K961403

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Device Name: Life Imaging Systems LIS 6000A – Image Processing System
Life Imaging Systems LIS 8000A – Endocavity Probe Positioner
Life Imaging Systems LIS 8030A – Linear Probe Positioner
Life Imaging Systems LIS 8100A – Alignment Phantom
Life Imaging Systems LIS 8150A – Endocavity Probe Alignment Jig

Common Name: 3D/4D Ultrasound Image Acquisition and Postprocessing System

Predicate Device: TomTec EchoScan, K941332.

Device Description:

LIS6000A

The LIS 6000 is a device which can acquire, display, and post process diagnostic ultrasound images.

Acquisition

Data acquisition involves video grabbing a set (or sets) of ultrasound frames, each frame representing a planar image, while positioning the ultrasound probe such that the set of 2D planes acquired spans a predefined volume with a known relationship between the planes. The probe positioning devices are described below. Three types of acquisitions are defined for the LIS 6000A: ungated, single phase gated and multiphase gated.

Ungated Acquisitions

In this type of acquisition the probe positioner moves at a pre-determined, constant rate set by the system as appropriate for the imaging conditions.

Single Phase Gated Acquisitions

In this type of acquisition at each pre-determined 2D slice position the gating criteria must be satisfied for a video frame to be acquired. Once a frame has been acquired the positioner can move to the next acquisition position.

Multi Phase Gated Acquisitions

In multi-phase gating acquisitions the gating criteria must be satisfied, and video acquisition accomplished, for all required phases at each slice position, before the positioner moves the probe to the next position. The resulting "3D Loop" data set compises an independent 3D data set at each phase of the acquisition. As with any motion picture, cartoon or the like, when like

images from each phase are displayed in rapid succession a moving effect is created for the viewer.

Calibration
Calibration of the pixel dimensions is provided either through operator input immediately after an acquisition sequence has been completed, or through direct communication between the LIS 6000 and the ultrasound imaging system.

Alignment
Probe to probe variations of true image position are determined via a semi-automated alignment procedure utilizing the LIS Alignment Phantom and Alignment Jig, described below.

Post-Processing
Post processing involves two distinct steps. In the first step the set of planar images obtained in acquisition are re-aligned, based on the parameters obtained in the alignment procedure. In the second step the aligned images are reconstructed into a volume of data. These two steps may be carried out simultaneously from the operator's perspective.

Visualization/Image Manipulation
In the visualization step the operator can interactively view the post processed data using the following display types: faceted sub-volumes (convex polyhedra) , 2D planar slices, and rendered images.

Planar Measurements
Planar measurements may be made based on the pixel calibration and acquisition parameters. Measurements offered include distance, area, curve length and volume. Volumes are calculated based on planar areas multiplied by slice thickness. No geometric assumptions are made or computation models used.

LIS 8030A Linear Probe Positioner

The linear positioner is an electromechanical device intended to translate a standard ultrasound probe in as straight line across a patient's body. In operation the probe is mounted in a probe cradle which has been designed to accept a specific probe or probe family. The probe cradle is in turn mounted to a probe stage which is on the linear positioner. The probe stage is attached to and driven by a lead screw which in turn is driven by a DC motor/position encoder assembly. The position encoder allows the LIS 6000A software to track the absolute position of the probe.
An optional stabilizer assembly mounts on the linear positioner to assist the operator in maintaining a steady contact with the patient.
The linear positioner does not attempt to follow a curved body surface. In order to acquire images from body parts which have significantly curved surfaces, multiple shorter acquisitions may need to be utilized. Some degree

of flexibility is afforded by having the probe slide across a small pool of acoustic couplant.

