

CMP 200[®] Energy Assist X-ray Generator

Essential User Information

Introduction

This document presents Essential User Information for the CMP 200[®] Energy Assist X-ray generator (referred to as the generator) and its associated Control Console, Touch Screen, or Mini Console. This comprehensive document is designed to provide essential details regarding identification, safety, and performance. Its purpose is to equip users with the necessary information to operate the generator safely and effectively.

Intended Purpose

The Generator is intended to supply and control the electrical energy applied to a diagnostic X-ray tube for medical/veterinary radiographic examinations. It is used with film-based systems or with DR flat panel detectors along with an imaging system for diagnostic radiographic imaging. It is a non-invasive device and is designed to image the major systems of the body: skull, shoulder, thorax, upper arm, lower arm, abdomen, pelvis, femur, knee, tibia-fibula, and foot.

The Generator features state-of-the-art computer-based control to ensure minimum radiation dose, excellent reproducibility, and superior image contrast. The operation of the console is designed to be simple and user-friendly.

Intended Use

The generator and accessories were designed to be integrated into a complete X-ray system for use by trained Medical Professionals (Radiologists, Radiology Technicians, and Medical Physicists) in a Professional Healthcare Environment (Hospital, Medical Clinics, small private practice). The generator and optional accessories are stationary components intended for use with other diagnostic equipment found in an examination room for Hospital and Clinical Grade Radiographic X-ray procedures, and they provide and control the power delivered to the X-ray tube. The generator is not provided with an X-ray tube therefore cannot fulfil the medical purpose without first being integrated into an X-ray system.

These products are intended to be permanently installed by qualified individuals in a healthcare facility, which would typically include shielded lead rooms to protect operators, patients, and the environment from unwanted radiation exposure. The control console, where the operator programs the X-ray exposure, is usually located outside the radiation-protected area. To work with X-ray radiation-producing equipment in clinical applications, both the facility and the equipment operator must be granted a license according to local regulations.

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Warnings:

Installing or operating the equipment in a manner inconsistent with the intended use or intended use environment, installing, and servicing the equipment in a manner inconsistent with the service manual or related rework instructions, or installing, servicing, or operating the equipment by unqualified individuals may result in an increased risk of Electric Shock, Fire, or Radiation hazards, as well as a negative impact on the equipment's Essential Performance.

Note:

Any serious incident related to the use of the Generator resulting in the deterioration of health to the user and/or patient should be reported to the X-ray system manufacturer and to the local regulatory or competent authorities in which the user or patient resides. Incidents involving CPI X-Ray Generator or Accessories will be investigated and addressed cooperatively with the X-ray system manufacturer.

Patient Population

- Age: infant to geriatric.
- Weight:
 - APR mode: Pediatric, small, medium, and large patients. The selection of pediatric patient size may be disabled by the service engineer.
 - Manual mode: Exposure factors are set manually, will allow weights from newborn to obese adult.
- Health: Patients requiring an X-ray may have conditions ranging from mild trauma to chronic, life-threatening illnesses.

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Radiographic Performance

Table 1: Radiographic performance

kVp range:	40 kV to 125 kV or 40 kV to 150 kV, depending on model
kVp steps:	variable in 1 kV steps
kVp accuracy:	$\pm (5\% + 1 \text{ kV})$ measured 5 ms after the beginning of the exposure; $\pm 2\%$ between 70-80 kVp Measured between the 75% points of the kV waveform
Rise time (10%-90%):	<1.5 ms (typically < 1.0 ms) with 30 m (100 ft) Locaflex L3 or equivalent HV cables
Time range:	1.0 to 6300 milliseconds
Exposure time Steps:	Variable in 1 ms steps via protocol Variable according to ISO 497 Series R'20 via CPI consoles
Exposure Time Accuracy:	$\pm (2\% + 0.5 \text{ ms})$ from 5 ms to 6300 ms and $> 0.5 \text{ mAs}$ $\pm (10\% + 1 \text{ ms})$ for $> 0.1 \text{ mAs}$ and for $< 5 \text{ ms}$ or $\leq 0.5 \text{ mAs}$ for 30 m (100 ft) HV cables Measured between the 75% points of the kV waveform
mAs range:	0.1 to 125 mAs (32/40 kW) 0.1 to 125 mAs (50 kW)
mAs accuracy:	$\pm (10\% + 0.2 \text{ mAs})$ for $> 0.5 \text{ mAs}$ $\pm (10\% + 0.05 \text{ mAs})$: 0.1 mAs – 0.5 mAs (preliminarily specified for the range beyond IEC standard)
mA range	10 to 400 mA (32 kW) 10 to 500 mA (40 kW) 10 to 630 mA (50 kW)
mA steps:	Variable in 0.1 mA steps via protocol Variable according to ISO 497 Series R'20 via CPI consoles (See Generator Exposure Tables in Appendix A of this manual)
mA Accuracy (10 mA – 1000 mA):	$\pm (5\% + 1 \text{ mA})$ for exposures $\geq 5 \text{ ms}$ and $> 0.5 \text{ mAs}$; measured 5 ms after the beginning of the exposure across a 10 Ω , 1% resistor at the HVM mA F/B terminals. $\pm (20\%) \text{ mA}$ for exposures $> 0.1 \text{ mAs}$ and for $< 5 \text{ ms}$ or $\leq 0.5 \text{ mAs}$; (0.1 – 0.25 mAs, mA $\geq 50 \text{ mA}$); measured between the 75% points of the kV waveform measured across a 1 Ω , 1% resistor at the HVM mA F/B terminals.
Coefficient of linearity:	≤ 0.1 (Station to Station) for exposures ³ 25mA or 3.2ms
Coefficient of reproducibility:	≤ 0.05 for a set of kV and mAs parameters
Duty Cycle:	Not to exceed 5 consecutive boosts, followed by a minimum 10 second wait period

