To : DEL Medical Imaging Corp.

SPECIFICATION FOR UX-51H-42 / UX-52H-42 / UX-53H-42

Toshiba Rotating Anode X-ray Tube Housing Assembly for Diagnostic Radiography

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| Hereinafter, the company name "TOSHIBA stated " TETD " | Electron Tubes & Devices Co., Ltd" is |

General Data

| IEC C | lassification | | | | Class I |
|--------|------------------------|----------------|-----------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Applic | cable Standards | | IEC | C60601-1/1988, I | C60522/2003, IEC60526/1978, EC60601-1-3/1994, 3, IEC60613/1989, |
| Electr | ical: | | | | |
| Cir | cuit (Center-grounde | ed) | | | Three-phase full-wave rectified |
| | | | | or S | Single-phase full-wave rectified |
| No | minal Tube Voltage: | | | | |
| | Radiographic | | | | 40 ~ 125 kV Max. |
| | Fluoroscopic | | | | 40 ~ 125 kV Max. |
| No | minal Focal Spot Va | lue: | | | |
| | Large Focus | | | | 1.5 mm |
| | Small Focus | | | | 0.6 mm |
| No | minal Anode Input P | ower (at 0.1s) | :(As shown in F | ig. 3 ~ 4) | |
| | Large Focus | | | | 50 kW |
| | Small Focus | | | | 18 kW |
| Fil | ament Characteristic | s | | | As shown in Fig. 5 |
| Fil | ament Frequency Lin | nits | | | 0 ~ 25 kHz |
| En | nission Characteristic | s | | | As shown in Fig. 5 |
| Mo | tor (Stator) Ratings: | | | | |
| | Duty | | Star | ting | Running |
| | Power source | (Hz) | 50/ | 60 | 50/60 |
| | Input power | (W) | 1050 | 270 | 43 |
| | Voltage 1) | (V) | 200 | 100 | 40 |
| | X | | | | - Name and the second s |

Note: 1) The every applied voltage must be never exceeded 110% of the above specification.

3.0

1.5

24

1.2

24

2) The speed-up time is allowed up to 110% of the above specification.

6.0

8.0

24

(A)

(s)

(µF)

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Current

Capacitor

Min. Speed up 2)

| Anode Speed: | |
|-----------------------------------|--------------------------------------------------------------------|
| | |
| | 3200 min ⁻¹ Min. |
| Stator resistance | |
| | 27.5 Ω |
| | 58.0 Ω |
| | Low Voltage Terminals 2 MΩ Min. |
| | using temperature |
| Normal operating range of the not | Ising temperature 10 70 0 |
| Mechanical: | |
| Dimensions (As shown in Fig. 1) | |
| | 479 mm |
| | 152.4 mm |
| | |
| | |
| Radiation Protection (To meet rec | |
| | |
| | |
| | Focal spot off-centering position shall be maximum 1.5mm from |
| | the center of X-ray port (axial, rotating direction respectively). |
| Weight (Approx.) | |
| | |
| | |
| Housing: | |
| | XH-121 |
| Model No. UX-52H-42 | XH-126 |
| | XH-150 |
| Finish | |
| | Leather tone, Gloss 50~60, |
| | Melamine and Silicone mixed system |
| | To be attached stator cord (TLA-210). |
| Accessory: Cross Recessed P | an Head Screw M5 × 10 mm 4p |
| (Nickel plated) | M6 × 25 mm 4p |
| | M6 × 30 mm 4p |
| \\/iring: | |

Wiring:

Do not connect stator coil and temperature relay line in series circuit (see Fig.1-1, Fig.1-2, and Fig.1-3).

