Technical Data

X-Ray Tube Housing Assembly

AU200-C40+LMB

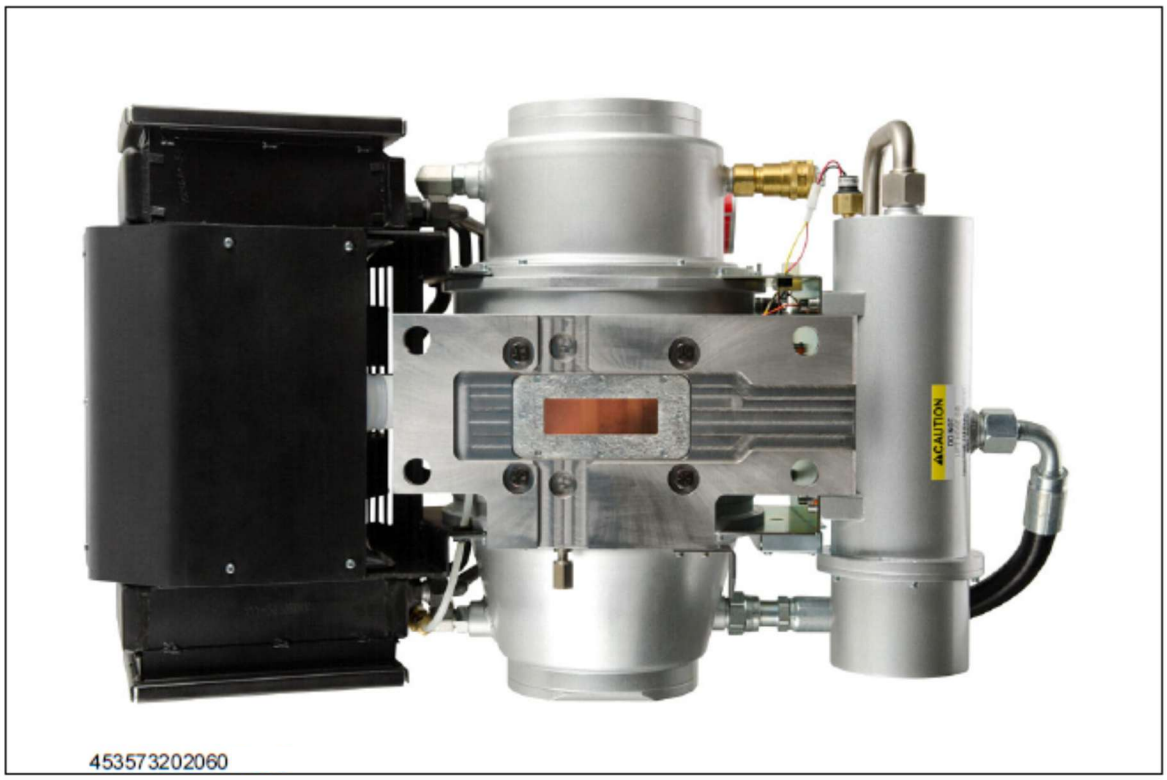


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1. Document Information

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Equipment is subject to change without notice. All changes will be in compliance with regulations governing manufacture of medical equipment. Printed in the U.S.A. Document originally drafted in English.

2. Intended Purpose

Intended Use

This diagnostic X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing that is intended for patient diagnostic imaging. The device is intended to be a replacement X-ray tube used in stationary installed C.T. Scanners that use the O.E.M. tubes for patient diagnostic imaging. The product does not come in direct contact with the patient or operator while in use. Only qualified field service technicians are authorized for installation, maintenance, and repair activities.

Intended User Population

Only qualified service technicians are authorized for installation, maintenance and repair activities.

Intended Context

This X-ray tube assembly is intended to be used in a non-condensing, climate controlled, indoor, clinical environment and is not intended to be used for homecare or by lay persons. The X-ray tube assembly is intended to be used in permanently installed stationary systems. The use frequency is not limited within the expected service lifetime. This X-ray tube assembly is intended to be re-used. The re-use of this X-ray tube assembly does not require special treatment. Additional treatment for re-use may be required and verified by the manufacturer of the X-ray system for specific applications.

Indications and Contraindications

Indications and contraindications are not defined at the X-ray tube housing assembly level. Indications and contraindications are defined by the manufacturer of the X-ray system in accordance with the intended use, the intended purpose and the medical purpose as described in the technical documentation of the X-ray system.

Essential Performance

The X-ray tube assembly itself does not have essential performance, nor is any function of the X-ray tube assembly intended to contribute to the essential performance of the X-ray system it is installed on.

Medical Benefit

This X-ray tube assembly is a component part of a diagnostic X-ray imaging system. As an integral part of patient care, diagnostic X-ray is used in the diagnosis of serious diseases. Diagnostic X-ray is a safe, painless and cost-effective way of gathering information that may otherwise be unavailable or require a more expensive and/or riskier diagnostic test. It is particularly useful in emergency diagnosis and treatment. X-ray imaging is useful to diagnose bone injury and disease such as fractures, bone infections, arthritis and cancer. Diagnostic X-ray imaging procedures often identify abnormalities early in the progression of a disease before some medical problems are apparent with other diagnostic tests. This early detection allows a disease to be treated earlier in its course. Diagnostic radiology involves some exposure to radiation. Special care is taken during the exam to ensure minimum exposure and maximum safety for the patient.

