GE Medical Systems

Technical Publications

CE 0459

2135575–100

Revision 6

SENOGRAPHE 800T
om
Operator Manual

do not duplicate

ATTENTION

LES APPAREILS À RAYONS X SONT DANGEREUX À LA FOIS POUR LE PATIENT ET POUR LE MANIPULATEUR SI LES MESURES DE PROTECTION NE SONT PAS STRICTEMENT APPLIQUEES

Bien que cet appareil soit construit selon les normes de sécurité les plus sévères, la source de rayonnement X représente un danger lorsque le manipulateur est non qualifié ou non averti. Une exposition excessive au rayonnement X entraîne des dommages à l'organisme.

Par conséquent, toutes les précautions doivent être prises pour éviter que les personnes non autorisées ou non qualifiées utilisent cet appareil créant ainsi un danger pour les autres et pour elles–mêmes.

Avant chaque manipulation, les personnes qualifiées et autorisées à se servir de cet appareil doivent se renseigner sur les mesures de protection établies par la Commission Internationale de la Protection Radiologique, Annales 26 : Recommandations de la Commission Internationale sur la Protection Radiologique et les normes nationales en vigueur.

WARNING

X–RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful x–ray beam becomes a source of danger in the hands of the unauthorized or unqualified operator. Excessive exposure to x–radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 26 of the ICRP, and with applicable national standards.

ATENCIÓN

LOS APARATOS DE RAYOS X SON PELIGROSOS PARA EL PACIENTE Y EL OPERADOR CUANDO NO SE RESPETAN LAS NORMAS DE PROTECCIÓN

Aunque este aparato está construido según las normas de seguridad más estrictas, la radiación X constituye un peligro al ser manipulado por personas no autorizadas o no cualificadas. Una exposición excesiva a la radiación X puede causar daños al organismo.

Por consiguiente, se deben tomar todas las precauciones necesarias para evitar que las personas no autorizadas o no cualificadas usen este aparato, lo que sería un peligro para los demás y para sí mismas.

Antes de efectuar las manipulaciones, las personas autorizadas y cualificadas en el uso de este aparato, deben informarse sobre las normas de protección fijadas por la Comisión Internacional de la Protección Radiológica, Anales No 26: Recomendaciónes de la Comisión Internacional sobre la Protección Radiológica y normas nacionales.

ACHTUNG

RÖNTGENAPPARATE SIND EINE GEFAHR FÜR PATIENTEN SOWIE BEDIENUNGSPERSONAL, WENN DIE GELTENDEN SICHERHEITSVORKEHRUNGEN NICHT GENAU BEACHTET WERDEN

Dieser Apparat entspricht in seiner Bauweise strengsten elektrischen und mechanischen Sichereitsnormen, doch in den Händen unbefugter oder unqualifizierter Personen wird er zu einer Gefahrenquelle. Übermäßige Röntgenbestrahlung ist für den menschlichen Organismus schädlich.

Deswegen sind hinreichende Vorsichtsmaßnahmen erforderlich, um zu verhindern, daßunbefugte oder unqualifizierte Personen solche Geräte bedienen oder sich selbst und andere Personen deren Bestrahlung aussetzen können.

Vor Inbetriebnahme dieses Apparats sollte sich das qualifizierte und befugte Bedienungspersonal mit den geltenden Kriterien für den gefahrlosen Strahleneinsatz durch sorgfältiges Studium des Hefts Nr. 26 der Internationalen Kommission für Strahlenschutz (ICRP) vertraut machen: Empfehlungen der Internationalen Kommission für Strahlenschutz und anderer nationaler Normenbehörden.

SERVICES OFFICES OF GE MEDICAL SYSTEMS

For service issues, contact the Service office in your country.

AMERICAS

UNITED STATES OF AMERICA

GE Medical Systems Headquarters
3000 North Grandview Blvd.
WAUKESHA, WI 53188
Mail:P.O. Box 414
MILWAUKEE, WI 53201

Tel: +1–414–544–3011

LATIN AMERICA

GE Medical Systems
Latin America Headquarters
5101 NW 21st Avenue, Suite 350
FORT LAUDERDALE, FL 33309
USA

Tel: +1–305–497–1200

ASIA

NIPPON *(Japan)*

GEMSA Headquarters
GE Medical Systems Asia
67–4, Takakura, Hachioji
TOKYO, 192–0033, JAPAN

Tel: 81–426–48–2940
Fax: 81–426–48–2905

REST OF ASIA

GE Pacific Pte. Ltd (GEMS Asia)
South East Asia Pacific Operations (SEAPO)
298 Tiong Bahru Road
#15–01/06 Tiong Bahru Plaza
SINGAPORE 0316

Tel: +65–291–8528
Fax: +65–291–7006

EUROPE

BELGIE/BELGIQUE *(Belgium)*
GE Medical Systems Benelux NV/SA
Manhattan Center
Bolwerklaan 21 b 9 Avenue du Boulevard
B–1210 BRUSSEL/BRUXELLES
(NL) Tel:+32 2 644 09 38
(F) Tel:+32 2 644 08 42
(LUX) Tel:0800 2973
Fax: +32 2 207 73 33

DANMARK *(Denmark)*
GE Medical Systems Danmark
Skovlytoften 4
DK–2840 HOLTE
Tel: +45 45 51 00 55
Fax: +45 42 42 59 89

DEUTSCHLAND *(Germany)*
GE Medical Systems Deutschland GmbH & Co. KG
Martin–Behaim–Strasse 10
D–63263 NEU ISENBURGS
Tel: 49–6102–36–0
Fax: +49 610–36–2588

ESPAÑA *(Spain)*
GE Medical Systems España
Avda. de Europa 22
Parque Empresarial la Moraleja
E–28100 ALCOBENDAS
Tel: +34 91 663 25 00
Fax: +34 91 663 25 01

FRANCE *(France)*
GE Medical Systems
283 rue de la Minière
BP34
F–78533 BUC CEDEX
Tel: +33 (0)1 30 70 40 40

HELLAS *(Greece)*
GE Medical Systems Hellas
41 Nikolaou Plastira Street
GR–171 21 NEA SMYRNI
Tel: +30 1 93 24 582
Fax: +30 1 93 58 414

ITALIA *(Italy)*
GE Medical Systems Italia
Viale Fulvio Testi 28–B
20126 MILANO
Tel: +39 02 64 22 01
Fax: +39 02 64 22 0401

NEDERLAND *(Netherlands)*
GE Medical Systems Nederland B.V.
Hambakenwetering 1
NL–5231 DD S HERTOGENBOSCH
Tel: +31 73 6 457 457
Fax: +31 73 6 441 233

ÖSTERREICH *(Austria)*
GE GesmbH Medical Systems Austria
Prinz Eugen Strasse 8/8
A–1140 WIEN
Tel: 0660 8651 (gebührenfrei)
Fax: +43 1 505 38 74
Tlx: 136314

POLSKA *(Poland)*
GE Medical Systems Polska
Krzywickiego 34
P–02–078 WARSZAWA
Tel: +48 2 625 59 62
Fax: +48 2 615 59 66

PORTUGAL *(Portugal)*
GE Medical Systems Portuguesa S.A.
Rua Sà da Bandeira, 585
Apartado 4094
P–4002 PORTO CODEX
Tel: +351 2 2007696/97
Fax: +351 2 2084494
Tlx: 22804

ROSSIYA *(Russia)*
GE Medical Systems
Kosmodamianskaya nab. 52, Bldg 1, 6th Floor
113054 MOSCOW
Tel:+7 095 935 72 41
Fax:+7 095 935 73 46 and 48
Tel (satellite): +7 502 220 30 39
Fax (satellite): +7 502 220 32 59
Tlx:613020 GEMED SU

SVERIGE *(Sweden)*
GE Medical Systems
Box 6768
St. Eriksgatan 117
S–113 85 STOCKHOLM
Tel: +46 8 457 95 20
Fax: +46 8 457 95 47
Tlx: 12228 CGRSWES

SCHWEIZ/SUISSE *(Switzerland)*
GE Medical Systems (Schweiz) AG
Sternmattweg 1
CH–6010 KRIENS
Tel: 155 6958 (gebührenfrei)
Fax: +41 41 421859

TÜRKIYE *(Turkey)*
GE Medical Systems Turkiye A.S.
Mevluk Pehliran Sodak
Yilmaz Han, No 24 Kat 1
Gayretteppe
ISTANBUL
Tel: +90 212 75 5552
Fax: +90 212 211 2571

UNITED KINGDOM
IGE Medical Systems
Coolidge House
352 Buckingham Avenue
SLOUGH
Berkshire SL1 4ER
Tel: +44 753 874000
Fax: +44 753 696067

Blank page.

REGULATORY REQUIREMENTS

Note: This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with emission limits for Group 1 Class A Medical Devices as stated in EN 60601–1–2.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause interference (which may be determined by switching the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem using one or more of the following measures:

- Reorientate or relocate the affected device(s).
- Increase the separating space between the equipment and the affected device.
- Power the equipment from a source different from that of the affected device.
- Consult the point of purchase or the service representative for further suggestions.

The manufacturer is not responsible for any interference caused either by the use of interconnect cables other than those recommended or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

To comply with the regulations applicable to an electromagnetic interface for a Group 1 Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Medical Device directive and FCC regulations.

This product complies with the regulatory requirements of the following:

- Council Directive 93/42/EEC concerning medical devices when it bears the following CE marking of conformity.

  CE 0459

  For a system, the location of the CE marking label is described in the system manual.

  European registered place of business:

  GE Medical Systems Europe
  Quality Assurance Manager
  BP 34
  F 78533 BUC CEDEX
  France

  Tel: +33 (0)1 30 70 40 40

- Green QSD 1990 Standard issued by MDD (Medical Devices Directorate, Department of Health, UK).
- Medical Device Good Manufacturing Practice Manual issued by the FDA (Food and Drug Administration, Department of Health, USA).
- Underwriters' Laboratories, Inc. (UL), an independent testing laboratory.
- Canadian Standards Association (CSA).
- International Electrotechnical Commission (IEC), international standards organization, when applicable.

General Electric Medical Systems is ISO 9001 certified.

TABLE OF CONTENTS

TABLE OF CONTENTS (CONT.)

TABLE OF CONTENTS (CONT.)

Blank page.

REVISION HISTORY

REV	DATE	REASON FOR CHANGE
0	Nov. 3, 1995	Creation
1	March 20, 1996	Update after proofreading
2	December, 1996	Updated Cleaning and disinfection Section.
3	June, 1997	Updated.
4	June, 2000	− The Stop symbol may be replaced for certain countries, such as China. − Addition of Four−position pedal option, − Update “Centering device light bulb replacement” section, Chapter 3.
5	February, 2001	Program Sapphire M3 SPR : BUCge62091 − 4 position Pedal − option cancelled Page 1−6 − AEC mode description modified page 1−1 and 2−3 − Preparing an examination − Chapter 2 Section 3: Patient positioning warning added (coming from Senographe 2000D) − Error messages − I25 added
6	February, 2002	Program: Innsbruck M3 – Introduction of a new console called “Console 2001”: modification of corresponding illustrations.

LIST OF EFFECTIVE PAGES

PAGE NUMBER	REVISION NUMBER	PAGE NUMBER	REVISION NUMBER	PAGE NUMBER	REVISION NUMBER
Title page	6				
Safety Instruction	6				
i thru xiv	6				
1–1 thru 1–22	6				
2–1 thru 2–6	6				
3–1 thru 3–30	6				
4–1 thru 4–6	6				
5–1 thru 5–2	6				

Blank page.

FOREWORD

This manual is provided for SENOGRAPHE 800T operators. It is designed to supply all the information required for the correct use of this equipment.

Blank page.

CHAPTER 1 – INTRODUCTION

SECTION 1
PRESENTATION

The SENOGRAPHE 800T is an x-ray system used primarily for mammography examinations in the standing or sitting position. Breast localizations by two dimensional localization is an additional function by using the optional cross hair device. If required, the system can provide as well, high image quality radiography of specimens and of the hand and foot.

The major features of the SENOGRAPHE 800T are: the Molybdenum x-ray tube – Rhodium and Molybdenum filters – an entirely automatic exposure mode – a digital readout and display of the arm angulation, of the compressed breast thickness and of the breast compression force – a manual compression fine tuning – and its new ergonomic design.

Molybdenum x-ray tube

The SENOGRAPHE 800T is equipped with the well proven GE Molybdenum X–Ray tube that provides high quality radiology images. The Rhodium filter allows better penetration of glandular tissue and dose reduction for dense breasts.

Standard or magnification examinations can be performed. Focal spot sizes are: 0.3 for contact exams and 0.1 for magnification exams.

Three modes of exposure are available:

AEC Mode

The Automatic Exposure Control (AEC) Mode controls density (mAs) and provides exposures of constant optical density.

AOP Mode

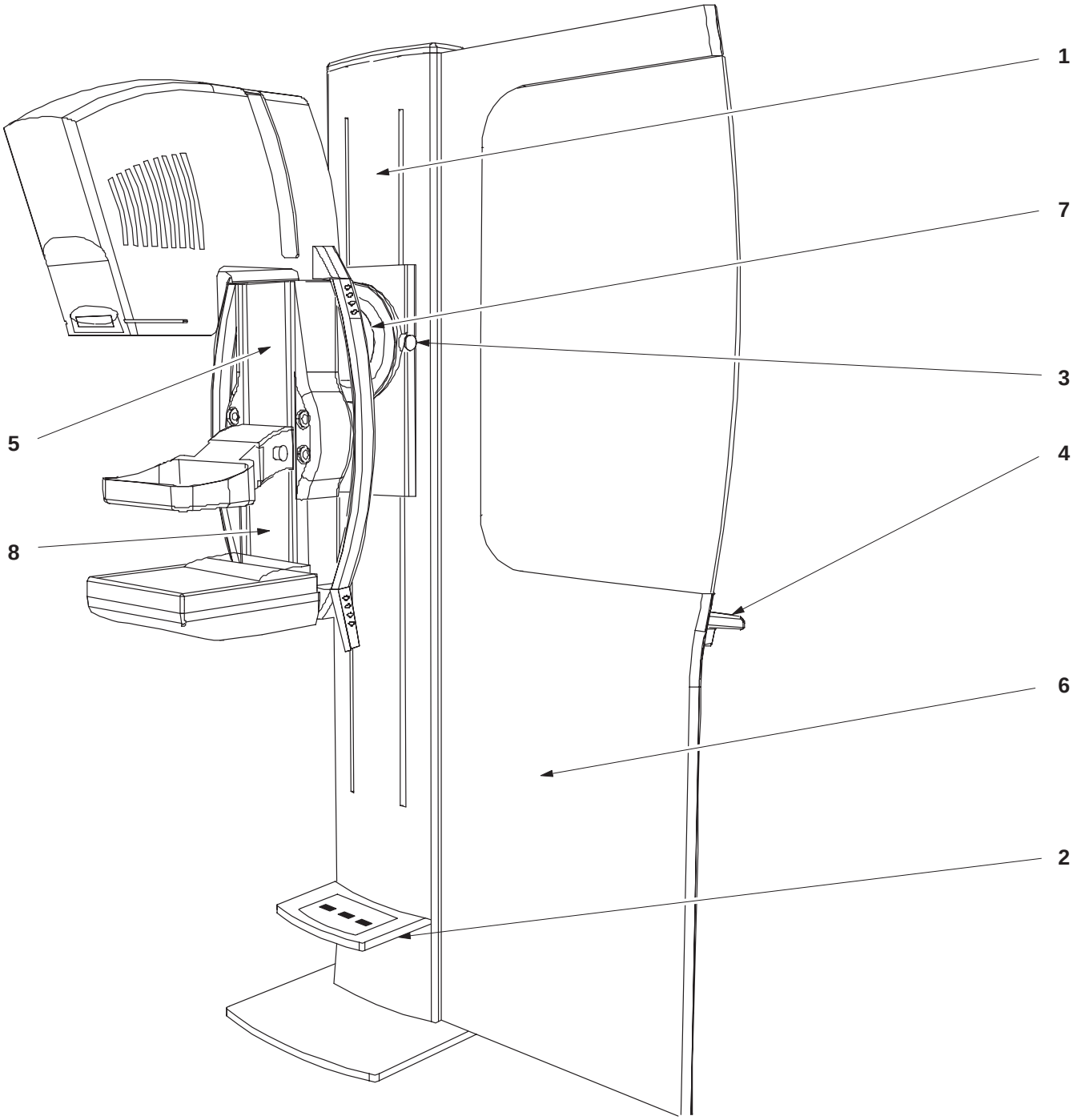
The Automatic Optimization Parameters (AOP) Mode controls radiation. For a given priority (dose reduction, contrast quality or compromise), the AOP Mode selects the filter, and kV. It includes the AEC mode, and provides an automatic selection of the radiological parameters (filter, kV, and mAs).

MAN Mode

In addition, a totally manual exposure mode **(MAN)** can be used in special cases. For example when the breast does not cover the entire photocell, when examining breasts with silicone implants, or when making examinations of extremities (hands, ...).