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Table 1: Radiographic performance

Note: The product of kV and mA is constrained by the maximum power rating. The kV ripple is constrained by the minimum cable capacitance shown in the *Minimum High Voltage Cable Requirements* section of this chapter.

Output Parameter and Loading Factor

Table 2: Output Parameter and Loading Factor

Output Parameter	Generator Series	Loading Factor
Maximum X-ray tube voltage and highest X-ray tube current at that voltage	32 kW	125 kV, 250 mA / 150 kV, 200 mA
	40 kW	125 kV, 320 mA / 150 kV, 250 mA
	50 kW	150 kV, 320 mA
Maximum X-ray tube current and highest X-ray tube voltage at that current	32 kW	400 mA, 80 kV
	40 kW	500 mA, 80 kV
	50 kW	630 mA, 80 kV
Combination of X-ray tube current and X-ray tube voltage resulting in highest output power	32 kW	320 mA, 100 kV
	40 kW	400 mA, 100 kV
	50 kW	500 mA, 100 kV
Highest constant output power at 100 kV, 0.1 sec	32 kW	320 mA, 100 kV, 0.1 s
	40 kW	400 mA, 100 kV, 0.1 s
	50 kW	500 mA, 100 kV, 0.1 s
Nominal shortest irradiation time (AEC exposures)	All models (AEC control is available over the full kV and mA range)	< 2 ms with a dedicated or 3 of 5 field AEC board. AEC control is achieved by varying the ms of the exposure. The AEC ms range is 15 ms to an installer-programmable maximum not to exceed 600 mAs.

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Safety

Safety and Warning Symbols

The following advisory symbols are used on the safety warning labels, and/or on circuit boards, and/or on the operator console.



High voltage symbol used to indicate the presence of high voltage



Warning symbol used to indicate a potential hazard to operators, service personnel or to the equipment



This is a radiation exposure symbol used on operator console. Lights indicate that an exposure is in progress. This is accompanied by an audible tone from the console.

WARNING

This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

Warnings:

- *Proper use and safe operating practices with respect to the Generators are the responsibility of users of such generators. CPI Canada Inc. ("The Manufacturer") provides information on its products and associated hazards but assumes no responsibilities for after-sale operating and safety practices.*
- *The Manufacturer accepts no responsibility for any generator not maintained or serviced according to this service and installation manual, or for any generator that has been modified in any way.*
- *The Manufacturer also assumes no responsibility for X-ray radiation overexposure of patients or personnel resulting from poor operating techniques or procedures.*
- *This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.*

Caution:

- *Do not exceed the X-ray tube maximum operating limits shown in the X-ray tube data section at the end of the operator's manual. Intended life and reliability will not be obtained unless the Generators are operated within published specifications.*

X-ray radiation exposure may be damaging to health, with some effects being cumulative and extending over periods of many months or even years. X-ray operators should avoid any exposure to the primary beam and take protective measures to safeguard against scatter radiation. Scatter radiation is caused by any object in the path of the primary beam and may be of equal or less intensity than the primary beam that exposes the film.

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No practical design can incorporate complete protection for operators or service personnel who do not take adequate safety precautions. Only authorized and properly trained service and operating personnel should be allowed to work with the Generator equipment. The appropriate personnel must be made aware of the inherent dangers associated with the servicing of high voltage equipment and the danger of excessive exposure to X-ray radiation during system operation.

