E S A O T E

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MyLab

CnTI OPTION

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CnTI OPTION

This section explains how to use the CnTI (Contrast Tuned Imaging) option[1], available with the **MyLab** system. This section includes the following chapters:

- Chapter 1: The CnTI option

  This chapter explains the intended use of the CnTI licence and provides some general information.

- Chapter 2: Running a CnTI exam

  This chapter explains hot to start a CnTI exam and how to run it.

- Chapter 3: Freeze and Exam Review

  This chapter describes the commands available in Freeze and how to review and archive CnTI images with the **MyLab**.

- Chapter 4: Configuration of CnTI protocols

  This chapter explains how to set a CnTI protocol.

In this manual, control panel keys and software keys are indicated using the following graphical conventions:

Control panel keys	They are indicated by **BLUE CAPITAL LETTERS**. Multifunction keys (e.g. **CLIP IMAGE** on MyLab25 Gold and MyLab 30 Gold models) are indicated with the mention of the first function only (i.e. **CLIP** in this example).
Software keys	They are indicated by **BLACK CAPITAL LETTERS**

The confirmation key is always indicated throughout the manual as **ENTER**, while the menu context key as **UNDO**.

[1] Not for the USA market

WARNING

In this manual a **WARNING** pertains to possible injury to a patient and/or the operator.

CAUTION

In this manual a **CAUTION** describes the precautions, which are necessary to protect the equipment..

Be sure that you understand and observe each of the cautions and warnings.

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Chapter 1

1 - The CnTI Option

CnTI icon

The CnTI license enables the Contrast Tuned Imaging™ (CnTI) technology, dedicated to Ultrasound Contrast Media (CA).

Intended Use

Refer to "Getting Started" manual for probes available on MyLab model.

In this Section of the Operator Manual, the term "**Tissue Mode**" is used to identify conventional B-Mode settings, while **Real Time CnTI Mode**, at low acoustic pressure, refers to B-Mode settings for CA Imaging.

The CnTI Technology is a non linear imaging modality optimized for harmonic signals display. When used at low acoustic pressures, it leverages on a property of specific CA, which reflect harmonics at lower pressures than tissues: this technology allows therefore to differentiate in real time CA from tissue.

WARNING!

Refer to the CA manufacturer specifications and instructions for the resonance characteristics, the regulatory status, the clinical indications and contra-indications of the Contrast Agent. This Manual does not contain information on the CA clinical indication, nor does it lists clinical protocols for use of the CA, for which you need to refer to the CA manufacturer.

On **MyLabFive**, **MyLab40**, **MyLab25**, **MyLab30** and **MyLab50** models, the following probes can be used for CnTI:

	Type	Cardiac	Abdomen	Vascular	SP
PA230[1]	Phased Array	✓	✓		
CA430	Convex Array		✓		
LA532	Linear Array			✓	✓

Refer to the "Getting started" manual for the applications covered by each probe

On **MyLab70** and **MyLab70XVision** models the following probes can be used in CnTI in all applications except Cardiac and Adult Cephalic:

	Type
CA430	Convex Array
CA431	Convex Array
LA532	Linear Array

In the same models the following probes can be used in CnTI in all applications (including Cardiac and Adult Cephalic):

	Type
PA230	Phased Array
PA240	Phased Array

On **MyLab70XVG** and **MyLab90** models the following probes can be used in CnTI in all applications except Cardiac and Adult Cephalic:

	Type
CA430	Convex Array
CA431	Convex Array
CA631	Convex Array
LA332	Linear Array
LA522	Linear Array
LA523	Linear Array
EC123	Convex Array
EC1123	Convex Array
IOE323	Linear Array
TRT33	Linear-Convex Array
BC431	Convex Array
BL433	Linear Array

In the same models the following probes can be used in CnTI in all applications (including Cardiac and the Adult Cephalic):

	Type
PA230	Phased Array
PA240	Phased Array

Safety Information

The guidelines indicated in the "Safety & Standards" manual fully apply to the CnTI technology.