The new ergonomic design, coupled with features like digital readouts for gantry angle – breast compressed thickness – breast compression force, and manual compression fine tune ensures speed, accurate positioning and ease of use, with examination comfort for the patient.

ILLUSTRATION 1–1
THE SENOGRAPHE 800T



SECTION 2
DESCRIPTION

2–1 Senographe 800T

See Illustration 1–1.

The SENOGRAPHE 800T is composed of the following components:

1. Column,
2. Readout for arm angulation, breast compressed thickness and compression force,
3. Emergency Stop push–button,
4. Control console,
5. Examination arm,
6. X–Ray protective shield,
7. Rotation shaft
8. Red light for cassette detection & exposure inhibit.

Note:

- The Senographe 800T is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky/cassette holder, or if the cassette from the previous exposure has not been changed. However, it is possible for special purposes such as physicist testing for example to disable this interlock (see chapter 3 for a detailed explanation).
- **Trying to make an exposure without a cassette in the Bucky/Cassette–holder or without having changed the cassette between two exposures will make the red light (8) come ON. The exposure will be inhibited.**
- **It is not recommended to remove the exposed cassette from the Bucky/Cassette holder by pushing it out with another cassette. This would prevent the exposure interlock feature from functioning correctly.**
- When inserting a cassette in the Bucky, make sure that it is inserted all the way in and firmly held between the two stoppers.

Examination Arm

This arm is connected to the Column by a rotating shaft. The Examination Arm can be rotated from +180° to –160° about this shaft.

Rotation Shaft

This couples the examination arm to the Column. The angle of the arm can be read on the digital display located at the bottom of the column.

Column

It consist mainly of a drive mechanism to hold and elevate the Examination arm. A readout, located at the bottom of the column indicates:

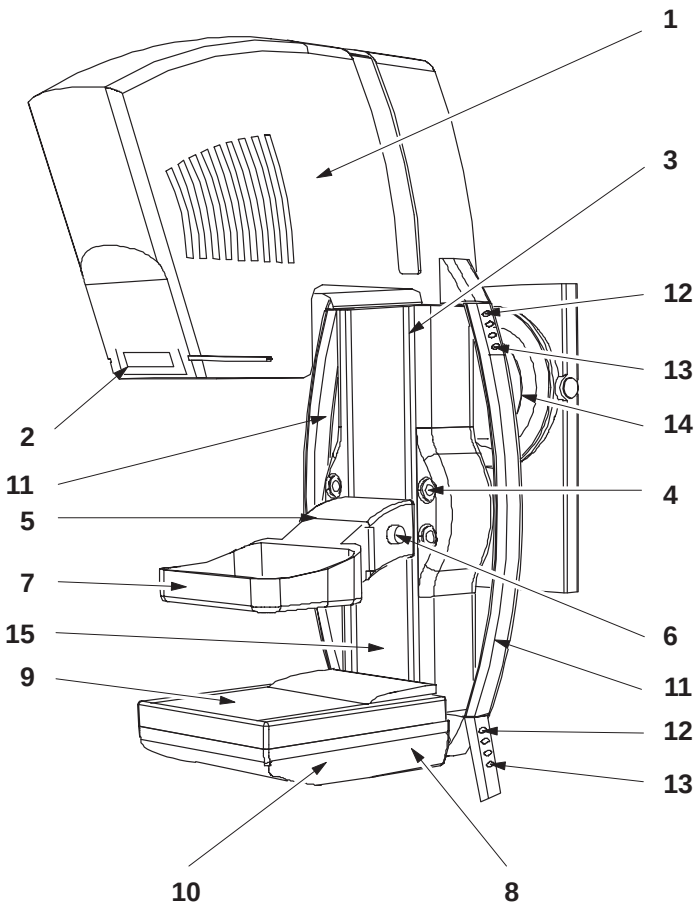
- Examination arm angulation (in degrees – °),
- Compressed breast thickness (in millimeters – mm),
- Compression force (in deca Newtons – daN).

Emergency Stop

Two Emergency Stop push–buttons are located one on either side of the rotating shaft.

Note: The CE marking label is located on the bottom left hand side of the power supply cabinet

ILLUSTRATION 1–2
EXAMINATION ARM



2–2 Examination Arm

See Illustration 1–2. The Examination arm consists of:

1. **X-ray Tube and Tube Housing Assembly.**
2. **The Collimator** consists of the slot for the diaphragms. It also allows easy access to the light bulb for easy replacement (see Chapter 3 – Section 1).
3. **Guide Rail and Compression system** including compression paddle and compression paddle support.
4. **Magnification Holes** The Magnification plate is installed by latching the plate onto the Receptor Arm in the holes provided for the selected magnification factor. To unlock the magnification plate, press the lever located on the left of the mag. plate, and pull the plate forward (as shown on label on top left side of the magnification plate).Two sets of holes are provided for magnification. Magnification factors (1.5 & 1.8) are printed onto the front part of the examination arm.

Note: Always make sure that the magnification plate is correctly locked in place before starting an exam.

Note: The cassette holder is exclusively reserved for magnification. It must not be used for standard exposures.

5. **Compression** is controlled by one pair of compression/decompression footpedals placed on the floor (a second pair is available as an option).

   Compression force, speed of compression and decompression height are programmed by the SET-UP functions of the system (see details in chapter 3).

6. **Manual adjustment** is via thumbwheels located one on either side of the compression paddle arm.

Note: As a safety measure, the compression system is fitted with magnetic braking to avoid the paddle from falling in the event of a power cut. If such a power cut occurred during an examination, a force of around 5 daN could remain on the compression paddle. To disengage the patient, the paddle should be gently raised to counteract this force.

Note: Pressing the compression pedals and moving the thumbwheels illuminates the centering light.

7. **Compression paddle change:** Slide the paddle arm sideways from the compression paddle support.

Note: For best results in AOP and in order to have the correct fit between the bucky and the compression paddle, it is mandatory to match the format of the compression paddle with the format of the Bucky when in contact mode, i.e. use the 18x24 compression paddle with the 18x24 Bucky and use the 24x30 compression paddle with the 24x30 Bucky. The 24 x 30 paddle must not be used with the 18 x 24 Bucky.

8. **The Film-Holder Assembly** can receive both the 18x24 and 24x30 Buckys, and the 18x24 cassette holder. It is also equipped with the AEC photocell.
9. **The Bucky** and cassette-holder are installed on top of the Film-Holder Assembly.

   Removal: Grip Bucky or cassette holder by its sides and pull forward to remove.

   Insertion: Slide Bucky or cassette holder on film holder assembly. Check that the Bucky pin located at the back of the Bucky is engaged in the pin guide located in the film holder assembly. Push Bucky or cassette holder in fully.

10. **Front adjustment of the photocell position** is accomplished via a lever located on either side of the film holder assembly. Five positions are available to suit patient anatomy.
11. **Patient handles.** The patient can steady herself during the examination by holding the handrail located on either side of the examination arm.
12. **The Up / Down and Rotation control buttons** are located at the top and bottom of each handrail.
13. **The light centering switch** is also located at the top and bottom of each handrail.
14. **Rotation** of +180° to –160° is available.
15. **Red light for cassette detection and exposure inhibit.**

Note:

- The Senographe 800T is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky/cassette holder, or if the cassette from the previous exposure has not been changed. However, it is possible for special purposes such as physicist testing for example to disable this interlock (see chapter 3 for a detailed explanation).
- **Trying to make an exposure without a cassette in the Bucky/Cassette–holder or without having changed the cassette between two exposures will make the red light (15) come ON. The exposure will be inhibited.**
- **It is not recommended to remove the exposed cassette from the Bucky/Cassette holder by pushing it out with another cassette. This would prevent the exposure interlock feature from functioning correctly.**
- When inserting a cassette in the Bucky, make sure that it is inserted all the way in and firmly held between the two stoppers.

2–3 Basic Accessories

The accessories delivered with the basic configuration of the SENOGRAPHE 800T consist of:

- 18 x 24 capability including:
  - 18 x 24 cm Bucky
  - 18 x 24 cm cassette-holder for magnification
  - 18 x 24 cm compression paddle
  - 18x 24 collimator diaphragm for large focal spot
  - 18x 24 collimator diaphragm for small focal spot
- Square spot capability including:
  - Square spot compression paddle
  - Square spot collimator diaphragm for large focal spot
  - Square spot collimator diaphragm for small focal spot, 1st magnification factor
  - Square spot collimator diaphragm for small focal spot, 2nd magnification factor.
- X–Ray Protective screen
- Magnification plate
- Face shield
- Film marker (standard basic set of 8 markers – 4 for each breast)
- Service manual
- Operator Manual

2–4 Optional Accessories

The optional accessories for the SENOGRAPHE 800T consist of:

- 24 x 30 capability, including:
  - 24 x 30 cm Bucky.
  - 24 x 30 compression paddle.
  - 24 x 30 cm collimator diaphragm for large focal spot.
  - 24 x 30 cm collimator diaphragm for small focal spot.
- Optical localizer (consisting of cross hair and biopsy paddle) for two dimensional biopsy.
- Data Flash for recording and printing all exam and patient data directly onto the film.
- Small round spot capability, including:
  - Small round spot compression paddle.
  - Small round spot collimator blade for large focal spot.
  - Small round spot collimator diaphragm for small focal spot, 1st magnification factor.
  - Small round spot collimator diaphragm for small focal spot, 2nd magnification factor.
- 18x24 axillary compression paddle
- Second set of compression / decompression footswitches
- Storage unit for collimator diaphragm (total capacity of 5 diaphragms)
- Cassette storage unit (capable of storing six 18x24 and six 24x30 cassettes, or six unexposed 18x24 cassettes and six exposed 18x24 cassettes).
- Mobile van installation kit
- Examination chair
- Accessories storage unit

2–5 Collimator Diaphragm – Bucky & Cassette Holder Selection Description

Choice of the Bucky, cassette holder and collimator diaphragms needed for the three key types of exposures (18x24 – 24x30 – Magnification) has been made easy and effortless by color coding these accessories:

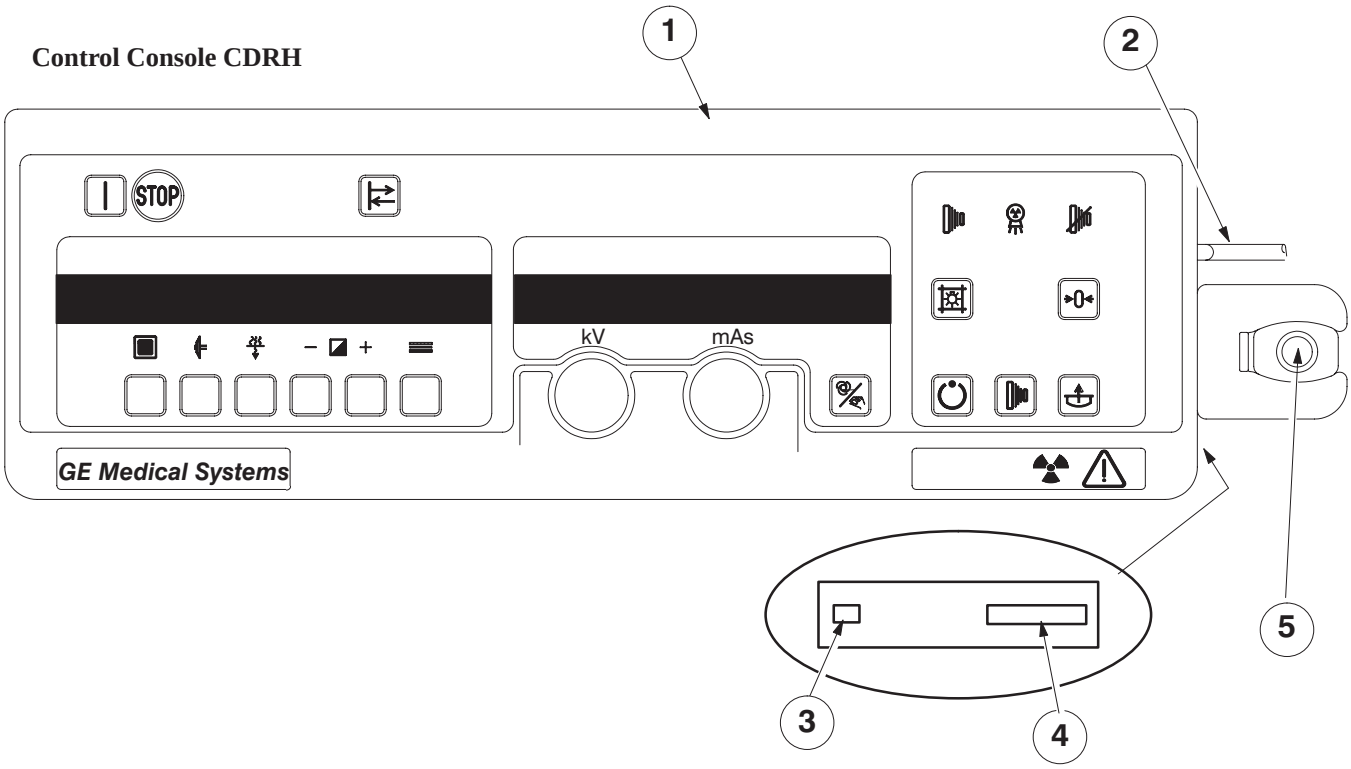
- **WHITE – accessories for 18x24 contact exposures:**
  - All collimator diaphragms needed for 18x24 contact exposures
  - 18 x 24 Bucky
- **PURPLE – accessories for 24x30 contact exposures:**
  - All collimator diaphragms needed for 24x30 contact exposures
  - 24 x 30 Bucky
- **GREEN & PINK – accessories for all magnification exposures:**
  - All collimator blades needed for magnification exposures:
    - GREEN for the 1.5 magnification factor
    - PINK for the 1.8 magnification factor
  - 18 x 24 cassette holder for magnification

The collimator diaphragms supplied with the unit are labeled as follows:

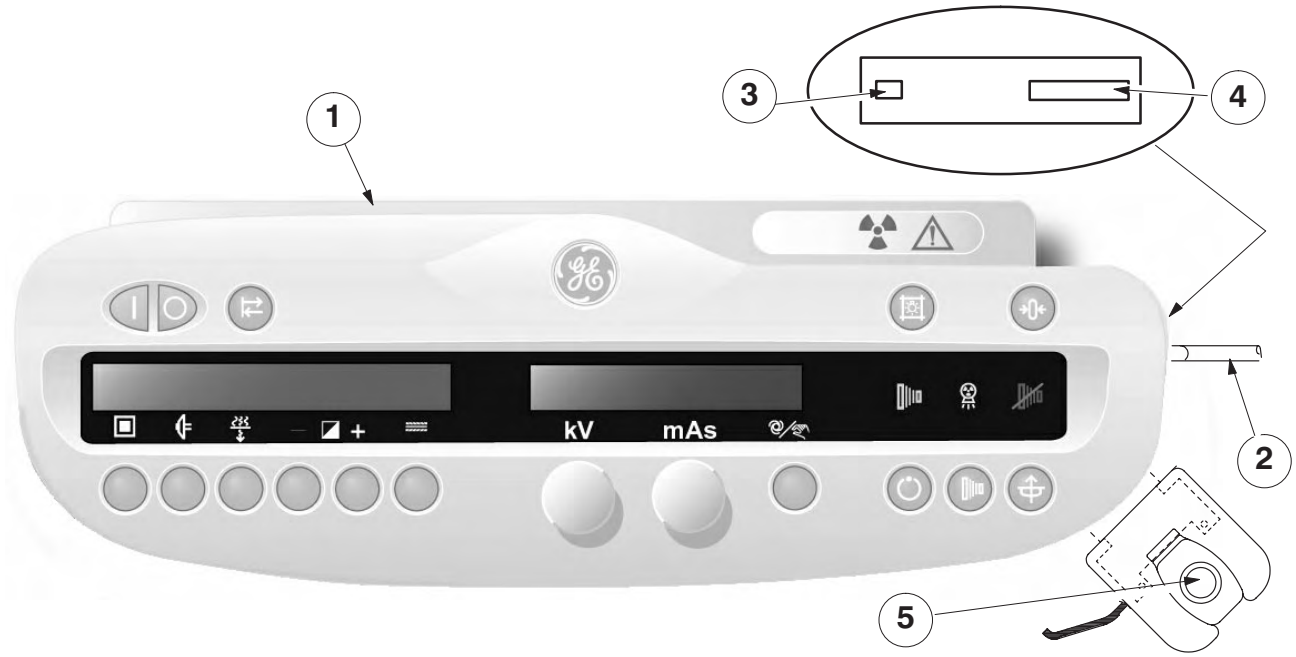
Size printed on diaphragm	Color	Focal spot used	Usage / Comments
18 x 24	White	Large (0.3)	• Large focus. Full field • Included in the basic configuration
10 x 10	White	Large (0.3)	• Large focus. Square collimation • Included in the basic configuration
18 x 24	White	Small (0.1)	• Small focus. Full field • Included in the basic configuration
14 x 14	Green	Small (0.1)	• Small focus. Square collimation. 1.5 magnification • Included in the basic configuration
16 x 16	Pink	Small (0.1)	• Small focus. Square collimation. 1.8 magnification • Included in the basic configuration
Ø 6	White	Large (0.3)	• Large focus. Spot collimation • Optional. Delivered with " small round spot capability "
Ø 9	Green	Small (0.1)	• Small focus. Spot collimation. 1.5 magnification • Optional. Delivered with " small round spot capability "
Ø 10	Pink	Small (0.1)	• Small focus. Spot collimation. 1.8 magnification • Optional. Delivered with " small round spot capability "
24 x 30	Purple	Large (0.3)	• Large focus. Full field • Optional. Delivered with " 24x30 capability "
24 x 30	Purple	Small (0.1)	• Small focus. Full field • Optional. Delivered with " 24x30 capability "

ILLUSTRATION 1–3
CONTROL CONSOLE

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



2–6 Control Console

See Illustration 1–3.

