Tomosynthesis for Digital Remote Controlled Table with dynamic flat panel detector

Appendix 1 to the User's Manual

REVISIONS HISTORY

Revision	Date	Reason for change
0	30 January 2015	First edition
1	12 February 2016	Graphical modification of interface
2	08 November 2019	New table console
3	30 June 2020	CE1639 New GUI

Please read the whole documentation before using the medical device

IMPORTANT ! ... X-ray Protection
X-RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR
UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

X-ray equipment if not properly used may cause injury. Accordingly, the instructions herein should be thoroughly read and understood before attempting to place this equipment in operation. We will be glad to assist and cooperate in placing this equipment in use.

Although this apparatus is built to the highest safety standards and incorporates a high degree of protection against X-radiation other than the useful beam, no practical design of equipment can provide complete protection. Nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any persons carelessly, unwisely, or unknowingly exposing themselves or others to X-radiation.

It is important that everyone working with X-radiation be properly trained and take adequate steps to insure protection against injury.

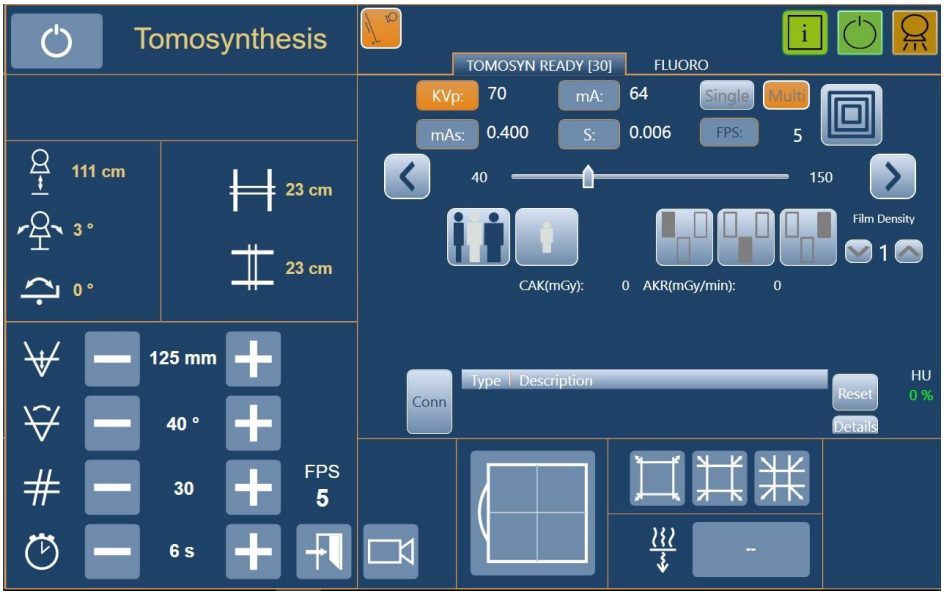
The manufacturer assumes that all operator and service personnel authorized to use, install, calibrate and maintain this equipment is cognizant of the danger of excessive exposure to X-radiation, is sufficiently trained and has the required knowledges for it. The equipment herein described is sold with the understanding that the manufacturer, its agents, and representatives are not liable for injury or damage which may result from exposure to X-radiation.

Various protective material and devices are available. It is recommended that such materials and devices be used.