Maximum and Minimum Ratings

(At any time, these values must not be exceeded.)

| Maximum Tube Voltage for Radiographic | 125 kV |
|--------------------------------------------------------------------|--------------------|
| Maximum Voltage to Ground | |
| Maximum Tube Voltage for Fluoroscopic | |
| Minimum Tube Voltage | |
| Maximum Tube Current: (As shown in Fig. 5) | 40 KV |
| Large Focus | 900 mA |
| Small Focus | |
| Maximum Filament Current: | 290 MA |
| | 5 2 A |
| Small Focus | |
| Filament Voltage: | 5.3 A |
| | |
| Large Focus (At max. filament current 5.3A) | |
| Small Focus (At max. filament current 5.3A) | |
| Average Input Power 1) | 240 W (335 HU/s) |
| (Fluoroscopic, repeated radiographic or mixed exposure) | |
| Thermal Characteristics: (As shown in Fig. 6) | |
| Anode Heat Storage Capacity | 142 kJ (200 kHU) |
| Maximum Anode Heat Dissipation Rate | |
| Housing Heat Storage Capacity | |
| Maximum Housing Heat Dissipation Rate: 2) | , |
| Without Air-circulator | 180 W (15 kHU/min) |
| Note: 1) "Average Input Power" is the X-ray tube anode input power | |

- Note: 1) "Average Input Power" is the X-ray tube anode input power.

 Therefore, when tube is used for long time exposure or frequent exposures, the stator input power and filament heating power need to be calculated not to exceed the "Housing Heat Storage Capacity".
 - 2) "Maximum Housing Heat Dissipation Rate" is specified at 900 kJ of full housing heat storage which is generated by X-ray tube anode input power, stator input power and filament heating input power.

Environmental Limits

| Operating Limits: | |
|------------------------------|-------------------|
| Temperature | 10 ~ 40 °C |
| Humidity | 30 ~85 % |
| | (No condensation) |
| Atmospheric Pressure | 70 ~106 kPa |
| Shipping and Storage Limits: | |
| Temperature | -20 ~ 70 °C |
| Humidity | |
| | (No condensation) |
| Atmospheric Pressure | 50 ~ 106 kPa |