The Control Console is the interface between the Operator and the SENOGRAPHE 800T. It provides two functions:

- Receives operator commands.
- Displays replies and/or machine messages.

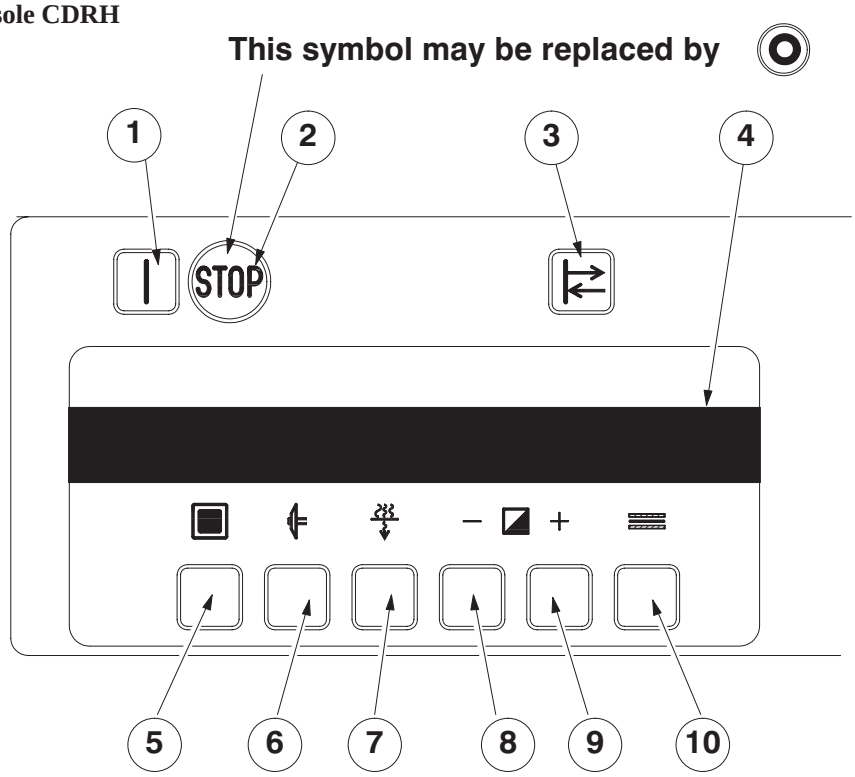
The Control Console consists of:

1. The Control Console, which is installed on the protective lead screen.
2. Connecting cable to generator.
3. Special plug reserved for Senographe
4. Plug for connecting cable to generator

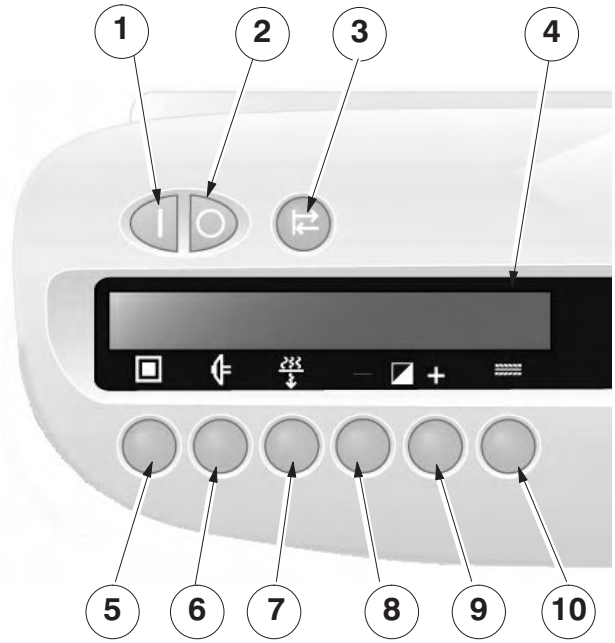
For a detailed description of the control console use, refer to Section 3.

ILLUSTRATION 1–4
CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



The control console is the same console on all GE Medical Systems units (DMR, 700T and 800T). But since the features are different between the Senographe DMR and 800T, some keys will not be operational on the Senographe 800T control keyboard (the focal spot and track selection keys).

The Control console consists of the following keys (see illustration 1–4):

1. SENOGRAPHE 800T 'ON'

Note:

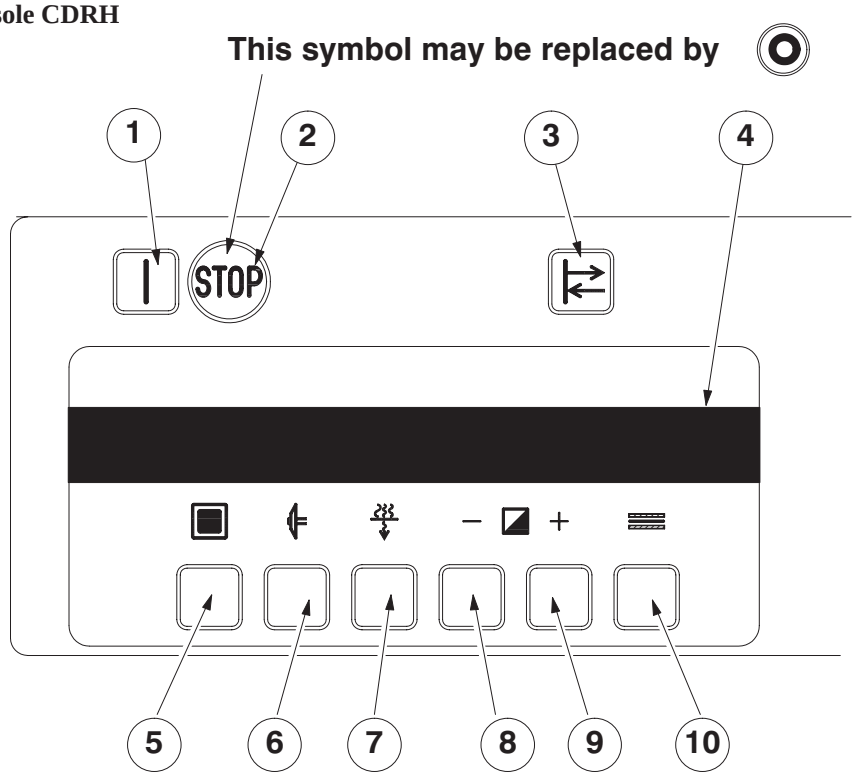
- It is important not to touch the compression/decompression footpedals or the compression manual adjustment knobs during the power–up sequence.
- After the power–up sequence, the footpedals must be used (not the manual adjustment knobs) to bring the compression paddle up.

2. SENOGRAPHE 800T 'OFF'
3. SET UP Menu
4. Readout for messages and keys selections
5. Focal spot selection (not operational on Senographe 800T because focal spot size is automatically selected by insertion of the appropriate collimator diaphragm into the collimator slot).
6. Track: Molybdenum (Mo) only. No other selection available.
7. Filter selection
8. Film Density Control (FDC) decrements (–)
9. Film Density Control (FDC) increments (+)
10. Screen/film Combination (SFC) selection
11. kV and mAs readout
12. kV selection
13. mAs selection
14. AOP, AEC, and Manual Mode selection
15. Exposure Enable indicator lamp
16. Exposure indicator lamp
17. Exposure Disable indicator lamp
18. Centering Light ON-button
19. Exposure Interrupt indicator button and reset
20. Rad prep
21. Exposure button
22. Compression release Button

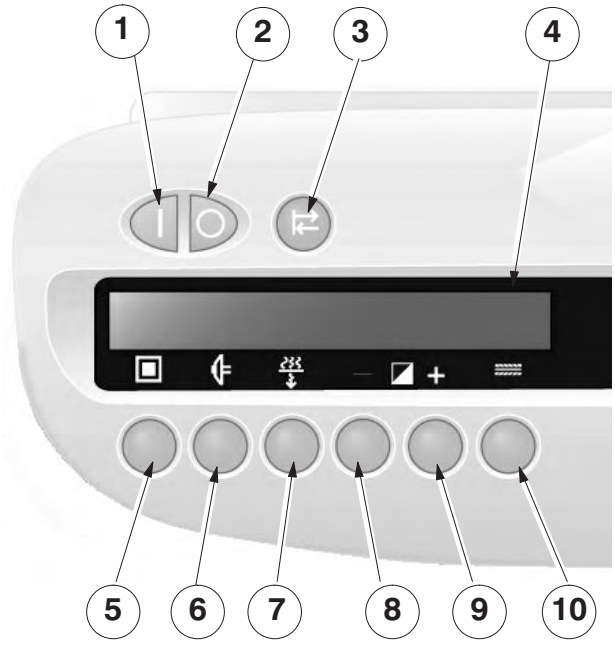
Note: The symbol ⚠ located on the control panel means that you must read the appropriate chapter in the operator manual before taking any action.

ILLUSTRATION 1–5
LEFT–HAND SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



SECTION 3
CONTROL KEYBOARD

3–1 Left–hand Section of Control Keyboard

See Illustration 1–5.

The left–hand section of the Control Console Keyboard is used to initialize or select generator parameters.

1. **SENOGRAPHE 800 T 'ON':** The green indicator lamp is illuminated. The Control Console displays the last configuration used.

Note:

- It is important not to touch the compression/decompression footpedals or the compression manual adjustment knobs during the power–up sequence.
- After the power–up sequence, the footpedals must be used (not the manual adjustment knobs) to bring the compression paddle up.

2. **SENOGRAPHE 800 T 'OFF':** The indicator lamp is illuminated.
3. **SET UP Menu:** Press key to enter Maintenance and Installation, or to access SET UP Menu which is used to modify the following parameters:
   - Speed of compression
   - Programming maximum compression force
   - Automatic decompression.
   - Height of automatic decompression.
   - Minimum Acceptable Optical density for each screen/film combination.
   - Language of messages
   - Disabling of exposure interlock

   Explanation and description of all these parameters is given in Chapter 3, Maintenance.
4. **Readout:** The readout consists of two lines of 40-characters each.
   - The upper line displays warning messages and fault messages.
   - The lower line displays selected parameters: focal spot, focal track (Mo), filter, FDC (Film Density Control), and SFC (Screen Film Combination).
5. **Focal Spot selection:** Since the focal spot selection is ensured by the insertion of the appropriate collimator diaphragm into the collimator slot, this key is not operational on the Senographe 800T.

   The readout indicates the size of the selected focal spot in the language programmed at installation.

   When magnification is selected, i.e. when the appropriate 0.1 small focal spot collimator diaphragm is inserted into the collimator slot, the system automatically selects the small focal spot. When a 0.3 collimator diaphragm is inserted, the large focal spot is selected..
6. **Track selection:** Molybdenum (Mo) only.

7. **Filter selection:** Press key to change filtration (two selections are available: Molybdenum – Mo or Rhodium – Rh).

   In AEC and manual mode, the key selects one of the two filters.
   The readout indicates the type of filter: Mo (molybdenum) or Rh (rhodium).
   In AOP mode, selection is automatic (pressing the key has no effect).

8. **Film Density Control (FDC) decrements FDC (-):** In AOP and AEC modes, press key to reduce density correction by one step.

9. **Film Density Control (FDC) increments FDC (+):** In AOP and AEC modes, press key to increase density correction by one step.

Note:

- FDC (+), FDC (–): pressing these keys in manual mode has no effect.
- Correction is available in 11 steps (-5 through +5). Density variation is 0.2 OD (optical density) by default for each step and may be programmed at installation by the GEMS service engineer.

10. **Screen-film Combination (SFC) selection:**

    – **In AOP** and **AEC modes,** press key to select screen-film combination speed.

    – **The cycle** turns on the number of SFCs calibrated at installation.

    – **A maximum** of five SFCs can be calibrated.

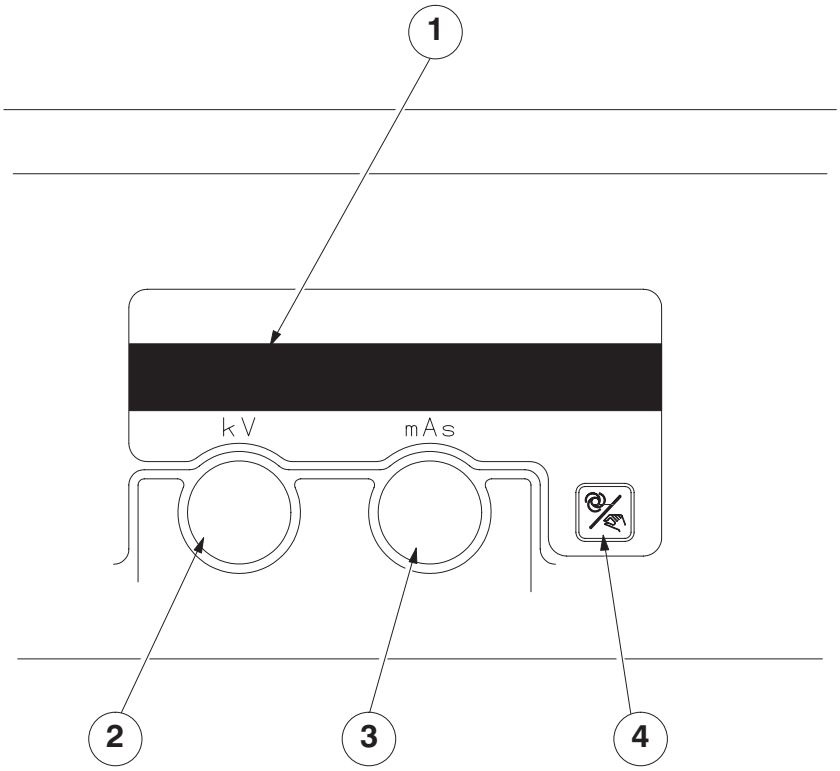
    – **The name** of the SFC (specified at installation) appears on the readout.

Note: Pressing this key in manual mode has no effect.

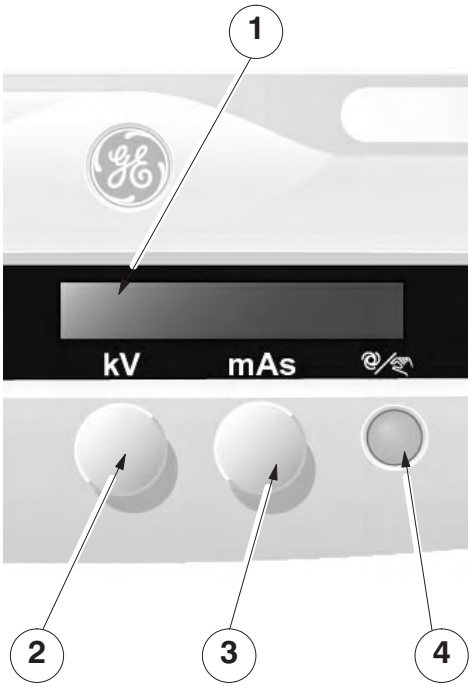
Blank page.

ILLUSTRATION 1–6
CENTRAL SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



3–2 Central Section of Control Console Keyboard

See Illustration 1–6.

The central section of the Control Console Keyboard is used to select and display the kV and mAs values.

1. **kV and mAs Readout**
   - **In AOP mode** the readout displays the kV values selected by the system and the mAs values output.

     At start of compression, the kV readout displays the code of the mode selected: CNT, STD, and DOSE. The mAs readout displays the AUTO mode.

     At end of exposure, the kV readout displays the kV values selected. The kV readout displays the first letter of the code of the selected mode (C, S, or D) and the mAs readout displays the mAs values output.
   - **In AEC mode,** the readout displays the kV values selected by the operator and the mAs values output preceded by the letter A.
   - **In manual mode** the readout displays the kV and mAs values selected by the operator.
2. **kV selection:** The kV values are displayed 22 through 35 in steps of 1 kV via the knurled knob (14 positions). At end-of-travel (there is no mechanical stop), the readout displays the maximum or minimum kV values (22 kV or 35 kV). In AOP mode, rotating the knob has no effect.
3. **mAs selection:** The mAs values are displayed 4 through 600 mAs via the knurled knob. At end-of-travel (there is no mechanical stop), the readout displays the minimum or maximum mAs values (4 or 600 mAs). In AOP and AEC mode, turning the knob has no effect.
4. **AOP, AEC, and Manual Mode selection**

   The key selects the AOP, AEC and Manual modes successively.

