FibroScan Reporting Guidelines

GENERAL CONSIDERATIONS

1. It is important to be aware of other factors that can influence the results and the need to look not just at the scan but also at these other factors that may influence the report.
2. Other medical data that is helpful in interpreting the scan is available on the Fibroscan Clinical Form and this should be referenced when you are reporting
3. Have a systematic step by step approach to Fibroscan reporting and use the same approach every time to minimize errors
4. If in doubt consider a second opinion from another MD on the TACKLE project team that also does Fibroscan reporting
5. The following cut offs should be used:

Fibroscan cut-offs:

- From American Gastroenterological Association, AGA guideline published in May 2017, results based on systematic literature search (1)

	Advanced Fibrosis (≥F3)	**Cirrhosis (F4)**
FibroScan (HCV)	**9.5 (±1)**	**12.5 (±1)**

- Cirrhosis (F4)
  - AGA recommends using cutoff of **12.5 (±1)** for diagnosing cirrhosis in patients with HCV (17 studies, 5812 patients)
  - Associated accuracy values:

Cirrhosis (F4): 12.5 (±1) kPa					
Pooled Sensitivity	Pooled Specificity	PPV		NPV	
		Low prevalence (5%)	High prevalence (30%)	Low prevalence (5%)	High prevalence (30%)
0.86	0.91	33	80	99	94

  - Pooled sensitivity and specificity were calculated and two illustrative scenarios were chosen to estimate PPV and NPV:
    - Population with low prevalence of cirrhosis: 5% (e.g. prevalence of cirrhosis in patients with HCV seen in primary care clinics)
    - Population with high prevalence of cirrhosis: 30% (e.g. prevalence of cirrhosis in patients with HCV with comorbid obesity, alcohol use, or **coinfection with HIV**)
  - 12.5 is a lower cutoff than 14 which was presented during FibroScan training –> lower cutoff minimizes false negative tests
  - Estimated that using cut-off of 12.5 may misclassify < 5% of patients as not having cirrhosis when they have cirrhosis and <10% of patients as having cirrhosis when they don't have cirrhosis
  - This is a conditional recommendation with low quality of evidence, thus, FibroScan shouldn't be the only method used to assess fibrosis grade, should be considered in context of other clinical information.

- Advanced Fibrosis (≥F3)
  - AGA recommends using **9.5 (±1)** to rule out advanced fibrosis/cirrhosis (13 studies, 4106 patients)
  - Associated accuracy values:

Advanced Fibrosis (≥F3): 9.5 (±1) kPa					
Pooled Sensitivity	Pooled Specificity	PPV		NPV	
		Low prevalence (5%)	High prevalence (30%)	Low prevalence (5%)	High prevalence (30%)
0.78	0.86	23	70	99	90

  - Conditional recommendation with very low quality of evidence

6. Fibroscan results should be considered in conjunction with either APRI or FIB-4 scores and the following cut-offs should be used

APRI and FIB-4 cut offs:

- From New England Journal of Medicine Review Article published in August 2017 (2)

Test	Advanced Fibrosis Cutoffs (low and high risk) (≥F3)	Sensitivity (%)	Specificity (%)
APRI	**>1**	61	64
FIB-4	**<1.45**	74	80
	>3.25	38	82

1. Singh S, Muir AJ, Dieterich DT, Falck-Ytter YT. American Gastroenterological Association Institute Technical Review on the Role of Elastography in Chronic Liver Diseases. Gastroenterology. 2017;152(6):1544-77.
2. Tapper EB, Lok ASF. Use of Liver Imaging and Biopsy in Clinical Practice. The New England journal of medicine. 2017;377(23):2296-7.