Fig.1-1 Dimensional Outline of UX-51H-42

Unit mm

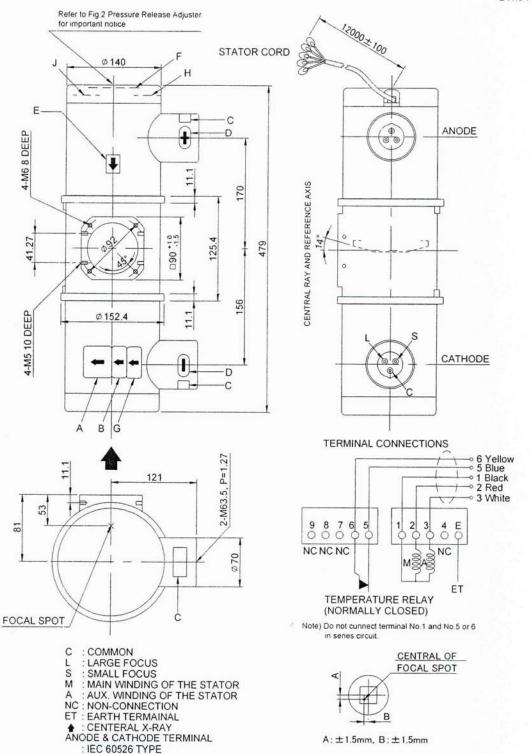


Fig.1-2 Dimensional Outline of UX-52H-42

Unit mm

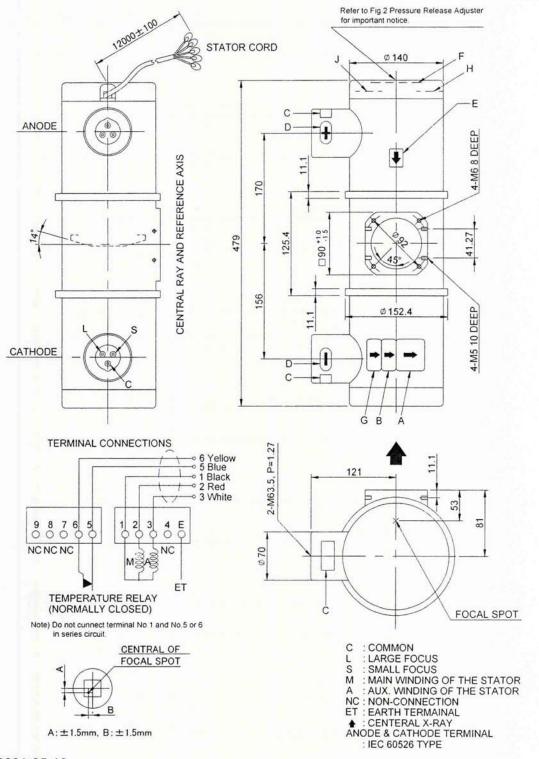
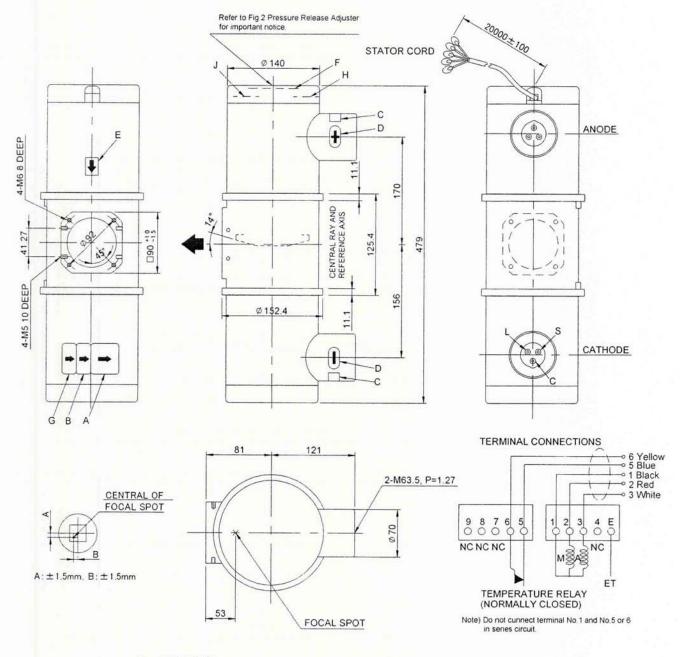


Fig.1-3 Dimensional Outline of UX-53H-42

Unit mm



C : COMMON

L : LARGE FOCUS

S : SMALL FOCUS

M: MAIN WINDING OF THE STATOR

A : AUX. WINDING OF THE STATOR

NC: NON-CONNECTION ET: EARTH TERMAINAL

★: CENTERAL X-RAY

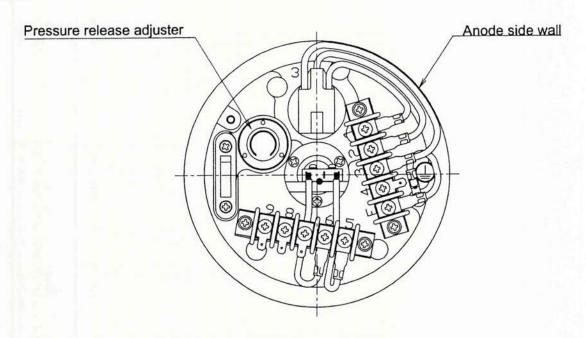
ANODE & CATHODE TERMINAL

: IEC60526 TYPE

Fig.2 Pressure Release Adjuster

The pressure release adjuster is mounted on anode side housing wall.

When external cosmetic cover is removed, it is visibly recognized as labeled with label H) in next page.



Followings are important notice of the pressure release adjuster:

Function: When housing inner pressure reaches to the working pressure of the adjuster, the adjuster collapses and vaporized oil and hot oil flow through the collapsed adjuster.

The external cover can protect the initial impact of oil flow, however, it can not protect oil drop or oil leakage.

Caution: 1. Never touch the pressure release adjuster or remove the label.

Otherwise, it could cause collapse of pressure release adjuster.

2. Please note it is not the device to protect X-ray tube from destruction when over rated power input but just to reduce the impact of housing rupture.