   The AOP mode is broken down into three positions, allowing **three priorities:**
   - **CNT:** contrast priority,
   - **STD:** standard dose/contrast compromise,
   - **DOSE:** dose reduction priority.

   Pressing the key selects the Contrast, Standard, and Dose priorities. At the start of compression, the three priorities are displayed on the kV readout. When the exposure is complete, the initial letter of the code selected is displayed on the kV readout.

   The filter is selected automatically (pressing the key for each has no effect). The following can be selected via their keys: screen-film combination, film density control.

BREAST COMPRESSION IS ESSENTIAL IN AOP.

The AEC mode is used to select the kV values manually, and mAs values automatically.

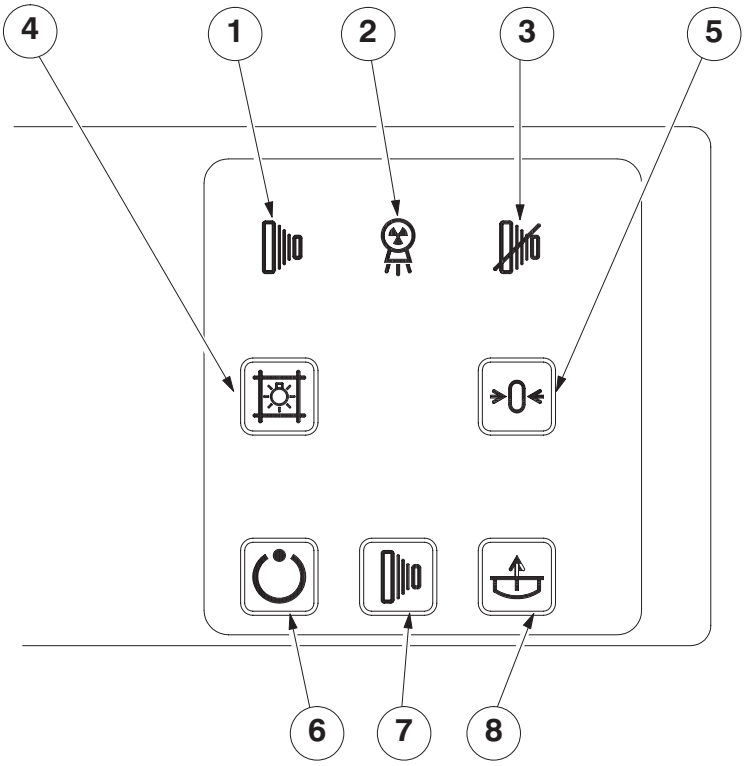
The following selections are available via their keys: filter, focal spot, and film density control.

The Manual mode is used to select kV and mAs values.

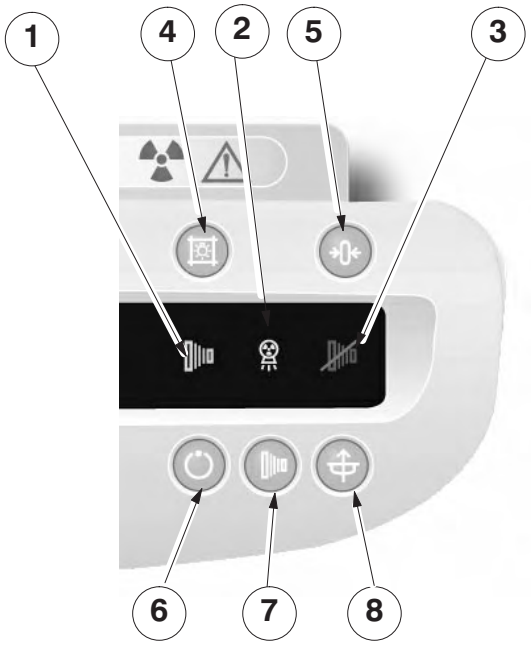
The Film Density Control key and the Screen-Film Combination key have no effect in manual mode.

ILLUSTRATION 1–7
RIGHT–HAND SECTION OF CONTROL KEYBOARD

Control Console CDRH



Control Console 2001 (in forward production from february 2002)



3–3 Right–hand Section of Control Keyboard

See Illustration 1–7.

This section is used to prepare and initiate an exposure, control the centering light, and for decompression and system reset.

1. **Exposure Enable lamp** (green)

   When illuminated, exposure is enabled.

2. **Exposure indicator lamp** (yellow)

   Lamp is illuminated from start to end of exposure.

   A buzzer sounds at the end of exposure.

3. **Exposure Disable lamp**

   When red lamp is illuminated, exposure is disabled. Follow instructions displayed on readout on left section of Control Console.

   A list of messages is given in Chapter 3 – Section 3.

4. **Centering Light ON-button.** Press key to illuminate centering light for 30 seconds. The key is illuminated.

5. **Exposure Interrupt lamp** (yellow indicator lamp). When the exposure is Interrupted, the lamp is illuminated and a buzzer sounds. Hit key to stop buzzer and reset system.

6. **Rad Prep** (activates green indicator lamp). Press key to prepare the exposure (anode rotation).When lamp is illuminated, exposure can be triggered.

Note: If Rad Prep is released before the lamp is illuminated, the preparation is canceled. When the green lamp is illuminated, preparation stops one second after release.

7. **Exposure button:** Press and hold to make exposure. To stop exposure immediately, release key. A buzzer sounds at the end of exposure.

   In AOP mode and following preparation (anode rotation), the total exposure is split into three phases:

   1. A test exposure of 15 ms is made. It allows selection of the optimum kV, and filter combination in the selected priority.
   2. A pause during which the kV, and filter are put in place.
   3. An exposure during which the X–Ray exposure is made. The operator should maintain pressure on the button until the buzzer stops

8. **Compression release button:** Press to release compression. The compression paddle automatically moves up to the pre–programmed autodecompression height.

   If autodecompression is “ ON ” it is not necessary to press the compression release button.

Blank page.

CHAPTER 2 – PREPARING AN EXAMINATION

SECTION 1
PREPARING THE EQUIPMENT

Set the image receptor, field size, collimator diaphragm and compression paddle for the required view.

For standard exposures, use 18x24 cm or 24x30 cm cassettes and a compression paddle suitable for the selected format. Use of the Bucky is mandatory for contact views. The cassette holder must only be used in Magnification.

Note: For best results in AOP and in order to have the correct fit between the bucky and the compression paddle, it is mandatory to match the format of the compression paddle with the format of the bucky when in contact mode, i.e. use the 18 x 24 compression paddle with the 18 x 24 Bucky and use the 24 x 30 paddle with the 24 x 30 Bucky. The 24 x 30 paddle must not be used with the 18 x 24 Bucky.

Note:

- The Senographe 800T is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky/cassette holder, or if the cassette from the previous exposure has not been changed. However, it is possible for special purposes such as physicist testing for example to disable this interlock (see chapter 3 for a detailed explanation).
- **Trying to make an exposure without a cassette in the Bucky/Cassette–holder or without having changed the cassette between two exposures will result in a beep sound and the red light (8) will come on. The exposure will be inhibited.**
- **It is not recommended to remove the exposed cassette from the Bucky/Cassette holder by pushing it out with another cassette. This would prevent the exposure interlock feature from functioning correctly.**
- When inserting a cassette in the Bucky, make sure that it is inserted all the way in and firmly held between the two stoppers.

Different field sizes and compression paddles can be used.

Note: Use of the Bucky is not recommended in magnification.

RAD PARAMETERS

The Rad parameter selection depends on the filter configuration.

FILTER CONFIGURATIONS

TRACK	FILTER	KV RANGE
Mo	Mo	22 through 35
Mo	Rh	22 through 35

As image contrast quality depends on kV values used, note that an increase in the kV value may reduce radiation dose to the patient, but it will reduce the contrast of the image.

A reduction in the kV value improves film contrast but increases the radiation dose to the patient.

The choice of priority to dose reduction or to optimum contrast is left to the discretion of the operator.

Use of the AOP Mode provides the best quality/dose compromise for each priority selected by the operator.

WARNING

THIS MACHINE USES A SOPHISTICATED ALGORITHM TO AUTOMATICALLY DETERMINE OPTIMAL PARAMETERS TO PRODUCE MAMMOGRAMS (AOP). FOR THIS, MANY KVP/FILTRATION COMBINATIONS ARE AVAILABLE TO BE CHOSEN FROM. IN REGULAR AUTOMATIC EXPOSURE CONTROL (AEC) MODE, THE SAME CONDITIONS ARE AVAILABLE, AND MAY BE CHOSEN BY THE USER. HOWEVER, FOR BEST RESULTS, ONLY CERTAIN CONFIGURATIONS SHOULD BE USED.

Compression

It is advised that sufficient breast compression be used to benefit the following image quality/dose reduction advantages:

- Compression reduces motion blurring.
- Compression reduces geometric unsharpness by ensuring direct contact between breast and image receptor, and by spreading apart glandular breast tissue.
- Compression improves film contrast and reduces scattered radiation in proportion to the reduction in the thickness of the tissue irradiated.
- Compression spreads the breast laterally, and reduces the breast to a constant thickness. This shortens exposure time, and consequently reduces the average glandular dose.

Good compression is obtained when the breast surface is taut to the touch.

Decompression can be programmed to occur automatically after exposure is complete

When exposure is complete, automatic decompression is available by pressing the button on the right hand side of the control console.

Note: As a safety measure, the compression system is fitted with magnetic braking to avoid the paddle falling in the event of a power cut. If such a power cut occurred during an examination, a force of around 5 daN could remain on the compression paddle. To disengage the patient, the paddle should be gently raised to counteract this compression force.

SECTION 2
EXPOSURE MODE

2–1 AOP Mode

The AOP (Automatic Optimization Parameters) Mode controls radiation and allows the system to select the main parameters.

It optimizes the filter/kV configuration as a function of the required image quality, and of the composition of the breast being examined.

The AOP Mode includes the AEC Mode, and ensures constant density.

The AOP Mode has three options:

- Contrast (CNT): Contrast priority
- Standard (STD): Compromise between contrast and dose.
- Dose (DOSE): Dose reduction priority

For each of the above options and as a function of the breast composition, the AOP Mode selects the filter/kV configuration.

The operator selects:

- Priority (CNT, STD, DOSE).
- Focal spot,
- Screen-film combination.
- Density correction, when necessary.

Density correction is used only when an optical density change in the image is required.

Breast compression is essential when using the AOP Mode.

The system displays inhibited messages and automatically selects the following parameters:

- Filter (Mo, Rh),
- kV values,
- mAs values.

The AOP Mode can be used for standard exposures, magnified exposures, or for the examination of the chest wall.

For standard exposures, the Bucky must be used.

In magnification, use of the Bucky is not recommended. The operator should use the cassette holder.

Always make sure that the magnification plate is correctly locked in place before starting an exam.

The system automatically selects the small focal spot (0.1) when magnification is selected, i.e. when the appropriate small focal spot collimator diaphragm is inserted into the collimator slot.

The system automatically selects the large focal spot (0.3) when a 0.3 collimator diaphragm is inserted.

To maintain optimal image quality, the user must check on the control panel display that the selected focal spot is dedicated to the selected examination mode: Contact examination (normal) = 0.3. Magnification = 0.1

2–2 AEC Mode

The Automatic Exposure Control (AEC) Mode controls density (mAs) and provides exposures of constant optical density.

The operator selects the following parameters:

- Filter (Mo, Rh),
- Focal spot (0.3 or 0.1 by inserting the correct collimator diaphragm),
- Screen/film combination,
- kV values.

The operator can modify the density correction.

Place the breast to be examined on the Bucky, making sure the breast is properly positioned over the photocell.

Inhibiting commands will be displayed on the system.

2–2–1 Contact Exposures

The Bucky must be used for contact exposures, not the cassette holder which is reserved for magnification.

Select configurations and kV values given in manual mode.

The screen-film combination selection depends on user preference.

2–2–2 Magnification

Note:

- Use of the Bucky is not recommended in magnification. The operator should use the cassette holder.
- Always make sure that the magnification plate is correctly locked in place before starting an exam.

When magnification is selected, i.e. when the appropriate small focal spot collimator diaphragm is inserted into the collimator slot., the system automatically selects the small focal spot (0.1).

When 0.3 diaphragms are inserted, the system automatically selects the large focal spot (0.3).

To maintain optimal image quality, the user must check on the control panel display that the selected focal spot is dedicated to the selected examination mode: Contact examination (normal) = 0.3.

Magnification = 0.1

Select configurations and kV values.

2–2–3 Examination of Chest Wall

Select configurations and kV values according to the composition of the region examined.

Note: The Bucky must be used.

2–3 Manual Mode

The Manual Mode can be used for standard exposures, magnified exposures, or for the examination of the chest wall.

It is recommended to use Manual Mode when the object to be x-rayed cannot be correctly positioned over the AEC photocell.

The operator selects the following parameters:

- Filter (Mo, Rh),
- Focal spot (0.3 or 0.1 by inserting the correct collimator diaphragm),
- Screen–film combination,
- kV values,
- mAs values.

The system displays the inhibit conditions.

Selecting the screen/film combination in Manual Mode has no effect. The user is recommended to consider the speed of the screen-film combination when selecting the kV and mAs values.

2–3–1 Contact Exposures

The Bucky must be used for contact exposures, not the cassette holder which is reserved for magnification.

According to the composition of the breast to be examined, select a configuration with suitable kV values.

Note that change to use of the Rhodium (Rh) filter for very dense breasts may provide better tissue visualization and a lower average glandular dose.

Tables 2–2 (below) gives examples of the most frequently used configurations and kV values.

COMMON EXPOSURES

TRACK	FILTER	KV RANGE
Mo	Mo	25 through 35
Mo	Rh	25 through 35

Note: The screen/film combination selection depends on user preference.

The mAs value selection depends on the screen speed.

2–3–2 Magnification

Note:

- Use of the Bucky is not recommended in magnification, the operator should use the cassette holder.
- Always make sure that the magnification plate is correctly locked in place before starting an exam.
- When magnification is selected, i.e. when the appropriate small focal spot collimator diaphragm is inserted into the collimator slot., the system automatically selects the small focal spot (0.1).
- When 0.3 diaphragms are inserted, the system automatically selects the large focal spot (0.3).

To maintain optimal image quality, the user must check on the control panel display that the selected focus is dedicated to the selected examination mode: Contact examination (normal) = 0.3.

Magnification = 0.1

Select configurations and kV values.

When the Bucky is removed and the cassette holder is being used, the mAs values are approximately divided by 2.

2–3–3 Examination of Chest Wall

Select configurations and kV values to suit thickness and density of region examined.

Note: Use of the Bucky is mandatory.

SECTION 3
PATIENT POSITIONING

Before beginning the mammogram, observe the following points:

- Before positioning the patient, make a visual assessment of the breast area, and note anything which may affect or be adversely affected by the correct positioning of the breast for the mammogram, for example, warts, scarring, or skin which is not intact. In patients with large breasts, perspiration under the breast can cause the skin to soften, and become paper-thin.

  To position the breast properly for a mammogram in the CC position, it is essential that the breast is lifted away from the chest wall and gently pulled forward, in order to visualize the maximum amount of breast tissue. Such pulling and lifting is necessary for correct positioning, but can cause damaged skin to tear slightly, and may cause bleeding.

  If any condition exists which may cause unusual discomfort or tearing of the skin, the patient should be told of the importance of correct positioning, and should be warned in advance of the possibility that minor tearing and /or slight bleeding might occur.

- Use suitable techniques for the positioning of patients with breast implants.
- GEMS can take no responsibility for injury to the patient caused by the use of heating or warming devices external to the system.

CHAPTER 3 – MAINTENANCE

SECTION 1
CLEANING & DISINFECTION

GENERAL INFORMATION

Adequate cleaning and disinfection is necessary to prevent disease transmission. Be sure to thoroughly clean and disinfect equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use.

The level of disinfection required for a patient contact device depends on the type of contact that occurs:

- A CRITICAL device is one which routinely penetrates the skin or mucous membranes during use and therefore poses a high risk of infection if it is not sterile. Such devices (e.g., surgical instruments, needles, catheters or infusion sets) must be made **sterile** prior to use.
- A SEMICRITICAL device is one which contacts mucous membranes but does not penetrate normally sterile areas of the body. Such devices (e.g., endoscopes, speculum) should be made sterile whenever practical, but **high level disinfection** is usually acceptable prior to use.
- A NONCRITICAL device is one which contacts intact skin during routine use. Such devices (e.g., patient exam tables, blood pressure cuff, etc.) present a much lower risk of infection and, therefore, a **low level disinfection** is usually acceptable. However, in cases when there is concern for cross contamination, an i**ntermediate level disinfection** should be done between patients.

The patient contact surfaces of mammography equipment are noncritical, and either low level or intermediate level disinfection is adequate for routine use. These surfaces are the Bucky/cassette holder, compression paddles and magnification plate. Other surfaces that may have casual contact with the patient and should be considered for intermediate level disinfection are the face shield and tummy shield.

