Hepatus Diagnostic Ultrasound System

Performance Specifications

System Overview

Functions

The system is intended to provide ViTE (Visual Transient Elastography) to estimate the liver stiffness, as well as ultrasound coefficient of attenuation LiSA (Liver Ultra-Sound Attenuation) to evaluate the liver steatosis with quantitative results.

The ViTE and LiSA can be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of liver.

Application

Abdomen

Physical Specification

Dimensions and Weight

Height:	1300±15 mm
Width:	584±15 mm
Depth:	710±15 mm
Weight:	approx. 57.5±5 kg

Transducer Types

Curved array transducer ViTE transducer

Probe Ports: 2 active universal probe ports

Standard Features

B-Mode M-Mode Color Doppler Imaging Power Doppler Imaging and Directional PDI Pulsed Wave Doppler Zoom/iZoom (Full Screen Zoom) Post processing function 256 GB SSD Built-in wireless adapter 4 USB 3.0 ports Touch Gestures iStorage MedTouch iScanHelper

Optional Features

DICOM iNeedle[™] (Needle Visualization Enhancement) iWorks DVR module McAfee iVocal Support voice recognition function by inputting systemrecognizable voice commands

through microphone Authorization software for ultrasound measurement ViTE License A ViTE License B ViTE License Free

Built-in battery

Replaceable and rechargeable lithium battery Light indicator

- Full battery lasts more than 22 hours in standby mode
- Empty battery recharged to full in less than 4 hours

Continuous work time: more than 2 hours Lithium-Ion Battery Pack 14.8V, 5800mAh (single battery)

Language Support

Software: English

Built-in Wireless Adapter

Encryption: WPA-PSK, WPA2-PSK Max transfer speed: 300 Mbps Protocols: 802.11b: 11.5.5.2.1 Mbps 54, 48, 36, 24, 18, 12, 9, 6 Mbps 802.11g: 802.11n: Up to 300 Mbps

Voltage: Frequency Input current: 3.5 A Power input:

30%-85% (no condensation)

Ambient temperature: -20-55 °C Relative humidity: 20%-95% (no condensation) Atmospheric pressure: 700 hPa-1060 hPa

Imaging Modes

B-Mode THI and PSH[™] (Phase Shift Harmonic Imaging) M-Mode/ Color M-mode Color Doppler Imaging Power Doppler Imaging/Directional PDI Pulsed Wave Doppler

15-inch high resolution color LED monitor Resolution: 768*1024 Viewing angle: 85°left/right; 85°up/down Digital on-screen display of brightness and contrast controls Frame rate (Hz): 60 Hz

System Boot-up

Boot-up from complete shut-down in about 34 sec Shut-down in about 6.5 sec Restore from standby mode: about 6 sec

Screen Lock

Lock the screen for 10 seconds for cleaning and disinfecting the main unit.

Comments

Supports text input and arrow Support freehand marking on touch screen Covers various applications User customizable

Body Mark

144 body marks for versatile application



Numbers of Exam Mode Presets

7 system exam modes (unlimited number for user-defined ones)

Positioning

Real time 2D ultrasound for ROI position, and adiustable Sample volume ≥6 cm³

Quality Control

Probe pressure index Indicate the proper probe pressure during the exam. Motion stability index Ensure the respiratory stability

Data Acquisition

Data acquisition Mod	e
C-scan (Continuous	
Acquisition):	The number of measurements can be set to (1, 5, 10, 15) for each group and all results will be recorded.
Q-Scan Acquisition:	Automatically acquire 10 valid measurements, and delete invalid results.

At least 3 type of method to start the data acquisition.

Acquisition Results

Measured Value Display Patient information Median value of liver stiffness Median value of liver steatosis E: Liver stiffness LiSA: Liver Ultra-Sound Attenuation Inter-Quartile value Success rate

Total number of acquisition results

Number of valid acquisition results

The Elastogram displays the propagation of shear wave. It shows the depth and transmission time of shear wave, and can help to verify the accuracy of acquisition results.

Data Edit

Support data curves, and allow to delete the selected result which is not accurate, the statistical results will be updated immediately.



Electrical Power

100-240 V~ 50/60 Hz 4.4-2.5 A

Operating Environment

Ambient temperature: 0-40 °C Relative humidity: Atmospheric pressure: 700 hPa-1060 hPa

Storage & Transportation Environment

Visual Transient Elastography (ViTE)

User Interface

Monitor

Elastogram

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Imaging Parameters

Available on probe LFP5-1s 8 mm x 30 mm - 10 mm x 60 mm, ROI: adjustable C-Scan: 1, 5, 10, 15 Q-Scan: Automatically capture 10 valid results as one group and delete the invalid result Elas, Metric: E, Cs Elastogram: EG1, EG2 **Display Format:** 2D, E, 2D+E Map: E1, E2, E3, E4, E5 Display Result: E + LISA, E, LISA New Batch: On/Off Recapture all: On/Off M-STB Index: On/Off M-STIB Sensi.: 0, 1, 2, 3, 4 Filter: 0.1.2 LiSA ROI: On/Off Probe Control: On/Off Tissue stiffness measurement Measurement depth 20 - 90 mm range: Elasticity display range: 1.5 kPa - 75 kPa Measurement accuracy: within ±5% Fat attenuation measurement LiSA display range: 90 dB/m - 450 dB/m Accuracy of LiSA Within 20% measurement. Repeatability of LiSA Within 5% measurement: 2D sampling Probe pressure motion stability indicator Shear wave frequency: 50Hz

