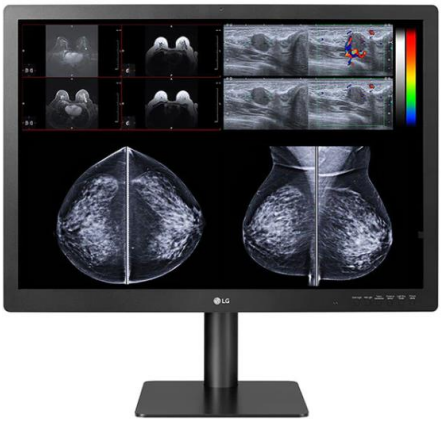
MQSA Quality Control Manual

LG Electronics 31HN713D-B, 12MP (4200x2800) IPS Diagnostic Monitor for Mammography



LG Electronics 21HQ613D-B, 5MP (2048x2560) IPS Diagnostic Monitor for Mammography

LG Electronics 32HQ713D-B, 8MP (3840x2160) IPS Diagnostic Monitor for Mammography

Diagnostic Imaging Displays

USED FOR MAMMOGRAPHY

MQSA Quality Control Manual
for
Diagnostic Monitor for Mammography

Foreword

Purpose of this Document

This document for Diagnostic Monitor for Mammography, diagnostic displays to perform the Quality Control (QC) tests to meet the guidelines / regulations of Mammography Quality Standards Act (MQSA) for the reading of the digital mammographic images. This document describes the procedure for performing the Quality Control (QC) tests for Diagnostic Monitor for Mammography, diagnostic displays based on the guidelines / regulations of Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b).
Reference the following U.S. Food and Drug Administration web site for any possible additions or changes that may not be covered in this document. (https://www.fda.gov/radiation-emitting-products/regulations-mqsa/mammography-quality-standards-act-mqsa)

Scope of this Manual

This document is referenced when conducting the Quality Control (QC) tests to Diagnostic Monitor for Mammography, diagnostic displays based on the guidelines / regulations of Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b) for the reading of the digital mammographic images through the Full-Field Digital Mammography (FFDM) system.

Regulatory Considerations

For the facilities under the MQSA regulations, application of this manual is MANDATORY. Failure to follow these quality assurance procedures can result in loss of MQSA certification at facilities subject to the MQSA regulations. For the facilities under the MQSA guidelines, application of this manual is RECOMMENDED. Otherwise, the facilities may identify other ways of meeting MQSA requirements.

Applicable Models

31HN713D-B, 12MP (4200x2800) IPS Diagnostic Monitor for Mammography
21HQ613D-B, 5MP (2048x2560) IPS Diagnostic Monitor for Mammography
32HQ713D-B, 8MP (3840x2160) IPS Diagnostic Monitor for Mammography

Contents

INSTALLATION

Installing calibration software

Install the calibration software “Display Calibrator software (LG Calibration Studio Medical)”

1) Minimum System requirements

Windows
- Win 10 (64-bit)
- Win 11 (64-bit)

Processor
- Minimum: Intel 4th i5 series or higher / AMD Ryzen 1500X or higher
- Recommended: Intel 6th i5 series or higher / AMD Ryzen 2700X or higher

Ram
- Minimum: 8 GB
- Recommended: 16GB

Storage
- Minimum: 100 GB
- Recommended: 500 GB

USB interface

2) Support Measurement devices

LG Electronics
- Front Sensor

X-Rite
- i1Display Pro

Calibrite
- ColorChecker Display Pro
- Display Pro HL

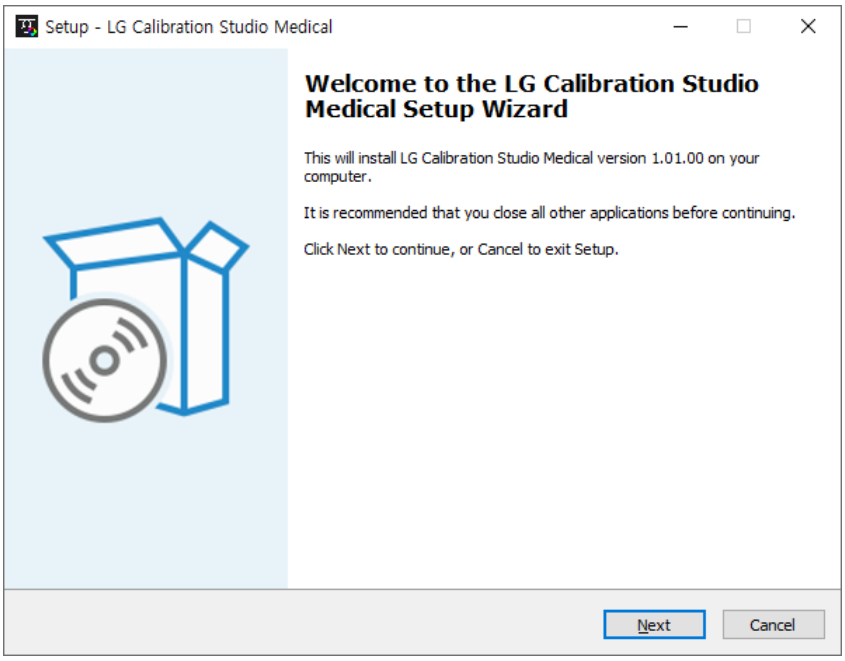
Data Color
- SpyderX

Pehamed
- CD Mon (Acceptance test only)

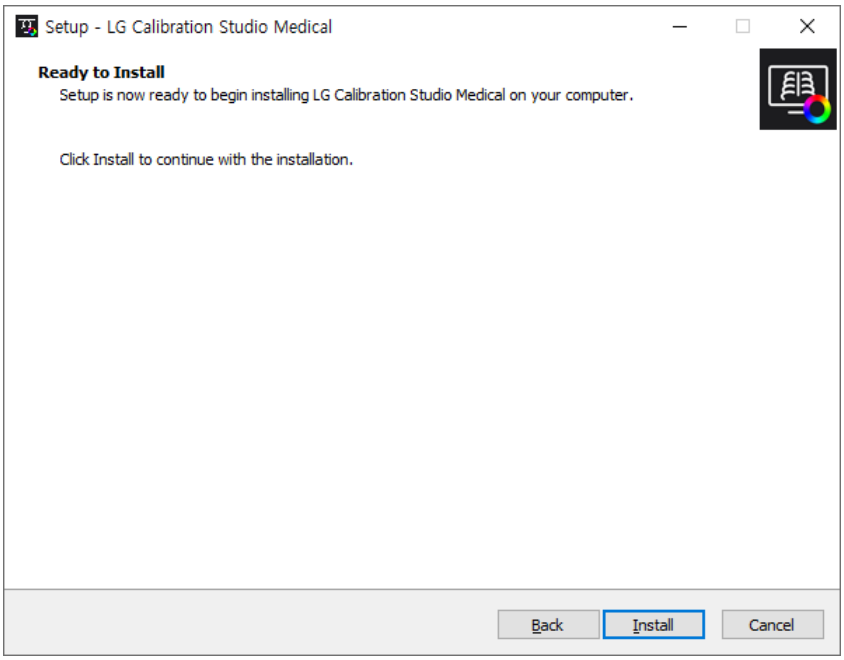
IBA Dosimetry
- LXcan (Acceptance test only)