Improper cleaning methods or the use of certain cleaning and disinfecting agents can damage the equipment, cause poor imaging performance or increase the risk of electric shock. To avoid possible injury or equipment damage:

- Do not use harsh detergents, abrasive cleaners, high alcohol concentration or Methanol at any concentration. If skin preparations contain high alcohol concentrations, allow sufficient drying time before applying compression;
- Do not expose equipment parts to steam or high temperature sterilization;
- Never allow liquids to enter the internal parts of the equipment. If you become aware of liquid entry, disconnect the electrical supply and have the equipment checked by qualified service personnel before returning it to use.

EQUIPMENT CLEANING INSTRUCTIONS

Patient contact surfaces should be washed with mild soap in lukewarm water. Removable parts that do not contain electrical components such as the compression paddles may be removed from the equipment and immersed if needed. Equipment parts such as the Bucky/cassette holder that enclose electrical components must not be immersed but rather cleaned with a soft dampened cloth, taking care not to allow liquids to enter the equipment. Surfaces should be scrubbed as needed using a soft sponge, gauze or cloth to remove all visible residue. Scrubbing with a soft bristle brush (such as a toothbrush) may be necessary to reach corners or to remove material that has dried onto the surface. Subsequent disinfection may not be effective if the surfaces are not thoroughly clean.

Rinse all surfaces with clean water to remove visible soap residue, taking care to avoid liquid entry to internal equipment parts. Dry surfaces with a soft cloth to remove any visible residue.

LOW LEVEL OR INTERMEDIATE LEVEL DISINFECTION

Patient contact surfaces may be disinfected with a suitable liquid chemical germicide. Surfaces must first be cleaned of all visible contamination (see above). The liquid germicide must have a minimum contact time with the surface to be effective. Equipment parts should be sprayed with a fine mist applicator or wiped with a wet cloth or sponge as directed by the instructions for use provided with the germicide. If needed, removable parts not containing electrical components (compression paddles and magnification plate) can be removed and immersed. Further rinsing or wiping with clear water and drying with a soft cloth should be done to remove any germicide residue that may remain. Take care to avoid liquid entry to internal equipment parts.

HIGH LEVEL DISINFECTION

In the event you feel a high level disinfection is necessary due to equipment contact with breached skin or being used with infected or immune compromised patients, the same patient contact surfaces may be high level disinfected with a liquid chemical germicide rated for high level disinfection. The same process used as that for intermediate level disinfection is generally followed; however, the time of contact is usually much longer for high level disinfection.

RECOMMENDED GERMICIDES

The following legally marketed products have been used on GE equipment without causing equipment damage.

Low or Intermediate Disinfection

LpH$_{se}$, manufactured by Calgon Vestal Laboratories, St. Louis, MO, U.S.A., EPA Reg. No. 1043–92 (510(k) K931342)

VESPHENE II$_{se}$, manufactured by Calgon Vestal Laboratories, St. Louis, MO, U.S.A., EPA Reg. No. 1043–87 (510(k) K931573)

High Level Disinfection

CIDEX, manufactured by Johnson & Johnson Medical, Inc., Arlington, TX, U.S.A., EPA Reg. No. 7078–1, EPA Est. No. 36126–PR–1 (510(k) K924434).

Always follow the germicide manufacturer's instructions and precautions for mixing, storage, method of application, contact time, rinsing requirements, protective clothing, shelf life and disposal to help assure effective and safe use of the product.

SECTION 2
PREVENTIVE MAINTENANCE

Despite its inherent qualities, the Senographe 800T requires minimum maintenance. A maintenance program, whose frequency varies according to the type of use of the equipment, is outlined in the table below.

Maintenance Program

Description	Diagnostic	Screening	Procedure
Elevator	15000 exposures or 6 months	15000 exposures or 3 months	– Check belt tension. – Lubricate elevator movement screw (grease bearings). – Check elevator movement speed.
Compression system			– Check belt tension. – Lubricate compression bar (grease bearings). – Check compression force calibration. – Check maximum compression force (20 daN). – Check limit force of programmed compression. – Check resistance of belts in decompression. – Check thickness measurement in compression.
Arm			– Check brake in rotation.
Image quality			– Check field covered by X–Ray beam. – Check field covered by centering light. – Measure half–value layer. – Measure the dose. – Check density (reference exposure).
Miscellaneous	15000 exposures or 6 months	15000 exposures or 3 months	– Clean format detectors. – Inspect accessories (including grids).
	90000 exposures or 3 years	90000 exposures or 18 months	– Replace the two belts of compression system. – Replace battery in microprocessor board.

SECTION 3
MESSAGES

Three types of messages may be displayed for the user on the gantry or on the Control Console:

- I xx: Information message: fault message which does not inhibit the exposure.
- E yy: Error message: fault inhibits the exposure.
- S zz: Stop message: exposure is stopped due to incorrect use of equipment.

A message displayed on the Control Console has 40 characters. The first three characters are identification characters. The next 28 characters comprise the message. The seven remaining characters are also identification characters.

Example: "**I69 MAGNIFICATION FAILURE 172/088"**

When calling the Field Service of GEMS, it is essential to note each message in its entirety

Listed below by type are all the messages which can appear on the Control Console, together with a detailed description and the necessary corresponding corrective action.

Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
I 07	SELECTED FILTER NOT ALLOWED: xx	The Filter selected by the operator is not allowed	Information message only, because the Senographe Automatically selects the correct filter.
I 12	MAXIMUM mAs = xx	Maximum available mAs are equal to xxx	Information message only. (If mAs exceeded, cell aborts exposure at 2 or 3 mAs if entire exposure cannot be made).
I 20	AEC FAILURE	The AEC is faulty	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. You can still work in Manual mode.
I 21	HEATING FAILURE TRACK 1	Large focal spot Track is out of use	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. It is still possible to use the small focal spot.
I 22	HEATING FAILURE TRACK 2	Small focal spot Track is out of use	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. It is still possible to use the large focal spot.
I 23	CONSOLE COMMUNICATION FAIL	generator to Control Console connection is faulty.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service.
I 24	LINE POWER INTERRUPTION	Micro power cut occurred on line supply.	Press RESET to suppress message.
I 25	POWER SUPPLY DEFECT		Call Service
I 27	**CPU BATTERY ERROR**	**CPU back up battery is discharged**	**Contact GEMS field service. DO NOT SWITCH THE EQUIPMENT OFF**
I 28	MAX. WAIT FOR SAME EXPOSURE: xx min.	It is necessary to wait the displayed amount of time to be able to repeat the same exposure.	Wait the required amount of time to repeat exposure. If an exposure is attempted before this time, an abort MAY occur (we have built in a safety margin to ensure proper operation). It also means that you can ignore the message if a different, less dense, breast is to be imaged next or if different technical factors are selected.
I 29	EXCESSIVE mAs FOR THIS MODE	The amount of mAs necessary to repeat the same exposure may be too large in the mode selected by the user.	Switch to a different mode or to a different filter if in AEC mode.

Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
I 54	POWER LIMITATION xxx S.	The gantry is hot and needs to cool down.	Wait until the gantry temperature goes down (the message will then disappear).
I 55	LIGHT CENTERING DEVICE FAIL	The light centering device is not functioning correctly.	If the light bulb needs to be changed, please refer to SECTION 5 in this chapter. If fault continues after changing the light bulb, note ALL messages and contact GEMS field service
I 69	MAGNIFICATION FAILURE	The magnification sensors are not functioning correctly.	Remove magnification stand, then reinstall the mag stand. If fault continues, Switch OFF and switch ON. If fault still continues, note ALL messages and contact GEMS field service
I 70	COMPRESSION FAILURE	Accurate thickness calculation is failing.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. AEC and manual modes will still be working with a default thickness. AOP mode is not available.
I 71	COMPRESSION ADJUSTMENT FAILURE	The manual fine tune adjustment of the compression is not working.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. Compression is still working, but without manual adjustment capability.
I 72	COLUMN MOTION FAILURE	Elevator is not functioning correctly	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
I 73	ROTATION BRAKE FAILURE	Brake rotation is not functioning properly, or gantry angle measurement is defective.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. If only gantry angle is defective, the rotation brake will still be performing correctly.
I 74	FAN FAILURE	The cooling fan is out of order.	Note ALL messages and contact GEMS field service for replacement of the Fan. You can continue to make exams with automatically limited throughput until the cooling fan is replaced.
I 75	BUTTON SECURITY FAILURE	Failure in operator presence interlock in control buttons.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service

Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
I 77	COMP PEDAL SECURITY FAILURE	Failure in operator presence interlock for compression pedal	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
I 98	ROTATION BRAKE OVER-HEAT	The rotation break is hot and needs to cool down.	Wait until the rotation brake temperature goes down (the message will then disappear).
I 99	AUTO–DECOMPRESSION IS OFF	The automatic decompression at the end of the exposure has been disabled in the user selectable menu.	See SET–UP menu programming if automatic decompression needs to be activated.
E 01	GENERATOR FAILURE	Failure in HV section of generator.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 02	FOCUS BIAS FAILURE	Failure in tube focus bias circuits	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 03	ROTOR FAILURE	Failure in anode starter	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 05	FAILURE DURING EXPOSURE	Current exposure aborted due to failure in equipment.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 06	SOFTWARE ERROR	There is an error in the software	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 07	**SWITCH OFF**	**There is an important problem in the machine that requires the user to switch it OFF.**	**Note ALL messages, switch the machine OFF, and contact GEMS field service**
E 08	POWER SUPPLY FAILURE	Supply of generator power circuits is not authorized	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 09	AEC FAILURE	The automatic exposure control is faulty	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 10	HEATING FAILURE TRACK 1	Large focal spot track is out of order.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. It is still possible to use the small focal spot

Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
E 11	HEATING FAILURE TRACK 2	Small focal spot track is out of order.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. It is still possible to use the large focal spot
E 12	CHECKSUM ERROR	Calibration parameters have been modified.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 14	CPU or INTERFACE FAILURE	The CPU board or the interface board are out of order.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 51	COLLIMATOR FAILURE	The collimator sensors are out of order.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 64	FILTER POSITIONING FAILURE	Filter rotation is out of order, so good filter positioning is not ensured. Exposure is inhibited.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
E 70	COMPRESSION FAILURE	The compression system is out of order or accurate thickness calculation is failing in AOP mode.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. In case of thickness failure, the AEC and manual modes will still be working
E 71	BUCKY FAILURE	Bucky cannot be moved under normal conditions.	Remove Bucky, then reinstall Bucky. Make a Rad Prep. Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service. exposures can be made without the Bucky.
E 72	COLUMN FAILURE	Failure in the column system.	Switch OFF and switch ON. If fault continues, note ALL messages and contact GEMS field service
S 01	ABORTED EXPOSURE	Exposure in progress has been aborted because exposure button was released by the operator before the end of exposure	Press RESET and start exam again.
S 02	EXPOSURE ABORTED BY HV ARCING	Exposure was aborted by equipment because in excess of eight X–Ray tube arcings were produced during the exposure so far.	Press RESET and start exam again.
S 03	EXPOSURE ABORTED BY AEC	Exposure aborted by AEC because not enough mAs are available to make exposure.	Press RESET, change parameters and start the exam again.

Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
S 06	kV TOO LOW	kV values are too low to use AEC (should exceed 24 kV)	Raise kV values.
S 08	REQUIRED POWER IS TOO HIGH	Power requested in manual mode is too high	Lower kV or mAs values.
S 09	NO COMPRESSION DETECTED	Breast is not compressed	Breast compression is Mandatory in AOP. Compress the breast.
S 10	GENERATOR COOLING xxx s	Generator requires xxx seconds to cool	Wait for cooling time to terminate (or lower mAs values in manual mode).
S 11	TUBE COOLING xxx s	Tube requires xxx seconds to cool.	Wait for cooling time to terminate (or lower mAs values in manual mode).
S 12	OPTICAL DENSITY TARGET NOT REACHED	The target pre–programmed optical density cannot be reached. The machine will make the exposure by allowing the optical density to go down to the minimum acceptable value programmed during installation.	Information message only. no action is required from the user. The machine will do the exposure.
S 13	BACKUP mAs < 50 . EXPOSURE INHIBITED	Maximum mAs <50. exposure is inhibited.	Wait for cooling time to terminate (or lower kV values in AEC mode).
S 14	MAXIMUM mAs EXCEEDED	Maximum mAs set at installation are exceeded. This message appears only if a value below 600mAs was calibrated at installation.	Lower mAs values.
S 15	ARM NOT PRESENT	Bad system configuration.	Switch OFF, then ON. If the fault continues, note ALL messages and contact GEMS field service engineer.
S 16	SELECTED FILM / SCREEN IS UNCALIBRATED	The selected film / screen pair is not calibrated.	Press the screen / film button to select a calibrated pair. If the fault continues, note ALL messages and contact GEMS field service engineer.
S 25	TUBE HOUSING OVER TEMPERATURE	The temperature of the tube housing is too high (> 65°C).	Wait for the tube housing temperature to fall.
S 26	EXPOSURE TOO LONG	The exposure is too long. This message only appears in manual mode.	Increase the kV value and reduce the mAs value.
S 30	COLLIM. / RECEIVER INCOMPATIBLE	The size of the collimator blade inserted in the collimator slot, and the size of the image receptor are incompatible.	Check collimator blade size, and insert correct collimator blade into the collimator slot.

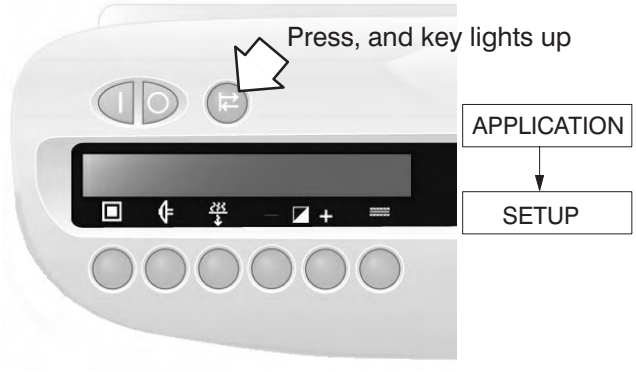
Message #	Message on Control Console	Explanation / Meaning of Message	Corrective Actions
S 31	INTERLOCK OFF	Some of the interlocking features in the machine are inhibited.	Switch OFF, then ON. If the fault continues, note ALL messages and contact GEMS field service engineer.
S 51	UNEXPOSED CASSETTE MISSING	There is no cassette in the Bucky, or the previous cassette has been exposed and has not been changed.	• Insert a cassette in the Bucky, or removed the exposed cassette, and insert a new, unexposed, cassette. • If the message is still displayed, check that the Bucky is correctly engaged. • If the message is still displayed after this last check, not ALL messages and contact GEMS field service engineer.
S 52	BUCKY INITIALIZATION	This message is displayed for 20 seconds only after power up or after Bucky is changed. Exposure is not allowed during these 20 seconds.	Wait the 20 seconds, and then make exposure.

SECTION 4
MEDICAL PROGRAMMING

4–1 Speed of Compression

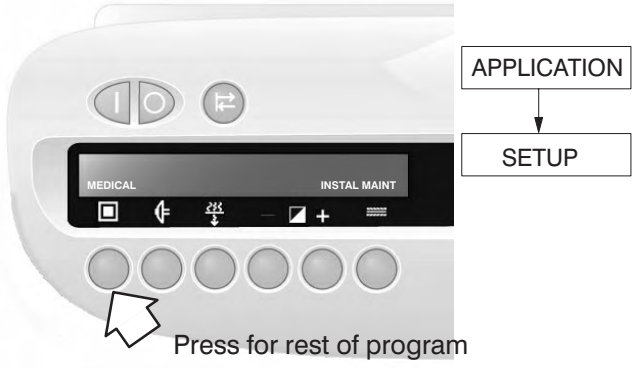
4–1–1 Access to Programming Mode

- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears

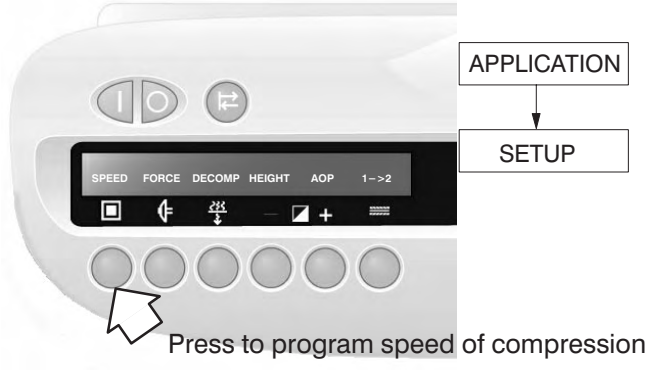


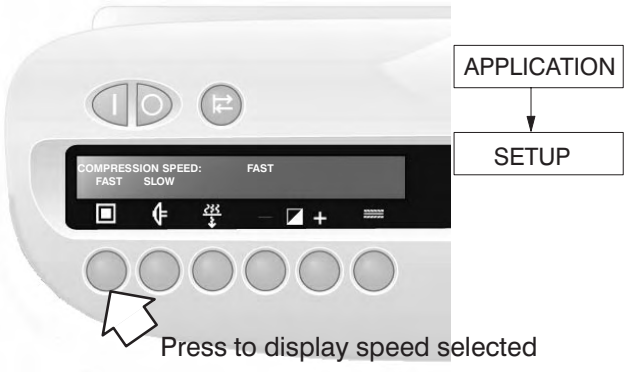
4–1–2 Selecting a Function

To select a function, press the key located under the symbol for that function.