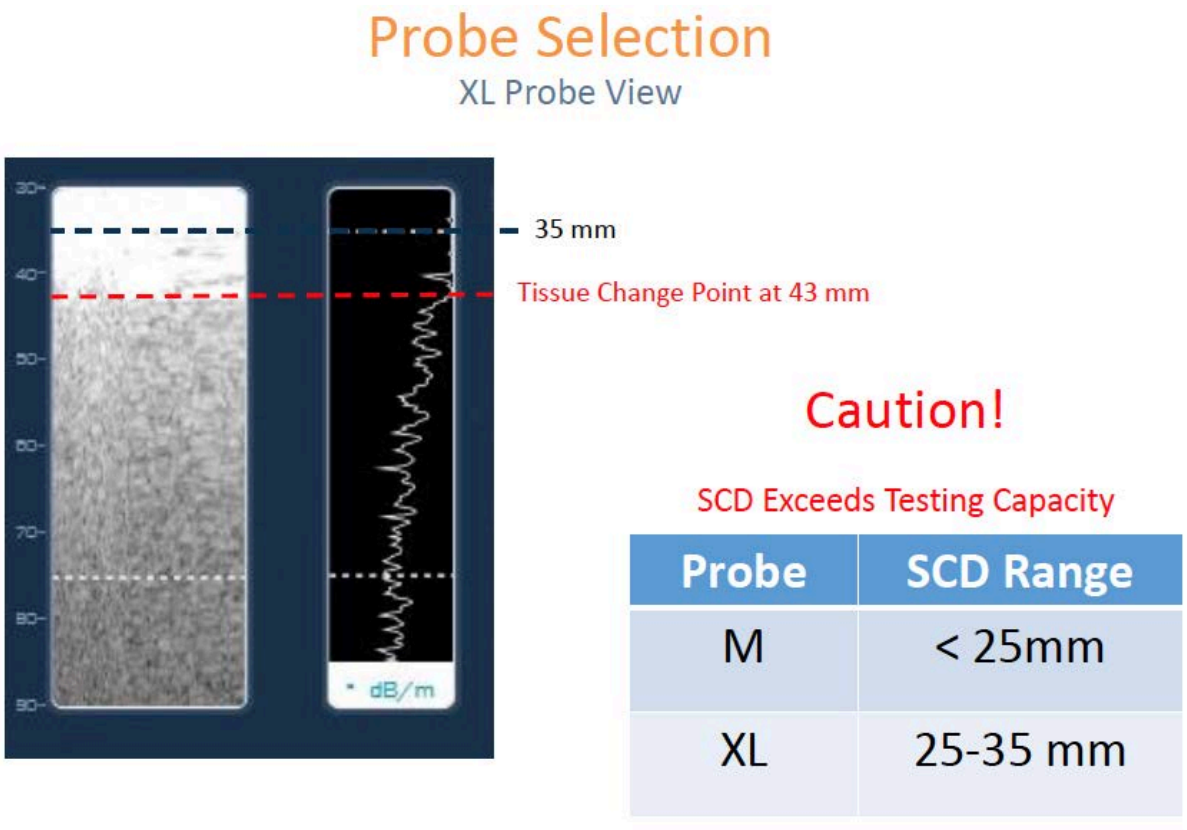
INITIAL CHECKLIST

Check √	Item
	Is patient fasting*? >>> if not, fasting study is not valid
	Is the correct probe being used? >>> if not, the study is not valid – see below for guidance on correct probe selection

*Drinking water is acceptable

- **Correct probe selection:**

Look for a clearly visible dotted line at the top of the screen that does not exceed the parameters for the probe size being used.



SUBSEQUENT CHECK LIST

Check √	Item
	Has fasting and probe size been checked?
	Are there any patient symptoms and signs or laboratory results that may affect the scan?
	Are there ≥ 10 measurements?
	Is the IQR/Med measurement ≤ 30%?
	Is the probe in the right place?
	Are there ≤ 2 rib echoes?

- **Are there any patient symptoms and signs or laboratory results that may affect the scan?**

Be aware that *liver inflammation* can affect liver stiffness and therefore the scan results. If lab results indicate a transaminitis for example scan results may be affected. *Liver congestion* can also affect liver stiffness and therefore the scan results. Any clinical or laboratory indication of right sided heart failure can also affect scan results.

- **Are there ≥ 10 measurements?**

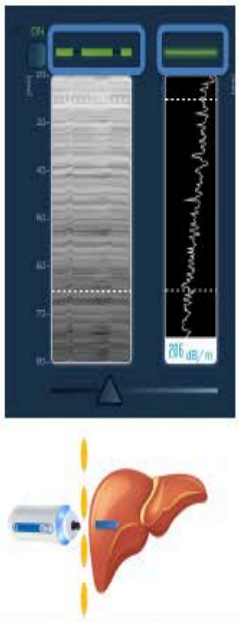
Ensure that the report states that there are at least 10 images

- **Is the IQR/Med measurement ≤ 30%?**

If these numbers are greater than 30% it indicates that there may be high numbers of rib echos or that there are some outlier measurements. Aim for a measurement of around 20-25%. If the IQR/Med measurement is greater than 30% and the study is suggesting significant fibrosis recommend that the study is repeated.