- Operators should be trained on the use of the equipment within the facility. They should have the knowledge in radiology, and the skills, attitude, and judgment to operate the equipment safely and effectively.
- Operators are trained on the use of the Generator by the installer of the Generator. The operator's manual may be used as a training aid.
- Wear protective clothing. Protective aprons with an equivalent of a minimum of 1/64" (0.35 mm) of lead are recommended.
- Repetitive or prolonged exposures may result in local skin dose levels that cause adverse tissue reactions.
- To protect the patient against radiation, always use radiation protection accessories in addition to devices which are fitted to the X-ray equipment.
- Keep as large a distance as possible away from the object being exposed and the X-ray tube assembly.
- Never operate this X-ray equipment in areas where there is a risk of explosion. Detergents and disinfectants, including those used on patients, may create explosive mixtures of gases. Please observe the relevant regulations.
- This X-ray equipment may only be operated in medical rooms which meet IEC requirements.
- The operator must not touch any part of the console or the Generator and the patient simultaneously.
- The operator console, or anything electrically connected to it, must never be used within 6 ft (1.8 m) of the patient environment.
- This equipment is not suitable for use in an oxygen-rich environment.
- Do not place liquids (coffee, beverages, flowers, etc.) on the control console or the Generator main cabinet.
- Always ensure adequate ventilation around the control console and the Generator main cabinet. Do not operate the equipment near curtains, drapes, etc. which may block the ventilation slots.
- The control console must be located inside an X-ray shielded control booth within the X-ray room, or outside the X-ray room.
- The control console is intended for fixed mounting. It is not a portable device. Do not operate the console or the Generator main cabinet in direct sunlight or near any heat sources.

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- Do not operate the console near strong magnetic fields (microwave ovens, speakers, etc.), and avoid routing the console cables near these devices.
- The console and the Generator main cabinet must be operated in locations that are clean (free of excess dust, dirt, debris, etc.), stable (free of vibration), and secure such that the console cannot slip or tip.
- Only trained maintenance staff may remove the covers of the Generator cabinet and the control console.
- The Generator's installation instructions are included in the service manual, which is a separate item from the Operator's manual. The designated service organization is qualified to perform the equipment installation.
- Do not connect unapproved equipment to the rear of the console. J3 is for connection of an external hand switch, J4 is a serial port for use by an external computer, and J8 is for the interconnect cable to the main cabinet. Incorrect connections or use of unapproved equipment may result in injury or equipment damage.

Generator Duty Cycle Limit

Internal X-ray generator components will heat up during normal use of the Generator. This is similar to X-ray tube heating during normal generator operation. The amount of heat produced is proportional to the product of kV, mA, and time.

Modern Diagnostic X-ray Generators are designed to operate with the majority of X-ray tubes over their rated power ranges. They are designed for operating duty cycles consistent with practical patient examination routines that allow for reasonable cooling intervals between X-ray exposures.

This Generator has internal duty cycle monitoring to warn of excessive heat build-up. If the Generator calculates that the next exposure will exceed the rated generator duty cycle limit, a warning message "GEN DUTY WARNING" will be displayed. Further exposures are inhibited at this point, and the Generator must be allowed to cool sufficiently such that this message is no longer displayed.

The Generator also monitors the X-ray tube's thermal switch and will inhibit exposures when the tube reaches its thermal limit. It is the responsibility of the installer to implement and verify this interlock.

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Daily X-Ray Warm-Up Procedure

Use this procedure when the Generator is first turned on for the day, or when it has not been used for several hours. This procedure provides for exposures at medium power before the tube is used at maximum mA or kV values. This will reduce the possibility of damaging the anode and high voltage components. No test setup is required.

For maximum stability and reliability, use the following techniques at start up:

Select the following:

- Large focal spot.
- 80 kV.
- Normal 50/60 Hz anode rotation.

For a 300 kHU to a 400 kHU tube, use approximately 200 mAs per exposure. For a 200 kHU to 300 kHU tube use approximately 150 mAs per exposure.

- Depending on the X-ray tube power rating, select either 100 mA or 200 mA.
- Make one (1) to three (3) exposures (depending on tube loading) at 30-second intervals.

How to obtain a new operator's manual

To obtain a new operator's manual, contact CPI customer support and one will be provided. A model number and serial number of the equipment should be provided.

Phone Number: 905-877-0161

Toll Free Number: 1-888-274-9729

Fax: 905-877-3633 or 905-877-5327

Email: medicalmarketing@cpii.com

Attention: Customer Support Department

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Manufacturer

CPI X-Ray generator products are manufactured by Communications & Power Industries Canada Inc.

Manufacturer: Communications & Power Industries Canada Inc.
Manufacturer's Address: 45 River Drive, Georgetown,
Ontario L7G 2J4, Canada
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Manufacturer's SRN: CA-MF-000032904

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