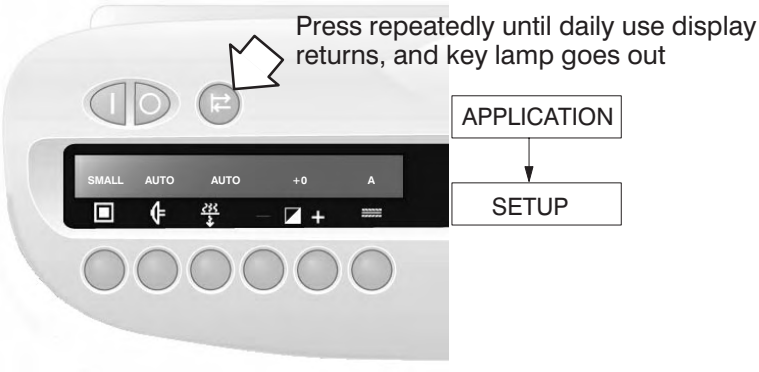
Confirm functions selection





4–1–3 Confirm & Return to Application Menu

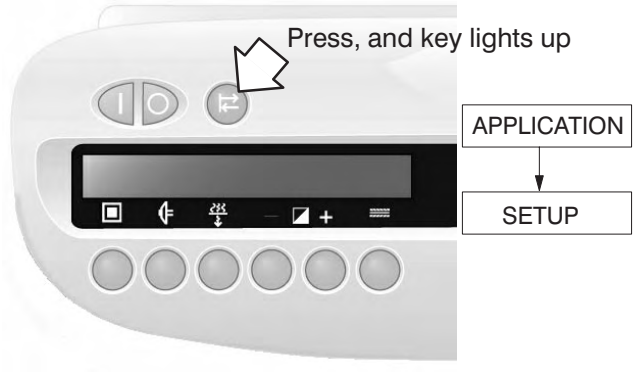
To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



4–2 Compressive Force

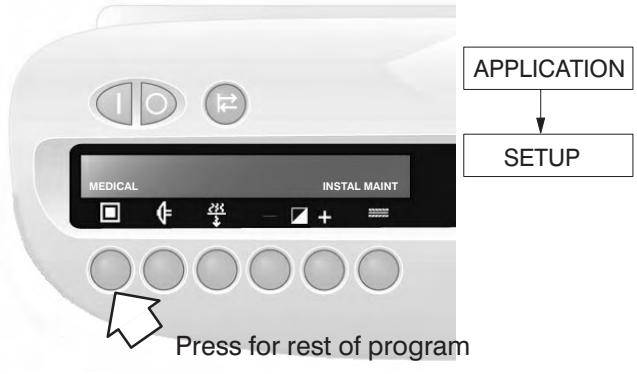
4–2–1 Access to Programming Mode

- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.

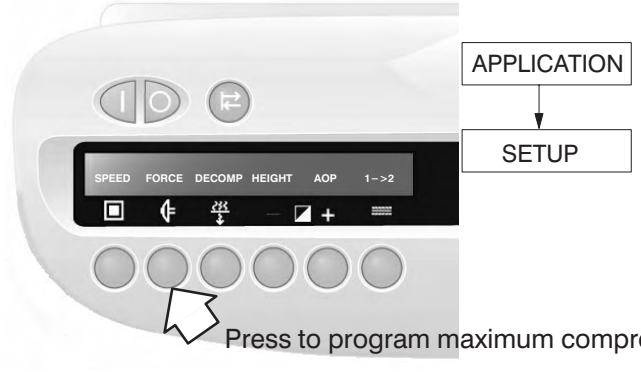


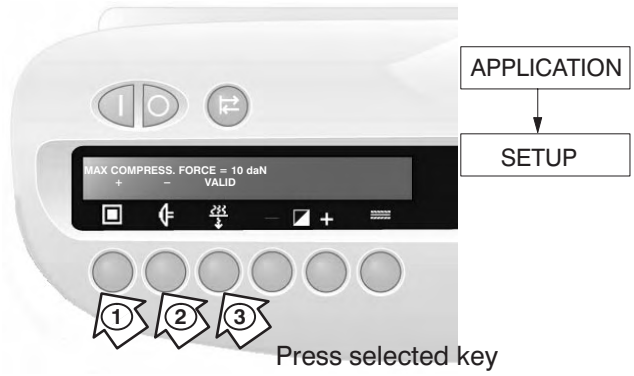
4–2–2 Selecting a Function

To select a function, press the key located under the symbol for that function.



Confirm functions selection





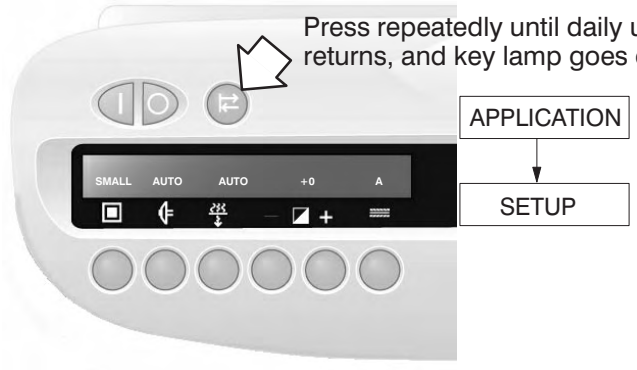
① By increments of 1 daN to maximum = 20 daN.

② By decrements of 1 daN to minimum = 4 daN.

③ To confirm.

4–2–3 Confirm & Return to Application Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press  repeatedly until “focal spot, focal track, filter, etc” return.

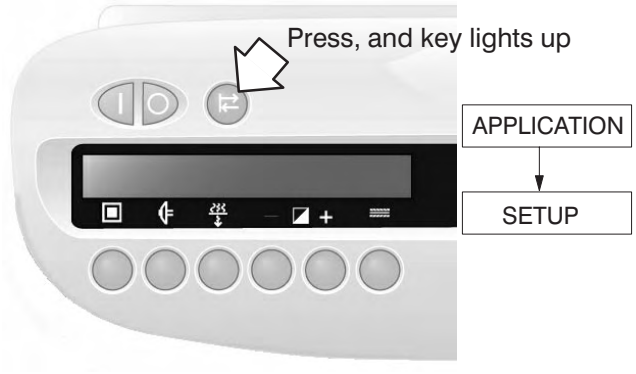


MAINTENANCE

4–3 Automatic Decompression

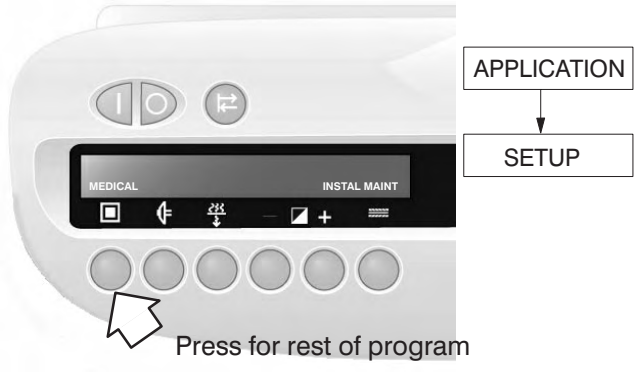
4–3–1 Access to Programming Mode

- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.

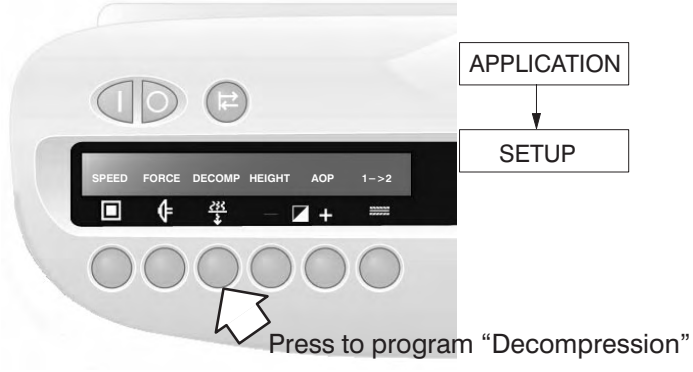


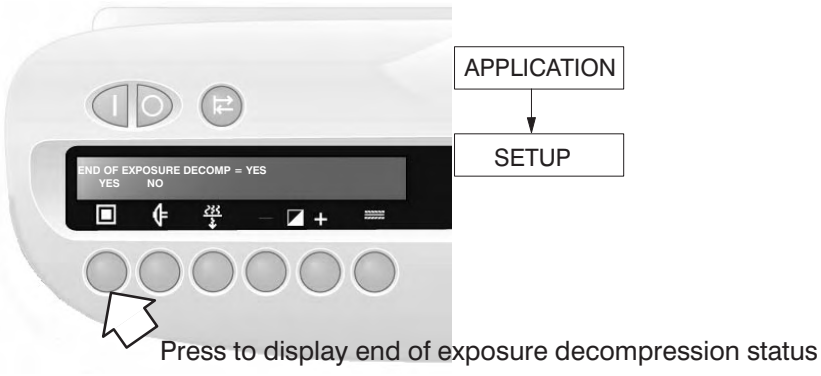
4–3–2 Selecting a Function

To select a function, press the key located under the symbol for that function.



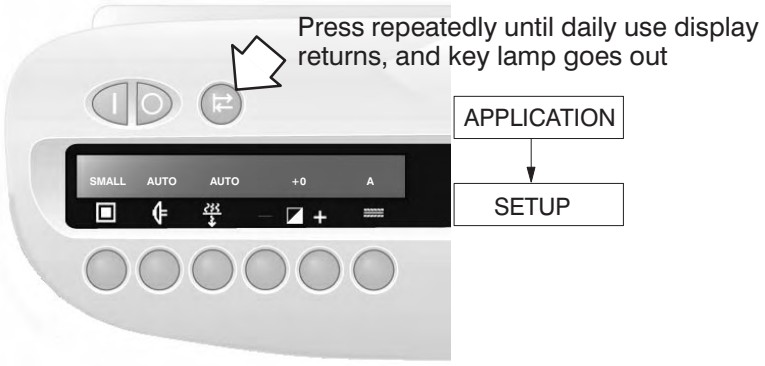
Confirm functions selection





4–3–3 Confirm & Return to Application Mode

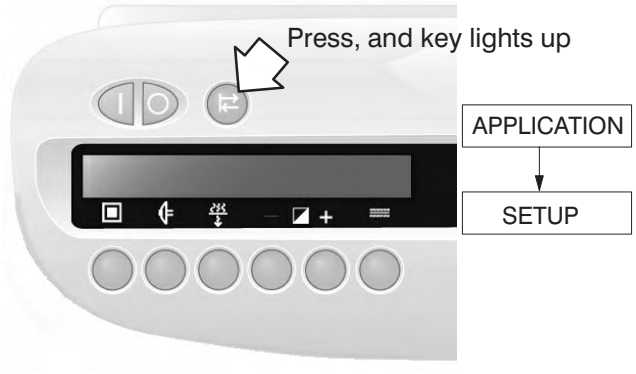
To confirm the function selected and return to the APPLICATION Menu (daily use), press  repeatedly until “focal spot, focal track, filter, etc” return.



4–4 Decompression Height

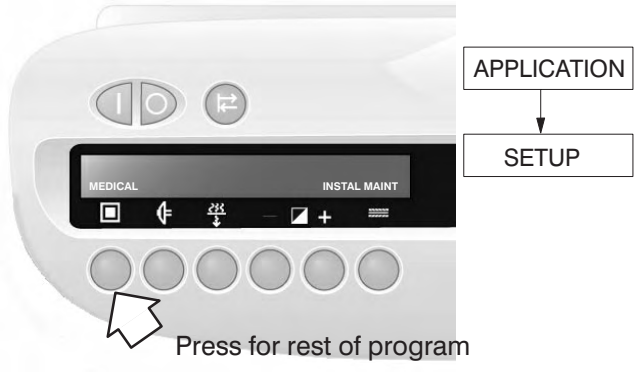
4–4–1 Access to Programming Mode

- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.

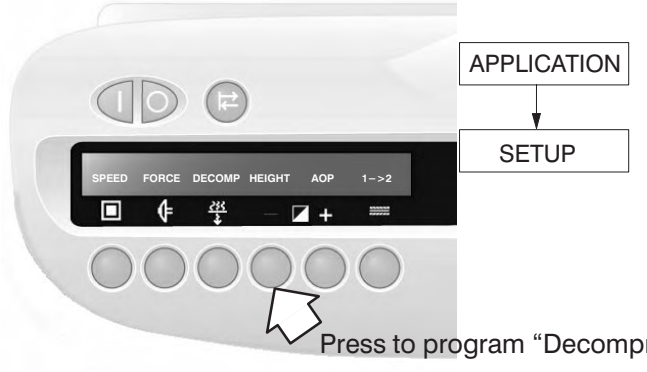


4–4–2 Selecting a Function

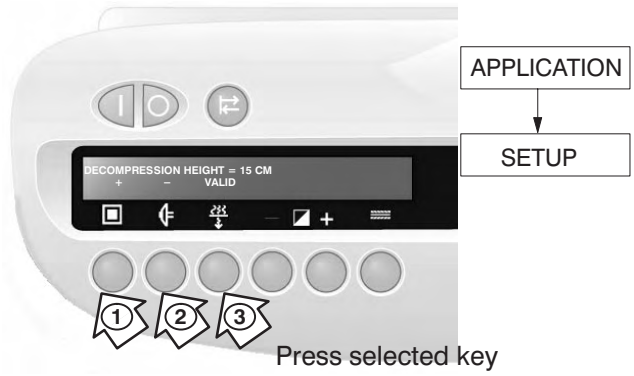
To select a function, press the key located under the symbol for that function.



Confirm functions selection



MAINTENANCE



① By increments of 1 cm to maximum = 20 cm.

② By decrements of 1 cm to minimum = 1 cm.

③ To confirm.

Note:

- The automatic decompression height that is being programmed represents the height from the last position of the compression paddle.

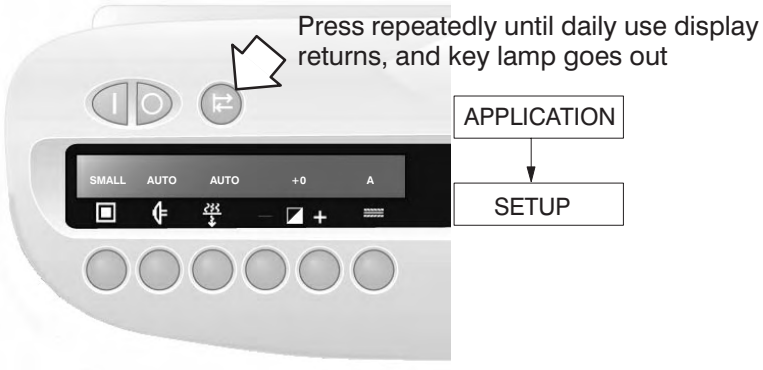
Example:

- If the compressed breast thickness was 4.6 cm before decompression and a 20cm automatic decompression height has been programmed, the paddle will go back up to 24.6cm.
- If the compressed breast thickness was 8.3 cm before decompression and a 20cm automatic decompression height has been programmed, the paddle will go back up to 28.3 cm.
- Etc, ...

MAINTENANCE

4–4–3 Confirm & Return to Application Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



4–5 Minimum Optical Density Selection

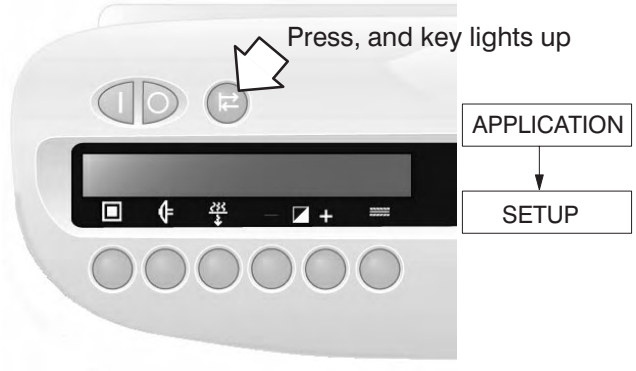
A target Optical Density has been programmed, based on your recommendations, by the GE field service engineer during the installation of your Senographe 800T. The machine will never allow an exposure if this target optical density cannot be reached, except if a maximum allowable drop in optical density has been programmed. If this is the case, then, in case the target optical density cannot be reached, the machine will allow the optical density to drop by the programmed value.

Example: If the target optical density has been set at 1.6, and a maximum allowable drop of 0.2 has been programmed, then the Senographe 800T will allow the optical density to drop down to 1.6 – 0.2 = 1.4 if the target optical density cannot be reached.

In order to guarantee best results, the programming of this maximum allowable drop must done by the GE field service engineer. If you do not wish to allow any drop in optical density, then a value of zero must be programmed for the maximum allowable drop.