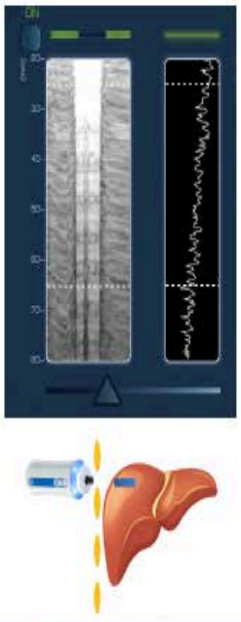
- **Is the probe in the right place?**

Probe Centered on Liver



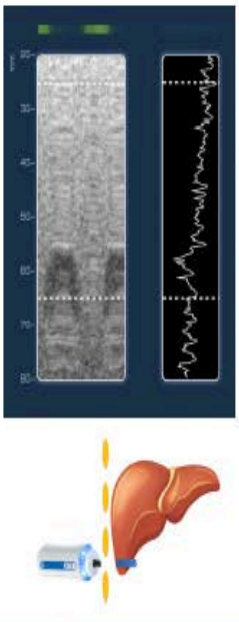
Attribute	Liver Sustained in Respiration
Impact	Measurements in Correct Location
Corrective Action	None

Probe Not Centered on Liver



Attribute	Intermittent View of Liver & Lung
Impact	Measurements Not in Center of Liver
Corrective Action	Move down (inferior) one Intercostal Space

Probe Not Centered on Liver

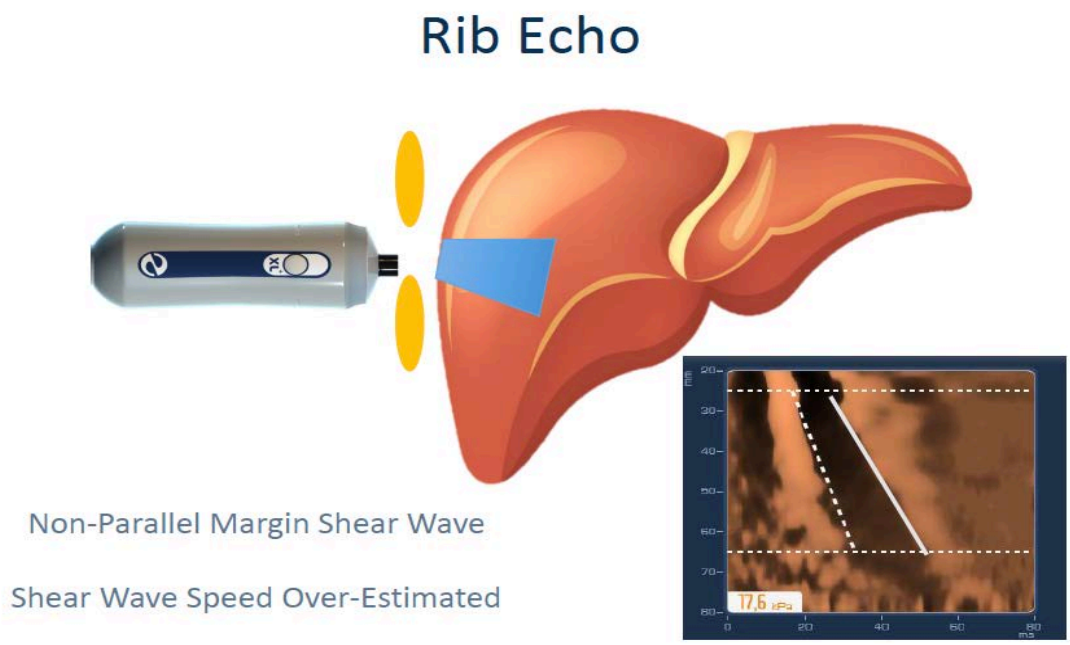


Attribute	Lower Lobe of Liver in Exam Field
Impact	Measurements Not in Center of Liver
Corrective Action	Move up (superior) one Intercostal Space