A medical procedure involving radiation should be done only when there is a justification. There should be an appropriate medical reason for the X-ray to be performed. The issue of medical radiation exposure is not a matter of safety. It is a matter of benefit compared with risk. That decision can only be made by someone who is familiar with the medical condition and the care that is necessary to properly manage it. The decision to have a medical test that involves radiation performed must be made collectively between the patient and his/her physician. All benefit/risk evaluations must be made on a case by case basis and are an inherent part of the medical art. Any diagnostic test should be justified by the risk of not having the test performed. This should be the basis for decisions made by physicians.

3. Safety Information

Safety Notice

As with any medical device, there are risks associated with use. Typical risks related to X-ray tube assemblies are X-ray tube arcing, oil leakage, use errors, biological hazards and energy hazards such as high voltage, low voltage, thermal and radiation hazards. These risks are inherent to X-ray tube assemblies and have been mitigated by conformity to harmonized standards. In addition, limiting use of the device to the useful lifetime, correct installation and verification of correct installation by the user ensure that any residual risks of the device are reduced as low as possible.

These Instructions for Use are designed to make it possible to work with the X-ray tube housing assembly in a safe manner. Operate the X-ray tube housing assembly only in compliance with the safety instructions in this manual and do not use it for purposes other than for which it is intended. The X-ray system may only be operated by qualified persons who have the necessary expertise in radiation protection and who have been instructed in how to operate the X-ray system.

It is always the user who is responsible for compliance with the regulations as applied to installation and operation of the X-ray unit.

- You must never use the X-ray tube housing assembly or any associated diagnostic imaging equipment if it has any electrical, mechanical or radiological defects. This particularly applies to malfunctioning indicators, displays, warnings and alarms.
- Do not install the X-ray tube assembly to another equipment or medical device other than those with which it is compatible.
- Chronos Imaging, LLC is responsible for the safety features of its products only if it is maintained, repaired or modified by persons explicitly authorized to do so.
- As with any technical appliance, this equipment requires

  - correct operation

  - regular, competent maintenance

  - care
- If you operate the X-ray equipment, and hence the X-ray tube housing assembly, incorrectly or if the user fails to maintain it properly, Chronos Imaging, LLC cannot be held responsible for any malfunctions, damages or injuries.
- Safe operation of the X-ray tube assembly is only guaranteed when it is used according to its specification. In case the specification limits are disregarded, there is the danger of oil leaks and expelled component parts as a result of implosion/ explosion. In such cases the manufacturer of the X-ray tube assembly excludes any liability. Any guarantee claims for this product are rejected.
- The safety circuit of the X-ray tube assembly that prevents the switching ON of radiation when the specified temperature limit of the X-ray tube assembly is exceeded shall be connected before the X-ray tube assembly is set to work for the first time. It shall neither be removed nor modified.
- Any serious incident that occurs in relation to the X-ray assembly must be reported to Chronos Imaging, LLC and, if in the European Union, the competent authority of the Member State in which the user and/or patient is established.

Radiation Protection



Make certain before every X-ray exposure that all necessary radiation precautions have been taken, including confirming acceptable image quality.

You can find information about radiation precautions in the instructions for use for the individual X-ray systems with which you are using this X-ray tube assembly.

Electrical Safety



Only trained maintenance staff may remove the covers from the X-ray tube assembly.

This X-ray tube assembly may only be used in medical rooms which meet the requirements of relevant national and international standards and laws.

To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth.

Thermal Safety



To prevent damage due to thermal overloading, precautions must be taken to ensure that the X-ray tube assembly is not operated outside its specified load parameters. This prevention reduces risks to the patient, operating staff, third parties and the environment.

The X-ray tube housing assembly may be equipped with a thermal housing safety switch. Activation of the switch will inhibit additional exposures.

When this occurs, the unit will remain inoperable only until a safe operating temperature is restored, as determined by the imaging systems software. Depending on the cooling system, it may require 5 to 10 minutes of cooling time to reduce the temperature.

Cooling / Insulation Oil



If there is evidence of oil leakage from the X-ray tube housing assembly, heat exchanger, or hoses, immediately cease operation of the system and inform your service organization or supplier.

In the event of leakage or spillage of oil, ensure that the oil is removed as soon as the equipment has ceased operation and the area is safe. Use liquid-absorbent material and dispose in accordance with local environmental laws and regulations.

Electromagnetic Compatibility (E.M.C.)



In accordance with its intended use, this electronic component designed as part of a diagnostic imaging system according to the laws governing E.M.C., which defines the permitted emission levels from electronic equipment and its required immunity against electromagnetic fields.

Electronic apparatus that satisfies the E.M.C. requirements is designed so that under normal conditions there is no risk of malfunction caused by electromagnetic interference. However, in the case of radio signals from high-frequency transmitters with a relatively high transmitting power, the risk of electromagnetic incompatibility when operated in close proximity to electronic apparatus cannot be totally ruled out.

In unusual circumstances unintended functions of the apparatus could be initiated, possibly giving rise to undesirable risks for the patient or user. For this reason, all kinds of transmission with mobile radio equipment should be avoided. This also applies when the apparatus is in STANDBY mode. Mobile telephones must be switched OFF in designated problem zones.

The responsibility to guarantee compliance with the electromagnetic emission limit values and the fulfillment of all associated regulations and laws lies with the company responsible for the installation of the X-ray tube assembly.

Limits for Operation

Safe operation depends on ensuring the X-ray tube assembly is used within its limits. Failure to obey these limits can result in the danger of oil leaks. This loss of cooling media can cause the X-ray tube assembly to overheat which can lead to expelled component parts as a result of implosion / explosion. Refer to the Environmental Limits for Operation in the supplemental I.F.U. documents.

