

Product Safety and Performance Information

1 Product Description

1.1 Product name and model

DM-3C Digital Mammography Systems

1.2 Basic UDI-DI

693896431700NY

1.3 Intended Purpose

The system generates full-field digital mammography images as well as tomosynthesis images for various procedures.

1.4 Indications for use

The DM-3C Digital Mammography Systems is intended to be used for mammography exams, screening, diagnosis procedures under the supervision of medical professionals. Mammography images can be interpreted by either hard copy film or soft copy workstation.


The DM-3C offers a high degree of patient comfort and care and features a low-dose concept. Smart features such as one-click image access and positioning with the push of a button greatly simplify handling and enable the clinical user to arrive at a precise diagnosis with ease due to its high patient throughput and its future proof design.

The DM-3C with tomosynthesis Option is indicated for acquisition of 2D as well as 3D digital mammography images to be used in screening and diagnosis of breast cancer.

1.5 Contraindications:

No contraindications are known. Patients have to be informed about the hazards and safety measures during an examination. Prior to the examination, it must be confirmed by qualified

medical personnel that an examination is permissible, and checked whether increased precautions are necessary.

 Warning	Do not use the machine for any purposes other than its intended use.
---	--

1.6 Intended user

The system can be used properly only by suitably qualified medical personnel in compliance with the relevant applicable country-specific regulations. This requires operating personnel to be familiar with the Operator Manual. This manual must be studied thoroughly prior to starting up the system. Special attention must be paid to the following sections:

- General Safety Information
- Personal Safety
- Equipment Safety
- Maintenance

Training: Instruction in the use of the system can take place through application training provided by a WDM qualified application trainer.















1.7 Intended Patient Population









This product can be used for examining all types of patients. When this system is used, the relevant applicable country-specific requirements must be complied with. Qualified medical personnel decide whether a radiographic examination is suitable or not based on the patient's health and physical condition.

2 Product Safety Information


2.1 Product label Safety Information


This product has the following external markings, as shown in the table below.


Marking	Location	Description
	Packaging Box	Fragile, handle with care
	Packaging Box	Keep dry
	Packaging Box	This Way Up
	Packaging Box	Package recycling
	Packaging Box	Center of Gravity
	Packaging Box	Sling here
	Packaging Box	Stacking limit by 2
	Packaging Box	Temperature Limit
	Packaging Box	Humidity Limit
	Packaging Box	Atmospheric Pressure Limit
	System Label	indicates that the electrical safety type of the X-ray machine is Type B.
	next to the system label	Environmental Control Label for Electronic Information Products with a 50-Year Period
	next to the system label, collimator label, and imaging system label	Refer to instruction manual/booklet
	High-Voltage Generator Mammography Gantry	Protective ground (earth) mark

Marking	Location	Description
	X-ray tube assembly cover	Ionizing radiation warning
	High-Voltage Generator	Dangerous voltage
N	High-Voltage Generator	Neutral symbol
	High-Voltage Generator	X-ray radiation danger warning
	Mammography Gantry	Crushing of hands
	Mammography Gantry	Emergency Stop Switch
	Mini control box	(Power) On
	Mini control box	(Power) Off
	Mammography gantry	Do not push


2.2 Electrical Safety


 Warning	<ul style="list-style-type: none"> ✧ Do not remove cabinet panels or covers of the equipment unless explicitly instructed in this manual, to prevent the risk of electric shock. Removing the covers could lead to fatal or other serious personal injuries. ✧ There are no user-serviceable or adjustable components inside the cabinet. Only trained and qualified personnel should handle the internal components of this equipment.
--	---


 Caution	Prevent metal objects or liquids from falling into the equipment, as this can cause a short circuit or generate smoke. If any foreign matter enters the system, turn off the power and contact the sales representative or after-sales service for inspection.
--	--

 <p>Warning</p>	<p>To avoid the risk of electric shock, this equipment must be connected to a power supply network with protective grounding.</p>
--	---

2.3 Mechanical Safety

 <p>Warning</p>	<p>Ensure that the patient or your hand is in a safe position within the range of motion of the product components. Also, ensure that the patient's or your clothing does not become entangled with the equipment.</p>
--	--


 <p>Caution</p>	<p>Do not place any unnecessary objects within the range of movement of the components of this product.</p>
--	---

 <p>Caution</p>	<p>When the equipment is in normal use, the parts expected to have physical contact with the patient are the carbon fiber cover plate located above the flat panel detector and the compressor. Before exposure, ensure that the patient is correctly positioned to avoid injury.</p>
--	---

2.4 Radiation Protection

X-rays are harmful to health; incorrect perceptions and operations can cause radiation damage to patients, operators, and other personnel.

