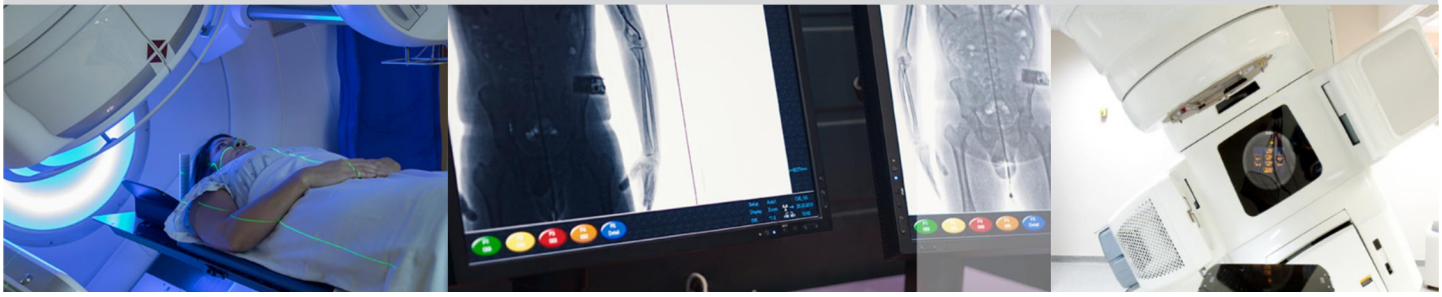
Supplement



Accessing Generator Products Documentation

CMP 150™

CMP 200®

CMP 200® DR

CMP 200® PF

CMP 200® EA

Mobile DR

Mobile Nano

Indico IQ®

Indico IQ® SP

CPI Antenna & Power Technologies
Power Electronics Division
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Communications & Power Industries

Doc. SUP95152000 Rev. A

Proprietary Information

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1. Accessing the Customer Portal

CPI's Customer Portal provides access to the latest as well as archived product documentation, including relevant manuals and bulletins.

To access the Customer Portal,

1. Using a mobile device or computer, scan the QR code or visit the website printed on the label affixed to the rear panel of your product, or displayed in the figure below.

   Your web browser is directed to CPI's Customer Portal.

Figure 1. CPI Customer Portal QR Code

2. Using the credentials provided in your CPI FileCloud welcome email, log into the portal.

   A one-time, 2 Factor Authentication (2FA) code is sent to your organization's email address.

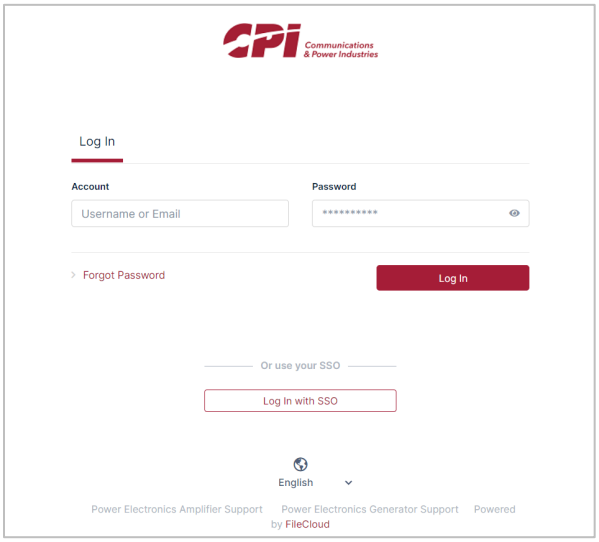

Figure 2. CPI Customer Portal

3. Enter the authentication code into the *2FA Authentication Code* field and press or click **Login**.

1.1 Need Help?

For assistance with creating an account or using the Customer Portal, click the appropriate support link located at the bottom of the portal's login page, or email power.care@cpii.com.

1.2 Mobile Device and Computer Requirements

Product documentation is provided in the PDF file format. To access, download, and view documents, users must possess an internet connection and PDF viewing software.

2. Requesting a Printed Copy

In compliance with (EU) Regulation 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices, operator's manuals are provided in electronic form unless the paper form is requested by the customer.

To request a printed copy of your product's documentation, please fill out and submit the form found at www.cpii.com/medical/manuals.

3. About the Manufacturer

Your generator product and its control console (if supplied) are manufactured by…

- Company Name: Communications & Power Industries Canada Inc., Antenna & Power Technologies, Power Electronics
- Address: 45 River Drive, Georgetown, Ontario, Canada, L7G 2J4
- Phone: +1 (905) 877-0161
- Fax: +1 (905) 877-5327
- Email: power.care@cpii.com

4. About the Product

CPI X-ray generators and accessories are designed to be integrated into complete X-ray systems. They are intended for use by trained medical professionals (radiologists, radiology technicians, and medical physicists) in professional healthcare environments (hospitals, medical clinics, and small private practices). Generators and accessories are stationary or mobile components intended for use with other diagnostic equipment found in examination rooms for hospital and clinical-grade radiographic X-ray procedures. They provide and control the power delivered to X-ray tubes.

