GE Healthcare

Performix™ HD X-Ray Tube

For GE Discovery™ CT750 HD

D3701T / D3702T / D3703T / D3704T

The Performix HD X-Ray Tube has re-invented the Performix family of GE tubes, invigorating the proven Performix brand with high definition technology. GE's Designed-for-Six-Sigma Performix tube product has been validated by 10 years in operation and over 25,000 installations. Supporting your clinical ability to see more and know more with less dose, the Performix HD satisfies this performance expectation by helping to deliver exceptional image quality.

Dynamic Focal Spot Control Translates Into Image Quality

Through dynamic focal spot control, Performix HD customizes focal spot size to maximize image quality. This technology relies on complex integration between components in the imaging chain to help enable:

- *Consistent Focal Spot Control,* maintaining image quality across images within the acquired dataset
- *High mA for Small Focal Spot,* bringing exceptional image quality to larger patient scans
- *Data Sampling,* offering additional information necessary for true anatomy reconstruction by the CT system
- *Fast kVp Switching*, necessary to support Gemstone Spectral Imaging
- *Outstanding Spatial Resolution*, as part of the image chain—along with the Gemstone Detector and Data Acquisition system—delivering spatial resolution improvements.

Integration

GE's integration of tube, generator and system dose-management technologies provides customers the imaging flexibility and power to meet demanding imaging requirements while optimizing patient care.

Maximize throughput

The Performix HD X-Ray Tube handles protocols while delivering high capability by helping to minimize cooling delays with greater than 5000 W dissipation rate.

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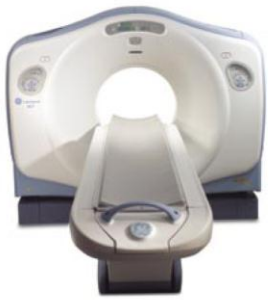
Date: 2024.03.12 09:02:03 EET
Reason: MoldSign Signature
Location: Moldova

Performix HD Specifications

D3701T/D3702T/D3703T/D3704T
(Tube Model Numbers 5195800 / 5195800-5 / 5195800-6)



Tube Insert Focal Spots

Small Focal Spot (680 max mA)

- 1.0 x 0.7 per IEC 60336/2005

Large Focal Spot (835 max mA)

- 1.6 x 1.2 per IEC 60336/2005

GSI Focal Spot (890 max mA) [GSI Scanning only]

- 2.0 x 1.2 per IEC 60336/2005

Target Angle: 7 degrees

Thermal Ratings:

Efficient anode heat transfer and casing design eliminates inter-patient delays for demanding helical scans

Anode

- Max anode heat content: 5.7 MJ
- Nominal anode input power: 100kW

Housing

- Max x-ray tube assembly heat content: 8MJ
- Max continuous heat dissipation: 5.1 kW

X-Ray Tube Housing Assembly

Anode-Grounded Technology

- Nominal tube voltage: 140kVp
- Leakage technique factor: 140 kV, 32.1 mA
- Quality equivalent filtration: Min 3.91mm Al equiv at 70 kV

Warranty

The published warranty in effect on date of shipment shall apply. Right reserved to make changes.

Regulatory Listings

CE Mark
Intertek (ETL) certified to meet applicable IEC and CSA standards.
This tube unit has been designed to meet or exceed all applicable 21 CFR Subchapter J performance standards for diagnostic X-ray equipment as stipulated by the Radiation Control for Health and Safety Act.

Included License

The GE Performix HD tube includes a standard license that automatically enables the use of tube-dependent advanced applications. The use of a non-Performix HD tube will require an additional license for the activation of these features.

