GAMMEX

Dx DIAGNOSTIC

Digital Compression Scale

Model 163-DIG

User’s Guide, Mammography Digital Compression Scale

This guide is written for Model 163-DIG.

Document 009287-00-00

Gammex Inc.
7600 Discovery Drive
Middleton, WI 53562 USA
+1 608-828-7000
www.gammex.com

GAMMEX

Contents

1 163-DIG Scale Overview

Product Overview

The Gammex Digital Compression Scale, Model 163-DIG, measures the compression force applied by mammography systems.

Accurate compression during mammographic image acquisition is essential to minimizing dose to the patient while achieving acceptable image quality. Compression minimizes patient motion, reduces scattered radiation, increases image contrast, and diminishes radiation exposure to the breast by spreading out and reducing the overall thickness of the breast tissue.

Routine testing of compression force with the Gammex Digital Compression Scale allows clinical users to comply with internationally recognized standards and manufacturer recommendations. For example, countries that follow ACR & MQSA guidelines can use the 163-DIG to fulfill the MQSA requirements for compression performance. For more information, please see the ACR Mammography Quality Control Manual, Technologist's Section on Compression.

Getting Started

Capacity

WARNING: Overloading the 163-DIG might permanently damage the scale – do not overload! The scale capacity is 0-55 lbs. (0-25 kg).

Assemble the Platform

Add the scale platform to the scale body by aligning the pins with the holes on the body and evenly pushing in all the pins.

Battery & Install

Batteries are not included with the 163-DIG product. Refer to *Scale Specifications* on page 6 for the type of batteries to use. A display of *Lo* or the battery symbol () on the 163-DIG readout indicates low batteries and replacements are required.

To install batteries in the 163-DIG:

1. On the bottom of the 163-DIG, press and slide the battery cover.
2. Note the polarity (+) and (-) and insert the batteries in the correct orientation.
3. Ensure all contacts make a strong connection with batteries. If necessary, use a small screw driver to bend battery terminals for a better connection.
4. Slide the battery cover into place until clicks shut.

Conditions for Use, Transportation, & Storage

When the 163-DIG is not in regular use or transported, removing one or more batteries is recommended to preserve battery life. If transporting, removing all batteries is recommended to prevent damage to the battery housing.

Transportation and storage within a soft case (sold separately) is recommended. Contact your Gammex sales associate (gammexsales@sunnuclear.com) for a transportation case to fit the 163-DIG.

Never store and transport in extreme heat or cold conditions, refer to *Scale Specifications* on page 6 for normal operating conditions. Also avoid high humidity, vibration, dusty, or magnetic environments in all cases of use, transport, and storage. Failure to follow guidelines voids the product warranty. Refer to *Scale Specifications* on page 6 for Operating Temperature.

High Oxygen Warning

WARNING: The 163-DIG is **not** intended to be used in oxygen rich environments or in the presence of anesthetic agents or gases. These environments are not within the scope of use for the 163-DIG.

Limitation of Use

Product is only to be used as intended and as described herein. Follow instructions to avoid misuse and errors that might potentially lead to voiding product warranty.

Independent Failure Mode Warning

Do not use results from the 163-DIG to make changes to your system, do use the results to perform additional system checks.

2 Features & Specifications

How it Works

The Digital Compression Scale uses an array of load cells to measure the compression force applied to the platform. The Scale continuously displays the maximum force as applied by the compression paddle and is thus well suited for testing compression over time. You can freeze the display of the maximum force reading by pressing the *Pause/Hold* button. Press the *Zero* button to reset.

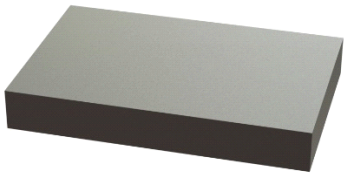
Components

Table 2-1. Parts and Accessories

Part Number	Description
163-DIG	Digital Compression Scale
603061	Compression Foam Block
805972	Soft Case for 163-DIG (optional)

Figure 2-1. Model 163-DIG Diagram

Table 1: Accessories

Foam Compression Block	Soft Case
	

Features

Initialization Sequence

Upon power-on, 163-DIG performs a startup sequence countdown. Keep the unit on a flat and stable surface during initialization. At the end of initialization 163-DIG automatically zeroes.

Zero/Tare

Zero/Tare allows users to zero the scale for relative measurements, or measurements in different orientations. Before any compression measurement is taken, the 163-DIG should be zeroed.

Note: *After a tare force is removed, the Scale will read a negative value. Press Zero/Tare to re-zero the 163-DIG.*

Hold/Pause

Hold/Pause (II) allows users to freeze the display on the Scale. Press it again to cancel, or use Zero/Tare.