X-ray tubes are **not** provided with CPI generator products. Therefore, generators cannot fulfill a medical purpose without first being integrated into X-ray systems.

4.1 Product Class

The section lists the medical device classification of CPI generator products by region.

Table 1. Product Class

Region	Class
EU/UK/AUS	Class IIb
USA	Class 1
CAN	Class 3
Japan	Class II

4.2 Transport and Storage Conditions

Generator products must be transported and stored in acceptable environmental conditions as described in this section.

Table 2. Transport and Storage Conditions

Parameter	Acceptable Value(s)
Ambient Temperature Range	-20 to 70°C (-4 to 158 °F)
Relative Humidity	5 to 95%, non-condensing

Parameter	Acceptable Value(s)
Atmospheric Pressure Range	1060 to 700 hPa (-400 to +3000 meters, 795 to 525 mm Hg); Reference: 1013 hPa nominal at sea level

Long-term storage over 40°C will reduce the service life of electrolytic capacitors in the generator.

The membrane control console is limited to a minimum temperature of -20°C with a maximum duration of 48 hours at that temperature. Transport and storage is limited to a maximum duration of 120 hours between 50 and 70°C with an absolute humidity not to exceed the humidity of 85% RH at 50°C.

Touchscreen console temperatures below -20°C and above +50°C are limited to 10 days maximum duration with a humidity not exceeding 50% RH.

4.3 Notes, Cautions, and Warnings

This section describes the notes, cautions, and warnings which apply to basic product operation as described in documentation provided through CPI's Customer Portal. Notes, cautions, and warnings apply to the relevant standard or optional features for a given product model and/or system configuration.

Read and understand the product's operator and/or service manuals in their entirety before attempting to operate or service the product.

4.3.1 Symbols

This section describes the hazard, warning, and caution symbols utilized throughout generator product documentation.

Warning symbols indicate a potential hazard to operators, service personnel, or to the equipment.

High voltage symbols identify the presence of high voltage electricity or conditions, operations, and procedures which expose personnel to potentially lethal high voltages.

Hot surface warnings identify part surfaces which become hot during operation and may remain hot for a period of time after operation. Such surfaces may burn skin or damage equipment which comes into contact with them if not allowed to cool down adequately.

Radiation exposure symbols indicate that an exposure is in progress.

4.3.2 Notes

- Default Anatomic Programming Radiography (APR) protocols are only examples or starting points. They must be replaced by more specific protocols developed by the responsible organization.
- Exposure parameters (described in kV, mA, and ms units) must be confirmed before making an exposure. These parameters may change when switching between Automatic Exposure Control (AEC) and non-AEC modes and are dependant on the AEC backup mode or generator programming.
- By design, CPI generators inhibit exposures if the X-ray tube is at risk of overheating.
- X-ray exposure charts are provided in the product's Operator Manual.
- The time shown on the console for Advanced Capacitive Discharge (ACD) exposures is approximate.
- For systems with the AEC feature, verification of the proper functioning of the AEC Device Error is recommended during calibration with the generator.
- All equipment connected to a CPI generator must be installed and serviced in accordance with its manufacturer's requirements.
- To promote correct and safe operation, operate all CPI equipment in accordance with the instructions and guidelines described in its operator and service manuals.
- Review and become familiar with the locations of warning labels adhered to the product where hazards are present, including when covers are removed and the generator is powered ON.
- Before installing the product, consult its service manual to ensure the required physical clearance is available at the installation site to

safely access the generator, ensure its cooling vents are unobstructed, and that periodic cleaning, maintenance, and service procedures can be conducted safely.

- Generators must be transported and stored in an upright position. They must NOT be stacked.

4.3.3 Cautions

- Do not allow liquid in the vicinity of an X-ray generator.
- Do not place any objects on an X-ray generator.
- Failure to implement ergonomic precautions when servicing the X-ray generator may result in physical injury.
- Do not exceed the tube maximum operating limits listed in the *X-ray Tube Data* section located in the equipment's operator's manual. Attempting to exceed published specifications will negatively affect equipment lifespan and reliability.
- The AEC verification procedure requires the production of X-rays. To protect personnel, observe correct operating procedures and apply appropriate safety precautions against X-ray radiation.
- Ensure that all interlocks are functioning correctly.
- To verify that Printed Circuit Board Assembly (PCBA) and Power or Energy Assist Modules are functioning properly when power is applied to the equipment, ensure Indicator LEDs are ON (illuminated) and Warning LEDs are OFF (not illuminated).
- For 1-Phase AC mains installations, consult the product's service manual for equipment wiring diagrams (including neutral conductor designations).
- The ADR2 function can only be disabled by the Original Equipment Manufacture (OEM) system. Please refer to the appropriate OEM manual for instructions.
- The exposure time displayed on the console for ACD exposures is an estimated time. The exposure ends when the set mAs is achieved.
- CPI strongly recommends that customers ensure that the electrical distribution which feeds generators are correctly fused and are compliant with locally regulated electrical safety codes.
- Consult the appropriate service manual for specified maintenance intervals regarding the required cleaning and re-greasing of generator high voltage connections.