LIS 8000A Endocavity Probe Positioner

The axial positioner is an electromechanical device which is intended to rotate a standard ultrasound endocavity probe about its long axis while it is positioned in its normal imaging position within a patient's body. In operation the probe is mounted in a probe cradle which has been designed to accept a specific probe or probe family. The probe cradle is in turn mounted to a probe stage which is on the axial positioner. A position encoder allows the LIS 6000A software to track the absolute position of the probe. When end-fired endocavitary probes are being rotated the Endocavity positioner an axial data set is obtained. When side fired probes are rotated with the Endocavity positioner a sector data set is obtained.

LIS 8010A Alignment Phantom

The Alignment Phantom is an accessory device intended to be used with the Endocavity Positioner. Its function is to allow the critical alignment parameters, to be determined.

LIS 8050 Endocavity Alignhment Jig

The Endocavitary Probe Alignment Jig is a mechanical device which is an accessory to the Endocavitary Positioner. It is used to make certain that the center of the tip of an endocavitary probe is aligned with its axis of rotation.

Intended uses of the LIS 6000A

B-Mode Acquisition, Ungated or Single Phase Gated

The LIS 6000A is intended to acquire a full resolution set of B-Mode images. The source of these images is the analog video or digital video output of a diagnostic ultrasound system. Image acquisition geometry shall be either linear (parallel slice), axial (propeller slice) or sector (fan slice).

Color Flow Acquisition, Ungated or Single Phase Gated

The LIS 6000A is intended to acquire a full resolution set of Color Flow images. The source of these images is the analog video or digital video outputs of a diagnostic ultrasound system. Image acquisition geometry shall be either linear (parallel slice), axial (propeller slice) or sector (fan slice).

B-Mode Acquisition, Multi-Phase Gated

The LIS 6000A is intended to acquire a high resolution set of B-Mode loops. The source of these loops is the analog video or digital video output of a diagnostic ultrasound system. Gating is accomplished by analyzing externally generated cardiac and/or respiratory signals. Image acquisition geometry shall be either linear (parallel slice), axial (propeller slice) or sector (fan slice).

Color Flow Acquisition, Multi-Phase Gated

The LIS 6000A is intended to acquire a high resolution set of Color Flow loops. The source of these loops is the analog video or digital video output of a diagnostic ultrasound system. Gating is accomplished by analyzing

externally generated cardiac and/or respiratory signals. Image acquisition geometry shall be either linear (parallel slice), axial (propeller slice) or sector (fan slice).

Image Display and Postprocessing

Reformatting and Basic Display

The LIS 6000 is intended to reformat the acquired B-Mode and Color Flow data sets into a single volumetric data space and subsequently display multiple planar cross sections of that space, either individually, or together in a 3D polyhedral display

Volumetric Rendering

The LIS 6000A is intended to display three different volumetric rendering display modes: Maximum intensity, surface rendering and volume rendering.

Measurements

The LIS 6000A will make basic distance, area, and volume measurements based on boundaries defined in user selected cross sectional planes.

Comparison of the LIS 6000A and the TomTec EchoScan

The following table compares the relevant features of the TomTec EchoScan and the LIS 6000A

Property/Feature	LIS 6000A	TomTec EchoScan
Device Use	Adjunct to ultrasound system	Adjunct to ultrasound system
Data Source	2D images from standard ultrasound system	2D images from standard ultrasound system
Scan Plane Positioning	Motor driven, ultrasound probe adapter	Motor driven, ultrasound probe adapter
Acquisition Gating types	None, Respiration, ECG, ECG and Respiration	None, Respiration, ECG, ECG and Respiration
Patient Contact Electrodes	No - Requires external ECG trigger and Respiration signals	Yes - On board ECG/Impedance plethysmograph
Effect on US acoustic output	None	None
Reconstructed 2D Slices	Yes	Yes
Rendering Modes	Surface, Volume, Maximum Intensity Projection	Surface, Maximum Intensity Projection, Minimum Intensity
Video Acquisition	Grayscale, Color	Grayscale
Measurements	Distance, Area, Volume	Distance, Area, Volume, 3D Distance
Artifact Reduction Processing	Probe mis-alignment and respiration	Respiration
Compression	None, Lossless	None