Overload Warning

Do not exceed the scale capacity – this can cause permanent damage and void warranty. Refer to the *Scale Specifications* on page 6 for the scales capacity. If the scale is overloaded, the display shows Err-0 and the load should be removed immediately.

Energy Saver

The scale automatically powers off after 90-seconds of inactivity to preserve batteries. Activity includes any button presses or change in force measurement.

Detachable Display Panel

Users might find removing the display helpful for testing prone or stereotactic systems. To remove the Display Panel of the 163-DIG:

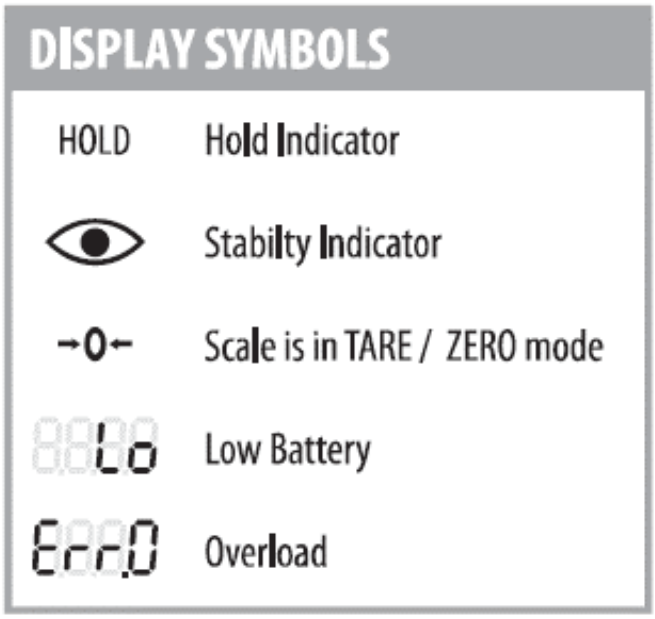
1. On the bottom, push the release tab with arrow indicting direction.
2. Wriggle and slide the Display Panel upwards in the direction of the Platform while holding the release tab.
3. The separated Display Panel is corded to the Platform Body and ready for use in desired orientation. Tare the scale when changing orientation.

Figure 2-2. Display panel removed from 163-DIG

Scale Specifications

Table 2-2. Specification table

Parameter	Value
Capacity	0-55 lbs. (0-25 kg)
Accuracy	± 0.005 lb [0 - 2 lb], ± 0.02 lb [2 - 55 lb], ±0.002 kg [0 - 1 kg], ±0.01 kg [1 - 25 kg]
Display Units	g, lb:oz, kg, lb, oz
Scale Dimensions	8.9 x 8.2 x 2.9 in. (225 x 208 x 73 mm)
Platform Dimensions	7.87 x 6.22 in. (200 x 158 mm)
Foam Compression Block Dimensions	7.25 x 4.75 x 1 in.
Scale Weight	2 lbs. (0.95 kg)
Power	Alkaline Batteries Size C (4x) (not included)
Energy Saver | Auto-Off	90 seconds
Operating Temperature	50 – 104° F (10-40° C)
RoHS Complaint	Yes



3 Using the 163-DIG

General Operation

Standard Setup (0-degree)

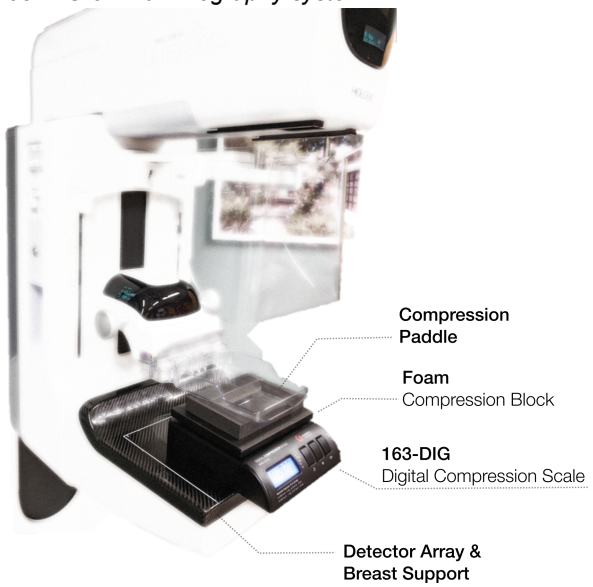
The ACR requires a mammography system to provide a compression force of no less than 25 lbf (111 Newtons) for initial power drive mode and no more than 45 lbf (200 Newtons) for subsequent power drives.

Unless otherwise specified by the manufacturer, the recommended procedure for testing compression is that described in the ACR Mammography Quality Control Manual. The procedure is summarized below.

