Ultrasound System EBQA Test Device
What we will cover

• Historical Perspective of Ultrasound Technology
• Development Rationale
• FirstAssist – Probe Emulator Device
• Intended Use
• Theory of Operation
• Captured and Displayed Data
• Indicators of Performance Variances
Ultrasound System EBQA Test Device

Ultrasound System Design Architecture
50 Years of Development

Howry's somascope reported in the LIFE magazine in 1954
Diagnostic Ultrasound

History of Modern Diagnostic Ultrasound

- A-Mode
- M-Mode
- B-Scan
- Mechanically Steered Real-time
- Linear Array Real-time
- Zero-crossing Doppler
- Spectral Doppler (FFT)
- Phased Array Real-time
- CW Doppler in Probe – Bernoulli Equation
- Color Flow Doppler
- Triplex modes of Operation
- Pseudo-Color
- Color “Angio” & Power Doppler
- Harmonic Imaging & Variants
- Contrast Media Imaging
- Spatial Compounding
- 3D Imaging – Volumetric
- 4D Imaging – Steered Curved Array
- Phase Aberration Correction
Evidence-Based Quality Assurance in Ultrasound

BPD

Ventricular Septal Defect
Development Challenges and Rationale

Traditional Methods of Performance Evaluation Are No Longer Relevant

Error Code: Yf6533RA7LLOp1

**Translation**: Non-deterministic Software Error
Development Challenges and Rationale

• Currently Available Tools
  – On-board Diagnostics
    - May have partial or no access
    - Only tests system (not probes)
    - Generally poor accuracy
  – Tissue Mimicking Phantom
    + Relatively inexpensive (~ $2000)
    + Widely used in industry last 15 years
    - Affected by environment
    - Most brands are susceptible to damage
    - Defective systems and transducers can appear to be OK
      - Results are very user dependent
    - Only tests 1 operating mode (usually B-mode)

“...it is impossible to state or test a tolerance of a machine acquisition error by itself”

Philips Ultrasound Op Man
Development Challenges and Rationale

• Great performance variability among different machines

• Measurement differences and therefore ultimate accuracy is machine dependent

• Operator variability

• Recognizing system performance change due to component degradation is a key early warning indicator
“Variability among transducers and systems is a significant factor. Transducer variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens focusing parameter variations. Differences in system pulser voltage control and efficiencies is also a contributor to variability.”

Philips Op Man
Acquisition and Algorithmic Errors

“Acquisition errors are introduced by ultrasound machine electronics, relating to the front end signal acquisition, signal conversion and the display of the image on the screen....it is impossible to state or test a tolerance of a machine acquisition error by itself.”

“Algorithmic error is the error introduced by taking the basic measurement acquisition error as input to higher order calculations for display to the user...this error is also subject to errors introduced by rounding versus truncating results for a given level of significant digit display of the values.”

Example: The Bernoulli Equation $4V^2$
Acoustic Artifacts

“...the control choices made by the sonographer that affect amplification, signal processing, and echo display can lead to significant differences in the displayed appearance of echo data.”

“...artifacts can originate from misadjusted equipment.”
Development Approach
Development Approach

Probe Emulator
Development Approach
Development Approach

Intended Use

1) Validate Manufacturer’s Performance Specifications
2) Verify reception of transmit signals from each transmitter
3) Input signals of various amplitudes into each receive channel
4) B-mode, Spectral Doppler, Color Flow and other variant modes

What Modes will the FirstAssist Signal be Seen on the System Monitor?

1) B-mode, along with various special processing schemes such as:
   a) SonoCT (spatial compounding)
   b) 2nd Harmonic Imaging
   c) Dynamic Focusing
1) M-Mode
2) Spectral Doppler
3) Color Flow
Development Approach

For Example:
“An error has been detected. Please record the following and call technical support.”

Diag Code: 200.BWRU.BYMD.5
Software Build Version: 1.1.1.504

Unisyn’s way allows the same access via CMCAA* compliant technology

* Computer Maintenance Competition Assurance Act

Unisyn’s way allows the same access via CMCAA* compliant technology
Development Approach - System Self-Diagnostics

Transmit (XMIT) IC

No self-diagnostic test at output of Xmit

With Channel Board Self-Test

Extents of Self Diagnostic Reach

Boards without defect
Boards with defect

Criterion value

False Positive rate (100-Specificity)

True Positive rate (Sensitivity)

MRI | ULTRASOUND | CT | MAMMOGRAPHY
Tested Channels: 1-32
Mean Vpp (Blue Line): 151, Standard Deviation: 28.0
Purple line (if visible) is the mean plus 3 standard deviation.
Gold line (if visible) is the mean minus 3 standard deviation.

OVERALL result: Fail - 1 warnings, 3 failures.

Detail:
- Failure: Channel 15 Transmit, No signal was captured (Channel Board 2).
- Failure: Channel 18 Transmit, No signal was captured (Channel Board 2).
- Failure: Channel 24 Transmit, No signal was captured (Channel Board 2).
- Warning: Warning: Channel 9 (Channel Board 2) is an outlier.
Development Approach
Transducer Evaluation Report

Manufacturer: HP
Customer: Customer
Contact: Contact

Probe Model: 21369A
Address: Address
City: City
State: CO
Zip Code: Zip

Serial Number: US17402993
Test Date: 5/26/2006 10:33 AM
Test ID: 29939
Operator: vince venincasa
Phone Number: Phone
Fax Number: Fax

Purpose: Repair Final Test
DX/Comments: 110318

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**Sensitivity**

- **Mean:** 0.436
- **Max:** 0.660
- **Min:** 0.008
- **Std Dev:** 0.056
- **Gain:** 17 dB

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**Capacitance**

- **Mean:** 377.587
- **Max:** 420.861
- **Min:** 304.591
- **Std Dev:** 27.546
End of Presentation