3) Installation

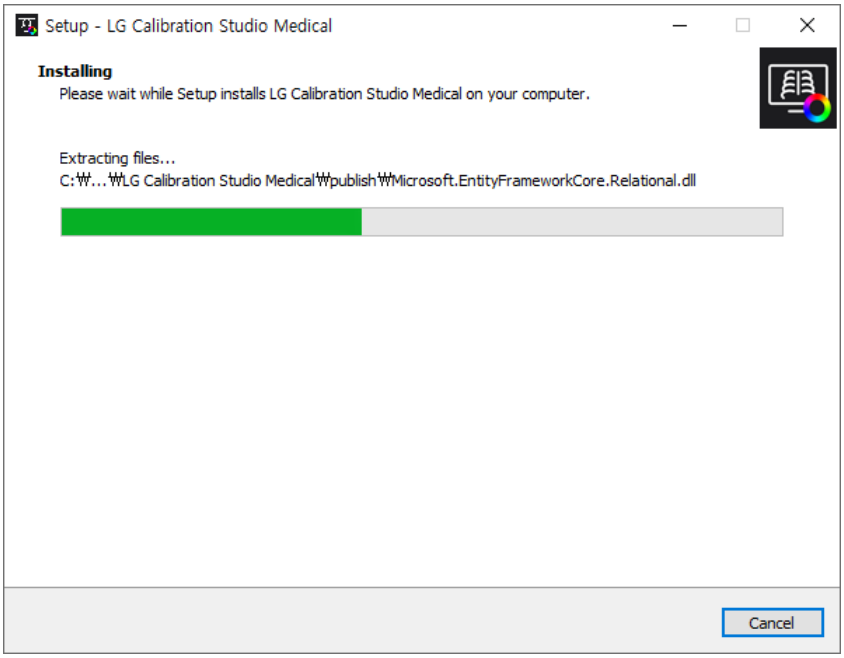
Double Click on the Setup

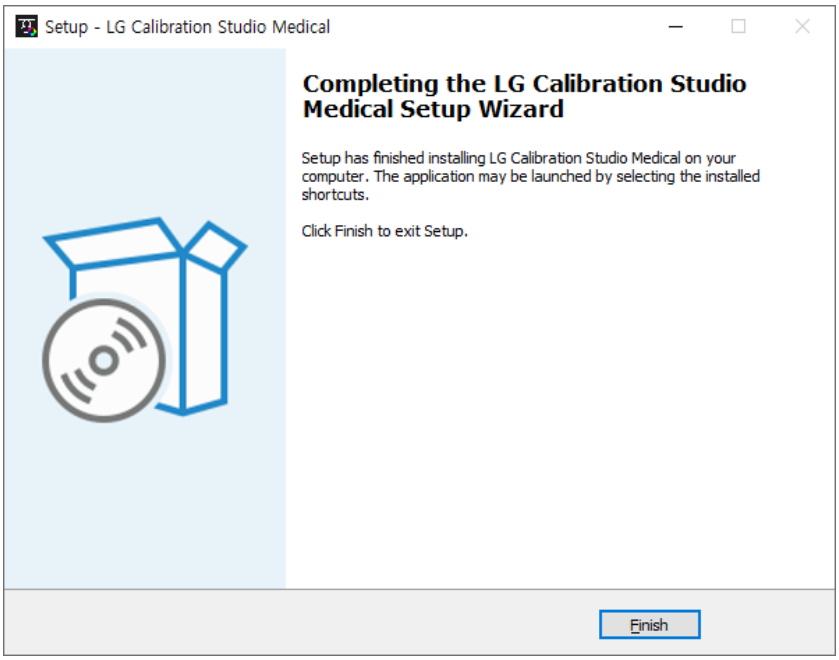


Follow the instructions presented in the installer and click on the [Next] button after reading it carefully



Click [Install] to begin the installation.





If the installation completes, the following screen appears.

Chapter 1: QC TESTS FOR THE RADIOLOGIC TECHNOLOGIST

1 INTRODUCTION

QC tests that are listed in this section are to provide the procedure for maintaining Diagnostic Monitor for Mammography, diagnostic Displays in its designed optimal quality conditions by keeping the displays free of any image quality deterioration and by performing the regular viewing conditions and image quality checks.

QC tests for the diagnostic display are described in the following sections:
• Section 3: Cleaning Display
• Section 4: Viewing Conditions Check
• Section 5: Image Quality Check - SMPTE pattern

2 INTERVALS FOR PROCEDURES

The table below shows intervals for each procedure described in this manual.

Procedure	Interval
Cleaning Display	Monthly
Viewing Condition	Monthly
Image Quality Check –SMPTE pattern	Monthly

3 CLEANING DISPLAY

3.1 Objective

To maintain the screen, clean by keeping the display screen free from any objects (dust, finger print, etc.) of the display of Diagnostic Monitor for Mammography

3.2 Frequency

Monthly

3.3 Required Equipment

Lint free cloth

3.4 Procedure

Note: The cabinet is made of plastic and coated metal plate. Do not apply thinner, benzene, or alcohol. It could damage the plastic and/or the coating could come off.

1. When cleaning the display, remove the AC adaptor from the display and the wall outlet for your safety.
2. Dampen the lint free cloth with cleaning agent designed specifically for cleaning Computer Display sand remove the dust gently. Finish up by wiping with the dry cloth.
3. Clean the LCD panel (protective filter) and the surface periodically with a dampened soft cloth.
4. Record the result on the form 1 in this manual.

Note
: Do not use Windex or household cleaners which can damage the Display’s AG coating.

Note
: Be careful when handling the LCD panel (protective filter). Do not rub or hit with sharp or hard objects. Do not press on the panel. It could cause unevenness in luminance or damage the panel.

4 VIEWING CONDITIONS CHECK

4.1 Objective

To keep and maintain the optimal viewing conditions on Diagnostic Monitor for Mammography

4.2 Frequency

Monthly

4.3 Required Equipment

None.

4.4 Procedure

1. Review the data form “Form 3: Viewing Conditions Check and Setting” on P19 (completed by the Medical Physicist during the most recent evaluation) posted in the reading room.
   Refer this form as optimal during your future evaluation.
2. Match the room configuration where each display is located to the one specified in the data form.
3. Adjust the room configuration if the current reading room configuration differs from the one established as optimal in the data form. (For example, if desk lights were specified to be turned off, turn them off, or, if curtains were specified to be closed, close them.)
4. Complete the record of the check on the form 1 in this manual.

