachable high line rate grid -8:1 ratio / 110cm

Ref: GE Portable Digital Flat Panel Detector or Equal

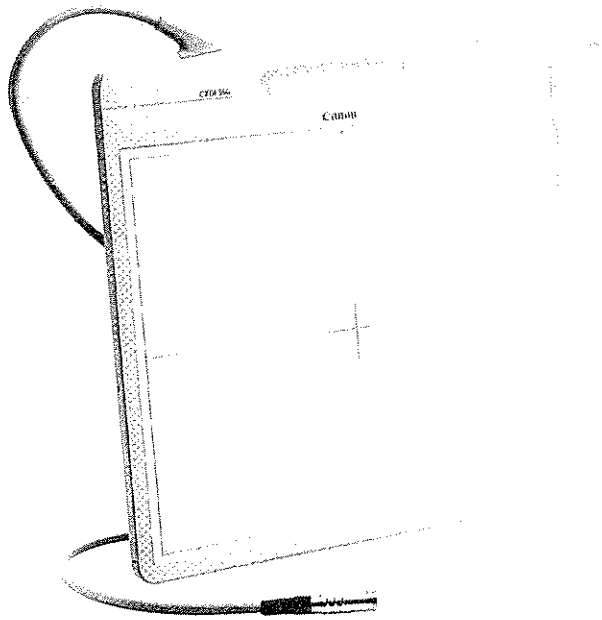
Detector Specifications:

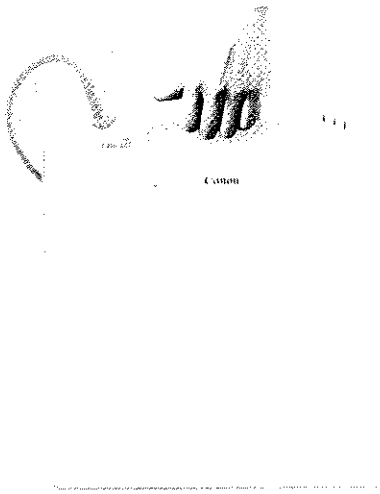
Detector Size: 41 cm x 41 cm	35 cm x 43 cm
Active matrix 2022 x 2022 pixels	Superior Resolution 2,688 x 2,200 pixels (5.9 Million Pixels)
Image depth 14 Bit	14 bits
Pixel pitch 200 microns	160 x 160 microns
Typical dynamic range 1.5 uR – 7 mR @ RQA5	
Typical DQE 65% @ 0 1p @ RQA5	70% at 0.1 1p/mm @RQA5
Max patient load 160 kg (352 lbs)	Highly Durable FPD Table - 295 kg

F. ACQUISITION WORKSTATION

Two (2) – 19 in. (48 cm) LCD color monitor (1260 x 1024 pixels)	Two(2)-19 in. LCD Color Monitor (1280 x 1024 pixels)
Hard disk storage: 73 GB, > 3200 Images	80GB HDD
RAM: 2GB minimum	Comply
Image processing times for single exposure exams (Including acquisition and image processing)	8 seconds

EXHIBIT "2"





Versatile DR Technology in a Thin, Lightweight Flat Panel Detector for High-Quality Imaging

Thin and Lightweight Body

The CXDI-55G/C is very thin – the same thickness of standard film cassettes. The 7.5 lb (3.4 kg) device is light enough for use in trauma centers and ICUs. Simple to grip and handle, both the patient and X- ray technician can comfortably hold the CXDI-55G/C in place during image capture.

Large Imaging Area

Equipped with a large 14 x 17in. (35 x 43 cm) imaging area, the CXDI-55G/C can accommodate a wide variety of DR. The generous size is suitable for radiographic applications including skull, spine, chest, abdomen, and extremity examinations.

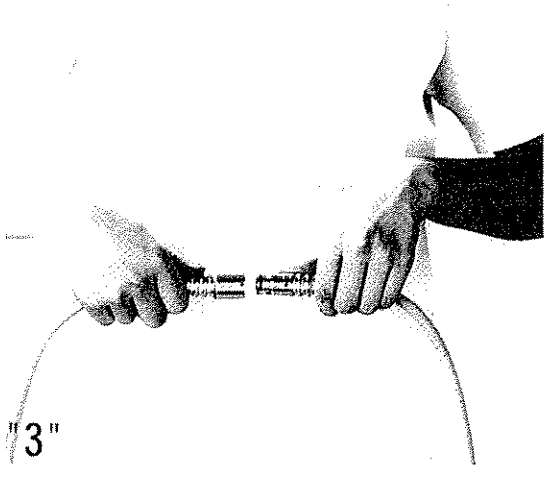
Convenience of Detachable Cable

The CXDI-55G/C and CXDI-60C offers the benefits of true portability with a detachable sensor cable: time-effective transport and simple installation.