- Consult the appropriate service manual for specified maintenance intervals regarding the required inspection of all cables (including exposure switch cables).

4.3.4 Warnings

- Installing, operating, or servicing generator equipment in a manner inconsistent with its intended use, intended environment, or product support documentation (procedures prescribed in operator's and service manuals) may result in an increased risk of electric shock, fire, or radiation exposure hazard.
- Only trained and qualified personnel who are familiar with the potential hazards associated with X-ray equipment can safely operate generator equipment.
- All generator product servicing must be performed by trained and qualified technicians who are familiar with the potential hazards associated with X-ray equipment.
- Users are responsible for the proper use and safe operation of generator equipment. The manufacturer assumes no responsibility for after-sale operating and safety practices and accepts no responsibility for generator products which are modified in any way or not operated, maintained, and serviced in accordance with the provided operator and service manuals.
- The manufacturer assumes no responsibility for the X-ray radiation overexposure of patients or personnel resulting from incorrect operating techniques or procedures.
- Generator products may be dangerous to patient and/or operator unless safe exposure factors, operating instructions, and prescribed maintenance schedules are understood and observed.
- Do not exceed the number of high-speed boosts based on X-ray tube capacity.
- Failure to properly install the mains power connection to an X-ray generator may result in electric shock.
- Failure to properly install all required electrical grounding connections may result in electric shock.
- Failure to properly terminate all high voltage cables external to an X-ray generator may result in electric shock.
- Failure to properly connect peripheral equipment that is powered by an X-ray generator may result in electric shock.

- Failure to recognize that the Emergency Power Off switch does not remove power supplied by the X-ray generator to peripheral equipment may result in electric shock.
- Failure to perform the required auto-calibration of an X-ray tube may result in incorrect exposures.
- Failure to correctly configure an X-ray tube starter may damage the X-ray tube and result in incorrect exposures.
- Always replace fuses with ones of the same type and rating.
- For the CMP 200 product, consult its Service Manual (CPI# MAN901471XX) for information regarding potential hazards related to the lithium battery used in its Control Board.

4.4 Contraindications

Some generator products do not have absolute contraindications that could be life-threatening. However, relative contraindications may include factors such as pregnancy or the patient's weight.

4.4.1 Clinical Benefits

The clinical benefits of diagnostic X-ray imaging are extensive. However, they are dependent on system-level configuration and the healthcare practitioner's utilization of available resources and assessment of patient condition. X-ray imaging is a well-established technology which offers invaluable insights into internal body structures. The risks associated with ionizing radiation are well known and generally accepted when weighed against the benefits. It is versatile, available in both hospitals and smaller clinics, and serves a broad range of medical disciplines.

Diagnostic X-ray imaging offers several benefits for patients. It can eliminate the need for exploratory surgery, assist in performing diagnosis, guide treatment decisions, and determine when surgeries are necessary.

While there are risks associated with radiation exposure, the clinical benefit of medically appropriate X-ray imaging outweighs these risks. This is apparent when considering the potential health improvements and prolonged life it can offer.

4.4.2 Clinical Limitations

Generator products cannot fulfill a medical purpose without first being integrated into X-ray systems. The intended purpose and indirect clinical

benefit of the equipment can only be realized when it is installed, maintained, and operated in accordance with its operator's manual.

4.5 Reporting an Incident to CPI

If an incident occurs involving a CPI generator product, please report it immediately by email to power.care@cpii.com.

Include the following details in your report…

- Product model
- Product serial number
- Date of the incident
- Description of the incident
- Whether or not the incident resulted in serious injury

4.6 Reporting an Incident to Regulatory Authorities

Any serious incident related to the use of a CPI generator product which results in the deterioration of health of 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 products will be investigated and addressed cooperatively with the X-ray system manufacturer.

4.7 Reporting a Malfunction

If your product experiences a malfunction, please contact CPI customer support by…

- Web: www.cpii.com/medical/support
- Phone: + 1-888-274-9729
- Email: power.care@cpii.com

4.8 Reporting Feedback

CPI welcomes any questions, comments, or concerns you may have regarding your product. Please submit feedback to us by emailing power.care@cpii.com.