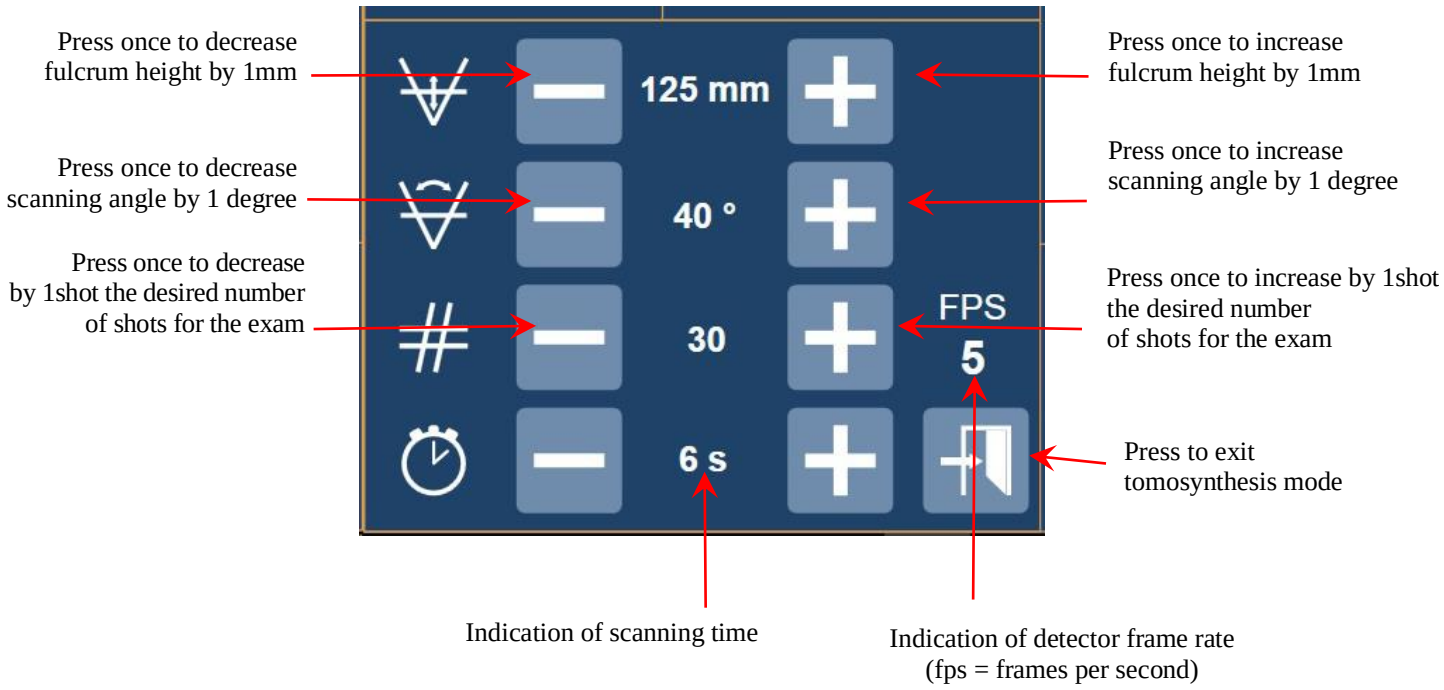
1. TOMOSYNTHESIS USE

The principle of use for tomosynthesis on remote controlled table is to make a simultaneous scanning with the x-ray tube and flat panel detector above and below the anatomical Region Of Interest, while making multiple x-ray acquisitions. With the acquired images, the imaging system reconstructs a volume that the user can explore in a coronal display mode

- Select a programme for Tomosynthesis on Digital system control console
  Refer to the User manuals of Digital System and generator interface for creation, modification of protocols and acquisition parameters
- The following screen appears on the table control console and displays the tomosynthesis parameters



The buttons and labels have the following meaning:



- Install and position the patient as explained in the corresponding chapter in user's manual. This can be done before or after table positioning regarding the exam to do and user working habits

☞***CAUTION:***

Before any table movement, overall tilting or tabletop movements, make sure there are no obstacles that can collide during movement.

To prevent injury to the patient, ensure that patient's clothing cannot be trapped in the equipment. Ensure that the patient remains to the specified handgrips.

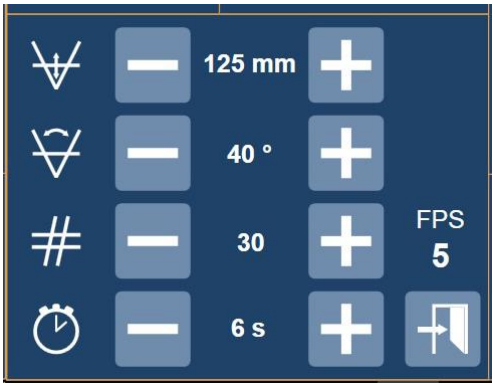
The patient must be correctly and securely positioned (using handgrips, footrest...), before moving or tilting the table (refer to the corresponding chapter in user's manual)

To ensure patient safety, it is essential that the operator keeps eye contact with the patient whereas he controls table motion.

- Press the "MOVE" button and hold it down until the table reaches its final position or position the table manually (refer to the corresponding chapter in the user's manual)

- Modify the acquisition parameters if needed (refer to corresponding manuals)

- Determine the fulcrum height (from 10 to 300 mm) and modify specific parameters for tomosynthesis if needed (total scanning angle under x-ray from 10° to 70°, number of shots from 10 to 80, total scanning time)



The scanning angle influences the quality of the reconstruction, the maximum width and height of the reconstructed volume

The number of shots influences the quality of the reconstruction and the spatial resolution

The scanning time influences on the patient's immobility and unsharpness, as well as total quality of reconstruction

Notes:

The scanning angle, the total scanning time, the number of shots for the exam, the constraints* of the system and the « FPS » (frames per second of the detector) are interdependent

**** System constraints are the minimum and maximum speed of the tube holder column, the combination of the number of frames per second (fps) to the acquisition field on the detector and the maximum number of shots for the exam (limited by the kHU heat capacity of the tube)***

Thus, the manual modification of the tomosynthesis parameters is software-assisted:
Priority to the angle and the number of shots that will never be adjusted by the software
Automatic time adjustment
Automatic adjustment of fps (if necessary) and thus recalculation of time

- Use exclusively the controls on the main table console, the first trigger (preparation) button and the second trigger (emission) button (refer to the corresponding chapter in user's manual)

- Press the Exposure Preparation (1st trigger) button, the column angulation will move to the starting position of the tomosynthesis.
  If needed, you can release the Preparation button and use the carriage movement to center the Xrays on the region of interest, using the light of the collimator
  Note: if tomosynthesis parameters are changed, such as scanning angle, when pressing the Exposure Preparation (1st trigger) button the tube holder will move to its new starting position.