Single Load Rating

Permissible mA values for single 5-second exposure from cold

Scan Mode	kV	Small Focal Spot mA	Large Focal Spot mA
Normal	80kV	620	700
	100kV	680	800
	120kV	570	835
	140kV	490	715
Hi-Res	80kV	620	700
	100kV	500	750
	120kV	420	625
	140kV	360	540

Permissible mA values for single 10-second exposure from cold

Scan Mode	kV	Small Focal Spot mA	Large Focal Spot mA
Normal	80kV	620	700
	100kV	650	800
	120kV	540	755
	140kV	460	650
Hi-Res	80kV	610	700
	100kV	490	710
	120kV	405	590
	140kV	350	505

Serial Load Rating

Permissible mA values for serial 5-second exposures (10 min IPD)

Scan Mode	kV	Small Focal Spot mA	Large Focal Spot mA
Normal	80kV	620	700
	100kV	610	800
	120kV	505	705
	140kV	435	605
Hi-Res	80kV	575	700
	100kV	460	670
	120kV	380	555
	140kV	325	475

Permissible mA values for serial 10-second exposures (10 min IPD)

Scan Mode	kV	Small Focal Spot mA	Large Focal Spot mA
Normal	80kV	620	700
	100kV	550	760
	120kV	455	630
	140kV	390	540
Hi-Res	80kV	535	700
	100kV	430	600
	120kV	355	500
	140kV	305	425

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The Performix brand is a registered trademark of GE Healthcare.
General Electric Company, doing business as GE Healthcare.

General Electric Company reserves the right to make changes in specifications and features shown herein or discontinue the product described at any time without notice or obligation. Contact your GE Representative for the most current information.

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 22462 rev. 6**
Délivrée à Paris le 25 octobre 2019
Issued in Paris on October 25th, 2019

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE MEDICAL SYSTEMS, LLC
4855 West Electric Avenue
MILWAUKEE, WI 53219 UNITED STATES

Catégorie du(des) dispositif(s) / *Device(s) category*

Gaine équipée (gaine + tube radiogène)

X-ray tube assembly (housing + tube)

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P173316, P601198, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P173316, P601198, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **October 25th, 2019 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

Digitally signed by Chicu Natalia
Date: 2023.11.07 12:18:26 EET
Reason: MoldSign Signature
Location: Moldova

GMED SAS GMED SAS

Lionel DREUX
Certification Director

GMED_b2p3-F-V0-07-2018

GMED - 22462 rev. 6
Renouvelle le certificat 22462-5

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Gaine équipée *X-ray tube assembly*	**MX100 HTG**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX100 FL**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray MX100 FL**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX100 RAD**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray MX100 RAD**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX75 HRT**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray HRT 275**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX150**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix 160A**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX165CT HiSpeed Advantage**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT HSA**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX165CT ProSpeed**	**IIb**

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Certification Director

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Gaine équipée *X-ray tube assembly*	**Maxiray MX165CT ProSpeed**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX135CT Sri**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix Advantage CTI**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT Advantage CTI**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX165NP**	**IIb**
Gaine équipée *X-ray tube assembly*	**Solarix 350 Brightspeed**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray Solarix**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX200CT NP/Performix**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix Advantage/Lightspeed**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT Advantage**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX200CT/Performix Ultra**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT Ultra**	**IIb**

GMED 0459

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Certification Director

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Gaine équipée *X-ray tube assembly*	**Performix 40**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix Pro VCT 100**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT VCT**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX135CT HiLight Advantage**	**IIb**
Gaine équipée *X-ray tube assembly*	**MX115 WJ**	**IIb**
Gaine équipée *X-ray tube assembly*	**Maxiray CT Pace**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix HD**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix HD Plus**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix 40 Plus**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix Plus**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix HDw**	**IIb**
Gaine équipée *X-ray tube assembly*	**Performix VCT Plus**	**IIb**
Gaine équipée *X-ray tube assembly*	**Quantix 160**	**IIb**

37 alinéas / *37 indented lines*

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Lionel DREUX
Certification Director

Identification du site couvert et des activités / *Identification of location and activities*

GE MEDICAL SYSTEMS, LLC - 4855 West Electric Avenue - MILWAUKEE, WI 53219 – USA
Conception, fabrication et contrôle final
Design, manufacture and final control

GMED 0459

Lionel DREUX
Certification Director

GE Healthcare

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU.