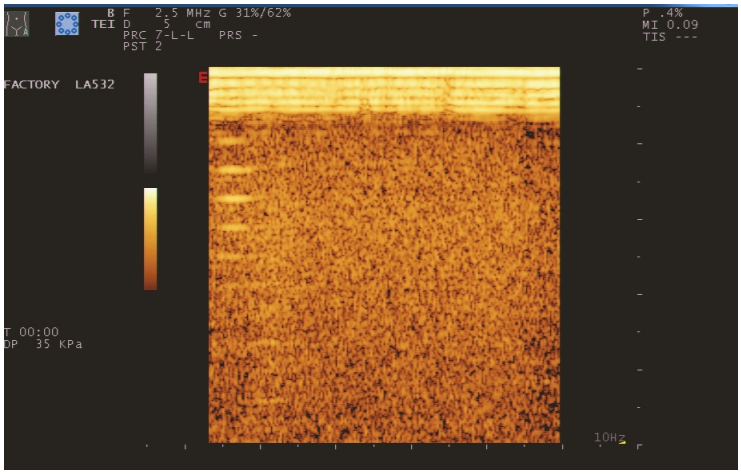
Ultrasound Safety is achieved through the **ALARA** principle during the pre-CA basal study, i.e. the Tissue Mode, while during CA imaging the acoustic pressure directly depends on the CA itself. Ultrasound safety is ensured by the **MyLab** maximal Acoustic Output values and the short duration of the ultrasound

exposure during CnTI studies, while for real time studies it is automatically provided by the low acoustic pressures required.

Disturbances in cardiac rhythm during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic rang of Mechanical Index (MI) values. For details, see the specific package insert of the contrast agent used.

Screen Layout

The following figure shows the screen layout during a CnTI exam:



The CnTI icon is displayed in the image section, next to the bodymark indicating current application.

The test timer (T mm:ss) can be used to control the exam duration. It is possible to activate or reset it. The applied acoustic pressure is indicated by the DP parameter. The value of acoustic pressure is always stored: this means that it will be available both in Freeze and in Exam and Archive Review.

Chapter 2

2 - Running a CnTI Exam

Running a Real Time CnTI Protocol on MyLabFive, MyLab40, MyLab25, MyLab30 and MyLab50

The CnTI package can be activated in real time through the **TOOLS** key: the system lists on the right the selectable real time CnTI protocols.

While in a CnTI Exam, your system keys and controls are regularly available; you can therefore run a complete study before the CA exam

The CnTI modality is automatically activated in Tissue Imaging through the **CONTRAST** key. Currently there's only one selectable protocol, i.e. the Real Time (low acoustic pressure).

In Dual Processing, grey and color scales are combined to separate fundamental from harmonic signals.

Also, there are two alternative CnTI displays when in "full screen" CnTI: it can be set to display only harmonic signals in grey scale, or to simultaneously show fundamental and harmonic signals. In this latter case, named Dual Processing, either harmonic signals or fundamental signals will be color-coded, depending on the selected map

WARNING

Refer to the CA manufacturer specifications and instructions for the resonance characteristics, the regulatory status, the clinical indications and contra-indications of the Contrast Agent. This Manual does not contain information on the CA clinical indication, nor does it lists clinical protocols for use of the CA, for which you need to refer to the CA manufacturer.

Procedure

- Press **START/END** to display the Exam Start page .
- Enter the patient's data.
- Select the desired application and press OK to confirm.
- Press the **TOOLS** key and select the desired protocol.

The **CONTRAST** key switches from Tissue to CnTI Mode (and viceversa) when pressed in Real-Time.

Software Keys in Tissue Imaging

The first two levels of software keys are the ones of the real time 2D mode, the third level shows key **TGC RESET**.