Unparalleled mobility, easy operation and immediate image review are only a few of CXDI-60C's impressive capabilities. Extremely versatile, this device provides unmatched quality digital images for a wide range of diagnostic exams and settings.

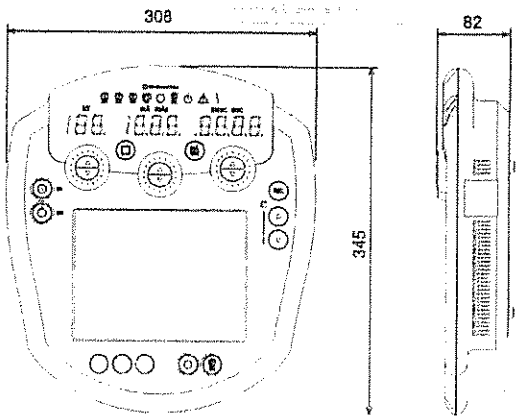
Superior-Quality Imaging

Using Canon's Amorphous Silicon Flat Panel Detector, known as LANMIT, the CXDI-60C produces high resolution, high contrast diagnostic images. The sensor's multi-objective frequency processing can be optimally calibrated to view captured images on LCD monitors.



DIMENSIONS AND WEIGHT

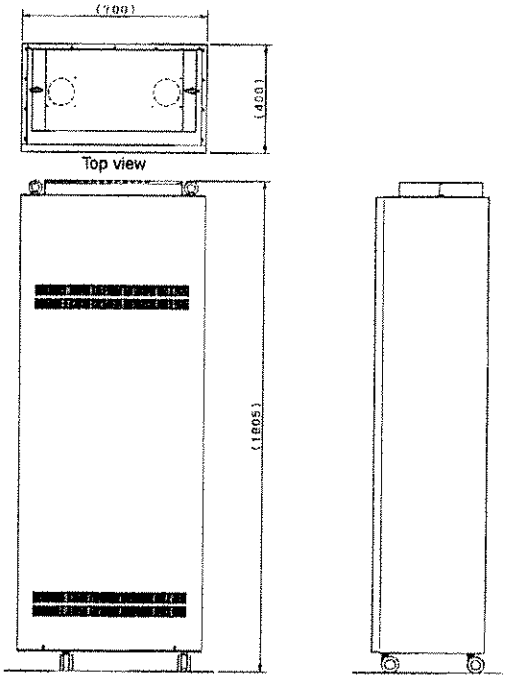
Control console



Front view　　Side view

Unit: mm
Weight: 2.5 kg

Control cabinet



Top view

Front view　　Side view

Unit: mm
Weight:
D150BC-40 (for UD150B-40) 250 kg
D150VC-40 (for UD150V-40) 250 kg
D150LC-40 (for UD150L-40) 240 kg

Remarks
- Every value in this Product Data Sheet is a standard value, and it may vary a little from the actual at each site.
- The appearances and specifications are subject to change for reasons of improvement without notice.

SHIMADZU

SHIMADZU CORPORATION. International Marketing Division
3. Kanda-Nishikicho 1-chome, Chiyoda-ku, Tokyo 101-8448, Japan　Phone: 81(3)3219-5641　Fax: 81(3)3219-5710

URL http://www.shimadzu.com

ISO 9001:2000
ISO 13485:2003
JIS Q 9001:2000
JIS Q 13485:1998

Shimadzu Corporation Medical Systems Group has been certified by TUV Rheinland as a manufacturer of medical equipment and systems in compliance with ISO9001: 2000 Quality Management Systems and EN ISO13485: 2003 Medical Equipment Quality Management Systems.

Remarks

* Every value in this Product Data Sheet is a standard value, and it may vary a little from the actual at each site.
* The appearances and specifications are subject to change for reasons of improvement without notice.
* Certain configurations may not be available pending regulatory clearance. Contact your Shimadzu representative for information on specific configurations.