Operators should have undergone training in radiation protection, possess the corresponding protective knowledge, and pay attention to the following matters:

 <p>Caution</p>	<p>Radiation Shield Precautions:</p> <ul style="list-style-type: none"> ✧ Overexposure not only affects image quality but may also cause damage in terms of radiation. Therefore, selecting appropriate exposure parameters and dose is very important. ✧ Unnecessary exposure or incorrect operation can cause radiation damage to patients, operators, and other personnel. ✧ Operators should position patients appropriately and use facilities designed to prevent
--	--

	<p>or reduce radiation damage to patients to ensure their safety.</p> <ul style="list-style-type: none"> ✧ To keep the patient's absorbed dose as low and reasonable as possible, the distance from the focal spot to the skin should be maximized. ✧ In any case, operators, medical staff, and other personnel should avoid direct exposure to X rays, and adequate measures should be taken to prevent direct X-ray irradiation. If operators, medical staff, and other personnel are exposed next to the equipment, adequate protection should be implemented, such as wearing lead aprons and placing lead shields, with the attenuation equivalent of the radiation shield being no less than 0.5mmPb. ✧ Pay attention to the protection against stray radiation and other secondary radiations. ✧ Operators should pay attention to personal dose monitoring and regular health check-ups. ✧ The X-ray room should comply with relevant requirements of national and local environmental protection departments and health and epidemic prevention departments to ensure no radiation damage to operators and other personnel. ✧ Do not modify the radiation protection circuit of this product without permission from this company.
--	--

3 Product Performance Metrics

3.1 Power

3.1.1 Maximum Output

Intermittent Mode: 5kW (40kV×125mA).

3.1.2 Nominal Output

When the X-ray tube loading time is 0.1s, and the X-ray tube voltage is 30kV:

The nominal output is 4.8kW (30kV × 160mA).

3.2 Loading Factors Control and Indication

3.2.1 X-ray tube voltage

The X-ray tube voltage should meet the following requirements:

- a) The voltage adjustment range should be (20~49)kV; step-adjustable, with a step size no greater than 1kV;
- b) The deviation of the X-ray tube voltage value should not exceed $\pm 5\%$.

3.2.2 X-ray tube current

The X-ray tube current should meet the following requirements:

- a) The current adjustment range: (10~200)mA, step-adjustable, with a step size of 5mA below 160mA;
- b) The deviation of the X-ray tube current value should not be greater than $\pm 20\%$.

3.2.3 X-ray tube loading time

The loading time should meet the following requirements:

- a) The adjustment range of the photography loading time (0.005~10)s, adjustable in steps of 5ms;
- b) The deviation of the photography loading time value should not be greater than $\pm(10\%+1\text{ms})$.

3.2.3 X-ray tube loading time

The loading time should meet the following requirements:

- a) The adjustment range of the photography loading time (0.005~10)s, adjustable in steps of 5ms;
- b) The deviation of the photography loading time value should not be greater than $\pm(10\%+1\text{ms})$.

3.2.4 X-ray tube current time product

The current time product should meet the following requirements:

- a) a) The adjustment range of the photography current time product is (0.5~630)mAs, adjustable in R'20 series steps;
- b) The deviation of the current time product value should not be greater than $\pm(10\%+0.2\text{mAs})$.

3.2.5 Overload Protection

The equipment should have overload protection measures to ensure that the selection of loading factors does not exceed the rated capacity of the X-ray tube. It should comply with the maximum loading factor combinations given in the user manual.

3.2.6 Maximum Tube Current

The maximum tube current the equipment can provide at 25 kV is 200 mA.

3.2.7 Maximum Tube Voltage

The maximum tube voltage the equipment can provide at 100 mA is 49 kV.

STATEMENT TO USERS

For detailed usage information, please refer to the paper version of the instruction manual.