Hepatoscope Initial Training Process

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Hepatoscope is intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging of the human body and provides measurements of shear wave speed and tissue stiffness, ultrasound tissue brightness parameters such as ultrasound beam attenuation and backscattering coefficient, and estimates of speed of sound, in internal structures of the body. The device is intended to be used by trained healthcare professionals, in a healthcare environment.

The Hepatoscope App using the e.C5-1 probe is indicated for imaging of anatomical structures in the abdomen and measurements of physical properties in the liver and the spleen. In particular, the device is intended to provide:

- *Linear distance measurements of anatomical structures,*
- *Measurement of shear wave speed at selected shear wave frequencies, and estimates of tissue stiffness in the liver and the spleen,*
- *Estimates of ultrasound tissue brightness parameters in the liver at selected ultrasound frequencies,*
- *Measurement of brightness ratio between structures and in particular between the liver and the kidney,*
- *Estimates of speed of sound in the liver,*
- *Estimates of an ultrasound-derived fat fraction index.*

The shear wave speed measurements, ultrasound tissue brightness parameters, elastic properties estimates, brightness ratio may be used as an aid to the diagnosis, monitoring and clinical management of adult and pediatric patients with liver disease. The Hepatoscope ultrasound-derived fat fraction index (HDFF) may be used as an aid to the clinical management of adult patients with liver steatosis.