- Check the position switching on the collimator light beam , using video camera (and finalizing with fluoroscopy if really necessary, refer to Digital System and Generator interface User manuals for fluoro mode)

- Adjust the patient position and centring using the movements described in the corresponding chapter in user's manual

- It is possible to reduce the X-ray field using the collimator shutters manual control joystick (, , ,)

- To start the exposure, make sure that the sensor is ready, then press the Exposure Preparation (1st trigger) button, then the Xray Emission (2nd trigger) button.
  The column will rotate and Xrays will be made.
  You MUST keep both buttons pressed during the whole movement. If you release one of them, the table will exit the tomosynthesis mode.
- Once the column rotation is finished, you can release the Preparation and Emission buttons.

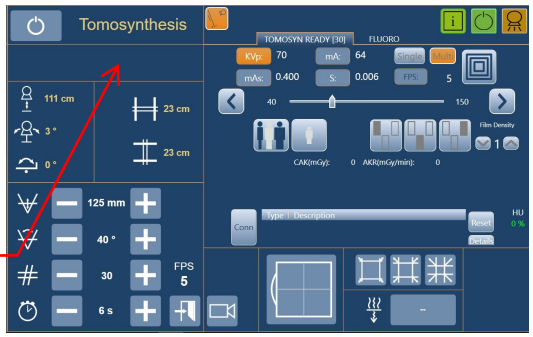
- The reconstructed image (coronal 2D volume) appears a few seconds later on the Digital system control console.
  Refer to Digital System User manual for analysis, post-processing, sending, archiving …

2. MESSAGES

During the routine use of the equipment, the display shows various messages about the status of the table. This includes movement restrictions due to either room configuration or clearance space parameters or present table status.
Please, refer to the corresponding chapter in the user's manual and to the table hereafter for the messages specific to tomosynthesis.

<u>INFORMATION MESSAGES</u>
<u>SPECIFIC TO TOMOSYNTHESIS</u>

These messages appear on the top of the touch screen of the main table control console



Messages displayed on screen	Description	What to do
Minimal scanning time for selected zoom	It appears when you decrease the scanning time and the desired combination of parameters time / number of shots / acquisition field (zoom) is not compatible	If you still want to decrease the scanning time, you can: - select a smaller acquisition field to allow a higher number of frames per second (fps) - decrease the number of shots for the exam
FPS MAX	It appears when you decrease the scanning time and the maximum detector frame rate (fps) is reached with the smallest acquisition field selected	If you still want to decrease the scanning time, you can decrease the number of shots for the exam
FPS MIN	It appears when you increase the scanning time and the minimum detector frame rate (fps) is reached	If you still want to increase the scanning time, you can increase the number of shots for the exam
Max Tube Angulation Speed, Decrease Angle	It appears when you decrease the number of shots for the exam and the desired value of number of shots for the exam requires a movement speed of the tube holder faster than the specifications allow	If you still want to continue, you can decrease the scanning angle
	It appears when you decrease the scanning time and the desired value of scanning time requires a movement speed of the tube holder faster than the specifications allow	
Min Tube Angulation Speed, Increase Angle	It appears when you increase the number of shots for the exam and the desired value of number of shots for the exam requires a movement speed of the tube holder lower than the specifications allow	If you still want to continue, you can: - increase the scanning angle - select a smaller acquisition field to allow a higher number of frames per second (fps) resulting in a longer scanning time and therefore a faster movement speed of the column tube holder
	It appears when you increase the scanning time and the desired value of scanning time requires a movement speed of the tube holder lower than the specifications allow	
Tube Max Capacity, please wait	It appears when you increase the number of shots for the exam and the current x-ray tube heat load does not allow to perform this number of shots	If you still want to continue, you can: - wait for the x-ray tube to recover its capacities to perform such an exam (cooling, anode load ...) - decrease the exposure parameters of the generator
Zoom unavailable. Increase the scanning time	It appears when you select an acquisition field larger than the current one whereas it is not compatible with the current frame rate (fps)	If you still want to continue, you can increase the scanning time so as to reduce the number of frames per second (fps), thereby allowing selection of larger field

In all cases, follow the instructions given on the display.

For any other messages, please first verify that they are not explained in the corresponding chapter in the user's manual before making a note of them and calling the After-Sales Service of your reseller or the manufacturer.