Form 1: Monthly Test

Monthly

Facility:

Room:

Checked by:

Year	Month											
Date	1	2	3	4	5	6	7	8	9	10	11	12
Initial												
Cleaning Display												
Viewing Conditions												

Display Serial No:

LG Serial Number

5 IMAGE QUALITY CHECK - SMPTE PATTERN

5.1 Objective

To calibrate the displays as accurate as possible for the reading of mammographic images on Diagnostic Monitor for Mammography

5.2 Frequency

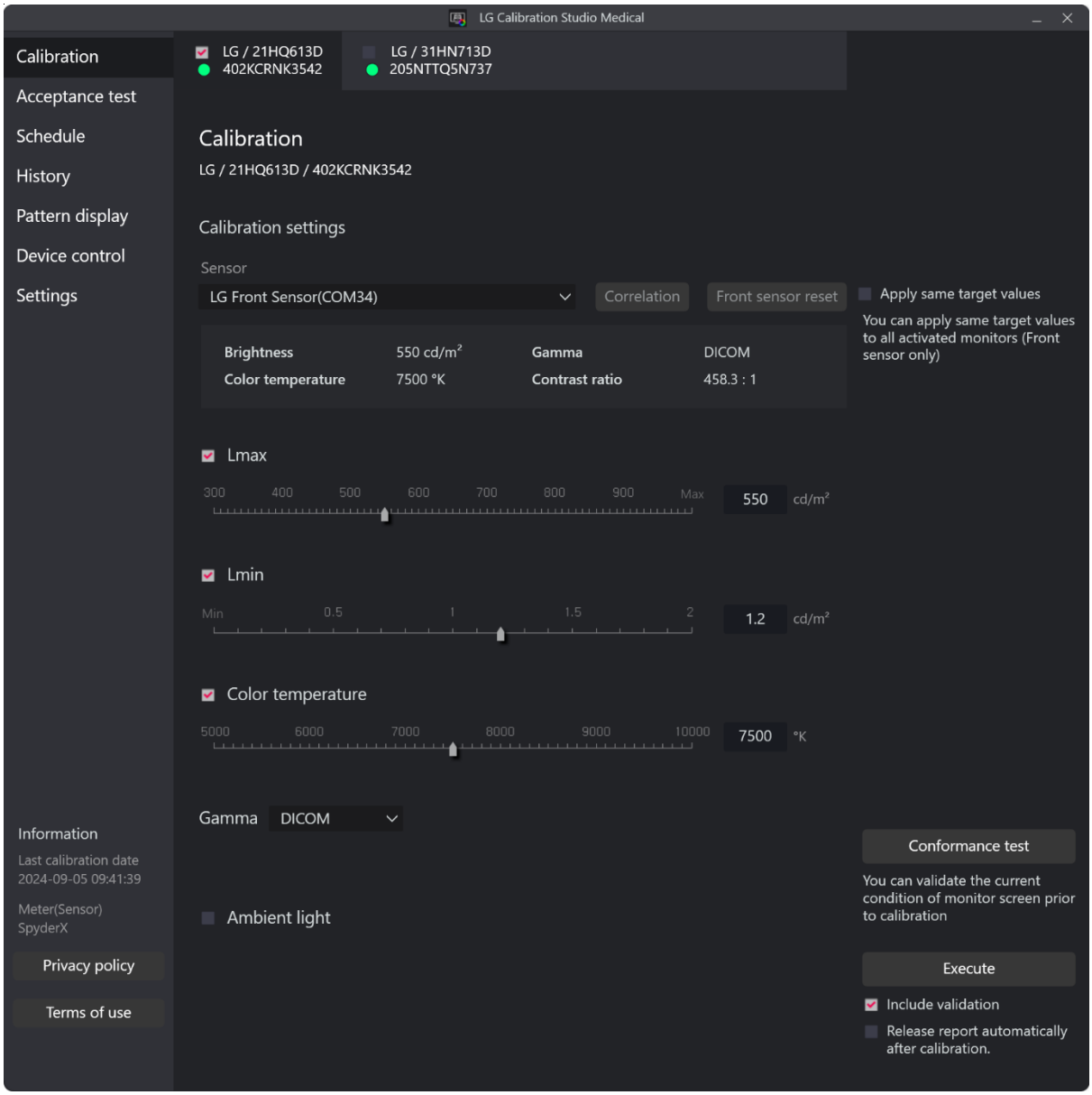
Monthly

5.3 Required Equipment

- 31HN713D or 21HQ613D or 32HQ713D LCD Displays
- PC with Windows Operating System
- Graphic board listed below
  - AMD Radeon Pro WX x100series
  - nVidia Quadro P series
  - nVidia Quardo RTX series
- Graphics board driver
- Calibration software (LG Calibration Studio Medical)
- Builtin sensor in the monitor or external sensor
- Display Color Analyzer CA310 or equivalent

5.4 Procedure

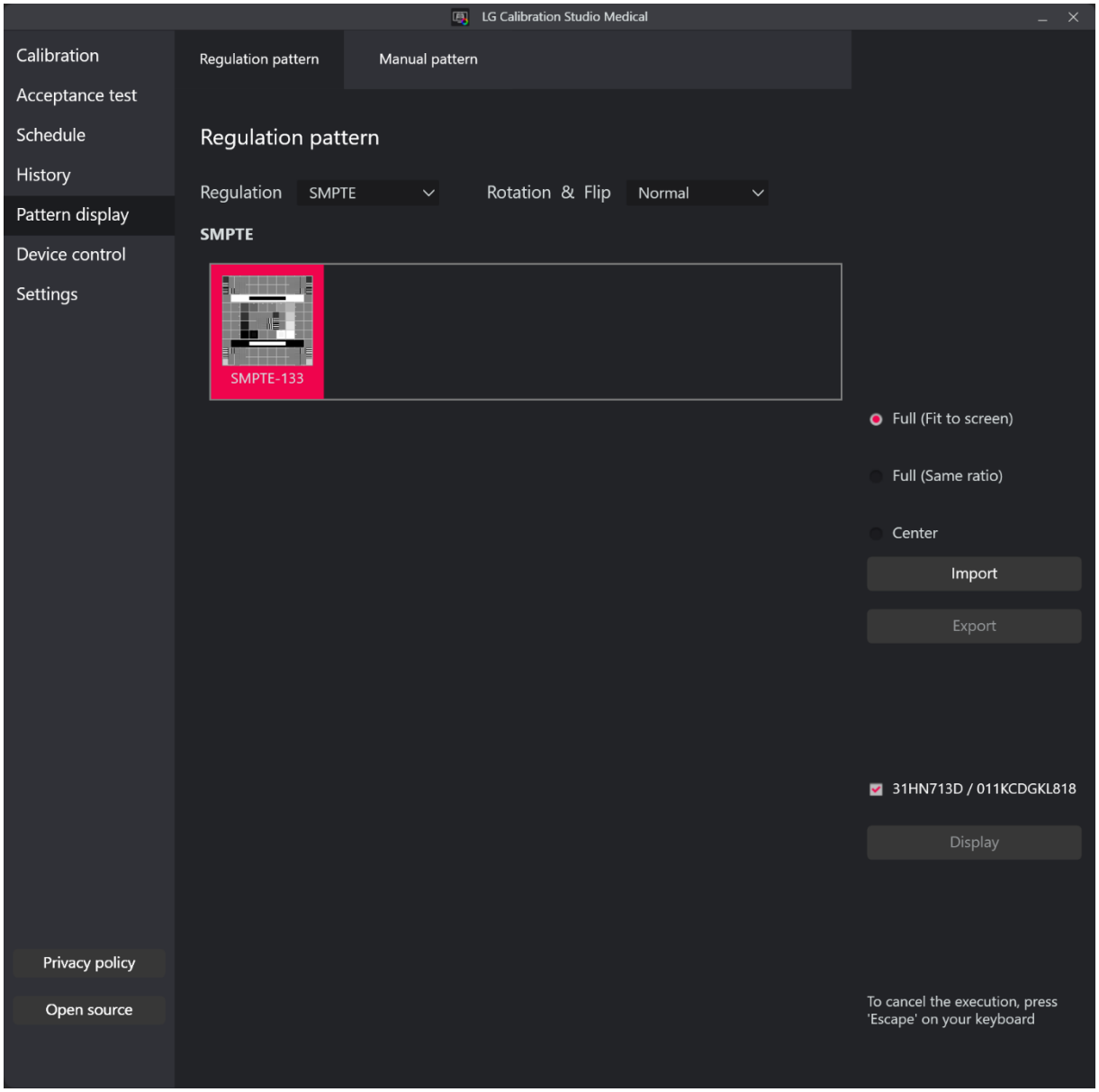
1. Select “Pattern display” from the left menu.