Transducers

ViTE Transducer

LFP5-1s

Application:	Abdomen
Bandwidth:	1.0-5.7 MHz
Number of elements:	44
FOV (max):	90°
Depth:	4-38 cm
Physical footprint:	22 mm x 21.4 mm
Footprint:	13.6 mm x 12.7 mm
B-mode Frequencies:	1.0~3.2, 1.9~4.6, 2.3~5.7 MHz
Harmonic Frequencies:	3.8, 4.0, 5.0, 6.0 MHz
Doppler Frequencies:	2.0, 2.5, 3.0 MHz
Shear Wave Frequency:	: 50 Hz
Biopsy Guide:	None

Curved Array

C5-1s

Application:	Abdomen
Bandwidth:	1.0-5.7 MHz
Number of Elements	: 128
FOV (max):	61°
Extended FOV:	101°
Convex Radius:	60 mm
Depth:	4-40 cm

Physical Footprint:	76.5 mm × 28 mm
Footprint:	64.9 mm × 16.2 mm
B-mode Frequencies:	1.0~3.2, 1.9~4.6, 2.3~5.7 MHz
Harmonic Frequencies:	3.8, 4.0, 5.0, 6.0 MHz
Doppler Frequencies:	2.0, 2.5, 3.0 MHz
Biopsy Guide:	NGB-022, multi angle, reusable

Report

Specific report template by applicationEditable value in report Images selectable Report content (including hospital information) editable Supports graphic and digital report, trend graphic viewing Able to Export as PDF/RTF/CSV file

Exam Storage and Management

Exam Storage

256 GB SSD. More than 172GB internal hard drive for patient data storage Capable of storing up to approximate 1685561 single frames Direct digital storage of single frame and cine 2D, color and Doppler. Exam Management iStation[™] workstation dedicated for patient exam management Patient exam query/retrieve

Support review of current and past exam

New exam, Activate exam, End exam are available Support measurements and calculations on archived exam and images

Export images as (BMP/JPG/FRM/CIN/TIFF/DCM/AVI format)

Exam data export in batches: export data in CSV file Support backup/send to USB devices (hide patient information); support back up to DVD-RW media Support data encryption and transmission encryption

Cine Review

Available in all modes Frame by frame manual cineloop review or auto playback with variable speed Maximum cine memory up to 29606 frames or

385.2 s (M) Retrospective and prospective storage are available

and length is pre-settable (Prospective: Max. time 480s; Retrospective: Max. time: 120s)

Connectivity

Ethernet Network Connection

Cable connection Wireless connection: built-in wireless adaptor

DICOM 3.0 DICOM basic Verify (SCU, SCP) Print Store Storage Commitment Media Exchange

DICOM Worklist (HL7 supported) DICOM Query/Retrieve DICOM Modality Performed Procedure Step - MPPS

iStorage (included in UltraAssist)

Direct network storage tool between ultrasound system and personal computer

HIS Query/retrieve

Obtain patient information from HIS server

MedTouch

Connect Ultrasound machine to smart devices based on Android and iOS system, such as tablet PC or mobile phone. Remote control of Ultrasound machine, and tutorial software iScanHelper study on smart devices Support Android and iOS powered smart devices

Android 4.0 and above iOS 7.0 and above

Anti-virus Software

McAfee Windows Defender

Peripheral Devices and Accessories (Option)

Black/white Digital Video Printer MITSUBISHI P95DW-N

Black/white Analog Video Printer SONY UP-X898MD

Digital Graph/text Printer HP OFFICEJET PRO 8100

Color Digital Printer SONY UP-D25MD

Footswitch

USB port: 971-SWNOM (2-pedal) USB port: 971-SWNOM (3-pedal)

Barcode Reader

Laser barcode scanner

- Model: DS4308 JADAK Barcode reader
- HS-1M and HS-1R (supporting Model: RFID)

External DVD R/W Drive ASUS:

SDRW-08D2S-U

iVocal Microphone

Mo	bde	el:		

SAMSON XPD1 Headset, SAMSON XPD1 Presentation, and PYLE PUSBMIC43

ECG Module		
ECG lead port:		

6 pin, IEC&AHA, for 3-lead wires

System Inputs and Outputs

HDMI:	1 port
ECG connector:	1 port
USB:	4 USB 3.0 ports
Ethernet:	1 port



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Performance Specifications

Ultrasound Extended Function

Overview

Echo-enriched Beamforming Up to 55296 channels Up to 8-beamforming

THI and PSH[™]

Patented PSH[™] technology, obtains purer harmonic, better contrast resolution, higher SNR, exceptional high frequency harmonic

Color Doppler Imaging

Power Doppler Imaging

Support directional power doppler Dual Live: On/Off

PW

Safety and Conformance

Quality Standards ISO 9001 ISO 13485

Design Standards

EN 60601-1 and IEC 60601-1 EN 60601-1-2 and IEC 60601-1-2 EN 60601-1-6 and IEC 60601-1-6 EN 60601-2-37 and IEC60601-2-37 EN 62304 and IEC 62304 EN 62366 and IEC 62366 EN ISO 17664 and ISO 17664

Page 3 of 3

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