- Do not operate the X-ray tube assembly in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Do not use detergents or disinfectants, including those used on the patient, that can create explosive gas mixtures.

Transportation and Storage

Safe operation depends on ensuring the X-ray tube assembly is used within its limits. Failure to obey these limits can result in the danger of oil leaks. This loss of cooling media can cause the X-ray tube assembly to overheat which can lead to expelled component parts as a result of implosion/ explosion.

It is recommended to transport X-ray tube housing assemblies in the original packaging material. Transportation using other packaging material or in any other way may result in injury and/or product damage and may void the warranty.

Environmental Limit	X-Ray Tube Assembly AU200-C40+LMB
Transport and Storage	
Ambient Temperature [°C]	
Minimum	-25
Maximum	+70
Ambient Humidity [%]	
Minimum	10
Maximum	95
Ambient Atmospheric Pressure [kPa]	
Minimum	70
Maximum	106

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Disposal

The take-back obligation, correct disposal and recovery of the X-ray tube assembly refer to the European Waste Electrical and Electronic Equipment (WEEE) directive. They also refer to the requirements of local and transregional legal requirements.

The X-ray tube assembly manufacturer assembles state-of-the-art X-ray tube assemblies in terms of safety and environmental protection. If no parts of the X-ray tube assembly are opened and if the X-ray tube assembly is used correctly there are no risks to persons or the environment.

To obey regulations, sometimes it is necessary to use materials that are harmful to the environment. Discard these materials in a correct manner.

This X-ray tube assembly contains materials that are toxic. Do not discard the X-ray tube assembly together with industrial or domestic waste.

The manufacturer

- supports you in the disposal of the X-ray tube assembly in accordance with valid legal requirements.
- takes back the X-ray tube assembly.
- returns re-usable parts to the production cycle. Extensive test and quality assurance procedures as well as detailed checks of the components qualify these parts to meet the same high level of quality and functionality that is expected from new materials.
- makes a contribution to the protection of the environment.

In case you have questions concerning safe disposal, please consult the manufacturer in full confidence.

4. Installation and Maintenance

Installation

This X-ray tube is designed, manufactured, and validated to be compatible with the following specific diagnostic imaging equipment:

- Optima™ CT660
- Revolution™ EVO

Only trained and qualified service personnel must perform installation of the X-ray tube housing assembly. The installation must be performed in accordance with the system documentation provided by the Original Equipment Manufacturer's installation, test and operating procedures. Consult the appropriate documentation for the removal and installation procedure.

This X-ray tube housing assembly is intended to be installed on a diagnostic imaging system that is fitted with appropriate audible warnings and/or visual displays, where practicable, while radiation is being emitted.

Failure to follow the O.E.M. procedure for removal and installation of the X-ray tube housing assembly may result in injury to user or patient, damage to equipment and will void the warranty.

X-ray Tube Assembly Conditioning

It is imperative for proper operation and extended life that the X-ray tube housing assembly be properly conditioned after a period of non-use. This procedure is defined in the Original Equipment Manufacturer's diagnostic imaging system operator's manual. Failure to follow this procedure may reduce the life of the X-ray tube housing assembly and may void the warranty terms.

General Maintenance

The responsibility to recommend preventive maintenance in accordance with all applicable regulations and laws lies with the company responsible for the installation of the X-ray tube assembly.

As with any technical appliance these X-ray tube assemblies also require:

- Regular checks by the operator
- Regular planned and corrective maintenance

Corrective Maintenance

Corrective maintenance on X-ray tube assemblies is allowed to be performed only by the manufacturer of the X-ray tube assembly.

Faulty components of the X-ray equipment which affect the safety of the X-ray tube assembly must be replaced by genuine spare parts.

Planned Maintenance – General

X-ray tube assemblies contain mechanical components, which are subject to normal wear due to operation.

The correct setting of the electromechanical and electronic assemblies safeguards the functioning, image quality, electrical safety and radiation exposure of the patients, operating staff, third parties and the environment.

By taking these precautions, you maintain the operability and operational reliability of the system. As the user of the X-ray unit, you are obliged according to accident prevention regulations, the medical products law and other regulations to perform such precautionary actions.

Maintenance consists of tests that the user of the diagnostic imaging system can perform and maintenance that is performed under service agreements or by persons explicitly authorized to do so.

The user must check the X-ray equipment for apparent defects. If operational defects or other departures from normal operational behavior occur, the X-ray unit must be switched off and the appropriate service organization informed. Operation of the X-ray equipment may only be resumed when repairs are completed. Operation using faulty components may lead to an increased safety risk or unnecessarily high exposure to radiation.

It is recommended that you perform the tests indicated in the table on a regular basis and have the unit serviced by authorized representatives at least once a year. For heavily used equipment, preventative maintenance should be scheduled more often.

These precautionary measures prevent personal injury to patient and operator.

Cleaning

Cleaning of the X-ray tube assembly is not necessary as it is behind the covers of the X-ray imaging system. Cleaning of the X-ray tube assembly should not be performed.

Disinfection

Disinfection of the X-ray tube assembly is not necessary as it is behind the covers of the X-ray imaging system, unless otherwise required by the manufacturer of the X-ray imaging system.

Checks performed by System Operator

Interval	**Scope of Work**
Each use	Check of system error messages Check for visible oil leaks or other contamination
Daily	Check for damaged parts, missing labels and warning plates
Weekly	Check of all cables and connections (loose, damaged or broken)
Weekly	Check for unusual noises
Per system manual and/or relevant local or transregional standards and laws	Stability test
Per system manual and/or relevant local or transregional standards and laws	Check of image quality

5. General Information

Carrier Damage

In the unlikely event of damage due to handling by the carrier, it is important to follow these steps in order to receive proper credit:

1. Inspect the X-ray tube housing assembly immediately upon receipt. Check both the packing and the product for physical damage.
2. If there is physical damage, call the carrier immediately and order a “Joint Inspection” of both the packing and the product.