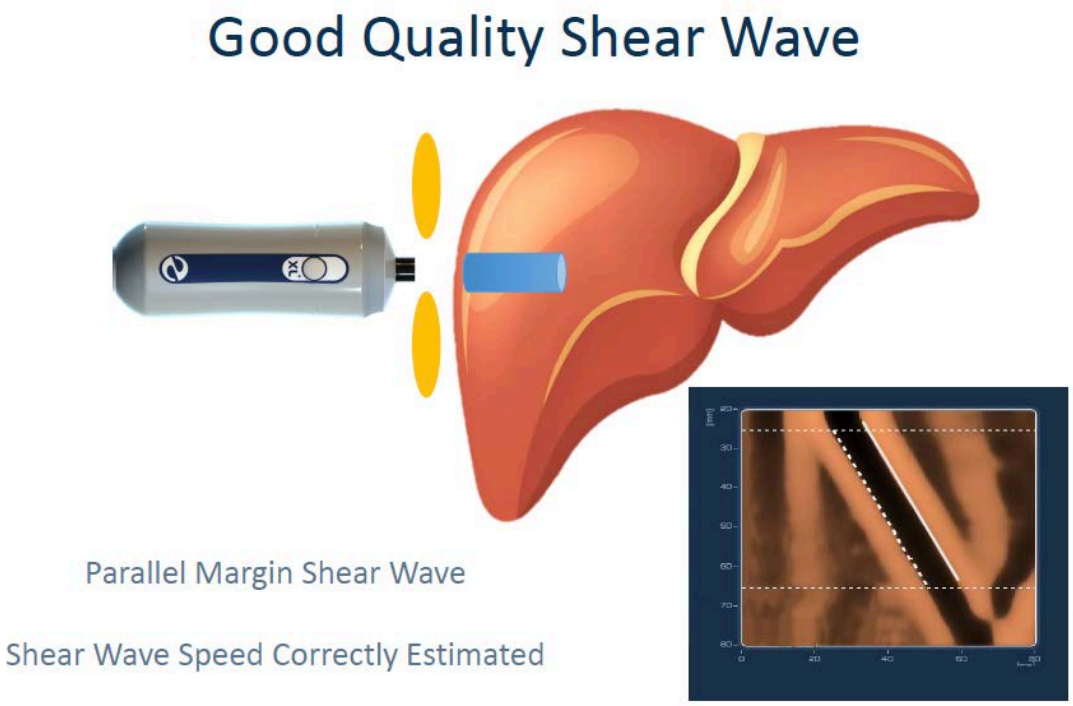
ENA-16-001, Rev. 1.0

- **Are there ≤ 2 rib echoes?**

FibroScan®



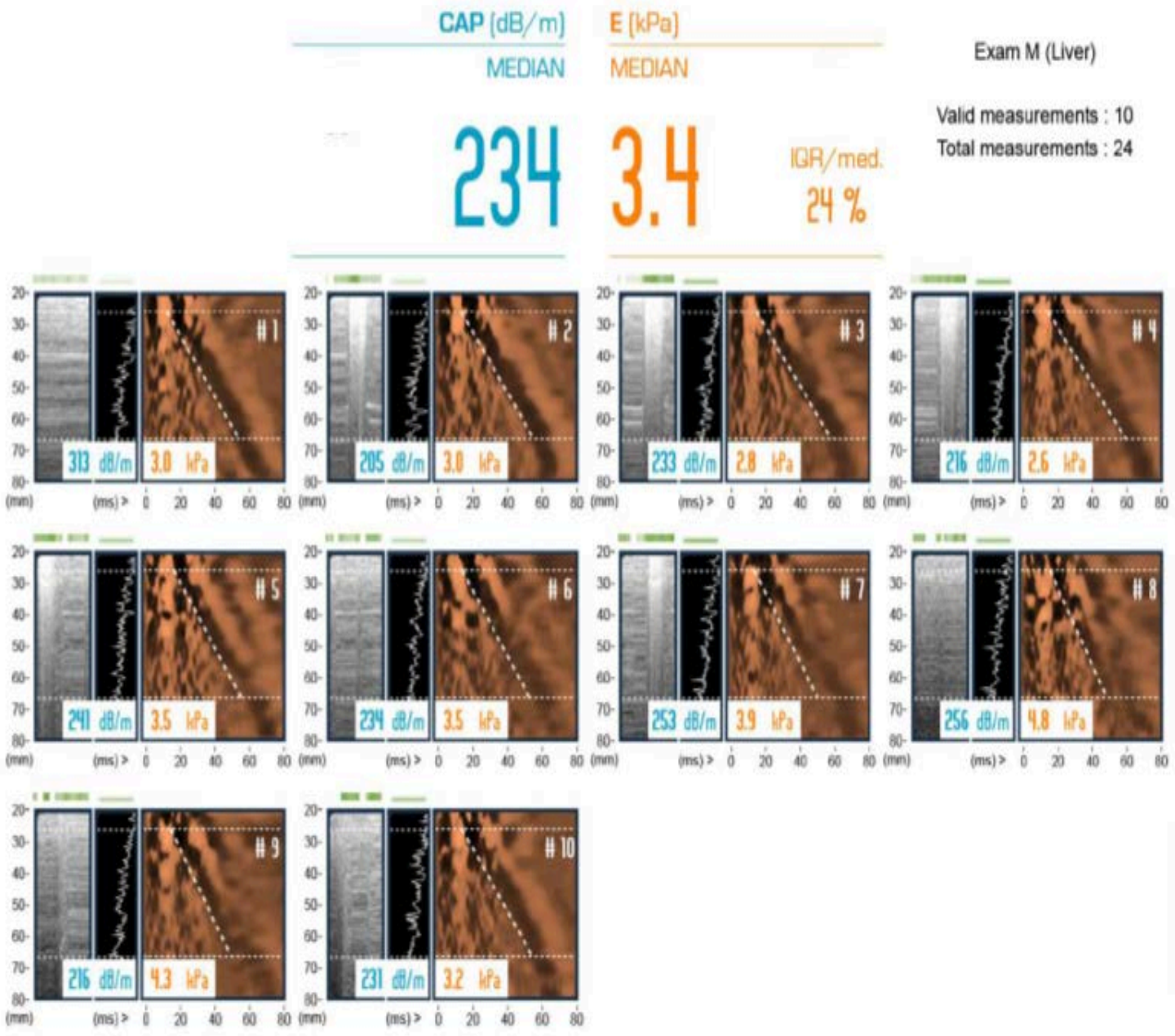
No rib echo:



CASE 1

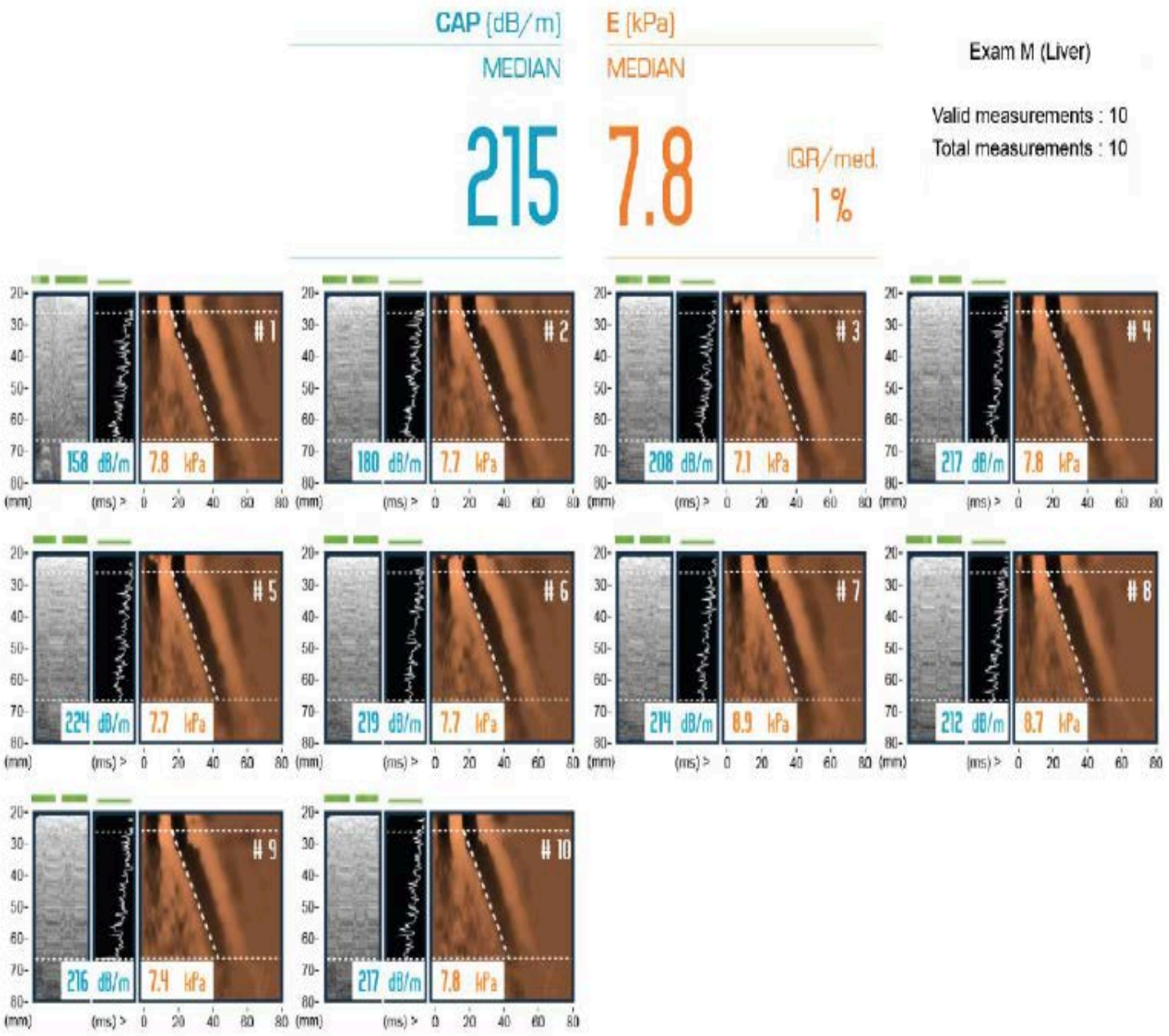
- Probe positioned on lower lobe
- Liver stiffness might be elevated due to proximity to capsule edge
- Study should be rejected