Third level of software keys

TEI
ORIENT
TGC RESET
CLIP DUR
TIMER

Software Keys in CnTI Mode

In real time three menu levels are available: the **NEXT/PREVIOUS** key scrolls the levels. The menu shown when activating the **CONTRAST** key is the following:

FLASH	**CLIP DUR**
ORIENT	**C-MAP**
TIMER	**C-MIX**
FR RATE	**FLASH DUR**

The keys in italics are available in CFM.

When pressing **NEXT** the menu available in the active mode (B-Mode, CFM) is displayed.

Baseline

Before injecting the CA, it is necessary to verify that the acoustic pressure (PR) and the gains of the CnTI Mode are properly set.

Moreover, it is recommended to set the Tissue Mode at low mechanical index (MI): this allows to eventually switch back to Tissue Imaging (**CONTRAST** key) avoiding disruptive effects on the CA..

While format controls (example: **DEPTH**) act on both modes (Tissue and CnTI), all other settings are independent; as an example, changing the transmit focal point position will not modify the Tissue Mode focal point.

Tissue Mode TGC is automatically reset at power on or when changing the probe.

CnTI and Tissue Modes may require different gains settings: Tissue Mode TGC levels are therefore stored when switching to CnTI, so that TGC adjustments can be optimized for CnTI without affecting the Tissue Mode. When back to Tissue Mode, TGC levels are still available but refer to the stored curve. To eventually reset their full range of action, press the **TGC RESET** key.

Tissue Imaging

- If necessary, select the lower imaging frequency out of the Real Time Menu (**FREQUENCY** key)
- Decrease the power level (**POWER** key) to obtain MI values below 0.10
- If necessary, compensate the energy loss by increasing the gains

CnTI Mode

MyLab provides two alternative CnTI: with maximal sensitivity (**FREQUENCY** values of PEN type) and with maximal resolution (**FREQUENCY** values of RES type). This latter option is recommended with the LA532 probe or whenever working at low depth.

- Position the focal point at the bottom of the area under exam
- Set the gains to obtain a homogenous amplification throughout the field of view, at the limit of electronic noise
- If necessary, optimize the acoustic pressure through the **POWER** key, to minimize the residual tissue signals.

Note

MyLab defaults the last used DP value for each probe / application.

The Real time Menu allows to eventually vary the number of transmit focal point (**FOCUSES** key). Options 2 to 4 use a progressive number of adjacent focal points, while option **ALTERNATE** activate two focuses out of three.

The Frame Rate (**FR RATE** key) can be set on a selected value, regardless of the system settings (ex.. PRF), or managed relating to the real time parameters (Free option). During exams with CA, it is recommended to keep the frame rate as allow as compatible with the acquisition of diagnostic images, in order to minimize the CA disruption.

The **C-MIX** key allows to display the fundamental (with the same power of the CnTI exam), the harmonic signal and the Dual Processing presentation. In this latter case it can be defines whether to display in a chromatic scale the harmonic or the fundamental signal (**C-MAP** key).

CnTI Mode in Dual Processing

- Position the focal point at the bottom of the area under exam
- Set the gains (2D gain) to obtain a homogenous amplification throughout the field of view, at the limit of electronic noise
- If necessary, optimize the acoustic pressure through the **POWER** key, to minimize the residual tissue signals.
- If necessary, set the fundamental signal by adjusting the Doppler/Color gain.

CnTI Mode in Fundamental

- Optimize the focus position when necessary.

Note

In fundamental the frequency is fixed and optimized for low MI imaging.

- If necessary, adjust the 2D gain e press **C-MIX** to switch to CnTI.

Performing an Exam with CAs

MyLab provides a timer in minutes: seconds, displayed on the left part of the image; it is possible to activate it (or to reset it) through the **TIMER** keys.

WARNING

Refer to the CA manufacturer specifications and instructions for the resonance characteristics, the regulatory status, the clinical indications and contra-indications of the Contrast Agent.