Within the United States:

- If the X-ray tube housing assembly has been shipped freight pre-paid, return the product in accordance with the instruction on the Return Form along with a copy of the Joint Inspection Report to Chronos Imaging, LLC.
- If the X-ray tube housing assembly has been shipped via the customer’s carrier, the customer must initiate the claim process directly with the carrier.

Outside the United States:

- Please consult your local sales and service office for instruction for return.

Warranty

Warranties vary according to the specific X-ray tube assembly model. Contact your local representative for detailed information. Written copies are available upon request.

Return Process

Use the re-usable packaging of the new delivered X-ray tube assembly for the return shipment of the decommissioned X-ray tube assembly. This guarantees a transport of the returning X-ray tube assembly in packaging designed for this purpose.

Follow the instructions on the Return Form, fill in all required information and send it together with the X-ray tube assembly being returned.

Outside the United States:

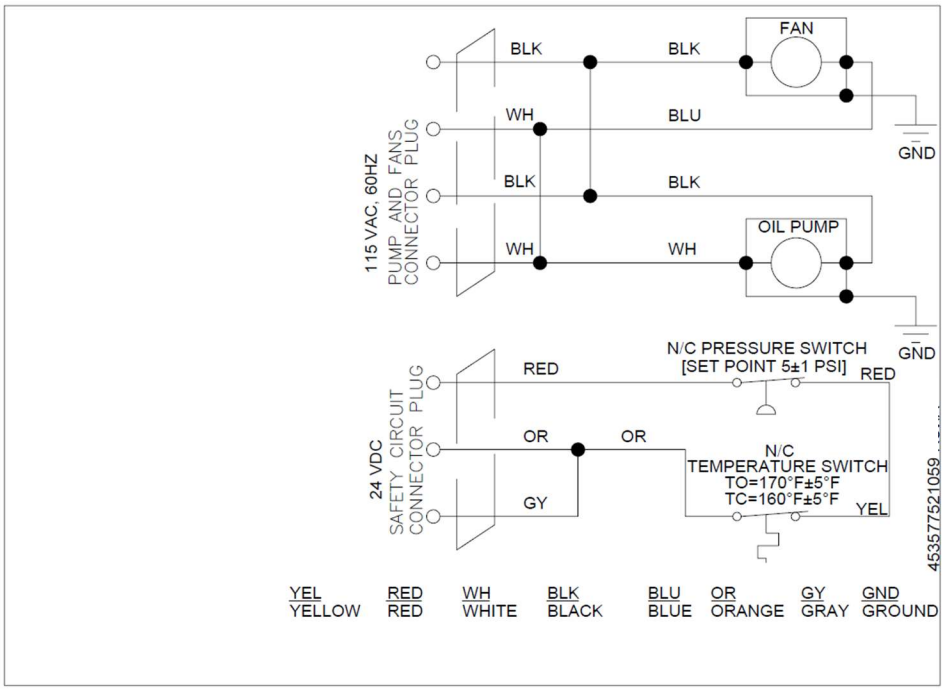
If returning a product from outside the United States, please contact your local sales or service representative for return instructions.