SHIMADZU

SHIMADZU CORPORATION, International Marketing Division
3, Kanda-Nishikicho 1-chome, Chiyoda-ku, Tokyo 101-8448, Japan Phone: 81(3)3219-5641 Fax: 81(3)3219-5710

URL http://www.shimadzu.com

ISO 9001:2000
ISO 13485:2003
JIS Q 9001:2000
JIS Q 13485:1998

Shimadzu Corporation Medical Systems Group has been certified by TUV Rheinland as a manufacturer of medical equipment and systems in compliance with ISO9001: 2000 Quality Management Systems and EN ISO13485: 2003 Medical Equipment Quality Management Systems.

EXHIBIT "4"

Remarks

- Every value in this Product Data Sheet is a standard value, and it may vary a little from the actual at each site.
- The appearances and specifications are subject to change for reasons of improvement without notice.
- Certain configurations may not be available pending regulatory clearance. Contact your Shimadzu representative for information on specific configurations.

SHIMADZU

SHIMADZU CORPORATION. International Marketing Division

3, Kanda-Nishikicho 1-chome, Chiyoda-ku, Tokyo 101-8448, Japan Phone: 81(3)3219-5641 Fax: 81(3)3219-5710

URL http://www.shimadzu.com

ISO 9001:2000
ISO 13485:2003
JIS Q 9001:2000
JIS Q 13485:1998

Shimadzu Corporation Medical Systems Group has been certified by TUV Rheinland as a manufacturer of medical equipment and systems in compliance with ISO9001: 2000 Quality Management Systems and EN ISO13485: 2003 Medical Equipment Quality Management Systems.

EXHIBIT "4"

ENVIRONMENT

Location	Ambient temperature	Relative humidity
Examination room	20 to 27℃ *Continuous running the air-conditioning for 24 hrs	15% to 75% (Non condensing)
Operation room	10 to 30℃	15 to 75% (Non condensing)

Remarks

- Every value in this Product Data Sheet is a standard value, and it may vary a little from the actual at each site.
- The appearances and specifications are subject to change for reasons of improvement without notice.
- Certain configurations may not be available pending regulatory clearance. Contact your Shimadzu representative for information on specific configurations.

SHIMADZU

SHIMADZU CORPORATION. International Marketing Division
3, Kanda-Nishikicho 1-chome, Chiyoda-ku, Tokyo 101-8448, Japan Phone: 81(3)3219-5641 Fax: 81(3)3219-5710

URL http://www.shimadzu.com

ISO 9001:2000
ISO 13485:2003
JIS Q 9001:2000
JIS Q 13485:1998

Shimadzu Corporation Medical Systems Group has been certified by TUV Rheinland as a manufacturer of medical equipment and systems in compliance with ISO9001: 2000 Quality Management Systems and EN ISO13485: 2003 Medical Equipment Quality Management Systems.

EXHIBIT "4"

JACO
Japan Audit and Certification Organization
for Environment and Quality

UKAS ENVIRONMENTAL MANAGEMENT
051

MS
JAB
CM021

SHIMADZU CORPORATION,

Headquarters and Factories in Kyoto and Shiga district

1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto, Japan

CERTIFICATE

Certificate No.: EC97J1031

ISO 14001:2004 • JIS Q 14001:2004

Development, design, manufacture, sales, services and logistics of Analytical and Measuring Instruments, Medical Systems, Aircraft Equipment, Hydraulic Equipment, Industrial Machinery and Laboratory Instruments

Our organization certifies above organization to be complied with the requirement of indicated above management system.

Registration Date : 24/Jun/1997
Recertification Date : 24/Jun/2009
Issue Date : 10/Jun/2009
Certificate Expiry : 23/Jun/2012

Japan Audit and Certification Organization
for Environment and Quality
2-2 19 Akasaka, Minato-ku, Tokyo, Japan

President
& CEO

To be used in conjunction with attached Appendix

EXHIBIT "4"

Certificate

Standard: **EN ISO 9001:2008, JIS Q 9001:2008**
Certification Registr. No. **01 100 096363**

TÜV Rheinland Cert GmbH certifies:

Certification Holder: **Shimadzu Corporation, Medical Systems Division**
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan
including the location / factories / branch offices / subsidiary companies according to annex

Scope: **Design, Development, Manufacturing, Importing and Sales of Medical Diagnostic Imaging Devices and Systems, Related Devices**
Product group and full product description:
Nuclear Magnetic Resonance Imaging Systems, X-Ray Computer Tomography Devices, Diagnostic X-Ray Devices, Angiographic X-Ray Diagnostic Systems, Diagnostic Ultrasound Systems, X-Ray Tube Assemblies, Image Intensifiers, Nuclear Medicine Diagnostic Devices, Medical Image management Systems, General Health Management Systems, Hospital Facilities and Devices, Oximeter

An audit was performed, Report No. 096363.