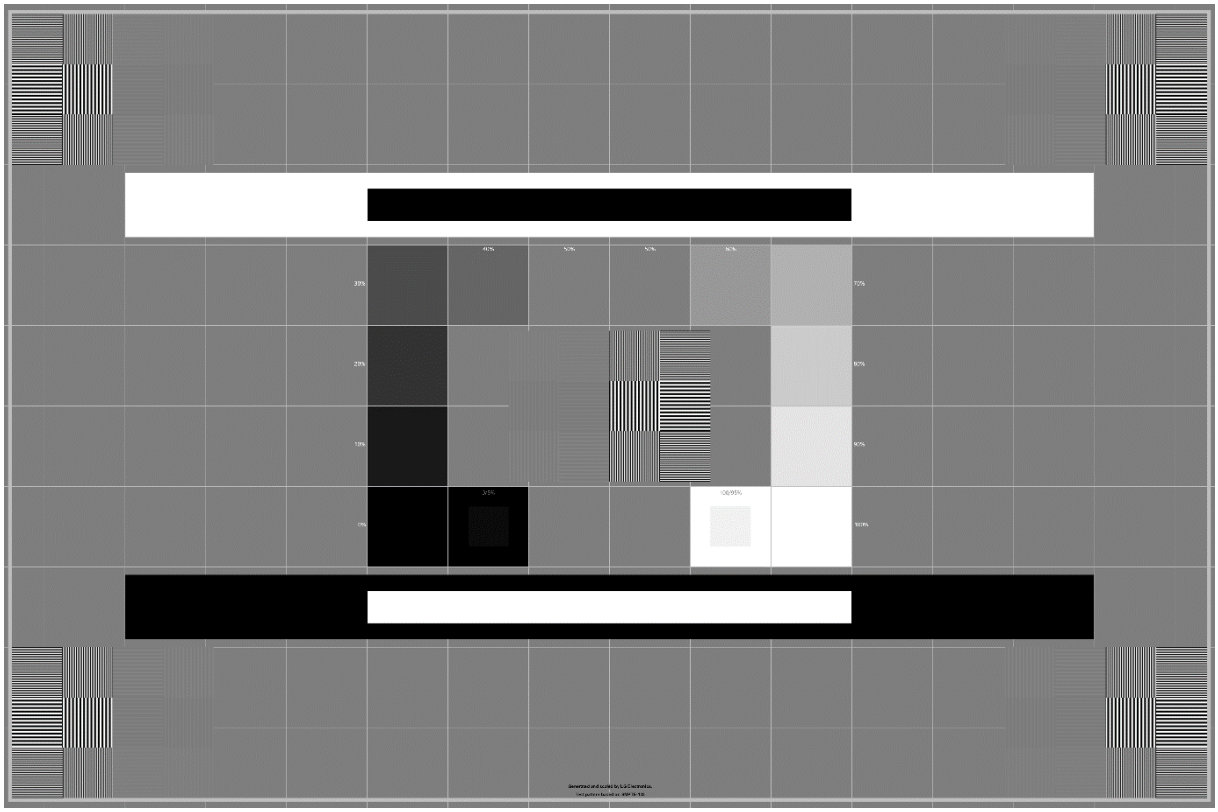
2. Select “SMPTE” on Regulation to find the “SMPTE-133”

3. Click the “SMPTE-133” pattern from Test-Pattern.

4. Check the target display(31HN713D or 21HQ613D or 32HQ713D) and Click the “Display”



5. Check the SMPTE pattern. The “SMPTE” pattern will appear.
   View the display directly in front of the display.
   (The observer must be at least 50cm from the display screen.)



6. Visibility of the following features must be examined.
   a. The 0 -5% contrast pattern
   b. The 95 -100% contrast pattern
   c. The 0 -100% each gray level step from the adjacent squares (For example: the 0 -10% square or the 90 -100% square)
   d. The borders and lines of the pattern and that they are straight and the pattern is in the active area of the display
   e. No distortion and misalignment using the grids across the screen (Linearity)
   f. The sharpness of the alphanumeric characters and that they are in focus
   g. The high contrast line - pair images (each line in vertical and horizontal stripes in the square) at the center and on the corners of the SMPTE pattern without magnification
   h. The streaking in and around the white and the black rectangles (Video Characteristic)

7. Records the results on the form 2 in this manual.

Form 2: SMPTE Pattern

Monthly

Location Name:

Address:

Display Serial No:

Test	Display
0%-5% contrast	
95%-100% contrast	
Gray level steps	
Boarders, lines, centering	
Linearity	
Line-pair images (center)	
Line-pair images (corners)	
Video Characteristics	

(Pass or Fail)

Testing Person Name:

Signature:

Date:

Chapter 2: QC TESTS FOR THE MEDICAL PHYSICIST

1 INTRODUCTION

The QC tests listed in this section must be performed by the Medical Physicist to ensure that the diagnostic display of Diagnostic Monitor for Mammography is operating in its optimal and highest quality standard. These tests also must be performed when a major change that possibly causes the change to its viewing quality and to its viewing performance such as the installation of a new diagnostic display of Diagnostic Monitor for Mammography, the repair or replacement of a major component of the system, or relocation of the diagnostic display happens.

QC tests for the diagnostic display are described in the following sections:

- **Section 3**: Viewing Conditions Check and Setting
- **Section 4**: Display Calibration
- **Section 5**: Image Quality Check – SMPTE pattern

2 INTERVALS FOR PROCEDURES

The table below shows intervals for each procedure described in this manual.