1. Raise compression paddle (plate) to maximum height and center it. Turn off Flex-mode.
2. Place the Model 163-DIG on the breast support approximately centered on the compression paddle. Optionally place the Foam Compression Block on top of the 163-DIG Platform, which is also useful for testing curved paddles.
3. Power On the 163-DIG Scale and wait for Initialization to complete.
4. Select the Unit for display by toggling to the appropriate unit of measure.

   Note: Units can be converted from kg to N by multiplying by 9.81 m/s2 (or by 0.981 to get N)
5. Press Tare if the scale is not at 0.
6. On the Mammography system, using the initial power drive, activate the compression scale and allow it to operate until it stops automatically.
7. Record the compression force.
8. Perform subsequent power-drive modes until it stops.
9. Record the compression force.
10. Follow directions from the local mammography QC standard for testing manual drive mode and compression over time.

Figure 3-1. Setup for 163-DIG on mammography system



Prone/Stereotactic Setup (90-degree)

The 163-DIG is suitable for measuring compression force for a wide range of patient setup orientations. For prone or stereotactic systems that compress at 90-degrees, the 163-DIG can be used on its side. Optionally, the Display Panel can be removed. Refer to the *Detachable Display Panel* on page 5 for more information.

To collect measurements in 90-degree orientation:

1. Power up and zero the 163-DIG flat and stable surface.
2. Rotate the 163-DIG onto its narrow side on a flat and stable surface and zero the scale.
3. Bring the 163-DIG to the Mammography system and very carefully apply pressure to clamp the scale between the compression paddle and detector.

WARNING: Only let go after the scale has pressure (~10 lbs). Damage from dropping the Scale is not covered by warranty.

4. Perform measurements per local Quality Standard (ACR, EUREF, etc.)
5. Place hands under 163-DIG at all times when compression force is released.

Figure 3-2. Example setup of 163-DIG on Prone/Stereotactic System. The scale is held in place by user until the machine applies the appropriate pressure.

4 Calibration

Routine Checks

Gammex no longer offers certificates of conformance for scales – please seek out a local metrology center for routine recertification if required. If adjustments are needed to dial in the scale, follow instructions below for the calibration process.

Note: *Calibration might be required upon first use. This is especially true after an altitude change, where gravitational force can vary for the same body of mass. Calibration of scales should be checked over time as mechanical components are subject to wear.*

Calibration Process

Required equipment:

- 10 kg certified weight or combination of certified weights.

Process

1. While the 163-DIG is off press and hold the *Unit* button while holding the *Power* button until the display reads CAL. Immediately after, a random set of numbers appear (raw load cell value).
2. Press *Unit* again. The display now shows - - - - - - and then flashes the calibration weight to be used (10 kg).
3. Place the 10 kg calibration weight on the 163-DIG platform.
4. When the stable indicator ( ) is displayed, press the *Unit* button again and the display shows - - - - - - followed by the new (raw load cell value).
5. Press the *Power* button to turn the scale off and then press *the Power* button. Calibration is now complete.

5 Maintenance and Support

Maintenance

- Avoid contact with alcohol.
- Wipe after use with a damp cloth, if necessary.

Contacting Gammex Support

Technical support is available from Gammex Inc. Contact the Support department:

- By telephone: +1 (321) 259-6862, option 3, then 3.
- By email: GlobalSupport@sunnuclear.com

GAMMEX
Gammex Inc.
7600 Discovery Drive
Middleton, WI 53562 USA
+1 608-828-7000
www.gammex.com

Appendix A: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Gammex Symbols

The following symbols are used in this guide and in Gammex's product labels.

WARNING: This symbol indicates a hazard that could result in major injury or equipment damage.

This symbol indicates a general mandatory action.

Manufacturer's Identification (name and address.

Date of Manufacture.

Serial Number.

Catalog Number.

Consult instructions for use.

Do not throw in trash; dispose of in an environmentally friendly way.

Quality and Regulatory Systems

Gammex meets worldwide standards including EN ISO 13485 and FDA 21 CFR 820.

Gammex Quality Management System is certified to 13485 by SGS.

Operator Responsibility

The instructions in this manual are intended for trained personnel. The operator is solely responsible for the accurate setup and use of the scale.

Reporting Health or Safety Related Issues or Concerns

Should the need arise to report any safety or health related issues or concerns regarding the use of Gammex products, contact Gammex directly.

Modifications to Equipment

WARNING: No modifications may be made to this unit without the expressed written consent of Gammex. Unauthorized changes may present a risk to user or patients and will void the warranty.

GAMMEX

Dx DIAGNOSTIC

Corporate Headquarters
7600 Discovery Drive
Middleton, WI 53562 USA

+1 608-828-7000
sunnuclear.com