Proof has been furnished that the requirements are fulfilled according to EN ISO 9001:2008, JIS Q 9001:2008.

The due date for future audits is 02-18 (mm-dd).

Validity: This certificate is valid from 2010-05-13 until 2013-05-12.

First certification: 2010

Yokohama, 2010-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

ID:0091004755

DGA-ZM-58-95-00

TÜVRheinland®
Precisely Right.

EXHIBIT "4"

Annex to Certificate

Certification Registr. No. **01 100 096363**
Standard: **EN ISO 9001:2008, JIS Q 9001:2008**

Location:	**Shimadzu Corporation Medical Systems Division** 1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto 604-8511, Japan
Scope:	Design, Development, Manufacturing, Importing and Sales of Medical Diagnostic Imaging Devices and Systems, Related Devices
Certification Registr. No.	01 100 096363/01
Location:	**Tokyo Office Medical Systems, Sales Section 1 and 2:** 1-3 Kanda-Nishiki-cho, Chiyoda-ku, Tokyo 101-8448, Japan
	Chiba Sales Office: Daiichi Ishibashi Bldg. 101, 2-1-6 Shinchiba, Chuo-ku, Chiba-shi 260-0031, Japan
	Yamanashi Sales Office: Green Heights Tachibana 101, 2-4-10 Sumiyoshi, Kofu-shi, Yamanashi , 400-0851, Japan
	Koriyama Sales Office: Koriyama Fukoku Seimei Bldg. 2F, 6-7 Domaecho, Koriyama-shi , Koriyama-shi, Fukushima 963-8877, Japan
	Nagoya Office Medical Systems, Sales Section: Nagoya Kokusai Center Bldg. 19F, 1-47-1 Nagono, Nakamura-ku, Nagoya-shi 450-0001, Japan
	Kyoto Office Medical Systems, Sales Section: 1 Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto-shi 604-8511, Japan
	Shiga Sales Office: Koto Bldg. 2F, 1205 Koshinohara, Yasu-shi, Shiga 520-2331, Japan
	Kansai Office Medical Systems, Sales Section: Hankyu Terminal Bldg. 14F, 1-1-4 Shibata, Kita-ku, Osaka-shi 530-0012, Japan
	Minami Osaka Sales Office: 4-9-20 Koryonishimachi, Sakai-ku, Sakai-shi, Osaka 590-0026, Japan
	Nara Sales Office: Nissei Naraekimae Bldg. 4F, 1-1-15 Omiyacho, Nara-shi 630-8115, Japan
	Okayama Sales Office: Sumitomo Seimei Okayama Newcity Bldg. 6F, 3-10 Togiyacho , Kita-ku, Okayama-shi 700-0826, Japan

Yokohama, 2010-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

DGA-ZM-58-95-00

TÜVRheinland®
Precisely Right.

EXHIBIT "4"

Annex to Certificate

Certification Registr. No. **01 100 096363**
Standard: **EN ISO 9001:2008, JIS Q 9001:2008**