Drawing of Labels

A) Main Label

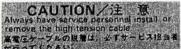
| TOSHIBA | ROTANODE ™ |
|--------------------------|------------------------------------------------------------------------------------------------|
| Manufactured : | |
| 医療用具許可番号: Unit Model: | |
| Ser. No. : | |
| Insert Model : | |
| Ser. No. : | |
| Max. Voltage : | ky Sup. Symbol : |
| Focal Spot : | mm |
| Permanent Filtration | |
| TOSHIBA ELECTRO | デバイス株式会社 SU 大田原市下石上 1385番社 N TUBES & DEVICES CO.,LTD. ami Otawara-shi, Tochigi |
| 324-8550, Japan | |

B) Certification Label

X-ray tube housing assembly complies with FDA Radiation Performance Standards, 21 CFR. Subchapter J. C € 0197

TETD is the Legal Manufacturer in the meaning of Medical Devise Directive, 93/42/EEC.

C) Caution Label



E) Pointer Label



F) Caution Label

D) Polarity Labels

Inside of anode side ornamental cover

注 意 管容器側面カバーは、X線しゃへい および電気安全のため、常時、管 装置の所定の位置に正しく 装着し てお使いください。 いかなる場合でも、このカバーを外 した状態では、決してX線管を動作 させないでください。 CAUTION

Housing end caps must always be mounted to the tube housing assembly properly and correctly for X-ray protection and safuty. In any case, the X-ray tube shall not be energized without fixing the cap in such a manner as directed.

G) Private Label

made for DEL Medical Imaging Corp.

H) Caution Label

Labeled on pressure release adjuster

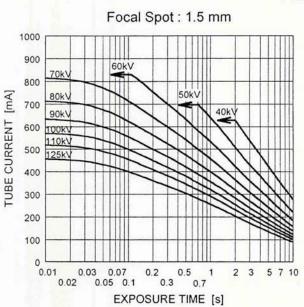


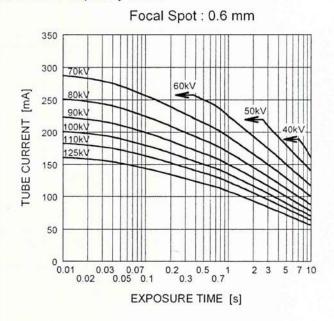
: 2001-05-19 Issued Revised : 2005-03-25

Fig.3 Maximum Rating Charts (Absolute Maximum Rating Charts)

Conditions: Three-Phase

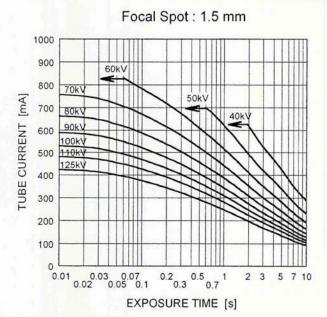
: Stator Power Frequency 60Hz





Conditions: Three-Phase

: Stator Power Frequency 50Hz



Focal Spot : 0.6 mm

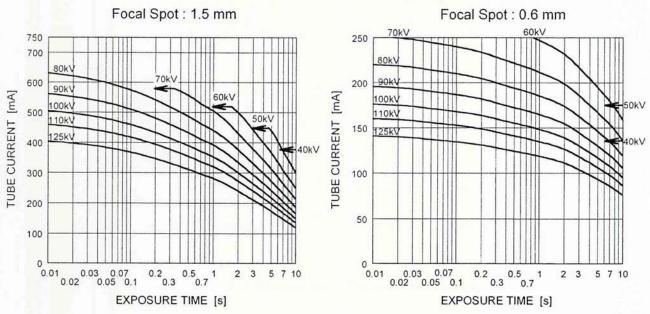
350

70kV
60kV
100kV
1100kV
11

Fig.4 Maximum Rating Charts (Absolute Maximum Rating Charts)