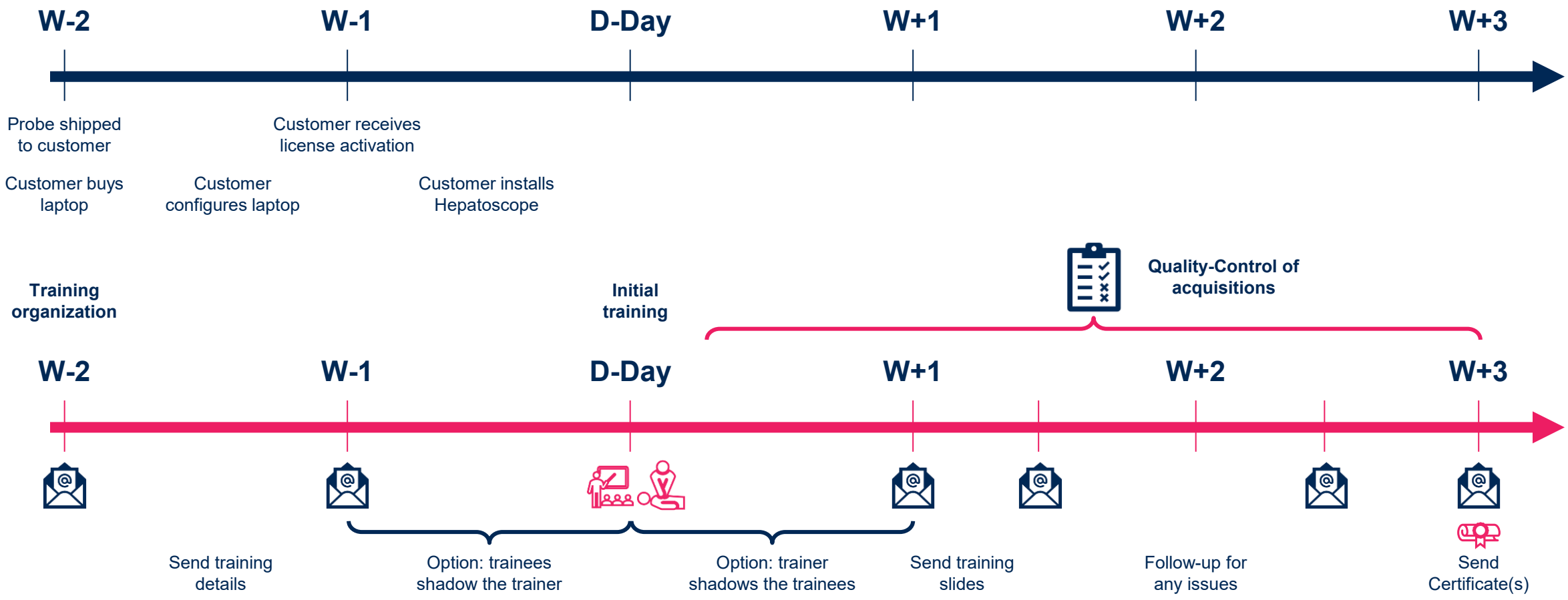
hepatoscope by escopics

A 5-week standardized process for efficient training & monitoring

From training organization to operator's certification

- **W-2: training organization, sharing of initial online training support material: tutorials for office managers, IT team, operators and physicians**
- **W0: practical onsite training on patients + practice shadowing during first 2 days / operators**
- **W+1-W+3: review of acquisitions either remotely (HepatoReader) or onsite (exams reports)**
- **W+1-W+3: corrective actions**
- **W+3 at earliest: certification**

Hepatoscope Onboarding & Training Timeline



W-2 - Training prerequisites

Onboarding actions

- **Probe shipped to customer**
- **Customer buys laptop**

Email sent automatically by E-scopics Support team to Hepatoscope System Administrator

- **General information**
- **Credentials to connect to ES Series App Store (ID & PW)**

Information shared

- **To all / Site admin**
  - Movie Intro to Hepatoscope
- **To IT team**
  - Laptop requirements
  - Tutos
    - ES Series App Store Download & Installation
    - Hepatoscope software Download & Installation
  - Instructions
    - Windows Update
    - Admin Settings
    - Laptop performance setting
- **To Operators**
  - Movie Essentials of Hepatoscope exam
  - Training agenda
  - Instructions Hepatoscope typical exam
  - Hepatoscope User Manual (current version)

W-2 – Training organization

Training requirements

- **Exact address, date & time**
- **2 to 4 trainees maximum**
- **Secure the following:**
  - 4-hour training slot
  - Standard examination room
  - Examination bed
  - Main power plug accessible
  - Table/support to place the laptop on it
  - Ultrasound gel, paper towels, disinfecting wipes.
  - **8 to 10 patients**
  - Connection to WiFi if allowed

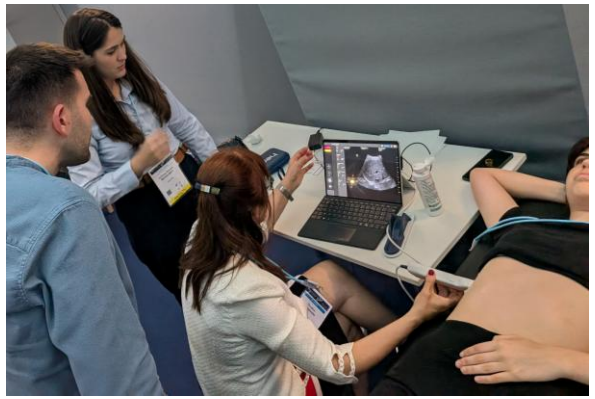
Share training details with customer

- **Logistics**
  - Use template email to confirm training session and secure practical/logistics details
  - Get number and names of trainees
  - Secure 8 to 10 patients can be booked for training
- **Send training documentation in advance for prior review by trainees.**
- **Ensure trainees have been informed and will be available**
- **Ensure patients will serve as models during training**

Option for sites having an internal certified Hepatoscope trainer: Organize shadowing activities (trainees to observe how trainer is performing exams during routine practice).