Tottori Sales Office:
6-1-32 Shinkai , Yonago-shi, Tottori 683-0801, Japan
Kobe Office Medical Systems, Sales Section:
Matsuoka Bldg. 8F, 70 Kyo-machi , Chuo-ku, Kobe-shi 650-0034, Japan
Hiroshima Office Medical Systems, Sales Section:
Meiji Yasuda Seimei Hiroshima Bldg. 15F, 4-25, Fukuro-machi, Naka-ku, Hiroshima-shi 730-0036, Japan
Yamaguchi Sales Office:
5-18 Ogoriminamimachi , Yamaguchi-shi 754-0013, Japan
Shimane Sales Office:
2698 Naoemachi, Hikawacho , Hikawa-gun, Shimane 699-0631, Japan
Fukuyama Sales Office:
1-4-37 Kinoshocho , Fukuyama-shi, Hiroshima 720-0082, Japan
Kyushu Office Medical Systems, Sales Section:
Shimadzu Hakata Bldg. 4F, 4-20 Reisen-machi , Hakata-ku, Fukuoka-shi 812-0039, Japan
Kita-Kyusyu Sales Office:
2-8-11 Katanoshinmachi , Kokurakita-ku, Kitakyusyu-shi 802-0062, Japan
Tosu Sales Office:
1311-8 Motomachi, Tosu-shi , Saga 841-0051, Japan
Oita Sales Office:
176-1 Houjyo, Oita-shi 870-0855, Japan
Miyazaki Sales Office:
952-1 Koukyu , Miyazaki-shi 880-0916, Japan
Kagoshima Sales Office:
1-33-1 Higashitaniyama , Kagoshima-shi 891-0113, Japan
Nagasaki Sales Office:
Sensyu Daini Bldg. 6-32, Chitosemachi , Nagasaki-shi 852-8135, Japan
Kumamoto Sales Office:
2-20-45 Hirata , Kumamoto-shi 860-0826, Japan
Yokohama Office Medical Systems, Sales Section:
Tobu-Yokohama No.3 Bldg. 7F, 2-8-29 Kita-Saiwai , Nishi-ku, Yokohama-shi 220-0004, Japan

Yokohama, 2010-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

ID:0091004755

DGA-ZM-58-95-00

TÜVRheinland®
Precisely Right.

EXHIBIT "4"

Annex to Certificate

Certification Registr. No. **01 100 096363**
Standard: **EN ISO 9001:2008, JIS Q 9001:2008**

Sapporo Office Medical Systems, Sales Section:
Sapporo Center Bldg. 8F, Kita 5-jo, Nishi 6-chome , 2-2,Chuo-ku, Sapporo-shi 060-0005, Japan
Tohoku Office Medical Systems, Sales Section:
Sendai Meihou Bldg. 3F, Chuo 2-10-30, Aoba-ku,Sendai-shi 980-0021, Japan
Akita Sales Office:
Toda Bldg., 2-25, Higashidori Nakamachi, Akita-shi 010-0002, Japan
Shikoku Office Medical Systems, Sales Section:
Sumitomo Seimei Takamatsu Bldg. 9F, 1-6-1 Ban-cho , Takamatsu-shi, Kagawa 760-0017, Japan
Matsuyama Sales Office:
Pure Dogo 1F, 5-48 Dogoimaichi , Matsuyama-shi 790-0845, Japan
Tokushima Sales Office:
6-7-2 Sumiyoshi , Tokushima 770-0861, Japan
Kochi Sales Office:
Seiryo Heights,1-4-17 Chiyoricho , Kochi-shi 780-0806, Japan

Scope:	Sales of Medical Diagnostic Imaging Devices and Systems, Related Devices
Certification Registr. No.	01 100 096363/02

Yokohama, 2010-05-13

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

DGA-ZM-58-95-00

TÜVRheinland®
Precisely Right.

EXHIBIT "4"

1. UD150B-40 Generator: Exempt

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR892.1700]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1700 **Diagnostic x-ray high voltage generator.**

(a) *Identification.* A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the x-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) *Classification.* Class I (general controls). **The device is exempt from the premarket notification procedures** in subpart E of part 807 of this chapter, subject to the limitations in 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

EXHIBIT "5"

2. CH-200 Ceiling Tube Support: Exempt

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR892.1770]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1770 **Diagnostic x-ray tube mount.**

(a) *Identification.* A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.

(b) *Classification.* Class I (general controls). **The device is exempt from the premarket notification procedures** in subpart E of part 807 of this chapter, subject to the limitations in 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

EXHIBIT "5"

3. BK-200 Bucky Table: Exempt

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR892.1980]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1980 **Radiologic table.**

(a) *Identification.* A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification.* Class II (special controls). **The device is exempt from the premarket notification procedures** in subpart E of part 807 of this chapter subject to 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 63 FR 59231, Nov. 3, 1998]

EXHIBIT "5"

4. BR-120T Wall Bucky Stand: Exempt

CFR - Code of Federal Regulations Title 21

See Related Information

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR892.1880]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1880 **Wall-mounted radiographic cassette holder.**

(a) *Identification.* A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use.