Conditions : Single-Phase

: Stator Power Frequency 60Hz



Conditions : Single-Phase

: Stator Power Frequency 50Hz

Focal Spot : 1.5 mm Focal Spot : 0.6 mm

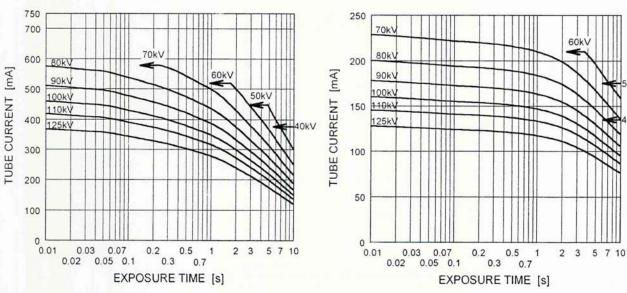
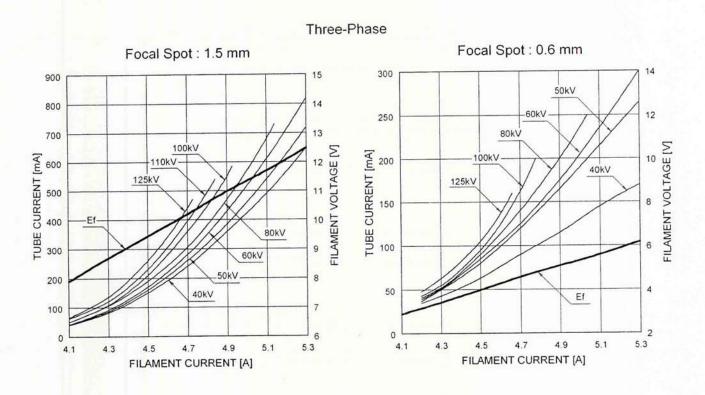
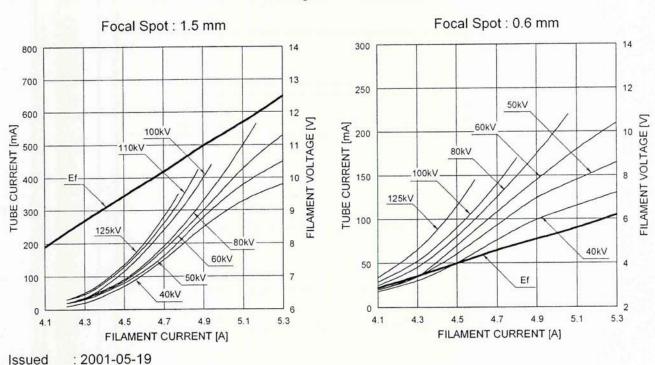


Fig.5 Emission & Filament Characteristics



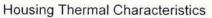
Single-Phase

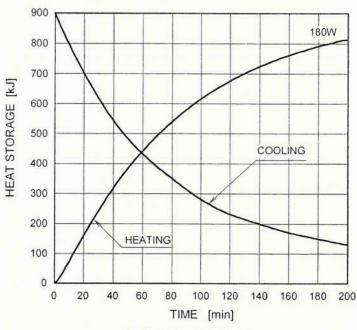


: 2005-03-25

Revised

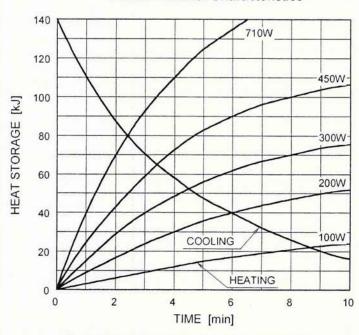
Fig.6 Thermal Characteristics





Cooling Without Air Circulator.

Anode Thermal Characteristics



The heating curves are showing examples of average input power to the anode in operation.

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Outgoing Test

The following table shows the outgoing test conditions and screening criteria, not contain the contract specification. Therefore, TETD can revise them anytime and they may not be necessarily applied to every delivered product.

However, even if they are changed, TETD shall guarantee all specified items mentioned in this contract specification.