CASE 2



- Probe not centered on liver
    - Heterogeneous TM
    - Inactive LTT
    - Probe too high
- Reject study

CASE 3



Case 3 (good study)

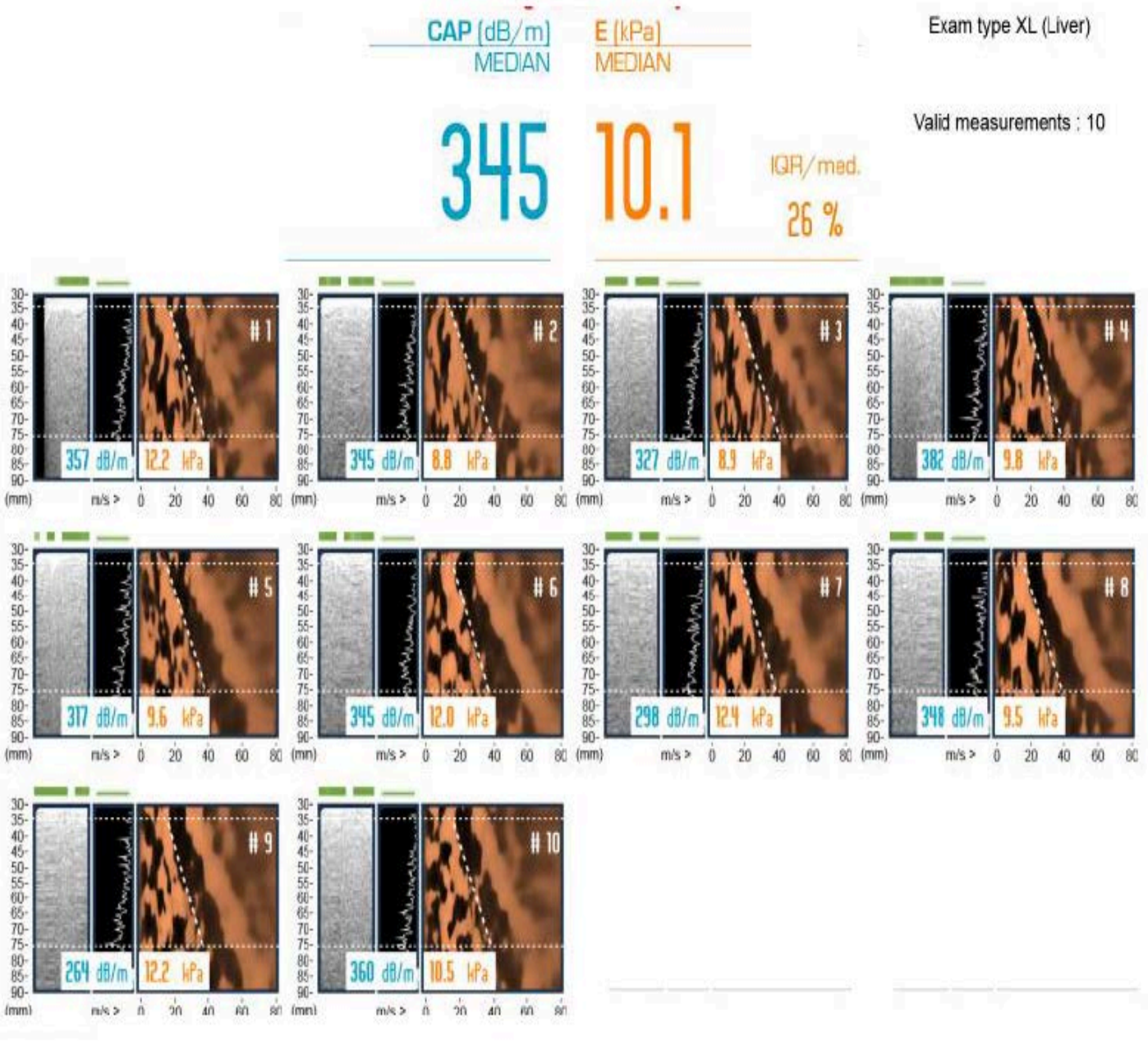
- Probe centered on liver
    - TM homogenous
    - LTT active
- Correct model probe used
- Adequate # measurements, 10
- Acceptable data variability, 1 %
- Accurate shear wave, parallel margins, less than 2 rib echos
- Well acquired study