(b) *Classification.* Class I (general controls). **The device is exempt from the premarket notification procedures** in subpart E of part 807 of this chapter, subject to the limitations in 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

EXHIBIT "5"

5. 0.6/1.2P324DK-85(SF) Tube: Exempt

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR892.1760]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1760 **Diagnostic x-ray tube housing assembly.**

(a) *Identification.* A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class I (general controls). **The device is exempt from the premarket notification procedures** in subpart E of part 807 of this chapter, subject to the limitations in 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38819, July 25, 2001]

EXHIBIT "5"

Medical Devices

Quality Systems Regulation

Quality System (QS) Regulation/Medical Device Good Manufacturing Practices

- Introduction
- Flexibility of the QS Regulation
- Applicability of the QS Regulation
- GMP Exemptions
- Additional Quality System Information
- Quality System Regulation and Preamble [1]

Introduction

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as current good manufacturing practices (CGMP's). CGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act). Under section 520(f) of the act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for medical devices. This regulation became effective on December 18, 1978, and was codified under part 820.

In 1990, FDA undertook the start of the revision of the CGMP regulation to add the design controls authorized by the Safe Medical Devices Act. Also, the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standards (ISO) 9001:1994 "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," and at the time the ISO committee draft (CD) revision of ISO/CD 13485 "Quality Systems--Medical Devices--Supplementary Requirements to ISO 9001." After an extensive effort, the part 820 revision was published on October 7, 1996 (61 FR 52602) [2] and went into effect June 1, 1997. For additional information on the history and international harmonization of the revised regulation, with international standards and the Global Harmonization Task Force (GHTF), see the preamble (pages 52602 - 52654) to the Quality System regulation (61 FR 52602) [3].

The preamble describes the public comments received during the development of the QS regulation and describes the FDA Commissioner's resolution of the comments. Thus, the preamble contains valuable insight into the meaning and intent of the QS regulation.

Flexibility of the QS Regulation

The QS regulation embraces the same "umbrella" approach to the CGMP regulation that was the underpinning of the original CGMP regulation. Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations, 21 CFR 820.5 of the QS regulation. Operating within this flexibility, it is the responsibility of each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated even though the actual work may be delegated.

FDA has identified in the QS regulation the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.

Applicability of the QS Regulation

The QS regulation applies to finished device manufacturers who intend to commercially distribute medical devices. A finished device is defined in 21 CFR 820.3(l) as any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Certain components such as blood tubing and diagnostic x-ray components are considered by FDA to be finished devices because they are accessories to finished devices. A manufacturer of accessories is subject to the QS regulation.

GMP Exemptions

FDA has determined that certain types of medical devices are exempt from GMP requirements. These devices are exempted by FDA classification regulations published in the Federal Register and codified in 21 CFR 862 to 892. Exemption from the GMP requirements does not exempt manufacturers of finished devices from keeping complaint files (21 CFR 820.198) or from general requirements concerning records (21 CFR 820.180).

Medical devices manufactured under an investigational device exemption (IDE) are not exempt from design control requirements under 21 CFR 820.30 of the QS regulation.

Additional Quality System Information

Quality System (QS) Regulation

- 21 CFR 820 [4]
- Medical Device Quality System Regulation and Preamble [5]

Quality System Regulation Guidance Documents

- Medical Device Quality Systems Manual [6]
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff [7]

Design Controls

- Design Control Guidance For Medical Device Manufacturers [8]

Human Factors

- Human Factors [9]
- Guidance for Industry and FDA Premarket and Design Control Reviewers - Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (PDF Version) (PDF - 1103KB) [10]
- Do It By Design - An Introduction to Human Factors in Medical Devices (PDF Version) (PDF - 257KB) [11]

Other Related Information

- Workshops & Conferences (Medical Devices) [12]
- CDRH Learn [13]
- What is the relationship between FDA's Quality System Regulation for Devices, Part 820 and ISO 9001: 2000? (PDF - 10KB) [14]

Links on this page:

1. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm
2. /downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/UCM122806.pdf
3. /downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/UCM122806.pdf
4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1
5. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm
6. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/default.htm
7. /MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070897.htm
8. /MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm
9. /MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/default.htm
10. /downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094461.pdf
11. /downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095061.pdf
12. /MedicalDevices/NewsEvents/WorkshopsConferences/default.htm
13. /Training/CDRHLearn/default.htm
14. /downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/UCM134625.pdf