WARNING

Refer to the CA manufacturer instructions for how to prepare and inject the Contrast Agent.

Usually, no further adjustments are required with respect to the Baseline; should the CA signal be not adequate, gains are available to eventually increase sensitivity; also, the focal point position can be varied to selectively enhance specific areas.

To archive a clip and the whole CA sequence, press the **CLIP** key in real-time. The **CLIP DUR** key selects the clip duration. When unlimited duration is set, the **CLIP** key both starts and stops the clip acquisition while the **FREEZE** key pauses the clip acquisition, which is then restarted when the **FREEZE** key is pressed again.

Flash

In some exams it might be useful to destroy the CA, to review its distribution pattern: the **FLASH** key can be used to generate a Flash, i.e. a preset sequence of images at the maximum acoustic pressure after which low pressure imaging of real Time CnTI is automatically resumed. The **FLASH DUR** key allows to select the duration of the desired Flash (from 2 up to 16 frames and 1 sec).

If needed, Tissue Mode can be resumed at any time (and then the CnTI mode can be reactivated); if not set to low MI, Tissue Mode will obviously have a disruptive action on the Contrast Agent.

Running a Real Time CnTI Protocol on MyLab70 and MyLab90

During a CnTI Exam, your system keys and controls are regularly available; you can therefore run a complete study before the CA exam.

WARNING

Refer to the CA manufacturer specifications and instructions for the resonance characteristics, the regulatory status, the clinical indications and contra-indications of the Contrast Agent. This Manual does not contain

information on the CA clinical indication, nor does it lists clinical protocols for use of the CA, for which you need to refer to the CA manufacturer.

The CnTI protocol can be activated in real-time by pressing the key **CONTRAST**. This key switches between Tissue and CnTI modes.

Software Keys in CnTI Mode

In real time three menu levels are available. The menu shown when activating the **CONTRAST** key is the following:

C-MIX	CLIP DUR
FLASH DUR	DCTI
TIMER START	FLASH
CNTI	

When pressing **NEXT**, the menu available in the active mode (B-Mode, CFM) is displayed. The next two levels of software keys refer to the real time 2D mode.

Baseline

Before injecting the CA, it is necessary to verify that the acoustic pressure (DP) and the gains of the CnTI Mode are properly set.

Moreover, it is recommended to set the Tissue Mode with a low mechanical index (MI): this allows to eventually switch back to Tissue Imaging (**CONTRAST** key), avoiding disruptive effects on the CA.

Low MI Tissue Imaging

- If necessary, select the lower imaging frequency out of the Real Time Menu (**FREQ/TEI** key)
- Decrease the power level (**POWER** key) to obtain MI values below 0.10
- If necessary, compensate the energy loss by increasing the gains

CnTI Mode

- Position the focal point at the bottom of the area under exam
- Set the gains to obtain a homogenous amplification throughout the field of view, at the limit of electronic noise
- If necessary, optimize the acoustic pressure through the **POWER** key, to minimize the residual tissue signals.

While format controls (example: **DEPTH**) act on both modes (Tissue and CnTI), all other settings are independent; as an example, changing the transmit focal point position will not modify the Tissue Mode focal point.

In CnTI **MyLab** can display of the CnTi mode only (that is the signal mainly generated by CA) represented with a chromatic scale; the fundamental mode only (that is the signal coming from the tissue) with the same MI of the CnTI exam; or both signals simultaneously. The display of the fundamental signal helps identifying the structure under exam before injecting the CA.

The **C-MIX** knob switches between the CnTI mode (**CONTRAST**) and the fundamental (**FUNDAMENT**); The **CNTI** knob switches between the CnTI mode (**SINGLE**) and the simultaneous display (**DUAL**) of both modalities.

When in simultaneous display, the fundamental image is shown on the left and the harmonic image on the right: both images are in real-time. By pressing keys ◨ e ◧ the system switches from one modality to the other one to allow controls adjustment.