| | | | Test Condition | | | | | | | | Limits | | Note | |
|----------------------------|-----------|-----------------|-----------------|------------|----------|---|-----------|-----------|----|-------------------|--------|--------|------|-------|
| Test Iter | Test Item | | Ep (kV) | lp (mA) | t (s) | N | ti (s) | If (A) | F | Sym | Unit | Min. | Max. | |
| High Tension | | S,FW | 135 | 1.5 | 60 | 1 | - | Adj | L | - | | - | • | 1,2,3 |
| Load | | S,FW | 100 | 500 | 0.1 | 2 | 5 | Adj | L | - | _ | _ | - 2 | 1,2 |
| | | 3,777 | 100 | 180 | 0.1 | 2 | 5 | Adj | S | | 2 | 12/15 | - | |
| - | | S,FW | 100 | 400 | - | - | - | | L | If | Α | 4.33 | 5.07 | 1 |
| Emission & Tube Current | | 3,500 | 100 | 125 | | - | - | | S | lf | Α | 4.19 | 4.91 |] |
| Characteristics | S,FW | 50 | 300 | 1 | - | - | | L | lf | А | 4.40 | 5.10 | 1 | |
| Characteristics | | 3,500 | 50 | 125 | | - | - | | S | If | Α | 4.40 | | 5.12 |
| Filament | | AC | | | | | | 4.7 | L | Ef | V | 8.8 | 11.8 | |
| Characteristic | s | 50Hz | | | | | | 4.7 | S | Ef | V | 4.2 | 5.6 | |
| F1 01 | Width | - S.FW I | 75 | 300 | Adj | | | Adj | L | - | mm | 1.5 | 2.0 | 1,4 |
| Focal Spot Size | Length | | | | | | | Auj | | | | 2.1 | 3.0 | |
| (Slit Method) | Width | S,FW | 75 | 110 | Adj | | | Adj | s | | mm | 0.6 | 0.9 | 1,5 |
| (One Mourida) | Length | 3,1 77 | 75 | 110 | Auj | | | Auj | 3 | | | 0.9 | 1.3 | |
| Rotation | | | (AC 100V, 50Hz) | | | | | | 3 | min ⁻¹ | 2800 | | | |
| | | (AC 100V, 60Hz) | | | | | | | - | min ⁻¹ | 3350 | - | | |
| Coasting Time | | | (AC 40V, 50Hz) | | | | | | | - | S | 30 | - | |
| Noise | | | (AC 100V, 50Hz) | | | | | | | | dB | - | 67 | 7 |
| X-ray Leakage | 9 | | 125 | 4 | | | | Adj | L | - | Note8 | - | 12.9 | 6 |
| Permanent Fil | tration | | 75 | 1 | | | | Adj | L | - | Note9 | 0.9 | 1.17 | 6 |
| Wiring Check | | | | | | | | | | | | Note 2 | | |
| Appearance | | | | | | | | | | | Note 2 | | | |
| Dimension | | | | | | | | | | | Note 2 | | | |

Terms (Abbreviated)

Cir : Circuit Ep : Tube Voltage Ip : Tube Current
t : Duration N : Number of Exposure ti : Interval Time
If : Filament Current F : Focus Sym : Symbol
Adj : Adjust L : Large Focus S : Small Focus

Ef : Filament Voltage S,FW : Single-Phase Full-Wave Rectified

T,FW: Three-Phase Full-Wave Rectified

Note

- 1. Anode, rotating (AC 100V, 50Hz)
- 2. It should not be abnormal.
- 3. Run without a kick during at least 1 minute.
- 4. Slit Magnification factor ×1.
- 5. Slit Magnification factor ×2.
- 6. Anode, rotating (AC 40V, 50Hz)
- 7. Noise level measuring conditions
 - Environment: acoustic shield room
 (Background noise level: under 40 dB)
 - (2) Place X-ray tube on the soft mat.
 - (3) The distance between X-ray port surface and microphone is 25 cm. (Precision sound level meter: Comply with IEC Publ. 179A characteristics A)
- 8. Unit : μ C / (kg·h)
- 9. Aluminum equivalent, unit: mm

Warning

Warning to Interface with X-ray Generator

1. Housing Rupture

Never input over rated power to X-ray tube assembly.

If the input power exceeds tube specification, it causes the over temperature of anode, insert tube glass shatter and ultimately the following serious problems due to generating over-pressure by oil vaporization inside housing assembly.

In such a critical condition causing housing rupture by over load, the safety thermal switch can not protect X-ray tube even if it works.

- * Housing sealing parts rupture
- * Human injury including burns due to hot oil escape
- * Fire accident due to flaming anode target

The X-ray generator should have a protective function which manages input power to be within tube specification.