Procedure	Interval
Viewing Condition Check and Setting	Annually
Display Calibration	Annually
Image Quality Check –SMPTE Pattern	Annually

3 VIEWING CONDITIONS CHECK AND SETTING

3.1 Objective

To keep and maintain the optimal viewing conditions on Diagnostic Monitor for Mammography

3.2 Frequency

Annually

3.3 Required Equipment

Illuminance Meter

3.4 Procedure

Before the measurement:
• Turn on displays for at least 60 minutes before starting measurement.
• Reduce any lighting coming from other sources such as view boxes, over head or task lighting to the minimum and check that the ambient lighting is stable (no flickering effect due to any of the lighting sources that are turned on).
1. Make each display as dark as possible.
   (For example, by minimizing the application windows or displaying a black flat field)
2. Measure the illuminance.
   (Face the photometer away from the surface of the display screen during the illuminance measurement.)
3. Check that the measured illuminance value does not exceed 20 lux.
   (Adjust the room ambient light and/or the room configuration to maintain the illuminance value under the limit if it exceeds.)
4. Fill out the display positions, room lights, desk lights, etc. established as optimal on the form 3 in this manual.
   (Note: This data form will be referred by the Radiologic Technologist as optimal during their daily “VIEWING CONDITIONS CHECK” on the page 8.)

5. Record the ambient light value on the form 3 in this manual.
6. Draw a room layout sufficiently accurate on the form in this manual, so that the Radiologic Technologist can reproduce the illumination conditions established as optimal during their daily “VIEWING CONDITIONS CHECK”.
7. Post the form in the reading room, so that the Radiologic Technologist can easily access and refer during their daily “VIEWING CONDITIONS CHECK”.
8. Restore each display to its normal condition, i.e., undo any measures taken in Step 3.4.1 to darken the display.

Form 3: Viewing Conditions Check and Setting

Annually

Facility:
Room:
Date:

Room Description

Display Positions:
Room Lights:
Desk Lights:
Others:
Ambient Light value:

Note: Confirmation of this value is not part of the daily check by the Radiologist Technologist.
Important: The ambient light level must not exceed 20 lux.

Room Layout

Note: Draw sufficiently accurate for the Radiologic Technologist

4 DISPLAY CALIBRATION

4.1 Objective

To ensure that an accurate evaluation of the display will be conducted to perform an accurate calibration for the reading of the mammographic images on Diagnostic Monitor for Mammography

4.2 Frequency

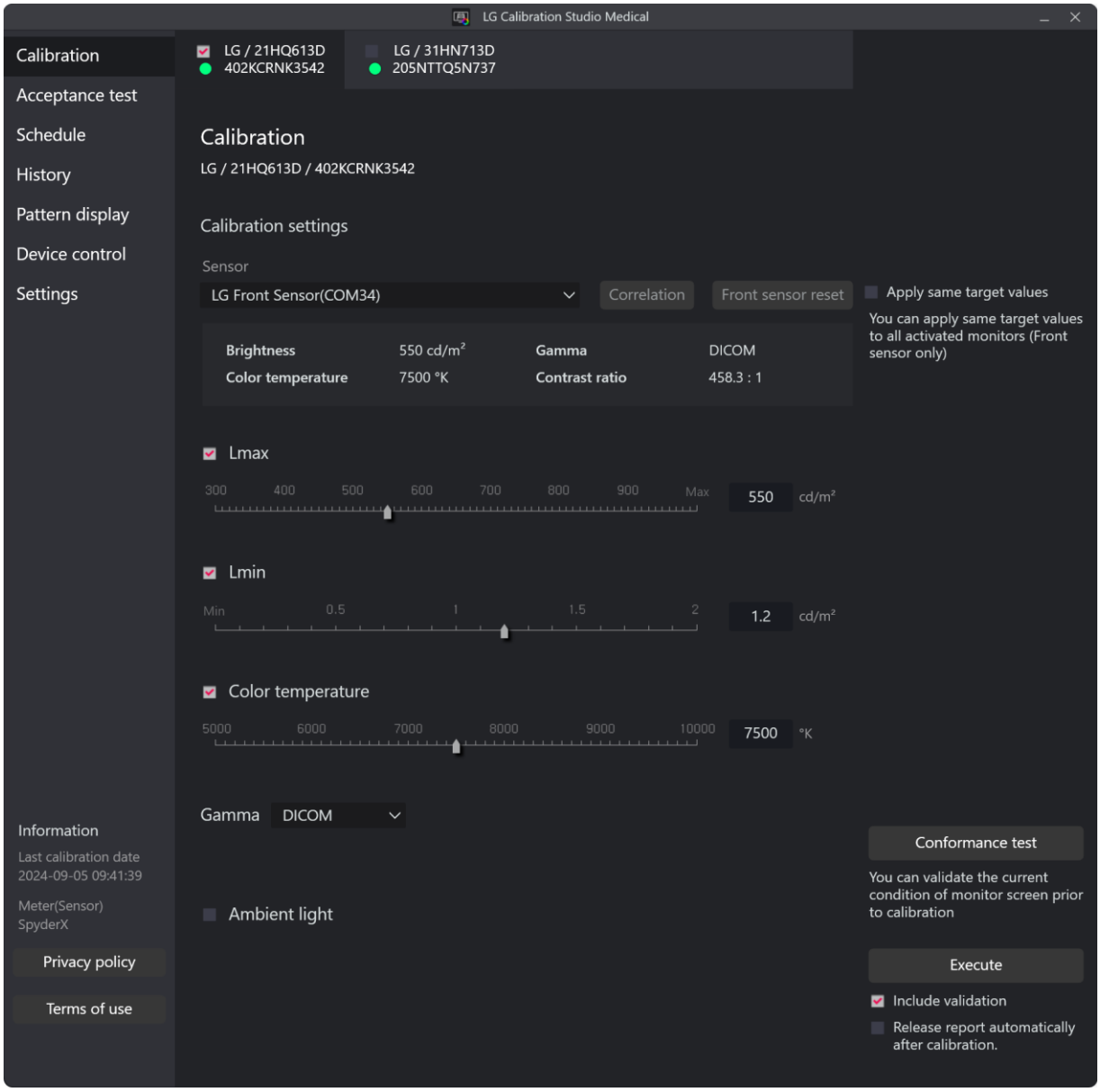
Annually

4.3 Required Equipment

- 31HN713D or 21HQ613D or 32HQ713D LCD Displays
- PC with Windows Operating System
- Graphic board listed below
    - AMD Radeon Pro WX x100series
    - nVidia Quadro P series
    - nVidia Quardo RTX series
- Graphics board driver
- Calibration software (LG Calibration Studio Medical)
- Builtin sensor in the monitor or external sensor
- Display Color Analyzer CA310 or equivalent

4.4 Procedure

1. Display setting should be performed according to the 31HN713D or 21HQ613D or 32HQ713D model. Select “Calibration” from the LG Calibration Studio Medical App.