We

Manufacturer

GE MEDICAL SYSTEMS, LLC
4855 West Electric Avenue
Milwaukee, WI 53219 USA

EU Authorized Representative

GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Manufacturing sites

Site #1
GE MEDICAL SYSTEMS, LLC
4855 West Electric Avenue
Milwaukee, WI 53219 USA

Site #2
GE BE PRIVATE LIMITED
#60 Export Promotion Industrial Park
Whitefield, Bangalore 560066 INDIA

Site #3
GE MEDICAL SYSTEMS MONTERREY MEXICO SA DE CV
Parque Industrial Huinala Calle Espana 300
66645 Apodaca NL MEXICO

Site #4
GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Declare under our sole responsibility that the class IIB device:

X-ray Tube Assemblies (Housing and Tube)

Ref: see addendum

GMDN Code: **35618**

Classification rule (93/42/EC Annex IX) **10**

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

Digitally signed by Chicu Natalia
Date: 2023.11.07 12:18:35 EET
Reason: MoldSign Signature
Location: Moldova

This conformity is based on the following elements:

- Information included in the documents:
  Technical Documentation/DHF Ref./ réf, of the product to which this declaration relates:

  DOC0819831, DOC0380539, DOC0848726, DOC0862891, DOC0842659, DOC0856374, DOC1196928
- EC certificate: Approval of Quality Assurance System delivered (Annex II excluding section 4 Directive 93/42/EEC concerning medical devices) delivered by LNE/G-MED (Notified body 0459) on Certificate N° 22462 with expiration of December 20th, 2020.
- List of harmonized standards applied for CE marking

Product Standards	EN 60601-1:2006/AC:2010	IEC 60601-1:2005
	EN 60601-2-28:2010	IEC60601-2-28:2010

Waukesha, WI USA
9-July-2018

Lee Bush
Manager, Regulatory Affairs

This EC declaration of conformity supersedes the previous declaration dated 19-April-2018.

ADDENDUM TO THE DECLARATION OF CONFORMITY dated 19-April-2018

Product Description	Catalog Designation
MX100 HTG	D2251C, D2252C
MX100 FL *Maxiray MX100 FL	D2262F, D2281F, D2282F, *D2289F, D2311F, D2312F, *D2319F
MX100 RAD *Maxiray MX100 RAD	D2282R, D2342R, D2301R, D2302R, *D2309R, D2311R, D2312R, *D2319R, 5237529, 5237530
MX75 HRT *Maxiray HRT 275	D2631P, D2632P, *D2639P, D2641P, D2642P, *D2649P
MX150H.3	D2711C, D2712C
Performix 160A	D2801A, D2804A, D2805A
MX165CT HiSpeed Advantage/Zeus *Maxiray CT HSA	D3101T, D3102T, *D3109T
MX165CT ProSpeed/QJ *Maxiray MX165CT ProSpeed/QJ	D3111T, D3112T, *D3119T
MX135CT SRi/Venus *Maxiray CT SRi	D3121T, D3122T, *D3129T
Performix Advantage CTI *Maxiray CT Advantage CTI	D3131T, D3132T, *D3139T
MX165NP/ Solarix 350 Brightspeed *Maxiray Solarix	D3141T, D3142T, D3145T, D3146T, *D3149T, 5373079, 5373080
MX200CT NP/Performix	D3151T, D3152T
Performix Advantage/Lightspeed *Maxiray CT Advantage	D3175T, D3176T, *D3179T
MX200CT/Performix Ultra *Maxiray CT Ultra	D3185T, D3186T, *D3189T, D3885T, D3886T
Performix 40	D3187T, D3188T
Performix Pro VCT 100 *Maxiray CT VCT	D3193T, D3194T, D3195T, D3196T, D3194TR, *D3199T
MX135CT HiLight Advantage/Jupiter *Maxiray CT HLA	D3201T, D3202T, *D3209T
MX115 WJ/CT Pace/Sytec *Maxiray CT Pace	D3301T, D3302T, D3307T, *D3309T
Performix HD	D3701T, D3702T, D3703T, D3704T
Performix 40 Plus	D3887T, D3888T
Performix Plus	D3889T, D3890T