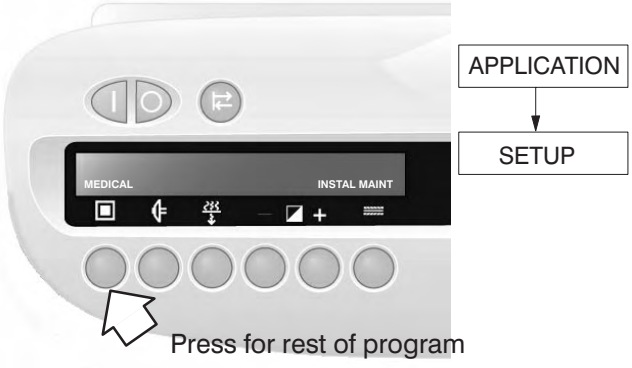
4–5–1 Access to Programming Mode

- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



4–5–2 Selecting a Function

To select a function, press the key located under the symbol for that function.



Confirm functions selection

APPLICATION

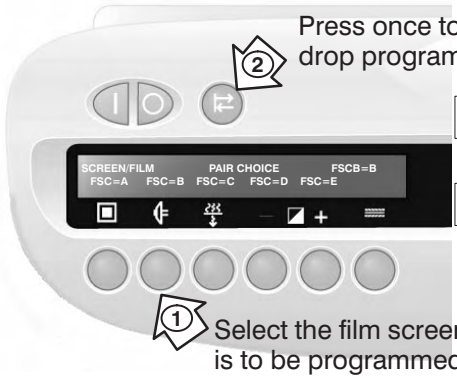
SETUP

Press to program maximum drop in O.D.

APPLICATION

SETUP

Press to select Film Screen Combination on which maximum drop in O.D. is to be programmed



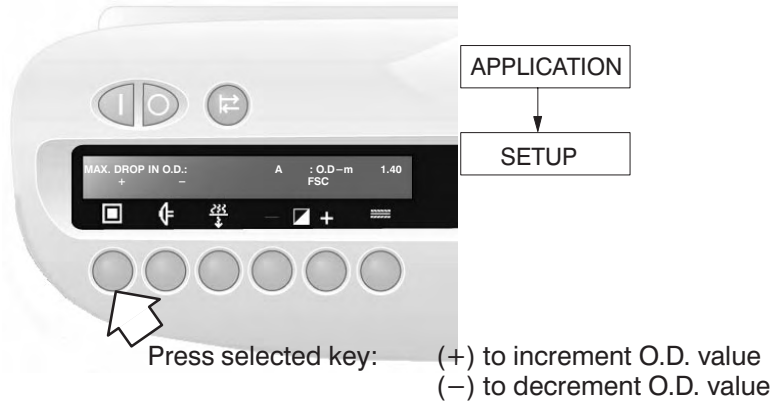
Press once to go back up to maximum drop programming

APPLICATION

SETUP

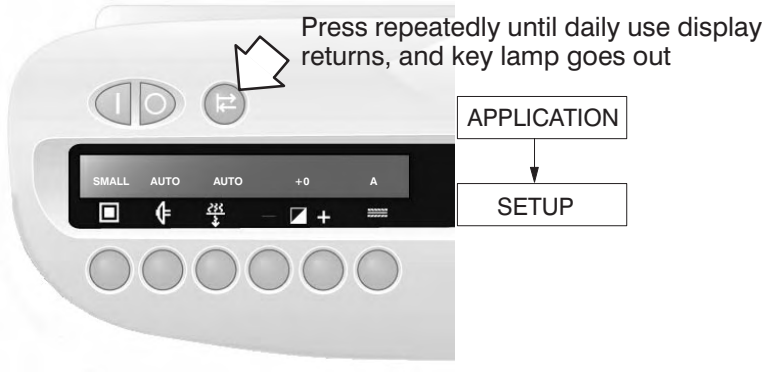
Select the film screen combination on which maximum drop in O.D. is to be programmed by pressing appropriate key

MAINTENANCE



4–5–3 Confirm & Return to Application Menu

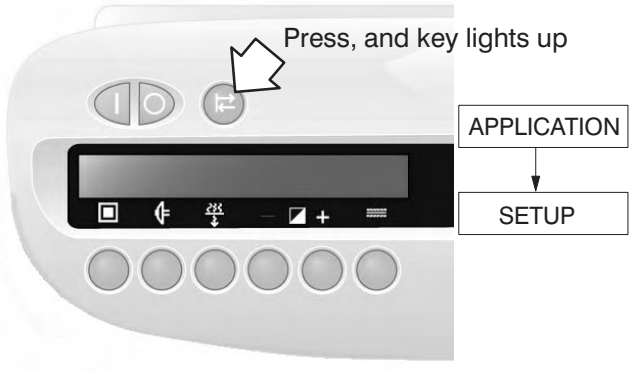
To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



4–6 Language Programming

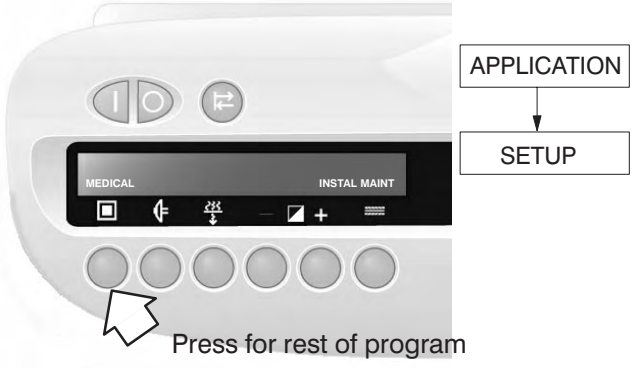
4–6–1 Access to Programming Mode

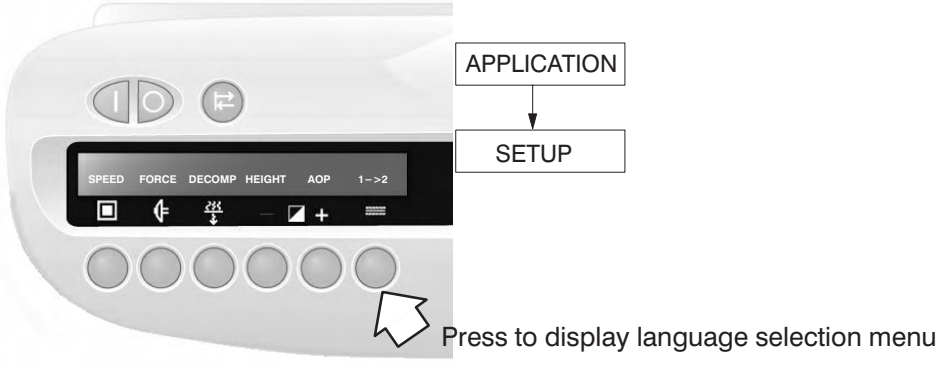
- To access the programming mode, press  .
- The APPLICATION Menu, focal spot, focal track, filter, etc., disappears.



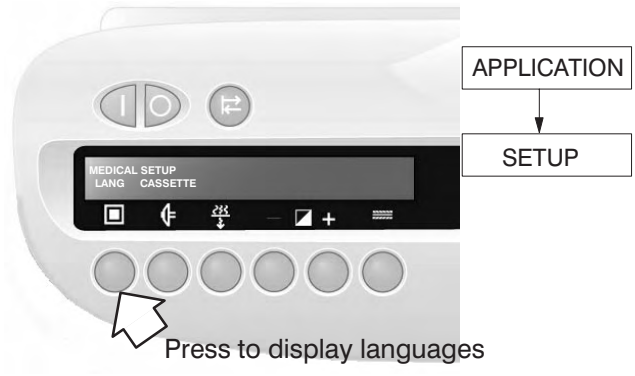
4–6–2 Selecting a Function

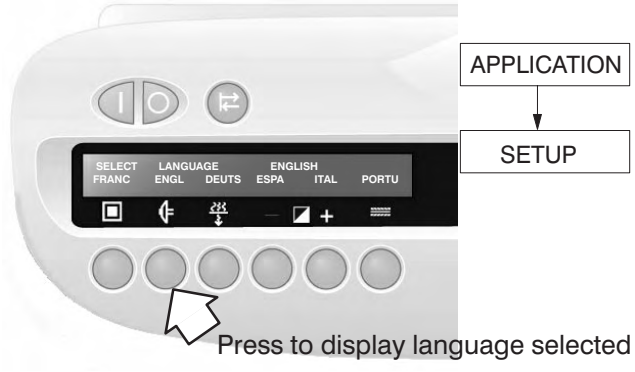
To select a function, press the key located under the symbol for that function.





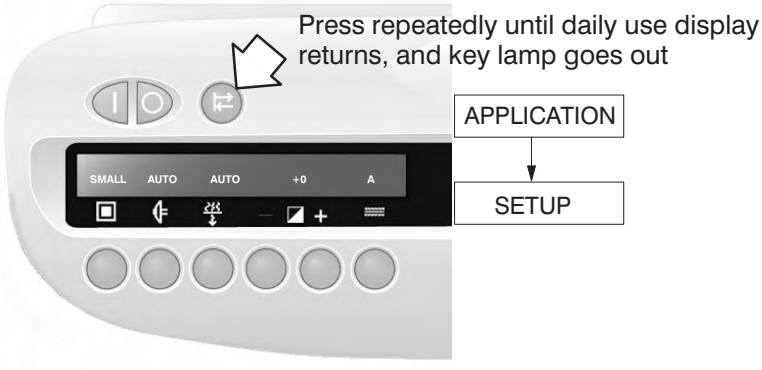
MAINTENANCE





4–6–3 Confirm & Return to Application Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press  repeatedly until “focal spot, focal track, filter, etc” return.



4–7 Exposure Interlock Disable

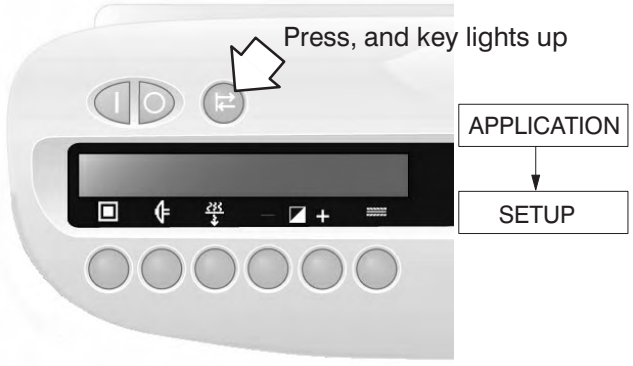
The Senographe 800T is equipped with an exposure interlock feature which prevents an exposure from being made if there is no cassette in the Bucky, or if the cassette from the previous exposure has not been changed.

Trying to make an exposure without a cassette in the Bucky or cassette holder, or without having changed the cassette between two exposures will result in a beep sound and the red indicator light located above the Bucky will come ON. The exposure will be inhibited.

However, it is possible, for special purposes such as physicist testing, to disable this interlock.

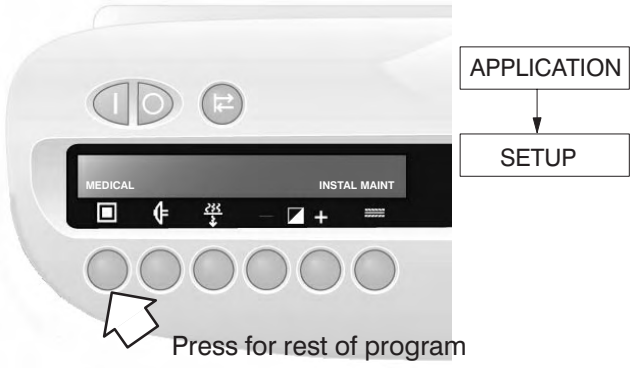
Note: The Senographe 800T AUTOMATICALLY enables exposure interlock when powered on.

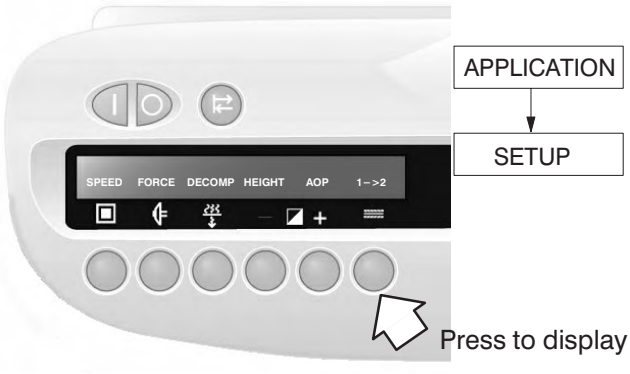
4–7–1 Access to Programming Mode

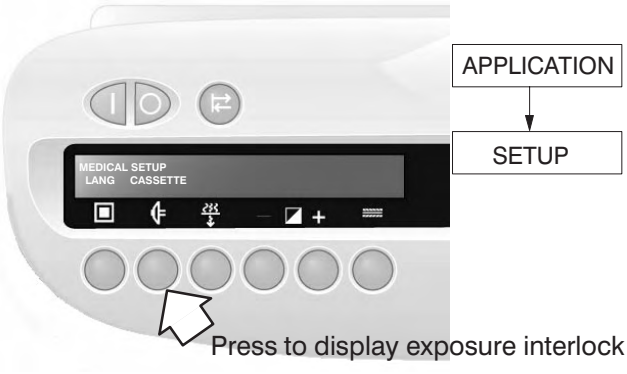


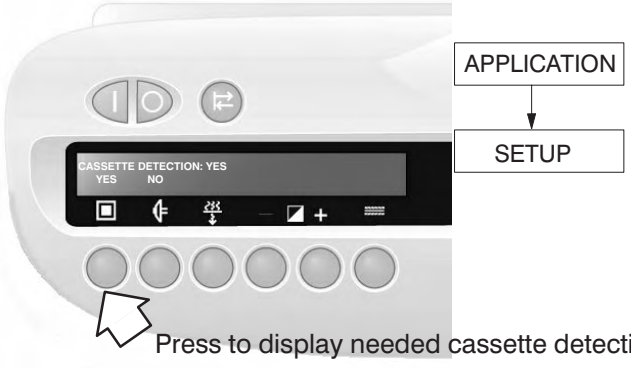
4–7–2 Selecting a Function

To select a function, press the key located under the symbol for that function.







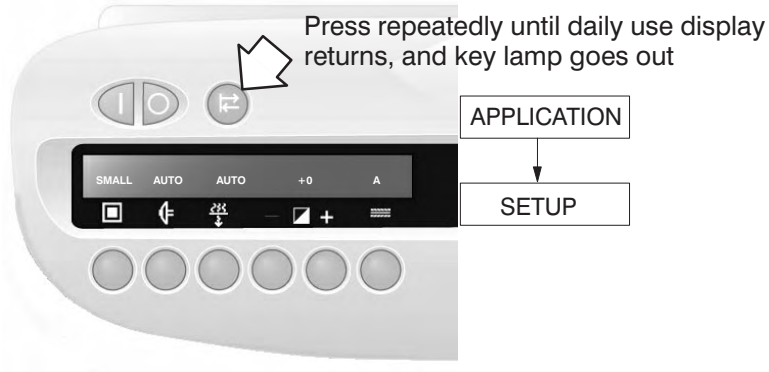


- Press ”YES” to disable exposure if there is no cassette in the bucky, or if the cassette has not been changed.
- Press ”NO” to allow exposure even if there is no cassette in the bucky or if there is no bucky (physicist testing for example).

Note: The machine automatically selects ”YES” each time the unit is powered ON. Regardless of the previous selection.

4–7–3 Confirm & Return to Application Menu

To confirm the function selected and return to the APPLICATION Menu (daily use), press repeatedly until “focal spot, focal track, filter, etc” return.



SECTION 5
CENTERING DEVICE LIGHT BULB REPLACEMENT

When the light bulb of the centering device fails it can be easily replaced by the user following the instructions below. This operation takes only one minute **(after the bulb has cooled down).**

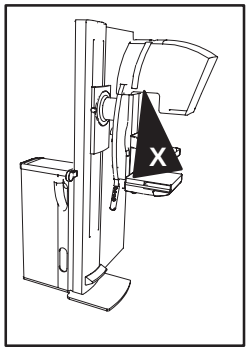
Use the spare bulb in the first–aid kit.

You are advised to order a new replacement bulb now, from your local GE After Sales Service or by using the accessory catalogues (DIA, Numéris).