CASE 4

Case 4 (right location, wrong probe)

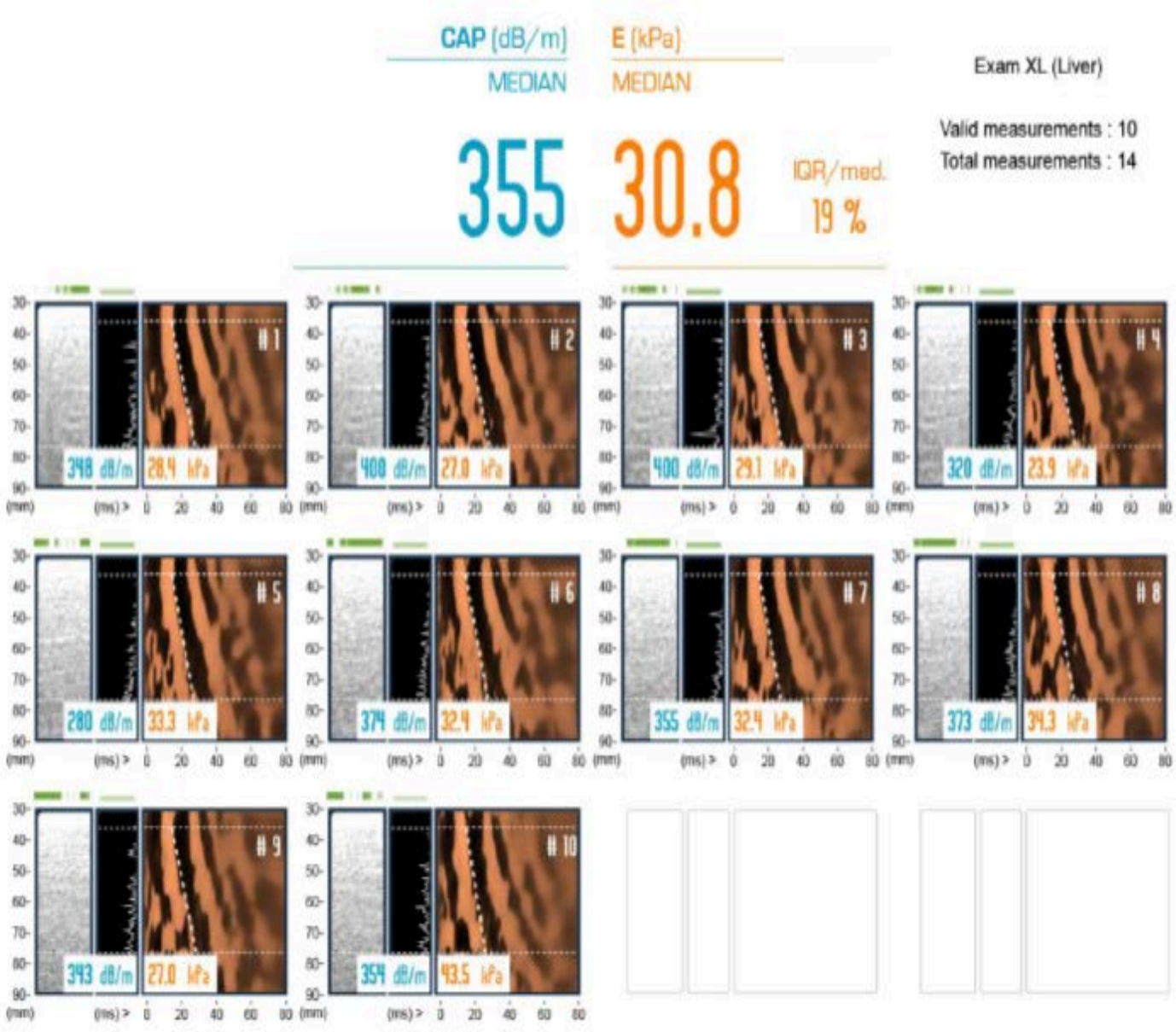
- Probe centered on liver
    - TM homogenous
    - LTT active
- Incorrect model probe used
    - SCD > 25 mm
- Note high CAP value
- Reject study