Performing an Exam with CAs

MyLab provides a timer in minutes: seconds, displayed on the left part of the image; the **START TIMER** key allows to activate it (or to reset it) .

WARNING

Refer to the CA manufacturer specifications and instructions for the resonance characteristics, the regulatory status, the clinical indications and contra-indications of the Contrast Agent.

WARNING

Refer to the CA manufacturer instructions for how to prepare and inject the Contrast Agent.

Usually, no further adjustments are required on the baseline; should the CA signal be not adequate, gains are available to eventually increase sensitivity; also, the focal point position can be varied to selectively enhance specific areas

Flash

In some exams it might be useful to destroy the CA, to review its distribution pattern: the **FLASH** key can be used to generate a Flash, i.e. a preset sequence of images at maximum acoustic pressure, after which low pressure imaging of real Time CnTI is automatically resumed. The **DCTI** key activates a flash at the end of which the system automatically freezes. When in freeze, the **FRAME 1** software key shows the first frame after the flash.

The **FLASH DUR** key allows to select the duration of the desired Flash (from 1 frame to 32 frames).

By pressing **CLIP** in real-time, clip archival is activated to save the whole CnTI phase. The **CLIP DUR** knob selects the clip duration.

The "Contrast" tab of the "General preset" option (**MENU** key) allows further CnTI settings:

- "Automatic storage of flash first frame" automatically saves the first frame of the flash.
- "Lock keyboard on clip" automatically locks the keyboard when acquiring clips in real-time.

If needed, Tissue Mode can be resumed at any time (and then the CnTI mode can be reactivated); if not set on low MI, the Tissue Mode will obviously have a disruptive action on the Contrast Agent.

Chapter 3

3 - Freeze and CnTI Exam Review

This chapter does not apply to MyLab70 models.

This chapter explains the commands available in Freeze and how to review and archive CnTI images.

Freeze Functions on MyLabFive, MyLab40, MyLab25, MyLab30 and MyLab50 Models

The available measurements in CnTI are the ones set for the application.

The **FREEZE** key freezes the image. The system shows the memory scrollbar, where images acquired immediately before freezing the system are temporarily stored.

This scrollbar shows the number of the displayed image or, if the timer was active, the timer value relating to the image.

The **START/END** key allows to automatically place the cursor at the beginning or end of the sequence.

In Freeze the sequence of stored images can be reviewed in cine mode, if the **PLAY** key is active, and at different velocities (**SPEED** key). The **CINE MODE** key displays the whole memory content (when enabled on **FULL**) or individual cardiac cycles, if an ECG trace is available, or seconds intervals, when no ECG is available. In this latter case use the trackball to scroll the bar and display a new cycle/interval.

The single cardiac cycles/intervals, which can be selected through the **CINE MODE** key, can be stored as clips by pressing the **CLIP** key.

The **GRAY MAP** and **COLORIZE** keys allow to select a different post-processing map: **MyLab** provides the same maps range available in real time.

Reviewing the Exam

The **EXAM REV** key, pressed during the exam, allows to review the stored images and sequences. When this key is pressed, the trackball is automatically set in pointer mode and allows to scroll the thumbnails and to select the desired exam. The **SCROLL** software key allows to scroll thumbnails, when more than eight images or sequences are stored. The **PAGE** key scrolls the list by eight thumbnails at a time.

Clips are directly displayed in cine mode: the **PLAY** key disables the cine mode, and allows to scroll the sequence frame by frame through the trackball, with the same rules described for the Freeze mode.

Flash CLips

If the stored clip includes flash sequences, the **CINE MODE** key also includes the option **FLASH**. In this case the system will only show the image sequences relating to the flash interval. The trackball allows to scroll the bar and skip to next flash interval.

Single frames can be stored with the **IMAGE** key; single cardiac cycles and clip portions, which can be selected through the **CINE MODE** key, can be saved by pressing the **CLIP** key.