2. Over Load Protection

X-ray tube housing assembly has a thermal protection device to notice the generator to terminate the input power. However it only works for gradual temperature increase when the tube is operated within the specified X-ray condition (but too long repetitive use). And the protection is not effective in such a case that rapid increase of target temperature destroys insert tube under overrated input.

In this sense, over load protection is definitely required on X-ray generator.

From the point of effective and reliable operation, the followings are recommended:

- * Software control: CPU calculates the total input power and controls the target temperature.

 This protection is effective to human error.
- * Independent protection circuit: Independent shut down circuit separated from X-ray control unit is effective and reliable.

3. Pressure release adjuster

Never touch the pressure release adjuster located on anode side wall.

And when rotor cable is attached, be careful that the rotor cable should not be located on or over the pressure release adjuster for the following mechanical reason.

The pressure release adjuster is the device which protects X-ray tube housing assembly from harmful destruction by its mechanical collapse.

When extreme over rated power is input to X-ray tube assembly, the pressure release adjuster activates and hot oil escapes through the collapsed adjuster for safety purpose.

For the reliable mechanical process, nothing should be located on or over the pressure release adjuster.

Cautions

Caution to Interface with X-ray Generator

1. Over Rating

X-ray tube assembly can be broken with applying just one over rated shot. Please read the technical data sheets carefully and follow the instructions.

2. Permanent Filtration

The total filtration and the distance between x-ray focal spot and human body are regulated legally. They should be complied with the regulation.

3. Safety Thermal Switch

X-ray tube assembly has safety thermal switch to prohibit further input power when the tube housing reaches to the temperature of switch-open.

The switch should be hooked up with the x-ray generator which control output power to x-ray tube assembly.

The switch is not recommended connecting stator coil in series circuit.

Even if the switch works, never turn the system power off and the cooling unit should be activated.

4. Unexpected Malfunction

X-ray tube assembly may have the risk to be unexpectedly malfunctioning due to life termination or failure. If the serious problems caused by the above risk is expected, we recommend to have a contingency plan to avoid such a case.

5. New Application

If you use the product with new application not to be mentioned in this specification or with different type of x-ray generator, please contact to us for confirming its availability.

Caution for Installation, Adjustment and Maintenance

1. Qualified Persons

Only qualified persons who have technical training and professional knowledge can handle x-ray tube assembly.

2. Fragile Glass

X-ray tube is assembled with glass, therefore, it can be broken with the mechanical vibration or pulsed shock over 19.6m/s2 (2G).

Careful handling is required to treat or transport.

3. Ground Terminal

X-ray tube assembly has ground terminal. Ground cable should be connected.

4. High Voltage

All x-ray tubes operate at voltages high enough to kill through electrical shock. Never touch the high voltage delivered plugs or terminals.

When direct access to such parts is required, the primary circuit should be disabled and high voltage capacitors/cables discharged.

5. High Voltage Plug

High voltage plug should be cleaned up and free from any physical damages. Silicon compound application is required for high voltage stability.

6. Operation Atmosphere

X-ray tube assembly is not allowed to use in the atmosphere of flammable or corrosive gas.

7. Protective Cover

X-ray tube assembly is not allowed to use without the protective cover attached.

8. Handling

Appropriate jig or tools are required for tube installation to avoid physical damages.

9.Returning Tube

X-ray tube assembly should be repackaged with the original material when it is returned back for quality examination in our factory.

Be careful to put the tube upside cathode. If the packaging is not proper, the tube may not be correctly examined.

Caution in Operation

1. X-Ray Radiation

X-ray tube assembly should have the beam limiting equipment mounted on the x-ray port to protect unnecessary radiation.

2. Dielectric Oil

X-ray tube assembly has dielectric oil contained for high voltage stability. As it is poisonous for human health, if it is exposed to the non-restricted area, it should be disposed as following to the local regulation.

3. Operation Atmosphere

X-ray tube assembly is not allowed to use in the atmosphere of flammable or corrosive gas.