W0 – Onsite Training

- **Use currently approved versions of dedicated PowerPoint training decks**
  - DOC-1131 related to operations of Hepatoscope
  - DOC-1130 related to chronic liver diseases and clinical use of Hepatoscope
  - DOC-1133 related to physical parameters measured and interpretation with cutoff values



Initial Training Check-list of teaching points (1/2)

ITEM	COMMENT	CHECK
PROBE OVERVIEW	Trainees shall get used to plug/unplug the probe	
SWITCH ON / SWITCH OFF	Trainees shall get used to ensure laptop is plugged to main power before starting an exam	
PATIENT'S POSITIONING	- Patient lying on the back - Right arm in maximum abduction; right leg crossed over the left; "Banana shape"	
EXAM CONDITIONS	- Fasting; normal breathing status - Relaxed status (allow a few minutes for the patient to calm down if needed)	
COMFORTABLE WORKING ENVIRONMENT	Operator's ideal positioning - Height of laptop / examination bed / operator's chair - Forearm rested on the bed next to the patient abdomen - Stability of the hand is key	
PROBE HANDLING RECOMMENDATIONS	Hold the probe with fingertips or with the 2-hand technique	
PROBE HANDLING AND MOVEMENTS	- Rotation: show ribs coming in and out - Angling: show lack of contact on the sides and liver capsule not being horizontal - Tilting: show image becoming darker and darker as you shoot in the rib - Sliding: slide probe within a given space to get away from the lung - Translating: show forearm translation while sliding on the bed to move from one intercostal space to another; show right kidney for too low space, show only lung for too high space.	

Initial Training Check-list of teaching points (2/2)

ITEM	COMMENT	CHECK
ANATOMICAL LOCALIZATION	Demonstrate anatomical landmarks - Lung - Liver parenchyma and vessels and capsule - Kidney - Sub-cutaneous tissue	
HEPATOSCOPE UI	- Imaging area / Controls area / Measurements area - 2DTE: stiffness map color-coding + spatio-temporal diagrams - QI% + bright vs shadowed depending on > or < 85% - Real-time values next to image and series of 10 measurements displayed in the middle area	
ROI POSITIONING	- 2DTE: below capsule and stays on the left - Q.US: below reverberation and stays in the middle of image	
DEFAULT PRESETS	- Recommend using default presets to start with - Prefer to find a nice imaging spot rather than change all systems settings	
PROBE BUTTON	Review probe button actions: short press / long press	
END EXAM	Important to insist on PRINTING the report so it can be saved/printed. Otherwise all exam data are lost!!!	
REPORT	Generation, comments, settings, print, understanding of values	
TRANSDUCER CHECK	How it works Issue with pre-test gel on the probe head	

W0 – Onsite Training - Post-training recommendations

- Trainees shall be encouraged to keep on training on healthy colleagues until about 10 to 15 exams are performed successfully in optimal conditions.
- After these “easy” exams, trainees are encouraged to pursue training on “easy” patients with low BMI if possible, for about 10 to 15 cases, and then move to more challenging patients.
- Explain certification process that includes a review of acquisitions for every operator, either remotely (HepatoReader or deidentified pdf reports) or onsite (exams reports)
- Propose to organize follow-up meetings on a regular basis to track progress.

W+1 to W+3 – Quality-Control of acquisitions

Share training slide decks with customers

Training support documentation (pdf) can be sent to trainees by email.

Provide feedback on the quality of acquisitions and exams, *propose corrections as appropriate.*

Quality control shall be performed as long as exams show sub-optimal conditions (probe & ROI positioning)

Option for sites having an internal certified Hepatoscope trainer: Organize shadowing activities during which the onsite trainer will observe how the trainees are performing exams during routine practice, and propose corrections as appropriate.

Quality Control of acquisitions performed by trainees

- **Can be done via the cloud and HepatoReader is customers allow the connection to the Internet and export of deidentified exam data.**
- **If no connection to the Internet and/or no allowance of exported exam data, ask customers to send 5 deidentified exam reports with images (in 2DTE and Q.US) for review.**

W+3 – Hepatoscope operators’ certification

- **Send Hepatoscope Operator’s Certificate once any sub-optimal exam condition has been corrected and adjusted.**
- **Use certificate template**
- **Send Training satisfaction survey**

End of document

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