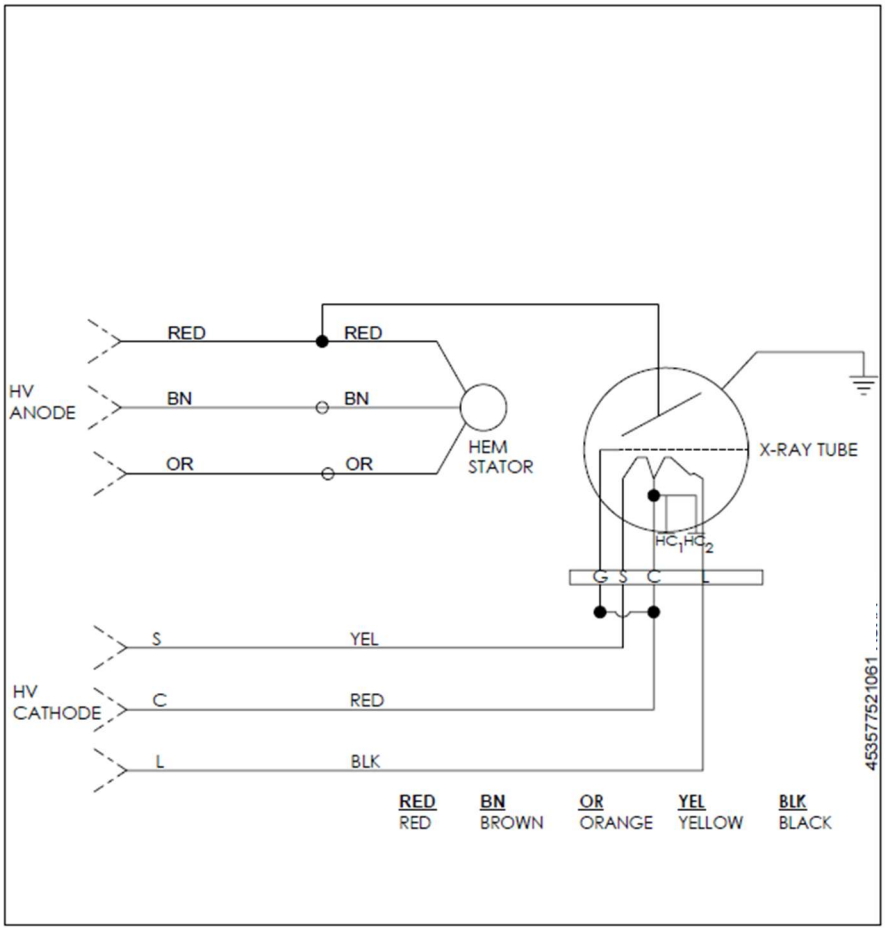
6. Technical Data

X-Ray Tube	
Product Identification (X-ray tube)	XT6308+LMB
Nominal Anode Input Power	■ 24 kW @ 1.0 s ■ 72 kW @ 1.0 s
Anode Speed	8400 RPM
Focal Spots	■ 0.9 x 0.7 IEC 60336: 2020 ■ 0.7 x 0.6 IEC 60336: 1993 ■ 1.2 X 1.1 IEC 60336: 2020 ■ 0.9 x 0.9 IEC 60336: 1993
Anode Heat Storage Capacity	5.0 MJ (7.0 MHU)
Anode Material	TZM, W, Re, Graphite
Anode Disk Diameter	200 mm (7.9 in)
Anode Angle	7.0°
Maximum Filament Operating Current	■ 6.54 A ■ 6.15A

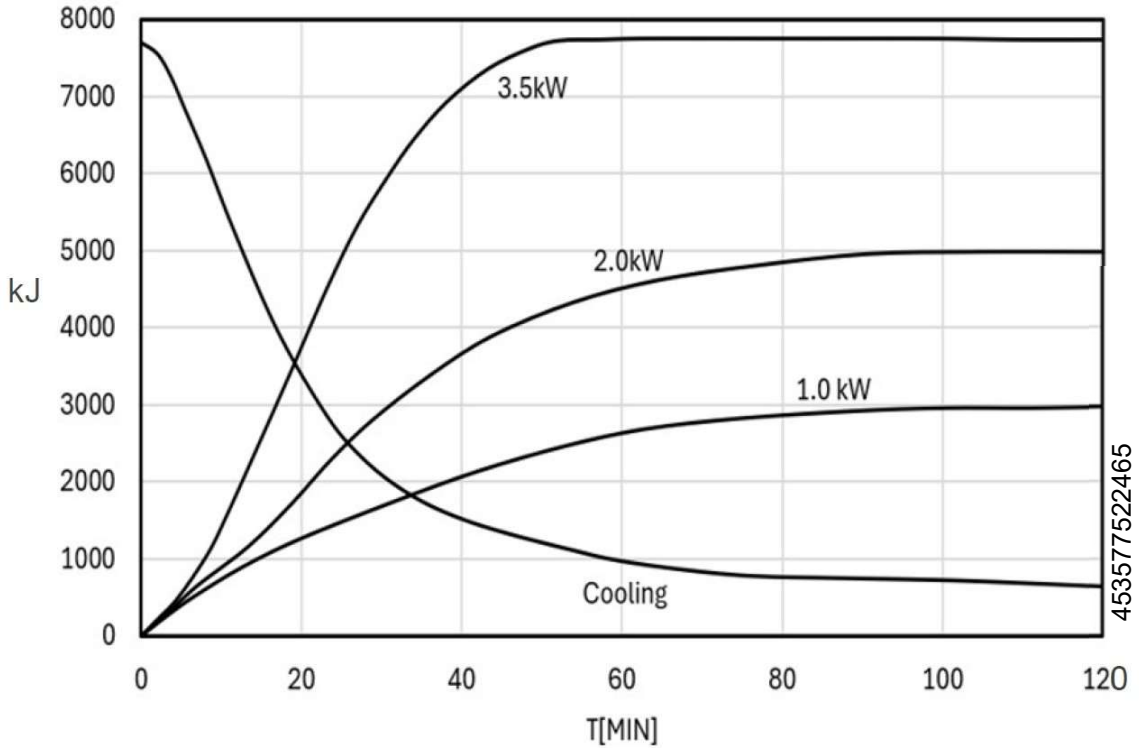
X-Ray Tube Assembly	
Product Identification (X-ray tube assembly)	AU200-C40+LMB 453577521747
Housing Material	Aluminum
Nominal Voltage	140 kV (max)
Nominal Continuous Rating	4.8 kW
Continuous Anode Input Power	3.5 kW
Distance between the center of focal spot to the mounting plane	81.05 mm (3.19 in)
Permanent Minimum Inherent Filtration (Al equivalent)	4.9 mm Al @ 75 kV IEC 60522-1/ 2020
Additional Filtration (Al equivalent)	0 mm Al
Minimum Total Filtration (Al equivalent)	4.9 mm Al
Temperature Range for Transportation and Storage	-25°C to 70°C (-13°F to 158°F)
Humidity Range for Transportation and Storage	10 to 95% RH non-condensing
Atmospheric Pressure for Transportation and Storage	70 to 106 kPa
Temperature Range for Operation	18°C to 26°C (64°F to 79°F)
Humidity Range for Operation	30 to 60% RH non-condensing
Radiation Leakage Technique Factor	25 mA, 140 kV
Stator Resistance	2.3 Ω phase to phase
Weight with accessories	92 kg (202.8 lb.)
Applicable Standards	IEC 60336, IEC 60522, IEC 60613, EN 60601-1, EN 60601-1-3, EN 60601-2-28, ISO 14971, US FDA 21 CFR
Safety Classification	FDA Class I IEC 60601-1 Class I, ME Equipment Directive 93/42/EEC IIB Regulation 2017/743 IIB
Mode of Operation	Intermittent
Suitability for use in an oxygen-rich environment	Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide

Electrical Wiring Data

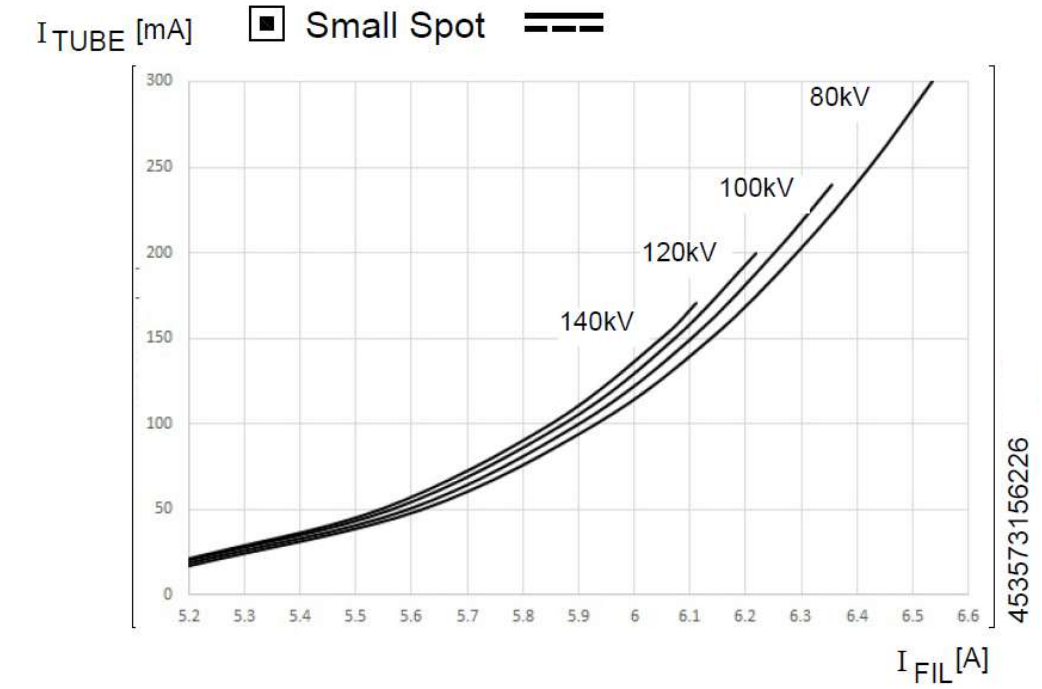


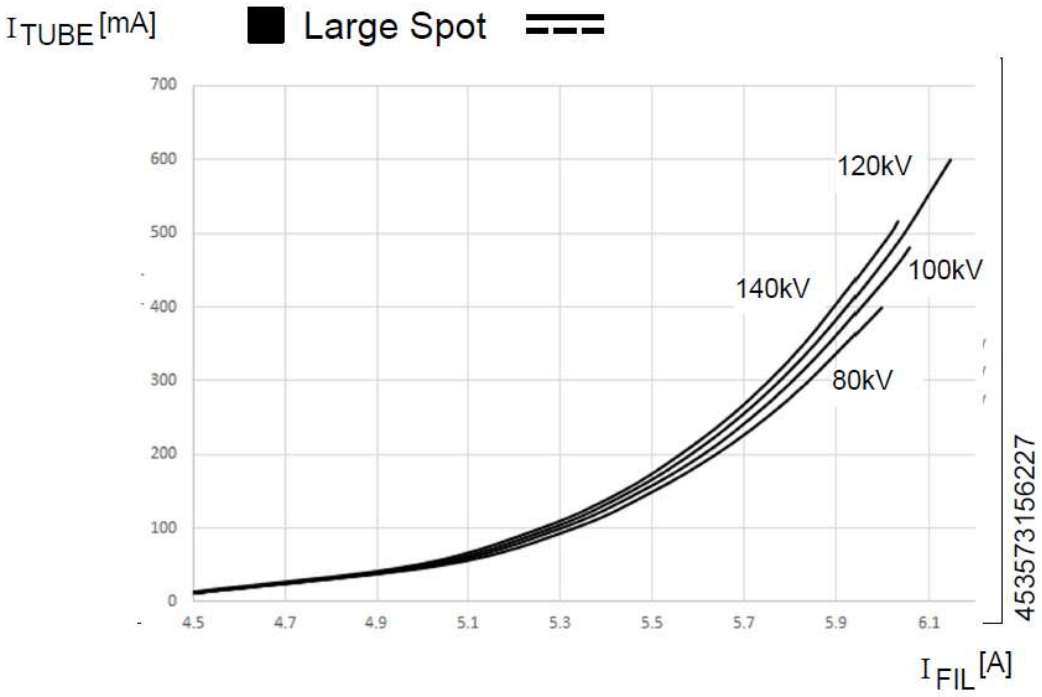


Heating and Heat Dissipation



Emission Characteristics





Rating Charts

Single Load Ratings for an Initial Anode Heat Content of 383 kJ

kV	5-second exposure		10-second exposure	
	Large Focal Spot mA	Small Focal Spot mA	Large Focal Spot mA	Small Focal Spot mA
80	400	300	400	300
100	480	240	480	240
120	600	200	570	200
140	515	170	485	170