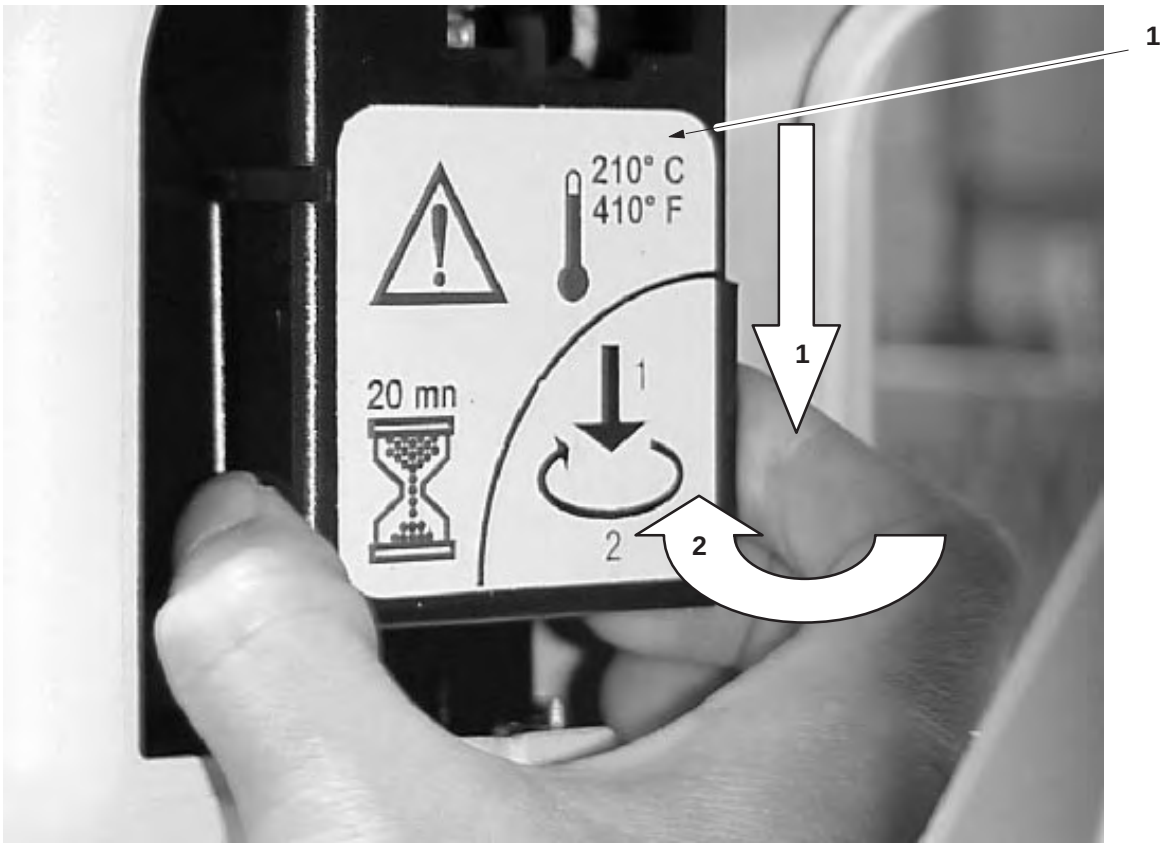
WARNING

THE BULB AND ITS PROTECTION COVER MAY BE VERY HOT. LEAVE THE CENTERING DEVICE SWITCHED OFF TO COOL DOWN FOR TWENTY (20) MINUTES BEFORE REMOVING THE BULB.

1. Switch off the Senographe 800T.
2. At the back of the collimator, remove the cover (1) by pulling on the handle at the bottom (2).

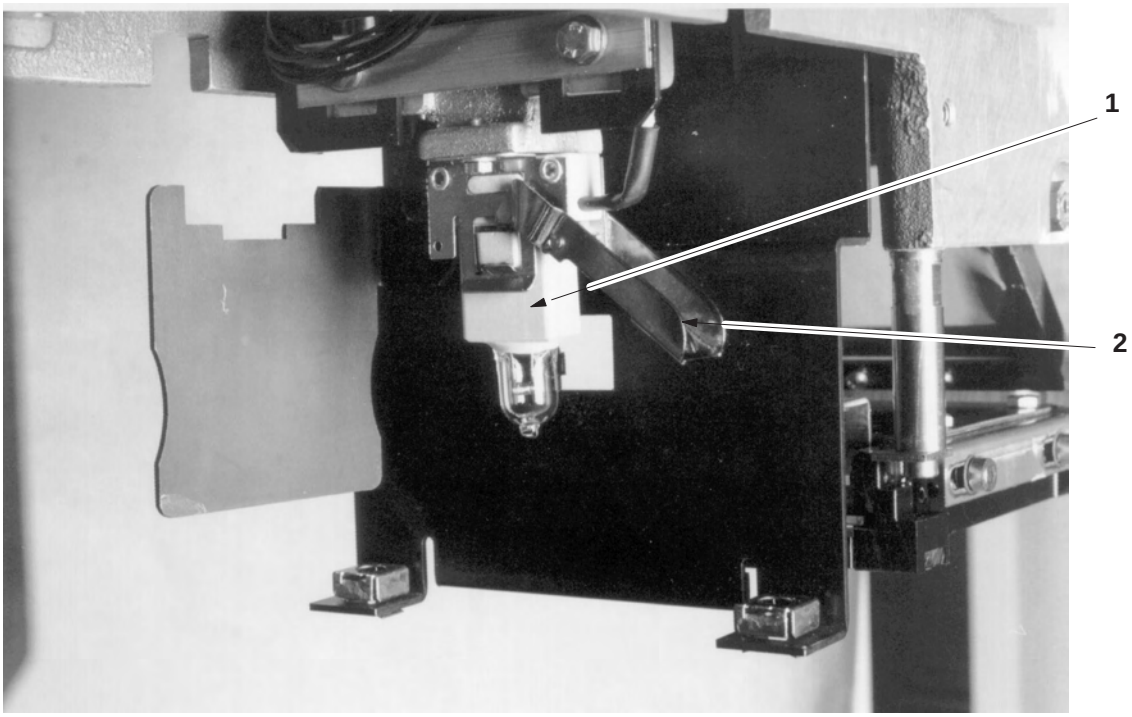


3. Open the bulb protection cover (1) by pulling down on it and pivoting as shown in the illustration.



Note: The symbol ⚠ located on the collimator cover means that you must read the appropriate chapter in the operator manual before taking any action.

4. To remove the bulb from its housing, hold it by its white part (1) and raise the lever (2). Discard the used bulb.



5. Remove the packing of the new bulb.

WARNING

ONLY HOLD THE BULB BY ITS WHITE PART. DO NOT TOUCH THE GLASS PART WITH BARE FINGERS OR THE BULB MAY BE PERMANENTLY DAMAGED.

- **IF YOU ACCIDENTLY TOUCH THE GLASS PART OF THE BULB WITH YOUR SKIN CLEAN THE BULB CAREFULLY WITH A SOFT CLOTH CAMPENED WITH ALCOHOL.**
- **TO AVOID ANY INCIDENTS YOU ARE ADVISED TO WEAR COTTON OR LATEX GLOVES WHEN REPLACING THE BULB, OR TO USE THE BULB PACKING WHEN HANDLING THE BULB.**

6. Align the two different–sized pins of the new bulb with its socked and push the bulb upwards.
7. Close the bulb protection cover by pulling it down and pivoting it.
8. Refit the collimator cover (see illustration in point 2 on page 3–28).

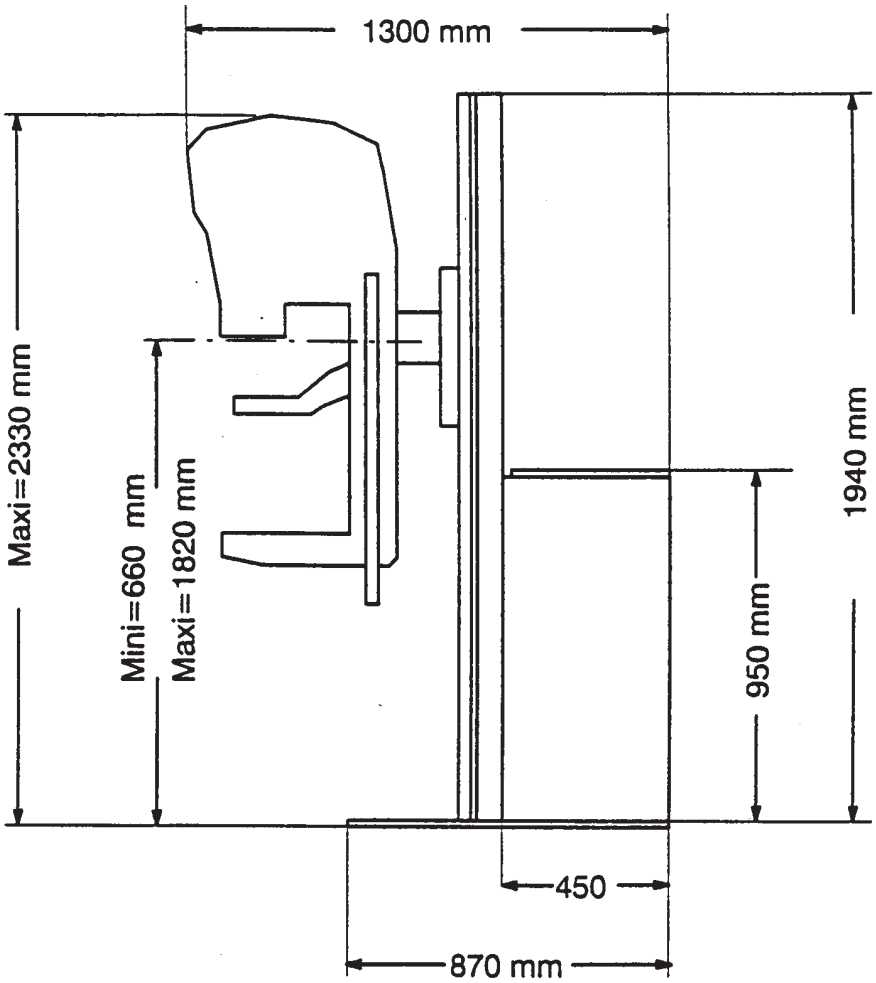
WARNING

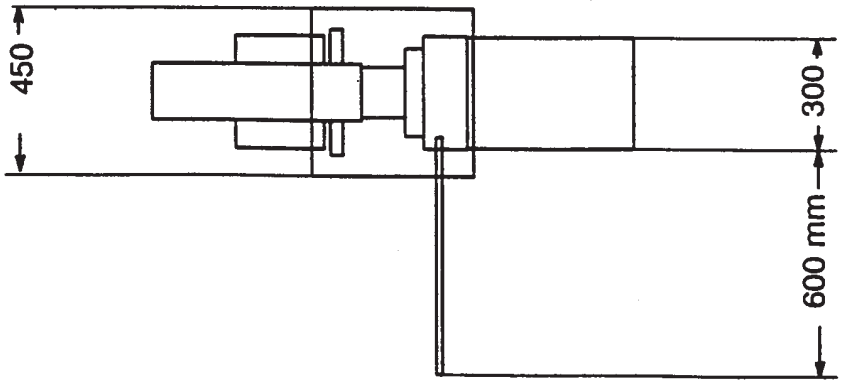
FOR ADEQUATE PROTECTION, AFTER REPLACING THE LAMP, AND BEFORE SWITCHING THE SYSTEM ON, REPLACE THE COLLIMATOR COVER.

9. Switch on the Senographe 800T.

CHAPTER 4 – SPECIFICATIONS

SECTION 1
PHYSICAL SPECIFICATIONS





SECTION 2
TECHNICAL SPECIFICATIONS

2–1 Electrical Specification

2–1–1 Line Power Supply

- Input voltage, single-phase: 200/208/220/230/240V (± 10%).
- Line frequency: 50 or 60 Hz (± 1 Hz).

2–1–2 Maximum Line Current

- Line power: 6 kVA during exposures
- Maximum line current:
  - 200V: 30A
  - 240 V: 25A

2–1–3 Permissible Line Resistance

The maximum line impedance authorized are the following, depending on the mains nominal voltage:

- 200V ——> 0.33 Ohms
- 208V ——> 0.36 Ohms
- 220V ——> 0.40 Ohms
- 230V ——> 0.44 Ohms
- 240V ——> 0.48 Ohms

2–1–4 Generator Output

- 22 through 35 kV,
- 20 through 100 mA.

2–1–5 Anode Current

- I max large focus = 100 mA at 30 kV,
- I max small focus = 30 mA at 30 kV.

2–1–6 Generator Power

- 3 kW maximum.

2–1–7 Duty Cycle

The generator is always limited by the tube:

- The generator can supply an average power 100 W to the tube.
- This example represents one 30 kV/200mAs exposure each minute.

2–1–8 Inverter Resonance Frequency

- 140 kHz approx.

2–1–9 Maximum Tolerance of Displayed Constants (with and without AEC or AOP)

- kV:+/– 2% + M1+M1'
- mAs: +/– 5% +/– 1 mAs + M4 + M4'

M: accuracy of the instruments used for the test.

M1 = +/– 0.6 kV +/– 1.5% — Dynalizer accuracy in cathode to ground configuration

M4 = +/– 0.1 mAs +/– 2.6% — Dynalizer accuracy

M1' = Accuracy of the measuring device

M4' = Accuracy of the measuring device

2–1–10 Measurement Conditions

kVp: Connect a voltage divider in series with the x-ray tube and measure the voltage with an oscilloscope,

mAs: Use a waveform analyzer connected in series with the x-ray tube. The oscilloscope receives a signal proportional to the high voltage applied to the tube. The mAs values are given by:

$$\text{mAs} = \int_{T2}^{T1} \text{idt}$$

Where T1 is the time at which the high voltage reaches 75% of its maximum value, and T is the time at which the high voltage returns to 75% of the maximum value.

SPECIFICATIONS

2–2 Filters

The filters are installed on a disk driven by a stepping motor which moves from one filter to the other.

Two different filters are supplied:

- Molybdenum: 0.03 mm,
- Rhodium: 0.025 mm,

The Column electronics control the filters according to operator requirements in AEC or MANUAL mode, or to software requirements in AOP mode.

TARGET	VOLTAGE (kV)	FILTER	EQUIVALENCE (half-value layer)
Molybdenum	30	0.03 Mo	0.3 mm Al minimum
Molybdenum	30	0.025 Rh	0.35 mm Al minimum

2–3 Beam-limiting Devices

The available collimator diaphragms and x–ray formats are as follows:

Size printed on diaphragm	Color	Focal spot used	Usage / Comments
18 x 24	White	Large (0.3)	• Large focus. Full field • Included in the basic configuration
10 x 10	White	Large (0.3)	• Large focus. Square collimation • Included in the basic configuration
18 x 24	White	Small (0.1)	• Small focus. Full field • Included in the basic configuration
14 x 14	Green	Small (0.1)	• Small focus. Square collimation. 1.5 magnification • Included in the basic configuration
16 x 16	Pink	Small (0.1)	• Small focus. Square collimation. 1.8 magnification • Included in the basic configuration
Ø 6	White	Large (0.3)	• Large focus. Spot collimation • Optional. Delivered with “ small round spot capability ”
Ø 9	Green	Small (0.1)	• Small focus. Spot collimation. 1.5 magnification • Optional. Delivered with “ small round spot capability ”
Ø 10	Pink	Small (0.1)	• Small focus. Spot collimation. 1.8 magnification • Optional. Delivered with “ small round spot capability ”
24 x 30	Purple	Large (0.3)	• Large focus. Full field • Optional. Delivered with “ 24x30 capability ”
24 x 30	Purple	Small (0.1)	• Small focus. Full field • Optional. Delivered with “ 24x30 capability ”

2–4 Special Material Specifications

Composition of materials in contact with the breast.

Transparent plastics used in compression paddles are of polycarbonate Lexan.

18 x 24 Bucky plate is of polycarbonate Lexan.

24 x 30 Bucky plate is of carbon fiber.

SECTION 3
ENVIRONMENT

TABLE 4–1
AMBIENT CONDITIONS

HUMIDITY			
In use		Storage (in original crates)	
Min.	Max.	Min.	Max
30%	70%	10%	95%

TEMPERATURE			
In use		Storage (in original crates)	
Min.	Max.	Min.	Max.
10° C *50°F*	40° C *104°F*	- 20° C *68°F*	70° C *158°F*

ALTITUDE	
In use	Storage
+ 4000 m *9842’*	+ 4000 m *9842’*

SPECIFICATIONS

Blank page.

CHAPTER 5 – REGULATIONS

The SENOGRAPHE 800T complies to the following regulations:

- UL 187 — X-ray equipment
- CSA 22.2, No. 114 — Radiation Emitting Equipment
- IEC 601–1 — Medical Electrical Equipment
  Part 1: General requirements for safety
- IEC 601–2–7 — Medical Electrical Equipment
  Part 2: Particular requirements for the safety of high voltage generators of diagnostic x-ray generators.
- 21 CFR, Part 1020.30, sub. J — Code of Federal regulation
  Performance standards for ionizing radiation emitting products.
- EMC (Electromagnetic compatibility):
  - Emission:
    - CISPR11 classA: Electromagnetic disturbances.
  - Immunity:
    - IEC 801–2: Electrostatic discharge (conducting parts: 3 kV, non-conducting parts: 8 kV).
    - IEC 801–3: Radiated electromagnetic field (3 V/m, from 26 MHz to 1 GHz).
    - IEC 801–4: Electrical fast transient/burst (2 kV on power supply cables, 500 V interconnection cables).
    - IEC 801–5: Shock waves: (2 kV common mode, 1 kV differential mode).
- CE marking according to council directive 93/42/EEC.

Blank page.