CASE 5



- Probe centered on liver
    - TM homogenous
    - LTT active
- IQR/Med is 26%, but the study has > 2 rib echoes, the liver stiffness is over-estimated
- XL probe correctly used

CASE 6



Case 6

- Probe centered on liver
    - TM homogenous
    - LTT active
- IQR/Med is 30.8%, too high
- SCD exceeds XL probe, > 35 mm

RECOMMENDED ADDIITONAL READING/RESOURCES

FIBROSCAN CLINICAL PRACTICE GUIDELINES

Guideline	Disease Etiology	Reference Citation
AASLD/IDSA	HCV	Recommendations for Testing, Managing and Treating Hepatitis C; When & In Whom to Initiate Antiviral Therapy, AASLD & IDSA Practice Guidelines; www.hcvguidelines.org
AGA Elastography Guidelines	HCV-HBV-NAFLD/NASH	American Gastroenterological Association Institute Guideline on the Role of Elastography in the Evaluation of Liver Fibrosis; Lim J, Flamm S, Singh S, Falck-Ytter Y, & Clinical Guidelines Committee of AGA; Gastroenterology 2017;152;1536-1543.http://www.gastrojournal.org/article/S0016-5085(17)30326-8/abstract
EASL	HCV	EASL Clinical Practice Guidelines : Noninvasive Tests for Evaluation of Liver Disease Severity and Prognosis; Journal of Hepatology 2015
WHO	HCV	WHO Guidelines for Screening, Care and Treatment of Persons with Hepatitis C Infection; ISBN 978 92 4 154875 5
WHO	HCV + HIV	Management of HCV & HIV co-infection WHO 2012 HIV/AID treatment. Clinical Protocol for the WHO European Region Chapter 6

TOP THREE HCV PUBLICATION REFERENCES

Author	Title	Link	Importance
AASLD/IDSA HCV Guideline	Recommendations for Testing, Managing and Treating Hepatitis C; When & In Whom to Initiate Antiviral Therapy	https://www.hcvguidelines.org/	States VCTE is a clinically useful tool for identifying advanced fibrosis and cirrhosis in patients with HCV
Tapper, E.B and Lok, S. F	Use of Liver Imaging and Biopsy in Clinical Practice; NEMJ 2017; 377: 756-768	https://www.nejm.org/doi/full/10.1056/NEJMra1610570	States same day VCTE + serological testing optimizes risk stratification

Lim, J. et al.	American Gastroenterological Association Institute Guideline on the Role of Elastrography in Evaluation of Liver Fibrosis. Gastroenterology 2017; 152: 1536-1543	https://www.gastrojournal.org/article/S0016-5085(17)30326-8/abstract	States thresholds for advanced fibrosis, cirrhosis, varices risk and surgical risk in HCV

WEBINARS

FibroScan Clinical Webinars on the Echosens Website, http://www.echosens.us

Dr. Kenneth Cusi, "Clinical Updates on the Management of Fatty Liver Disease in Patients with Type 2 Diabetes", July 26, 2018

Dr. Stephen Harrison, "EASL Update on FibroScan applications in NAFLD-NASH", May 16, 2018

Dr. Elliott Tapper, "The Evolving Role of Invasive and Non-Invasive Assessment Tools", November 1, 2017

Jerry Mabary, "FibroScan Threshold value update", October 18, 2017

Dr. Doug Dieterich, "Role of Elastography in Chronic Liver Disease: The AGA Guidelines", July 12, 2017

Dr. Nezam Afdhal, "Interpreting Liver Stiffness and CAP Scores in Clinical Practice", May 3, 2017

Dr. Stephen Harrison, "Evolving Diagnostics Strategies for NAFLD/NASH", December 7, 2106