4. Lead Disposition

X-ray tube housing is lined with lead to protect unnecessary radiation. As the lead powder or vapor is harmful for human health, it should be disposed as following to the local regulation or returned back to us with your cost of transportation. We dispose it in our facility with free of charge.

5. X-ray Tube Housing Temperature

Do not touch on X-ray tube housing surface just after operation due to high temperature. Stay X-ray tube to be cooled.

6. Any Malfunction

Please contact to your system service person immediately, if any malfunction is noticed.

Limitation of Product Liability

In case you receive a claim from a third party that any loss or damage to property, bodily injury or death of a person was caused by a defect of the Component, you shall immediately notify TETD of such claim and consult with TETD for any actions to be taken. In any event, TETD's liability shall be confined to the extent reasonably foreseeable and proximately caused by the defect of Component with a limitation of aggregated amount paid by you for the Components.

Provided, however, TETD shall not be liable in the cases, where,

- 1. it was impossible for TETD to discover the defect based upon the state of scientific or technical knowledge at the time of delivery to you,
- 2. the defect is due to the compliance with your instruction regarding the specification or design,
- 3. you failed to incorporate fail-safe design to your products in consideration of the reasonably expected failure ratio/pattern of the Components incorporated therein,
- the defect is due to the compliance with mandatory regulations/standards issued by the public authorities; or
- 5. the defect did not exist at the time of delivery.

Warranty on X-ray tubes

- TETD warrants the X-ray tube to be free of manufacturing defects which will impair their normal operational life during the warranty period, provided that the X-ray tubes are used within the ratings and in accordance with TETD's instructions and specifications.
- The warranty period extends for eighteen (18) months from the date of the original Bill of Lading or twelve (12) months from the date of original installation, whichever occurs first.
 If the X-ray tube shall prove to be defective during the warranty period, TETD shall refund the original amount.
- 3. Notification of the claim shall be received by TETD within three (3) months after discovery of failure, filling in TETD's report from. If return of the defective X-ray tube is required by TETD, each return shall be made without delay, and in accordance with TETD instruction.
- 4. The warranty shall not apply to defects resulting from accidents, alterations, abuse or misuse, or improper installation.

History of Revision

| 2004-10-27 | Page | Revised Contents | Revised Reason |
|------------|--------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2004-10-27 | 1/22 | Hereinafter, the company name "TOSHIBA Electron Tubes & Devices Co., Ltd." is stated "TETD"Addition | TETD Revised |
| | 2/22 | Motor ratings Note 1), 2)Addition | TETD Revised |
| | 3/22 | Normal operating range of the housing temperature | |
| a f f | | Inherent Filtration → Permanent Filtration WiringAddition | |
| | 4/22 | Note 1), 2) | TETD Revised |
| | 6~8/22 | Dimensional Outline | As per customer's |
| | 0 0/22 | G) Private LabelAddition Add technical information on the drawing. | request TETD Revised |
| | 9/22 | A) Main Label | TETD Revised |
| | 9122 | G) Private Label | As per customer's |
| | | G/ 1 IIVate LaberAddition | request |
| | 13/22 | Housing Thermal Characteristics | TETD Revised |
| | | Add. technical information on the graph. | The second secon |
| | 14/22 | Test Specification → Outgoing Test | TETD Revised |
| | | Inherent Filtration → Permanent Filtration Ep 62.5 → 75 | |
| | | Min. $0.7 \rightarrow 0.9$ | |
| | | Max →1.17Changed | |
| | 17/22 | 3. Safety Thermal SwitchChanged | TETD Revised |
| | 19/22 | 5. Safety Thermal Switch | TETD Revised |
| | | → X-ray Tube Housing Temperature | |
| | 20/22 | Limitation of Product LiabilityAddition | TETD Revised |
| | 22/22 | Warranty on X-ray tubes Toshiba → TETD | TETD Revised |
| 2005-03-25 | 3/23 | Stator resistance | TETD Revised |
| 2000 00 20 | 6~8/23 | Pressure Release Adjuster | |
| | 9/23 | Pressure Release AdjusterAddition | |
| | 10/23 | H) Caution LabelAddition | TETD Revised |
| | 17/23 | | TETD Revised |