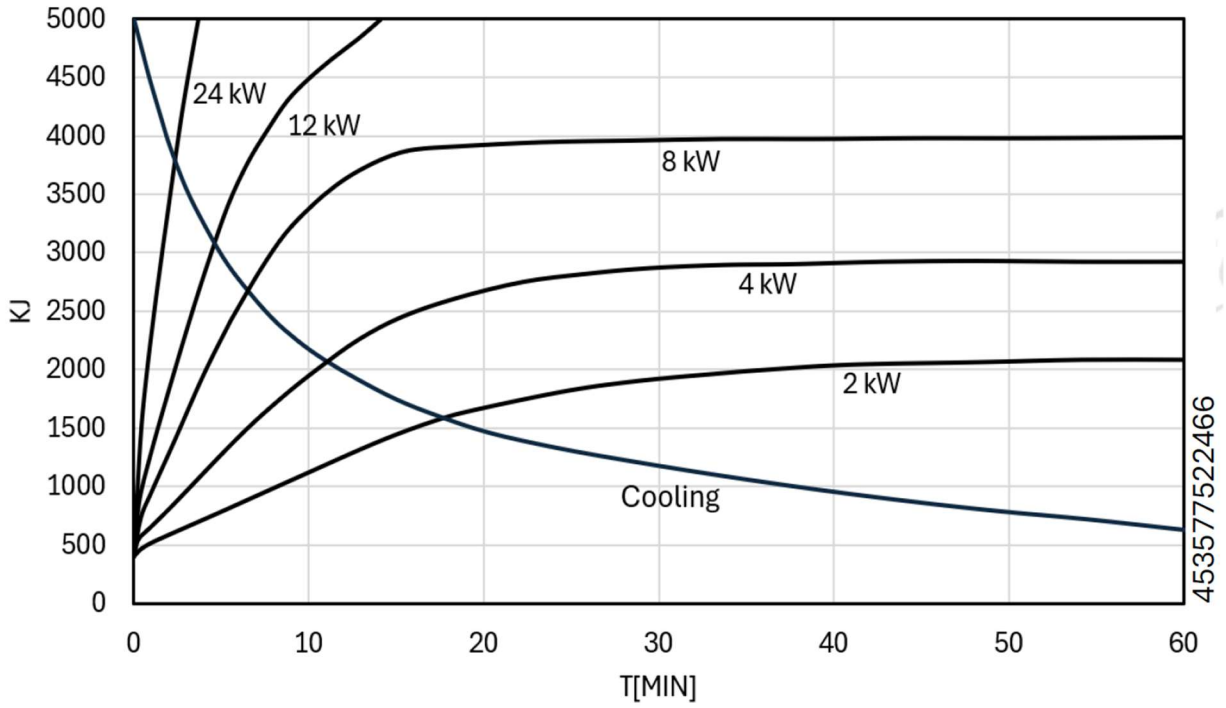
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Serial Load Ratings for an Initial Anode Heat Content of 383 kJ

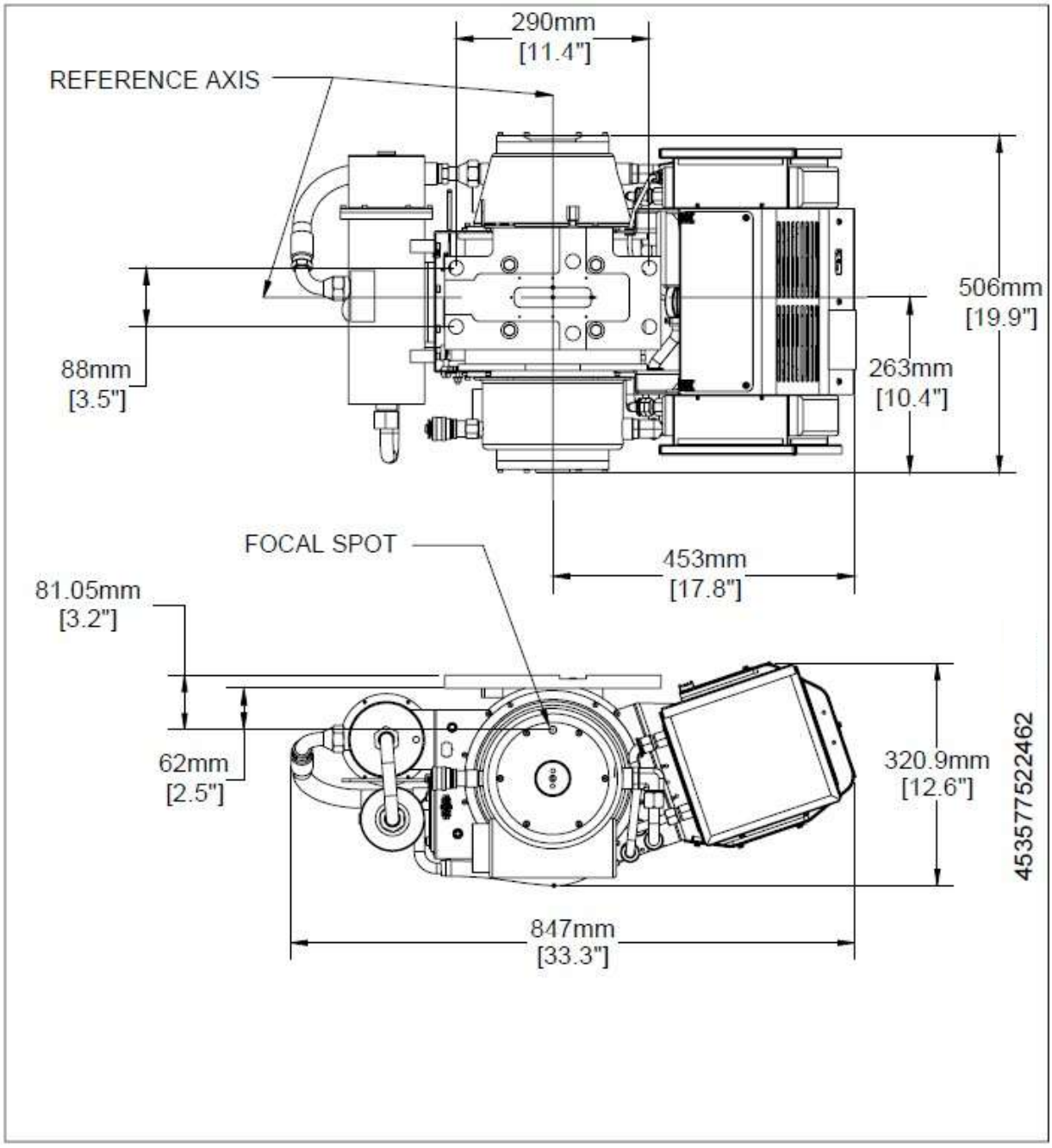
kV	5-second exposure		10-second exposure	
	Large Focal Spot mA	Small Focal Spot mA	Large Focal Spot mA	Small Focal Spot mA
80	400	300	400	300
100	480	240	480	240
120	540	200	485	200
140	465	170	415	170