Ending a Revision Session

Press **B-MODE** to resume real time.

The **MyLab** memory content will be erased only when a new exam is started or when the system is turned off.

Freeze Functions on MyLab70 and MyLab90 Models

The available measurements in CnTI are the ones set for the application.

The **FREEZE** key freezes the image. The system shows the memory scrollbar, where images acquired immediately before freezing the system are temporarily stored.

In Freeze the sequence of stored images can be reviewed in cine mode, if the **PLAY** key is active, and at different velocities (**SPEED** key).

The **GRAY MAP** key allows to select a different post-processing map: **MyLab** provides the same maps range available in real time.

Press **B-MODE** to resume real time.

Chapter 4

4 - Configuration of CnTI Protocols

CnTI Protocols Configuration on MyLabFive, MyLab40, MyLab25, MyLab30 and MyLab50 Models

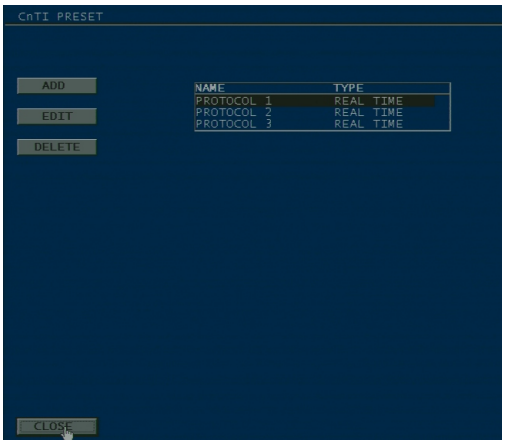
The "Tools Preset" option of the System Menu (**MENU** key) allows to create, modify and delete CnTI protocols.

Note

Only real time CnTI protocols with low acoustic pressure can be configured.

Procedure

- Press the **MENU** key
- Place the cursor on "Tools Preset" and press **ENTER** to display the drop-down menu.
- Select the "CnTI Preset" option.



The system allows to create a new CnTI Preset, to edit an existing one or to eventually delete it.

Setting Parameters

The configuration menu of a CnTI protocol has the following layout:

To quickly move within the configuration menu, use the Tab ⇆ key and the Pgdn ▾ key to open the drop-down menus.

The field **NAME** identifies the protocol to be selected to start the exam. The user can modify the available descriptions or enter new ones through the alphanumeric keyboard.

The field **PROTOCOL** isn't user configurable. Only real time protocols can be configured.

Parameter	
DERATED PRESSURE	Sets the acoustic pressure as Low (≤250kPa) or High (≤400 kPa)
CnTI	Defines whether the first modality optimizes resolution (**R**) or sensitivity (**S**).
C-MIX	Defines the initial value of the **C-MIX** key
C-MAP	Sets the chromatic map to be activated in CnTI.
DYN RANGE	Sets the initial value of the dynamic range.
GRAY MAP	Sets the gray map.
FLASH DURATION	Sets the initial value of the flash duration.
PERSISTENCE	Sets the persistence initial value.
FRAME RATE	Sets the frame rate initial value.

To save the new settings, press SAVE. Pressing CLOSE will exit the menu without saving the new settings.

Factory settings can also be assigned to the preset (FACTORY SETTINGS key).

This key goes back to the User Preset without saving the new settings.

Configuration on MyLab70 and MyLab90 Models

The "General" and "Other" Menu options (**MENU** key) allow to set the following configurations:

Option	Parameter	
GENERAL	**Automatic Storage of Flash First Frame**	The flash first frame is automatically saved when the DCTI key is pressed
	Lock keyboard on Clip	Only the Clip key is active when unlimited clips are acquired. The keyboard is unlocked at the end of the clip acquisition.
	Stop clip when freezing	Clip acquisition is interrupted when either Freeze or DCTI key is pressed.
OTHER	**Automatic unfreeze on 3D CnTI**	Activates real time after 3D CnTI acquisition