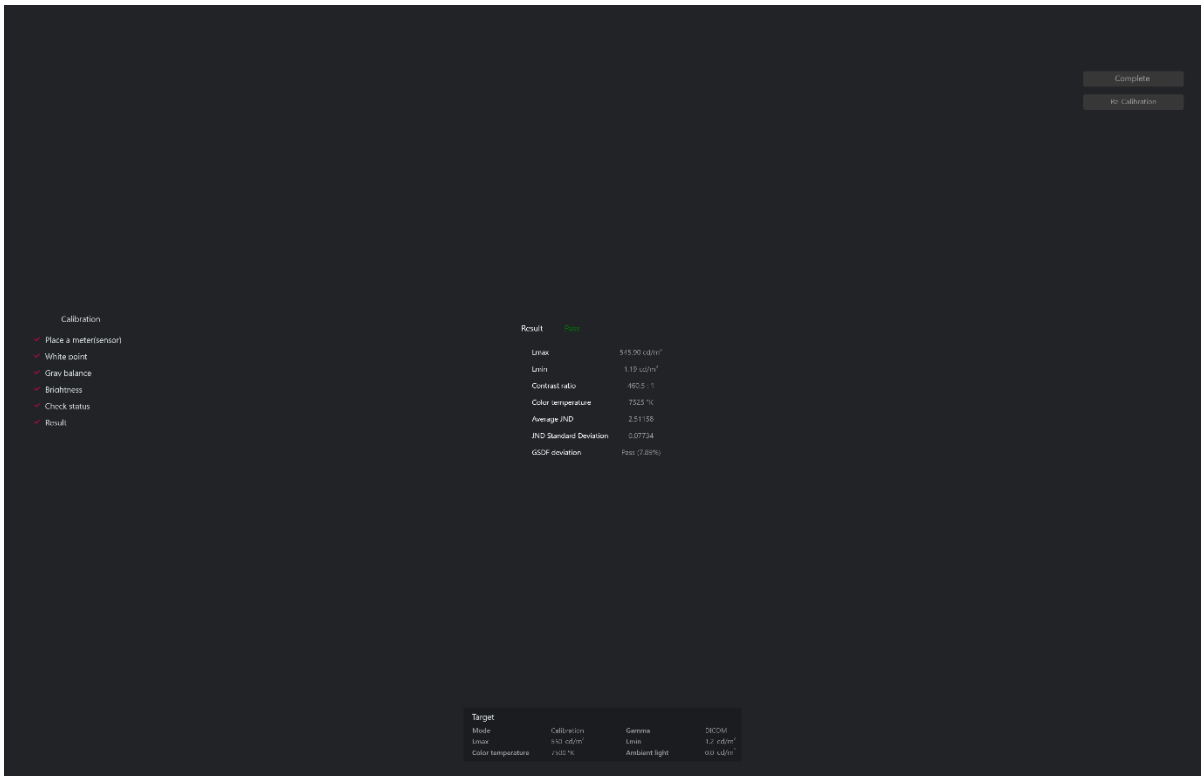
2. Check each item according to the model (31HN713D or 21HQ613D or 32HQ713D).
3. If you select “Calibration Settings” refer to the table below for detail information about each parameter and make necessary changes on the screen. (Lmax : 500cd/m^2~550cd/m^2)

Setting	Explanation
Calibration Type	1. DICOM: Calibrates to NEMA DICOM Part 14 GSDF (Grayscale Standard Display Function) 2. Normal: Calibrates towards the gamma function. Enter a value for gamma. Typically Gamma 2.2 is used.

Color Temperature	Enter a value for color temperature.
Ambient Light	Ambient Light is the reflection of ambient light on the switched off display panel. Enter a value for ambient light in candelas if you know it.
Lmax	Check the “Lmax” box to adjust the white level luminance of the display to a certain value. Enter the target value in candelas into the field.
Lmin	Check the “Lmin” box to adjust the black level luminance of the display to a certain value. Enter the target value in candelas into the field.

4. Record the Gamma setting, max. luminance, min. luminance and ambient light (optional) value of each display set at on the Form 4 in this manual

5. When calibration is completed, see the result and click the “Complete” button.



Form 4: Display Calibration

Annually

Location Name:

Address:

Display Serial No:

Test	Display	
	Setting	Result
Configuration		N/A
Gamma		N/A
Max. Luminance	cd/m2	cd/m2
Min. Luminance	cd/m2	cd/m2
Ambient Light	cd/m2	cd/m2

(Pass or Fail)

Testing Person Name:

Signature:

Date:

5 IMAGE QUALITY CHECK - SMPTE PATTERN

5.1 Objective

To ensure that the display calibration has been performed properly by the evaluation of the black & white levels, gray-scale display function, luminance uniformity and artifact (noise) for the reading of the mammographic images on Diagnostic Monitor for Mammography