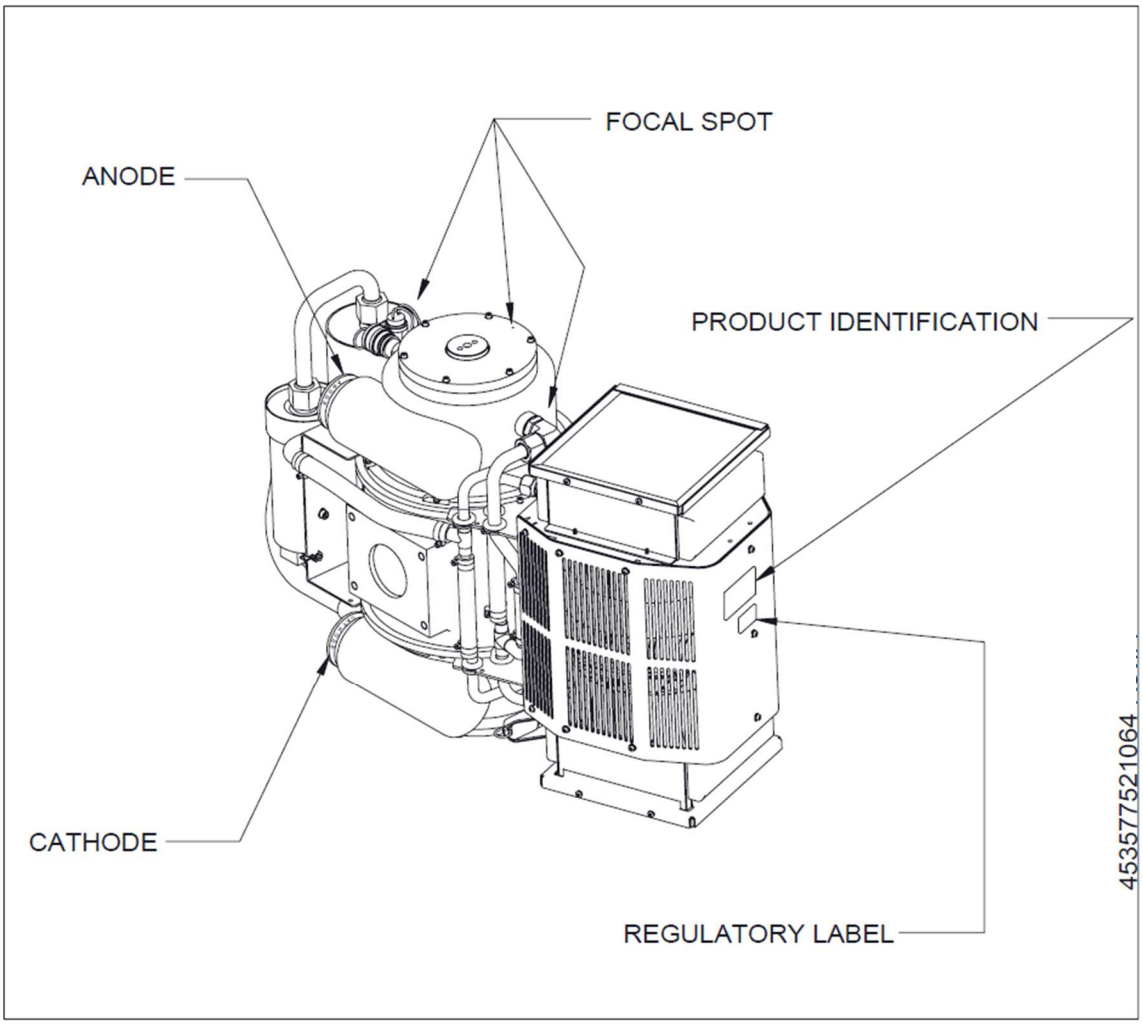
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Anode Heat and Heat Dissipation



Dimensional Data and Labeling




FOCAL SPOT
ANODE
PRODUCT IDENTIFICATION
CATHODE
REGULATORY LABEL
453577521064

7. Service and Manufacturing Locations

Device Manufacturer

Chronos Imaging, LLC

555 North Commerce Street

Aurora, IL 60586 USA



Visit us at www.chronosimaging.com