5.2 Frequency

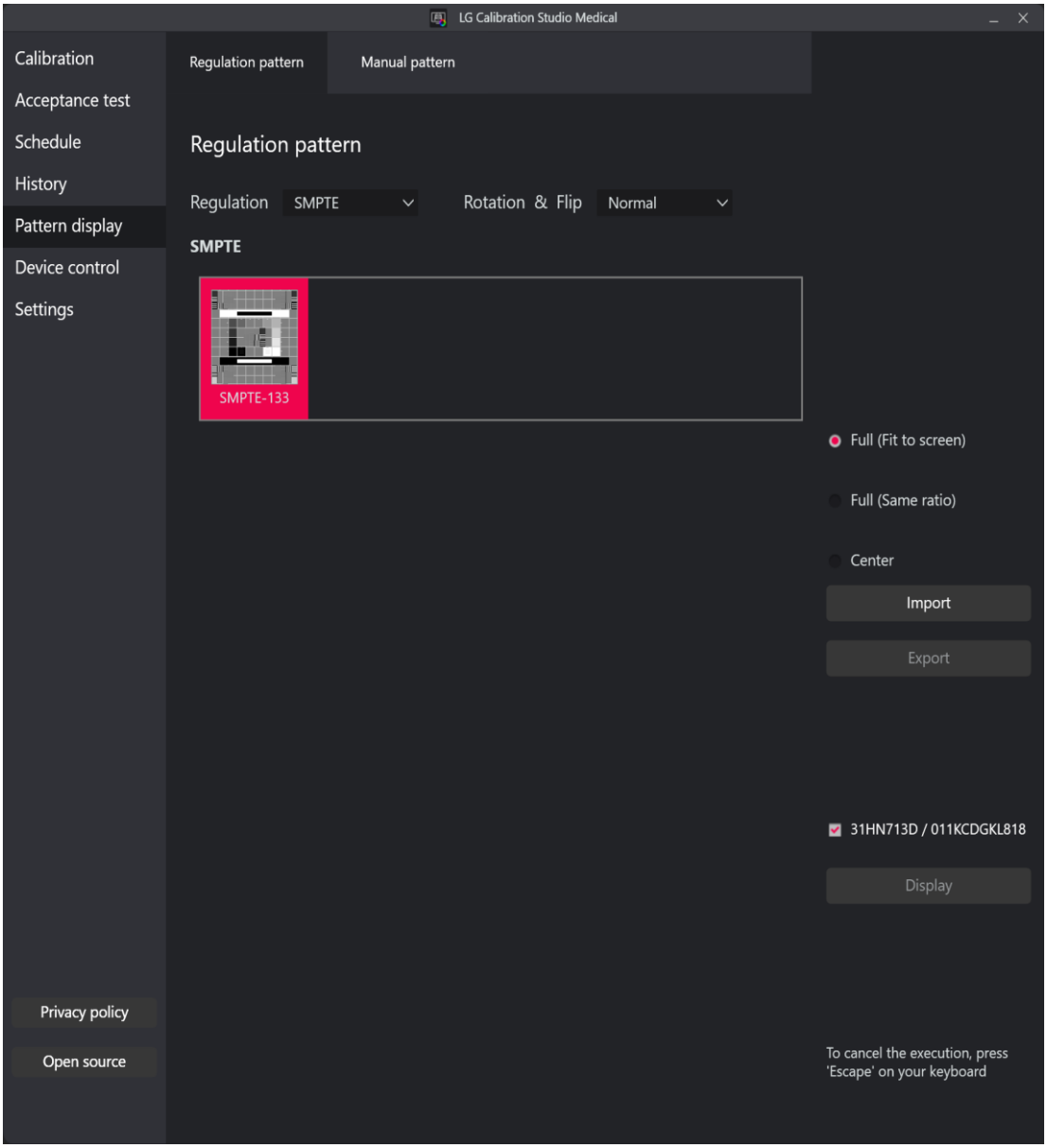
Annually

5.3 Required Equipment

- 31HN713D or 21HQ613D or 32HQ713D LCD Displays
- PC with Windows Operating System
- Graphic board listed below
  - AMD Radeon Pro WX x100series
  - nVidia Quadro P series
  - nVidia Quardo RTX series
- Graphics board driver
- Calibration software (LG Calibration Studio Medical)
- Builtin sensor in the monitor or external sensor
- Display Color Analyzer CA310 or equivalent

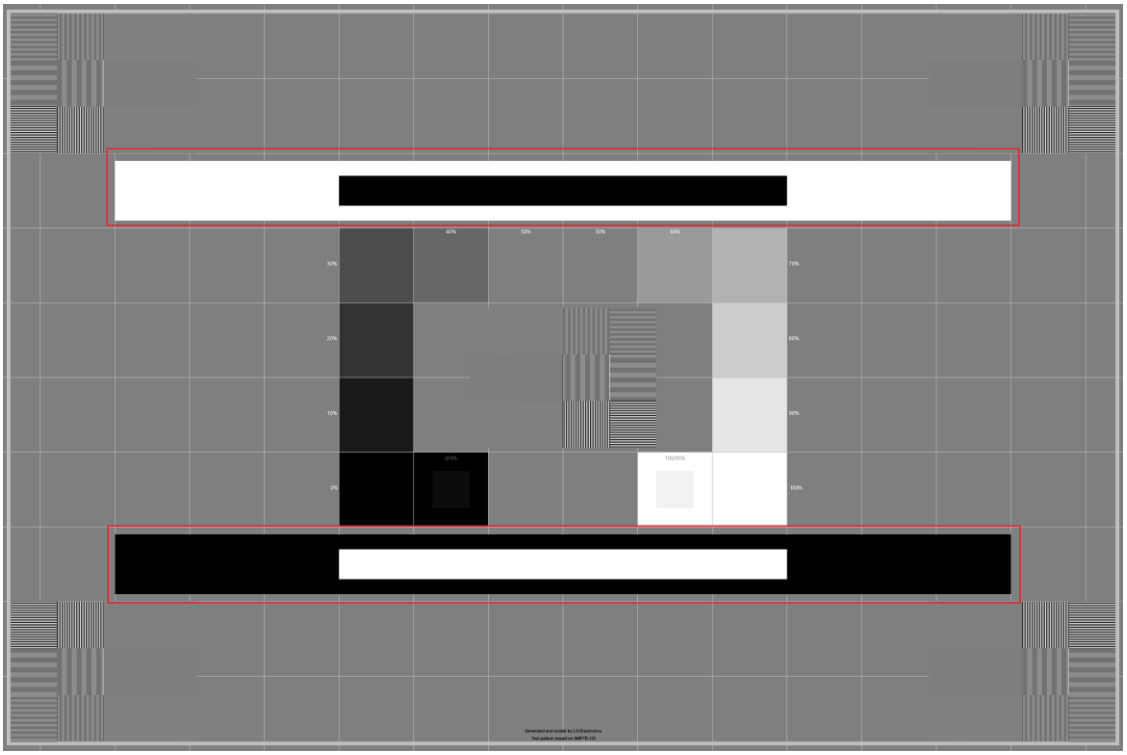
5.4 Procedure

1. Select “Pattern display” from the left menu.
2. Select “SMPTE” on Regulation to find the “SMPTE-133”
3. Click the “SMPTE-133” pattern from Test-Pattern.
4. Check the target display(31HN713D or 21HQ613D or 32HQ713D) and Click the “Display”

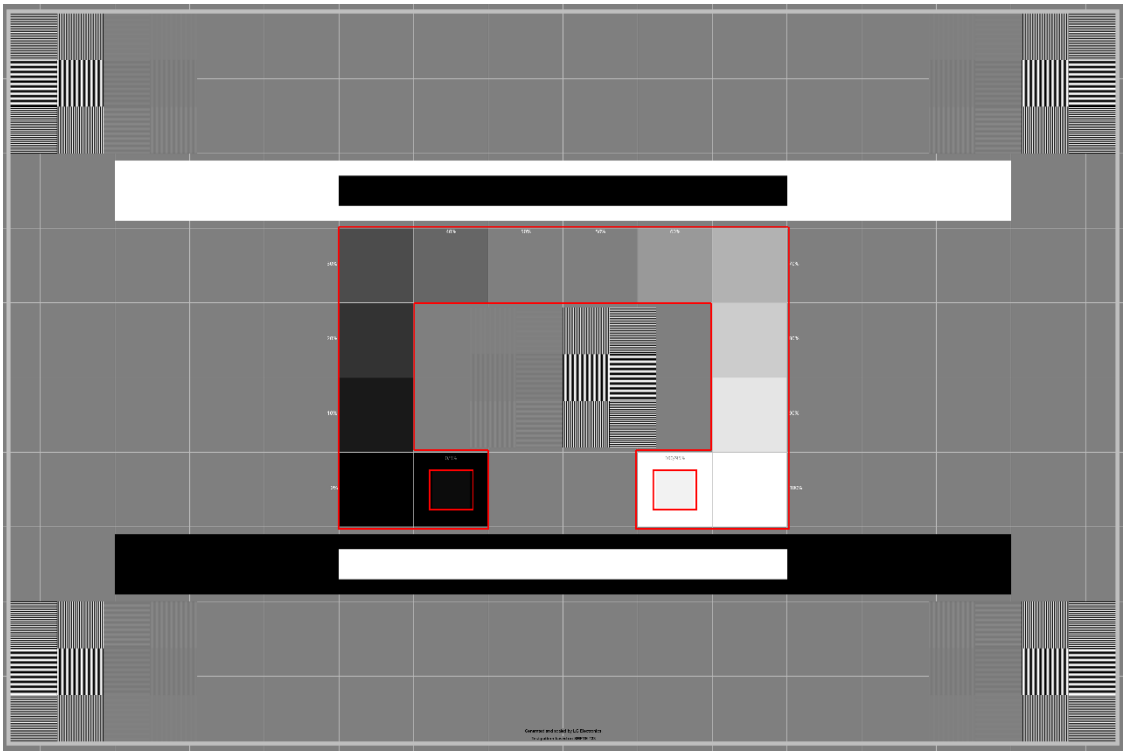


5. The “SMPTE” pattern will appear. View the display directly in front of the display. (The observer must be at least 50cm from the display screen.)

6. Check that black-in-white and white-in-black levels are distinguishable and no artifacts (noise) are observed. Record the result on the form 5 in this manual.



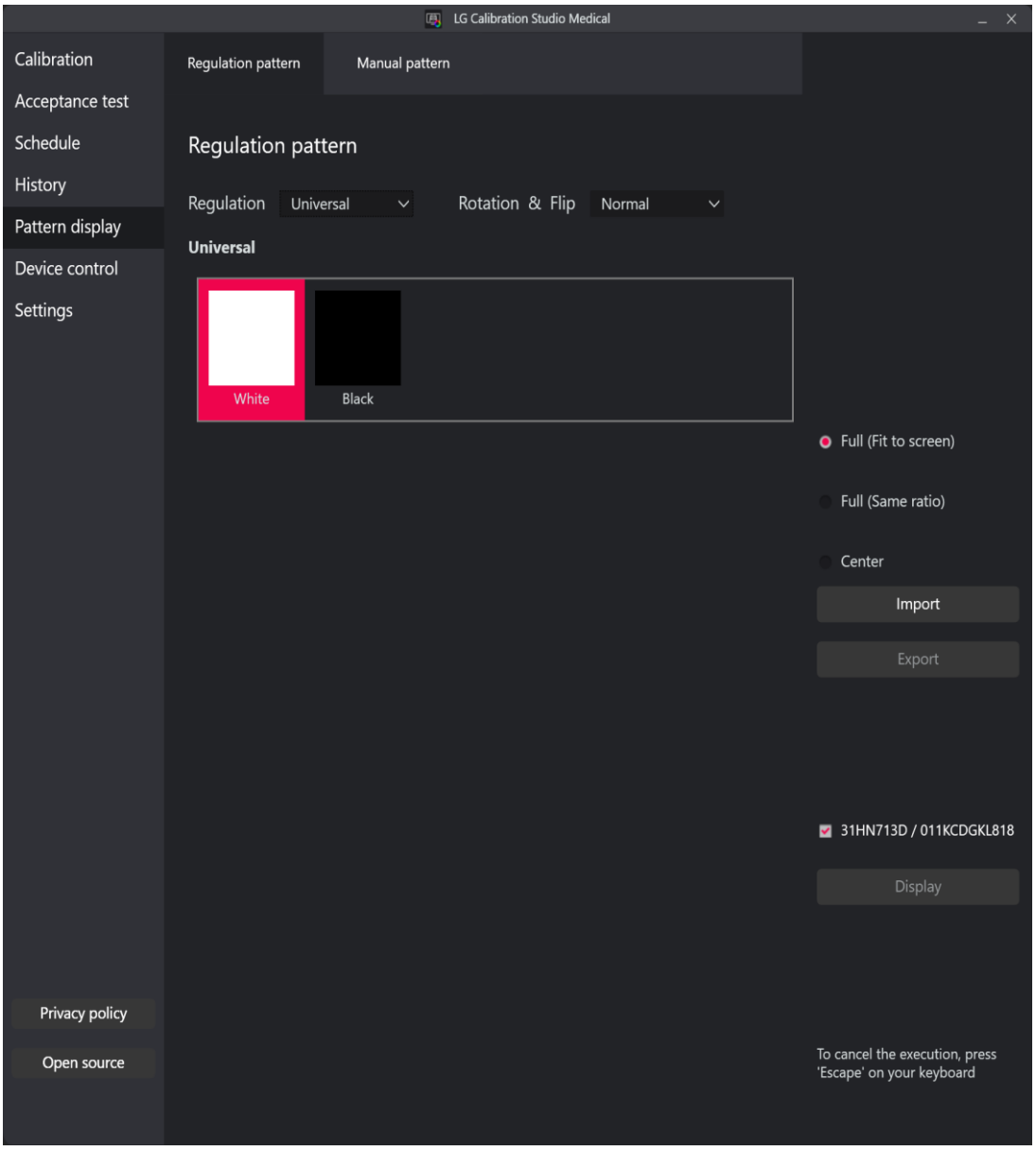
7. Check that each gray-scale pattern and 0-5% & 95 -100% contrasts are distinguishable and no artifacts (noise) are observed. Record the result on the form 5 in this manual.



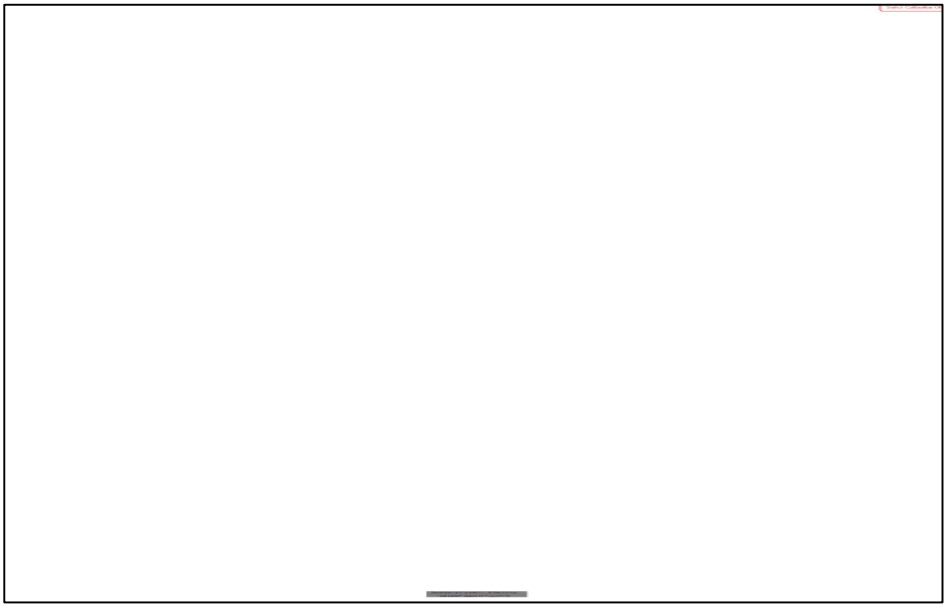
8. Go back to the main screen of “Pattern display”, and select “Universal” on Regulation.

9. Click the “White” pattern from Test-Pattern.

10. Check the target display (31HN713D or 21HQ613D or 32HQ713D) and Click the “Display”



11. The “White” pattern will appear. View the display directly in front of the display. (The observer must be at least 50cm from the display screen.)



12. Check that luminance non-uniformity is not observed from the center to the edges. Record the result on the form 5 in this manual

Form 5: SMPTE Pattern

Annually

Location Name:

Address:

Display Serial No:

Test	Display
Black-in-White & White-in-Black Levels (SMPTE)	
Gray-Scale Display Function (SMPTE)	
5-10%, 95-100% contrast (SMPTE)	
Artifact (Noise) (SMPTE)	
Luminance Uniformity (Full-White or TG18-UN80)	

(pass or fail)

Testing Person Name:

Signature:

Date: