Non-invasive intra-cardiac pressure monitoring

Automatic Assessing EDP through Jerks

Game changing approach to cardiology diagnostics and heart failure management

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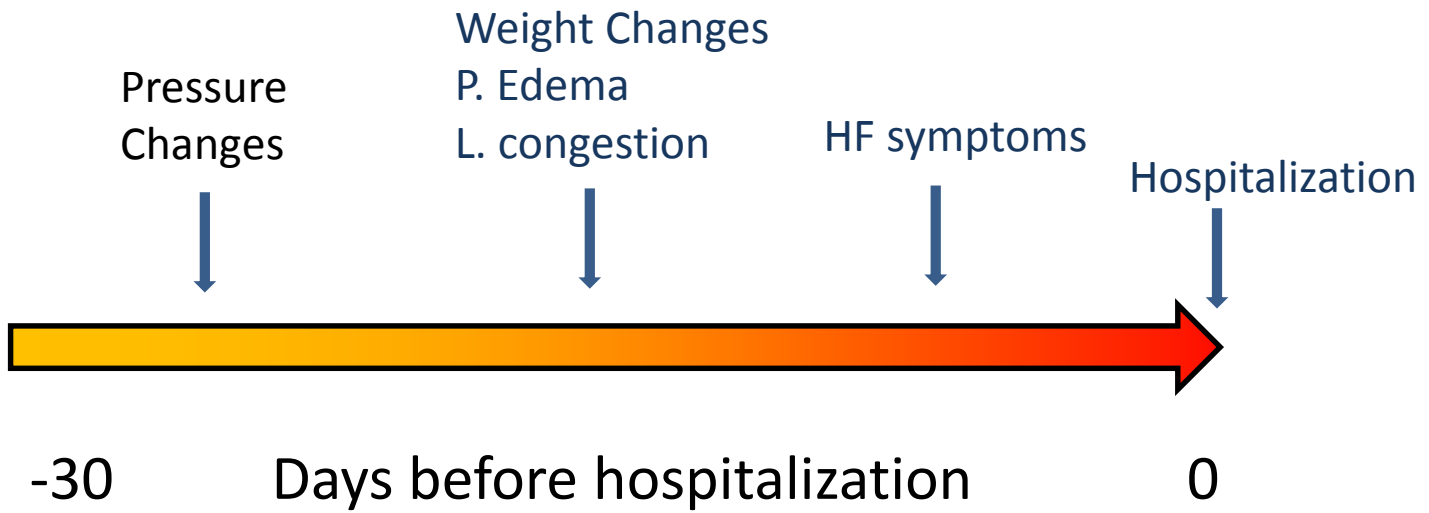
600,000 new CHF patients are diagnosed every year

and added to more than 5,700,000 CHF patients in USA only

Challenge: Cardiac Pressure monitoring to improve CHF management and delay NIHA Class II patients progressing to Classes III-IV

Physiological progression of ADHF



Hemodynamic Information is critical:

Cardiac pressure changes occur long before other HF symptoms become visible

ICPM goal is to meet this challenge by assessing hemodynamic changes in:

LVEDP = Left Ventricle End-Diastolic Pressure

- **acknowledged marker for CHF**

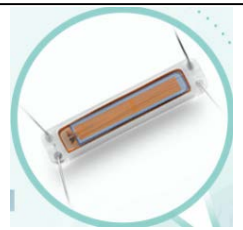
RVEDP = Right Ventricle End-Diastolic Pressure

- **acknowledged marker for RHF**

This goal has to ne achieved fully automatically without human interaction.

One of the problems is the full automation of LVEDP and RVEDP calculation from LV and RV measurements

Competitors - invasive and not covering the major domains

	Description	Size	State of development
Abbot cardiomems™ **RFID**	Low-frequency MEMS pressure sensor (35-45 MHz)	 3mm x 15mm	Clinical trials, PAP for Heart Failure, FDA, CHAMPION trial
X-Ray Vectorious	V-LAP is a wireless, battery-free microcomputer, placed directly on Inter-atrial septum.	 12mm x 12mm x12mm	The V-LAP is not yet commercially available. First in Man trial Jan, 2019
Imperial College London	High Frequency 868 MHz SAW pressure sensor **RFID**	 3mm x 7mm	Early animal testing – PAP, LAP and LVP.
ISSYS INTEGRATED SENSING SYSTEMS	Magnetically coupled MEMS sensor		Under development for Intra-Cranial Pressure, Left Atrial Pressure
endotronix Wireless health monitoring	Cordella -MEMS pressure sensor **RFID**		First in Man trial Feb, 2018

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ICPM unique capabilities

	Calibration	Heart Failure Parameters that can be Monitored	Remarks
Left heart Catheterization	• LAP, LVP • ECG • Additionally: Aortic Pressure	• **LAP** • **LVEDP**, LVSP • **RVEDP, RVSP**	• LVEDP, LVSP are calculated from LAP, LVP and ECG data
Right heart Catheterization	• PAP, RAP, RVP • ECG	• **PAP** • **RVEDP,RVSP**	• RVEDP, RVSP are calculated from RAP, RVP and ECG data
	• PCWP	• **LAP** • **LVEDP**, LVSP • RVEDP, RVSP	• LVEDP, LVSP are calculated from PCWP, RVSP and ECG data

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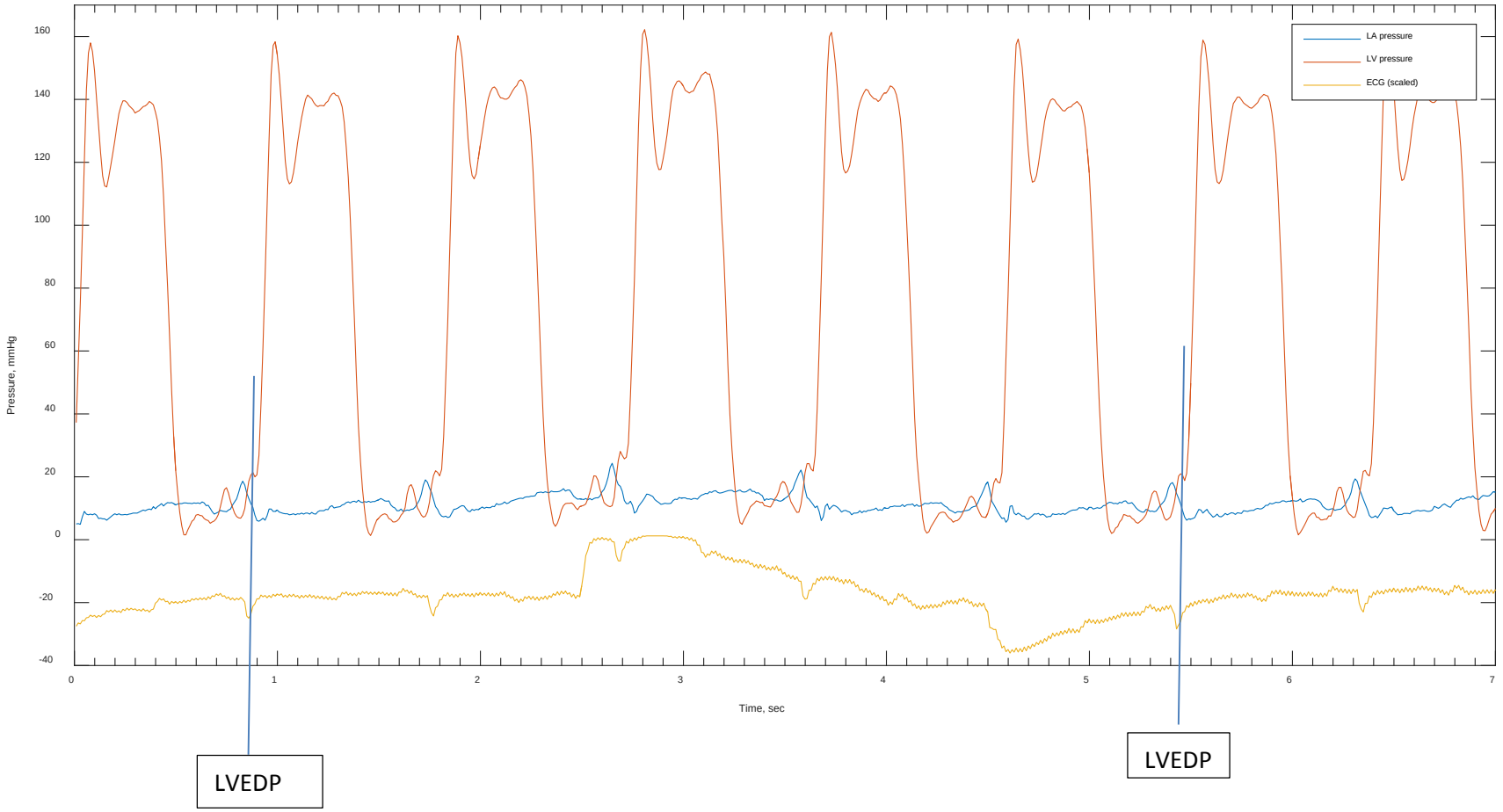
What is LVEDP?

Current definition:

LV pressure at the nadir of the atrial contraction wave before the onset of a rapid rise in LV systolic pressure or at the peak of R-wave on ECG.



It is simple to find when one has ECG (yellow) , LV (red) and LA (blue),

Channels de- synchronization and manual detection

Manually set

LVEDP

Manually set

LVEDP

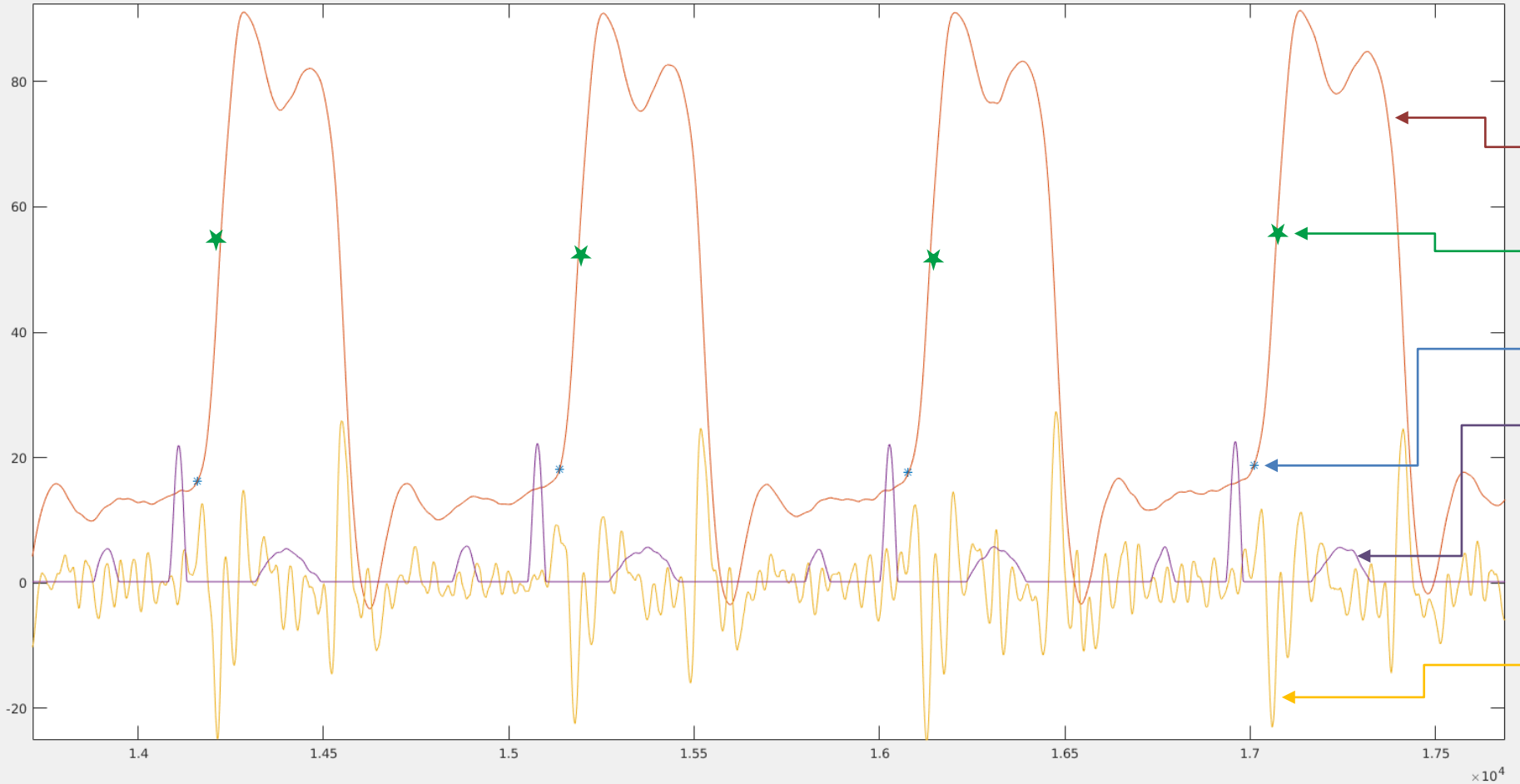
ECG (red) , LV (violet), manual stamps (yellow)

What is a Jerk ?

- Jerk is the rate of change of acceleration : $J(t) = \frac{da(t)}{dt}$
  the time derivative of acceleration,
- Jerk is the second derivative of velocity : $J(t) = \frac{d^2v(t)}{dt^2}$
- Jerk is the third time derivative of position: $J(t) = \frac{d^3r(t)}{dt^3}$
- Jerk dimension is $[length/time^3]$
- in SI units - m/sec^3
- Jerk is a vector, but we are interested in its scalar magnitude

- Examples:
- For most of the passengers a vertical jerk of 2.0 m/sec^3 in a lift ride as acceptable,
- For most of the passengers a vertical jerk of 6.0 m/sec^3 in a lift ride as intolerable,
- For a hospital environment 0.7 m/sec^3 in a lift ride is suggested.

LV Jerk and LVEDP



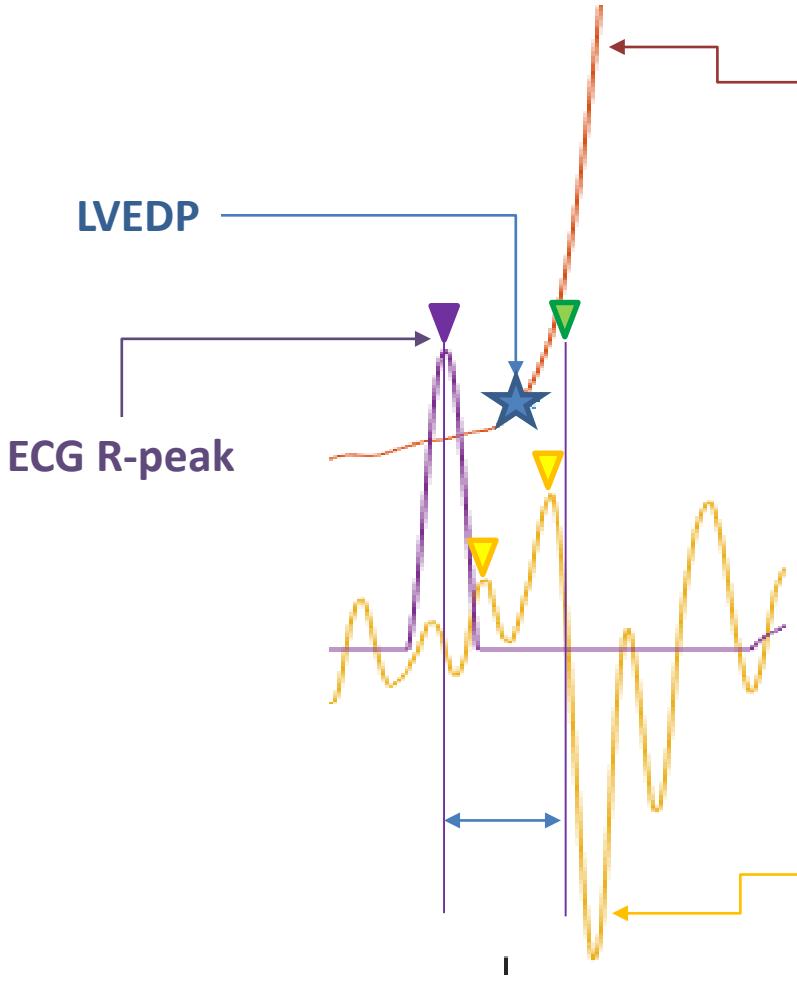
LV Jerk and LVEDP

LV

LV Jerk

LVEDP

ECG



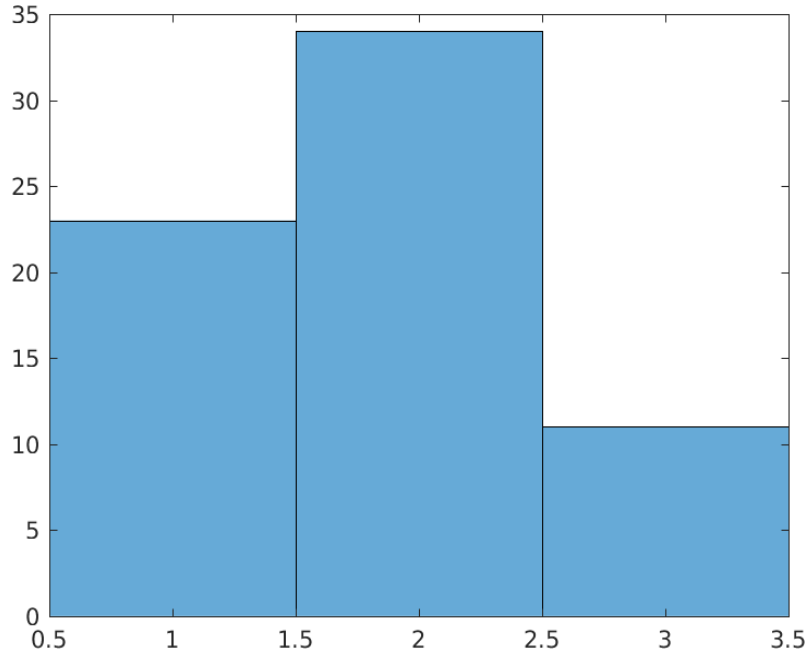
LVEDP time =
Weighted Average
of the Jerk Maxima times ▼
between
ECG R-peak ▼ and
Jerk Negative Zone ▼

Jerk Maxima points we shall call simply “Jerks” ▼

How many “Jerks” observed between ECG R-peak and LVEDP ?

Patient with NSTEMI myocardial infarction

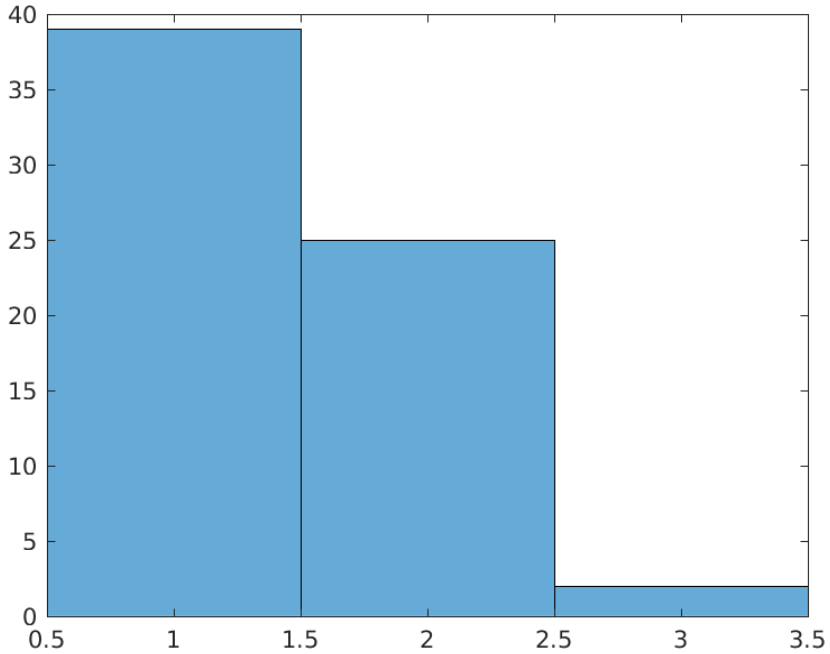
before stent insertion



Average № of Jerks per period
1.57

Average dP/dt_{max} = 1,362 mmHg/sec

after stent insertion



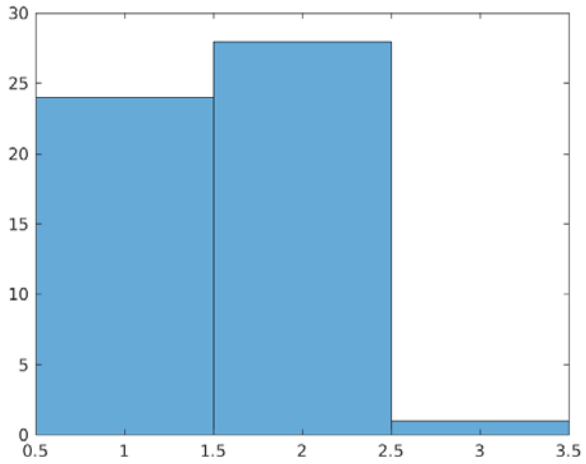
Average № of Jerks per period
1.26

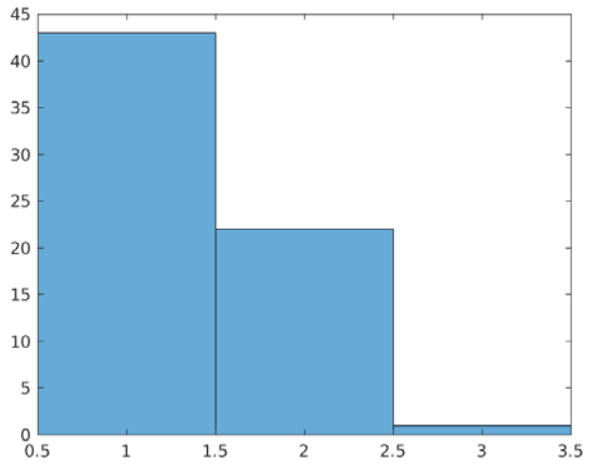
Average dP/dt_{max} = 1,919 mmHg/sec

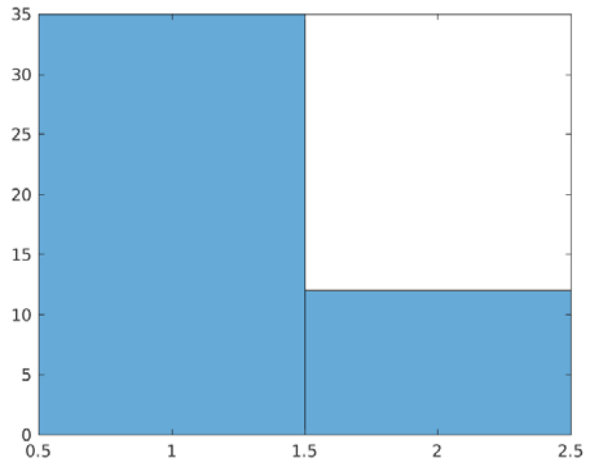
50 sec of Parallel LV and ECG recording

The “Jerks” histogram skewed left after stent insertion

Another Patient with NSTEMI myocardial infarction before and after stent insertion







Average № of Jerks per period
1.82

Average dP/dt_{max} = 1,137 mmHg/sec

Average № of Jerks per period
1.44

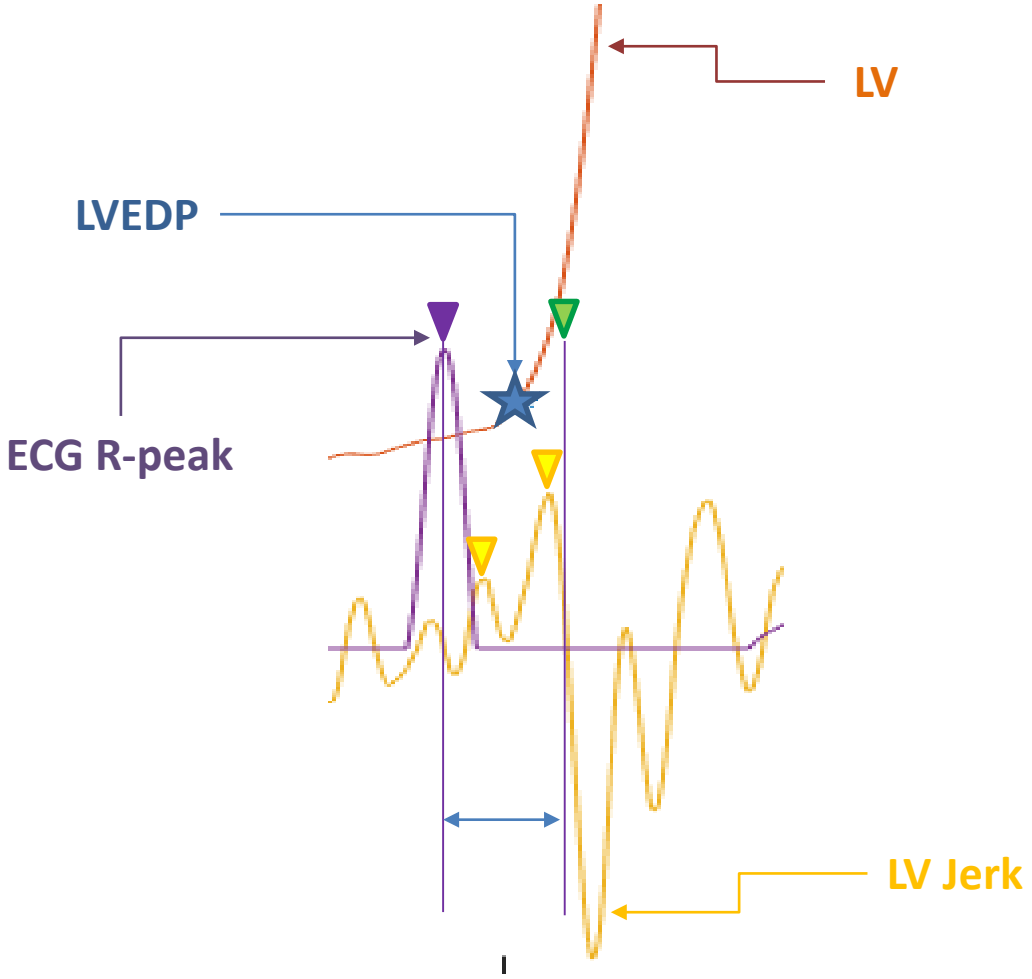
1,322 mmHg/sec

Average № of Jerks per period
1.36

1,350 mmHg/sec

50 sec of Parallel LV and ECG recording

LV “Jerk” and RV “Jerk” – new measures of detection and evaluation of heart failure severity

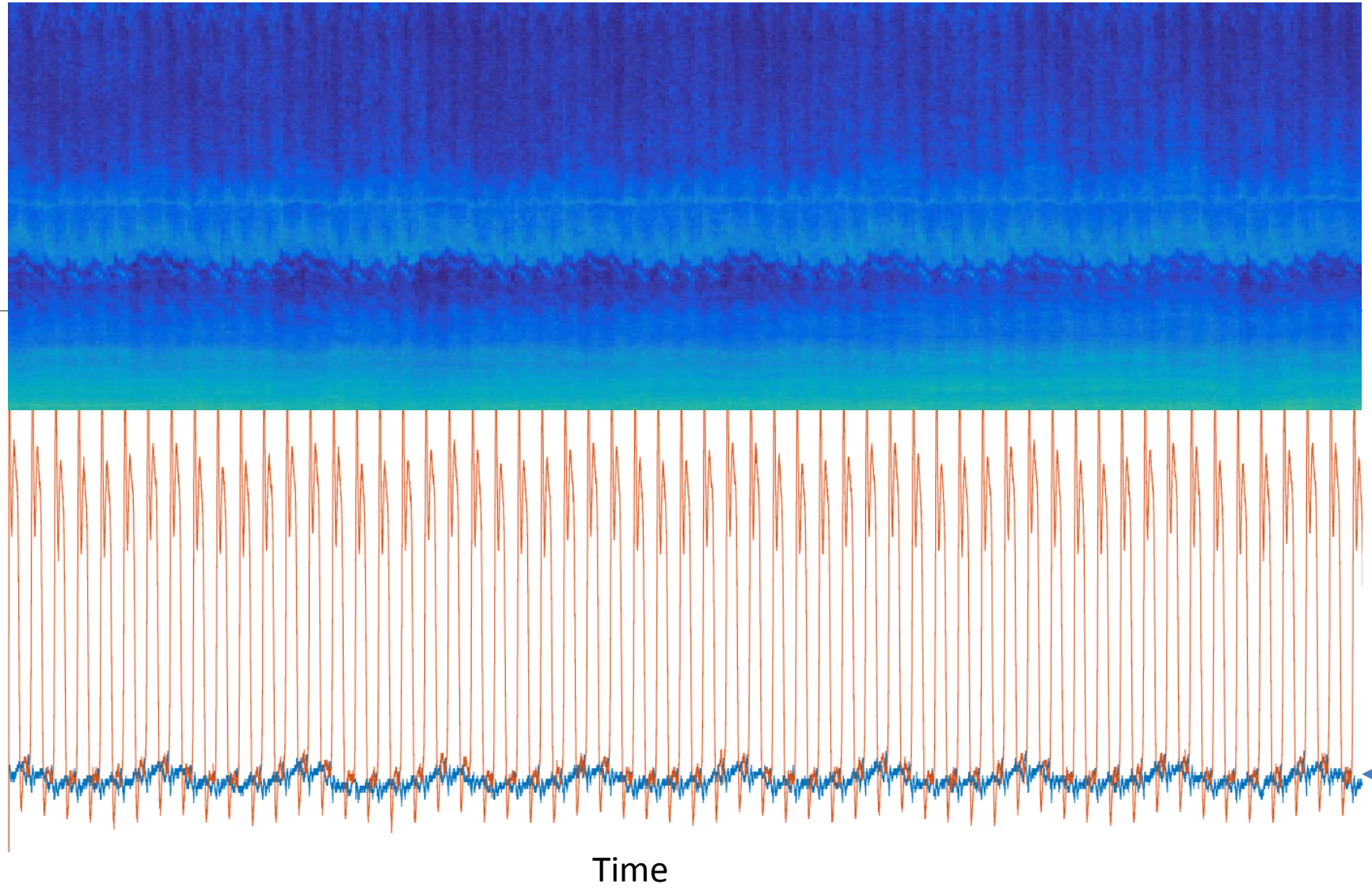


Average № of Jerk Maxima points ▼ between ECG R-peak ▼ and Jerk Negative Zone ▼ can measure myocardial contractility dis-synchrony

Hypothesis:

- **The healthier the person, the closer “Jerk” tends to 1.0**
- **“Jerk” can be a new marker for grading of congestive heart failure.**
- **“Jerk” is statistically independent from dP/dt_{max} (average correlation 6%)**

Back to US: Comparing Ultrasound Data to Measured Pressure and LVEDP calculated with “Jerks”



US processed data

LV catheter pressure data

LVEDP

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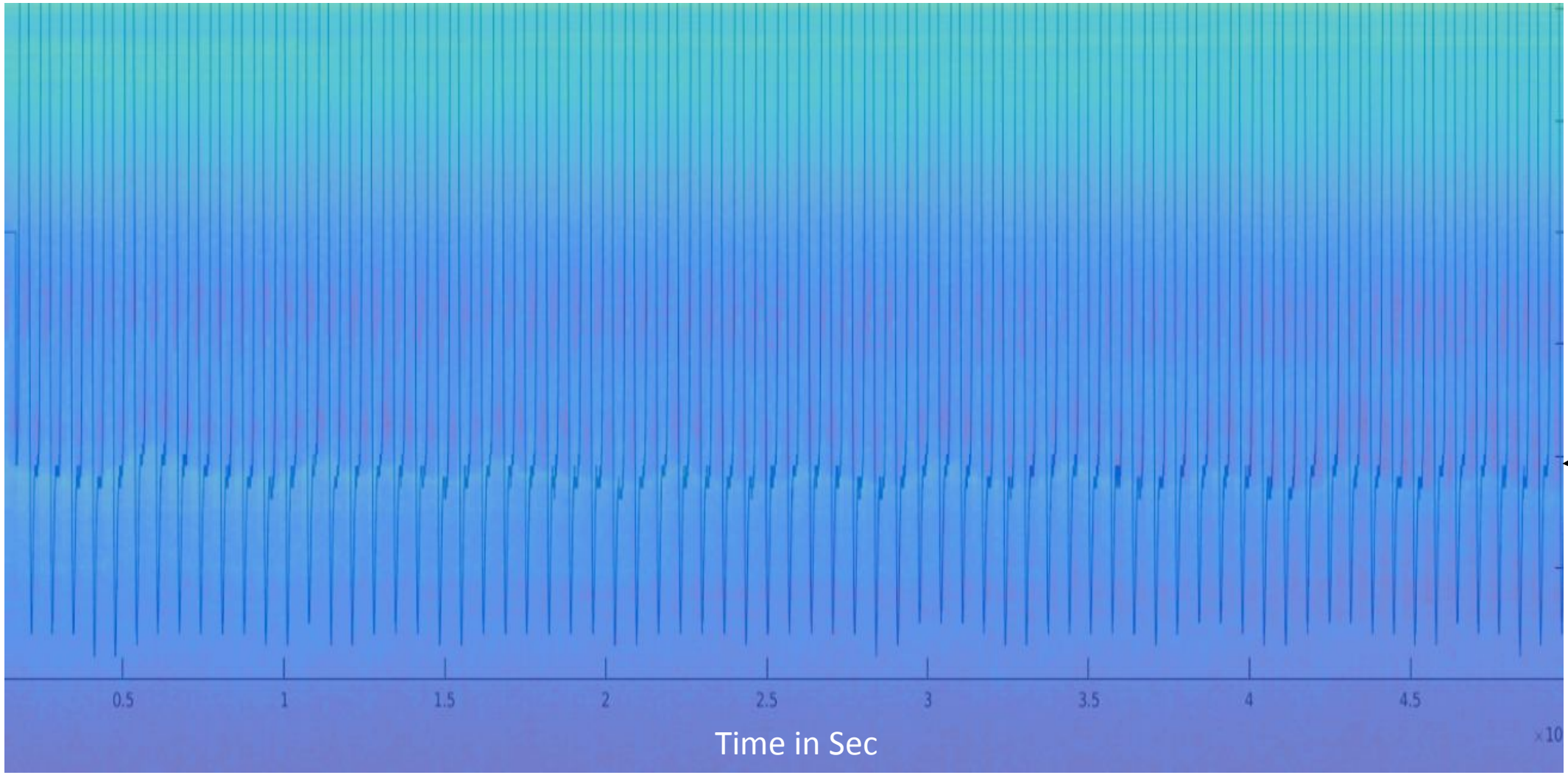
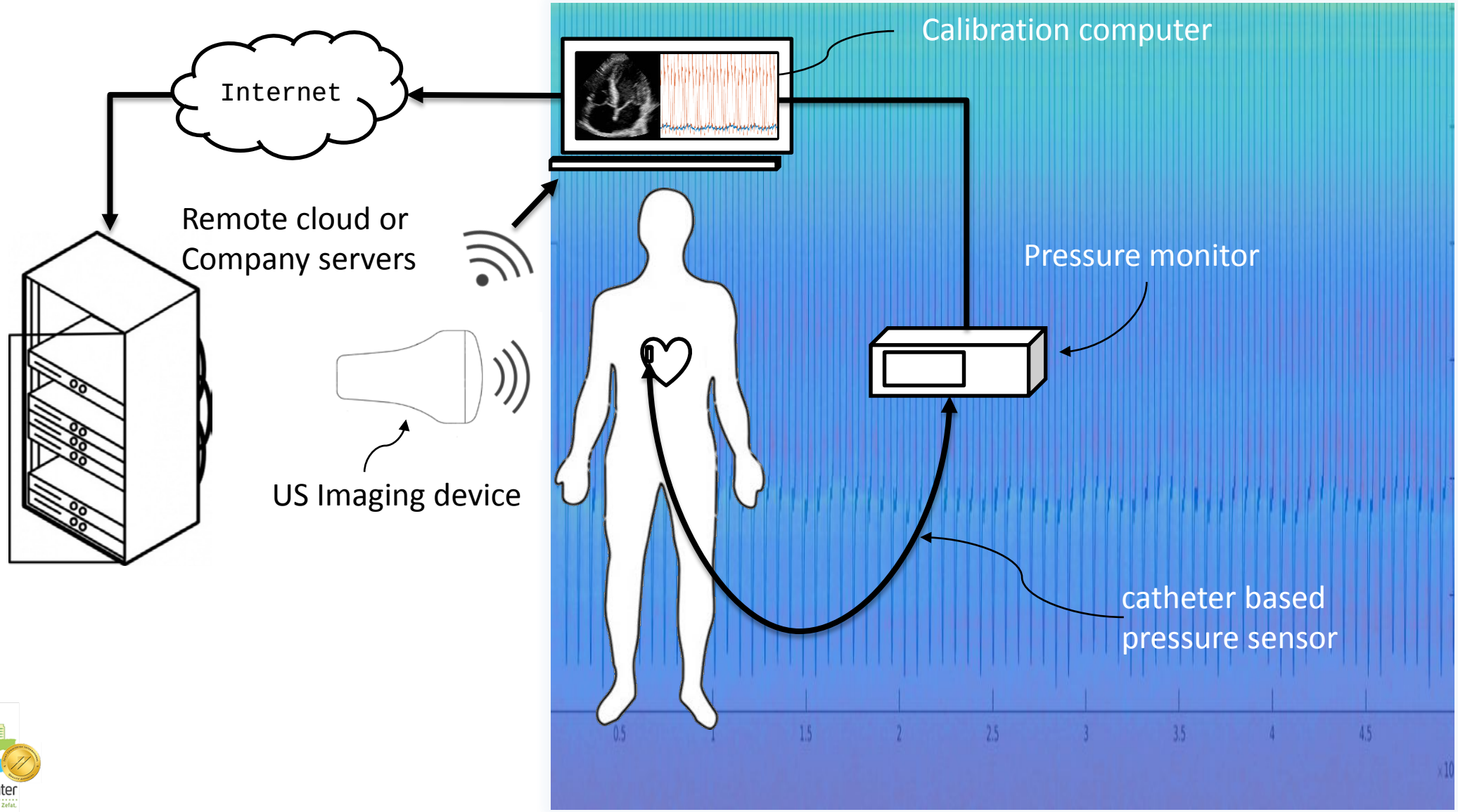
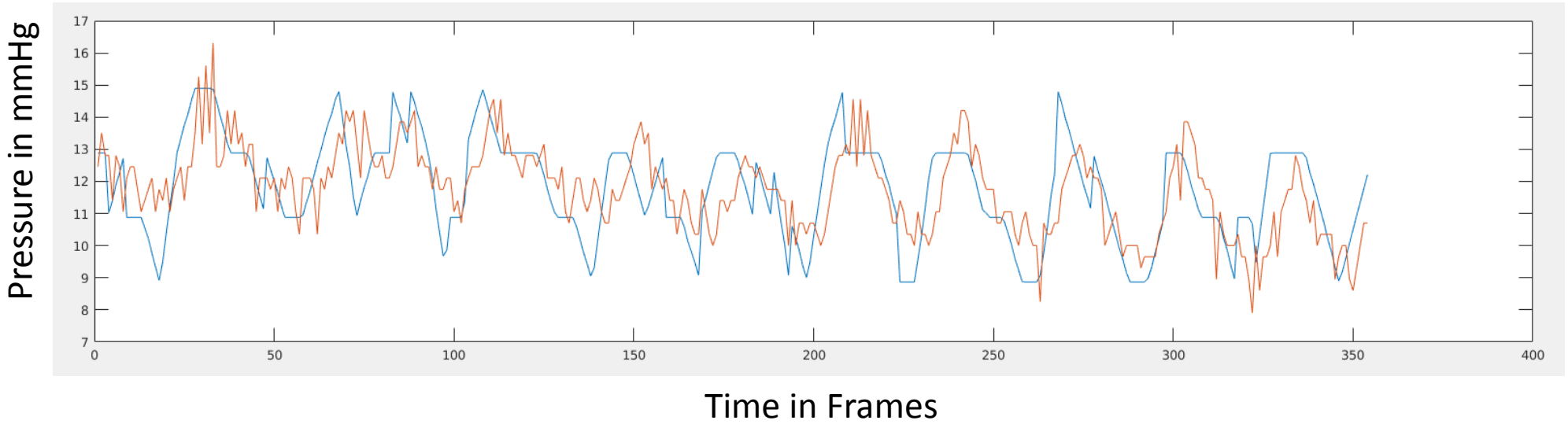
Superposition of Pressure Values on Processed Ultrasound Data



ICPM Calibration System Components



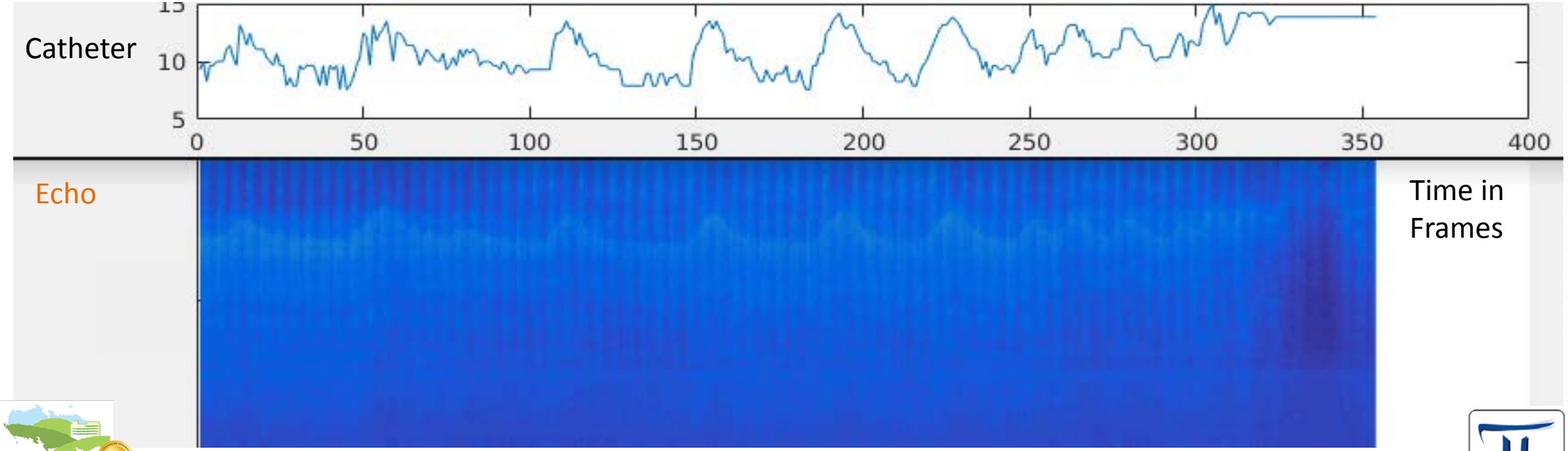
In ZIV Hospital 16-Dec-2018: Assessing LVEDP



Measured : 11.75 mmHg Calculated: 11.76 mmHg

Measuring LV pressure on 16 Dec 2018. Assessing LVEDP Control recording after Calibration. Calculated Data

Pressure in mmHg



Measured Average	Calculated Average
11.75	11.76
	10.93

In ZIV Hospital

Assessing LVEDP

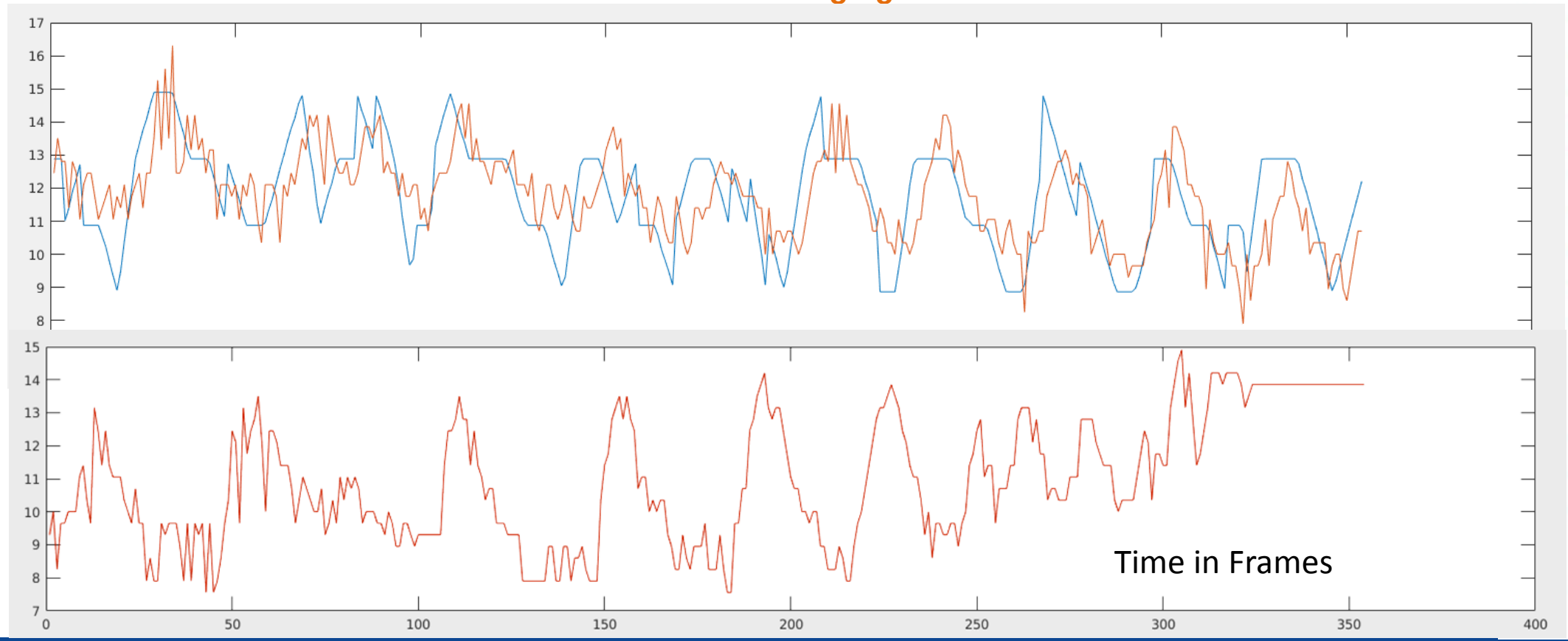
Calibration the model:

In Blue LVEDP from the Pressure acquired data

In Red – Model calibrated to data.

Lower Red is the calculated pressure from follow up ultrasound recording against the model above.

Test Results



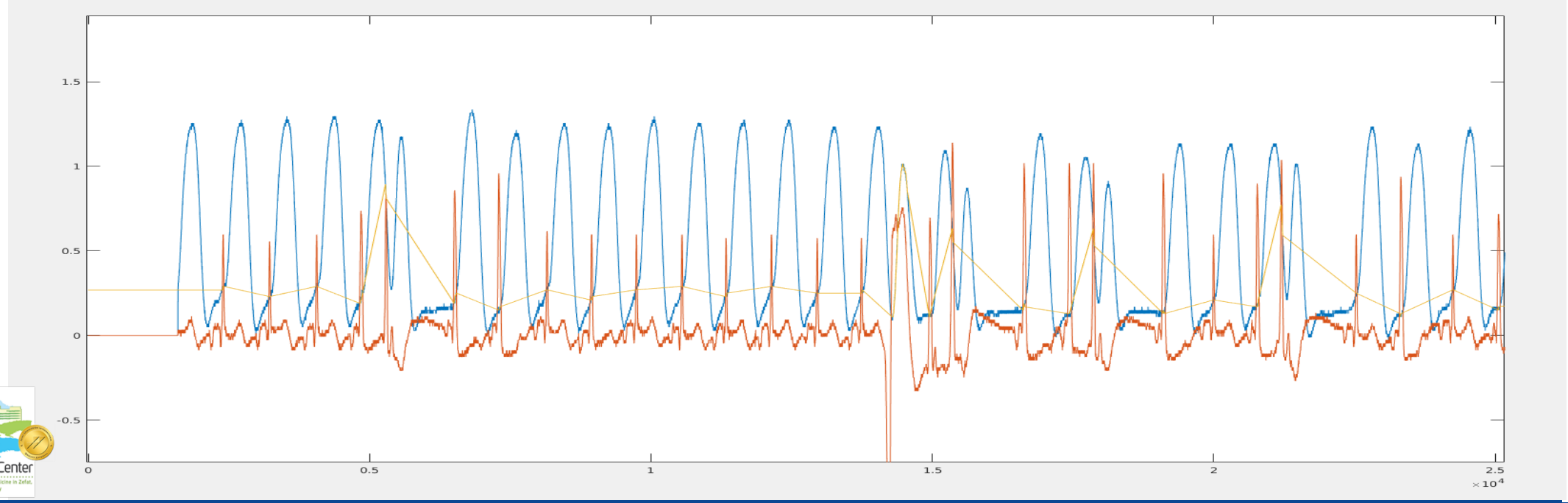
Measured Average
21.01
20.59

In ZIV Hospital

(30.12. 2018)
Assessing Extra- systoles of Patient 2.

Test Results

In Blue LV from the Pressure acquired data
In Red – ECG.
In Yellow calculates LVEDP points
(extra-systolic ones not yet excluded)



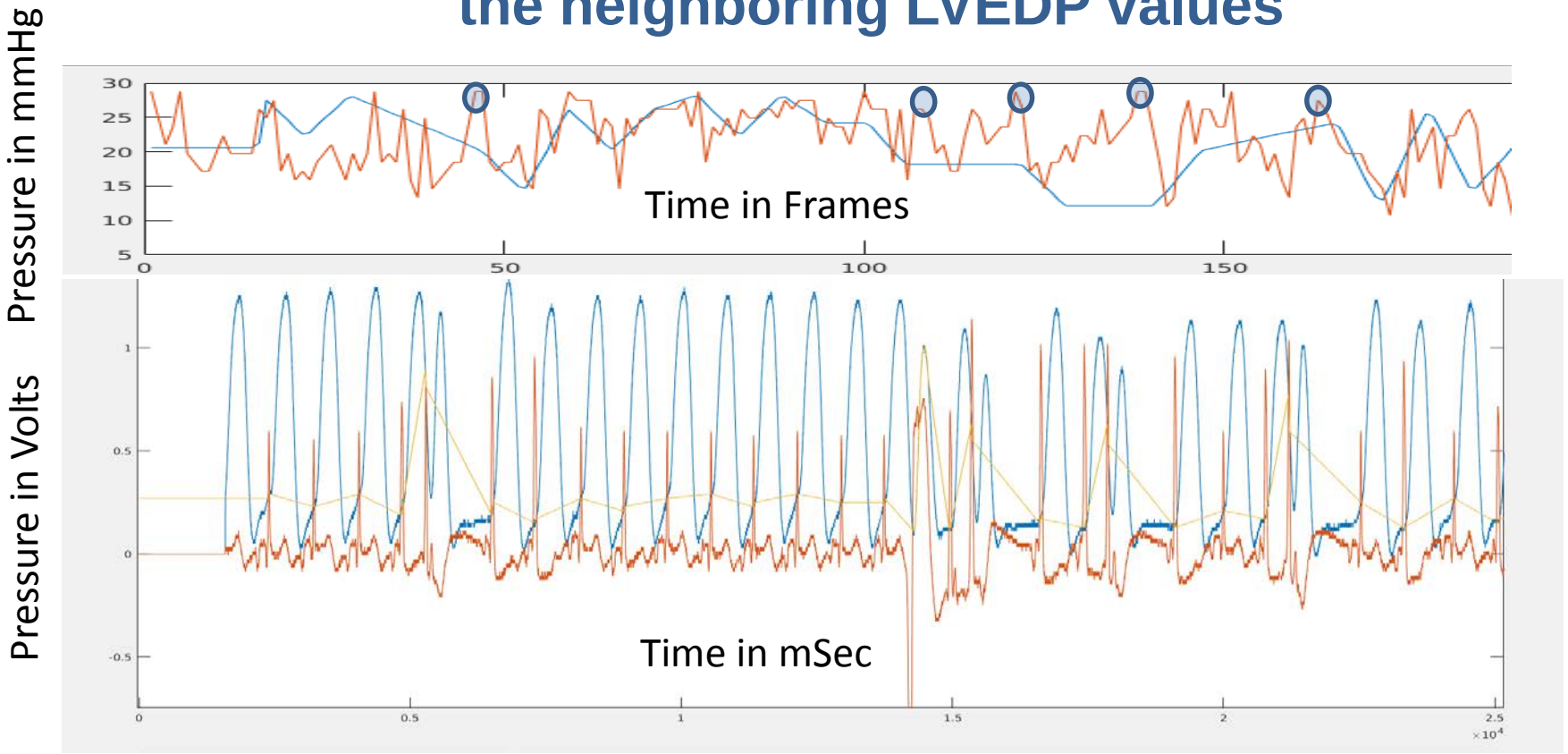
Measured Average	Calculated Average
21.01	21.03
20.59	20.66
	21.15

In ZIV Hospital

(30.12. 2018)

Test Results

Assessing Extra- systoles of Patient 2. Post-Extra-systolic LVEDP greater then the neighboring LVEDP values



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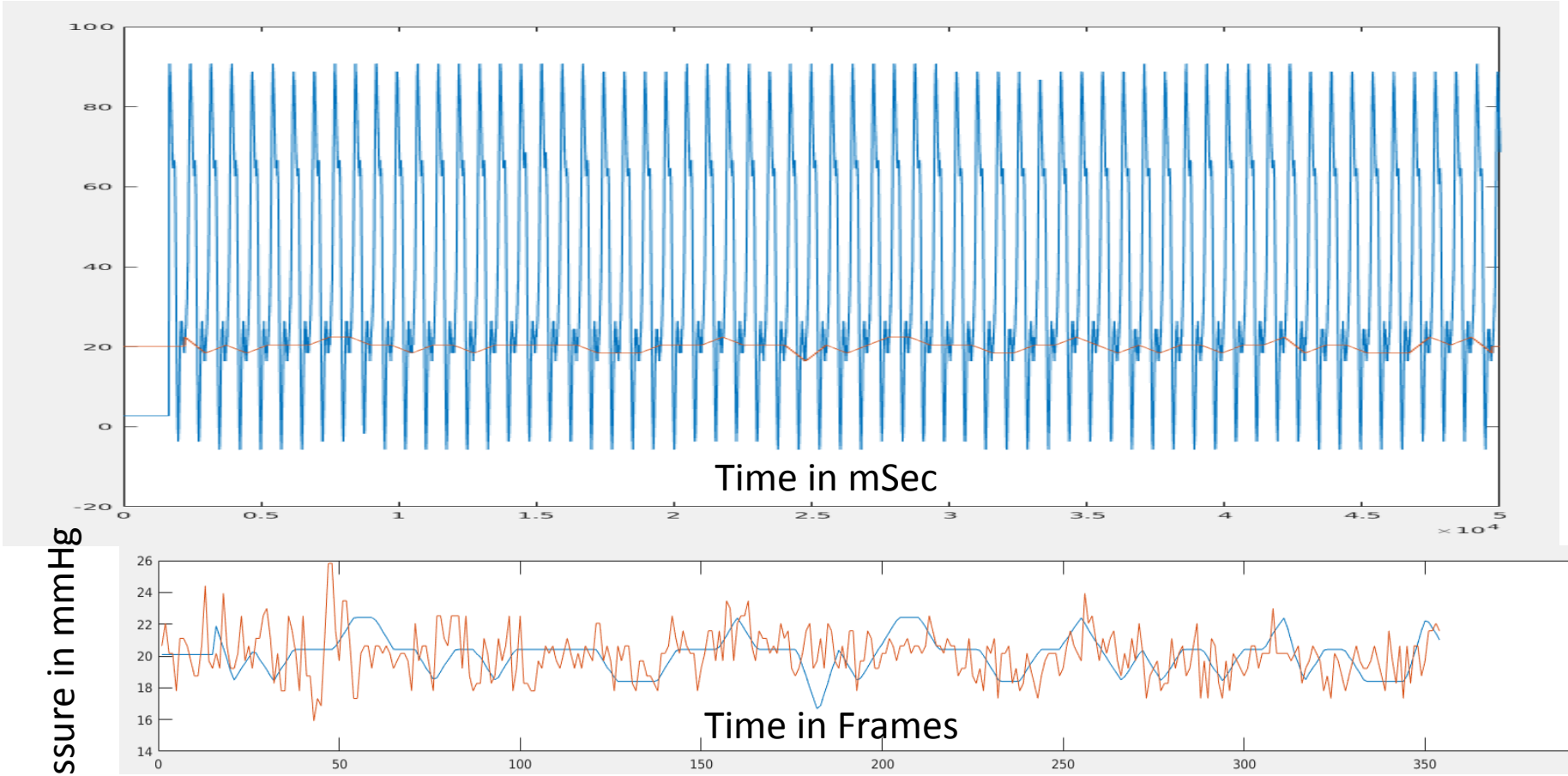
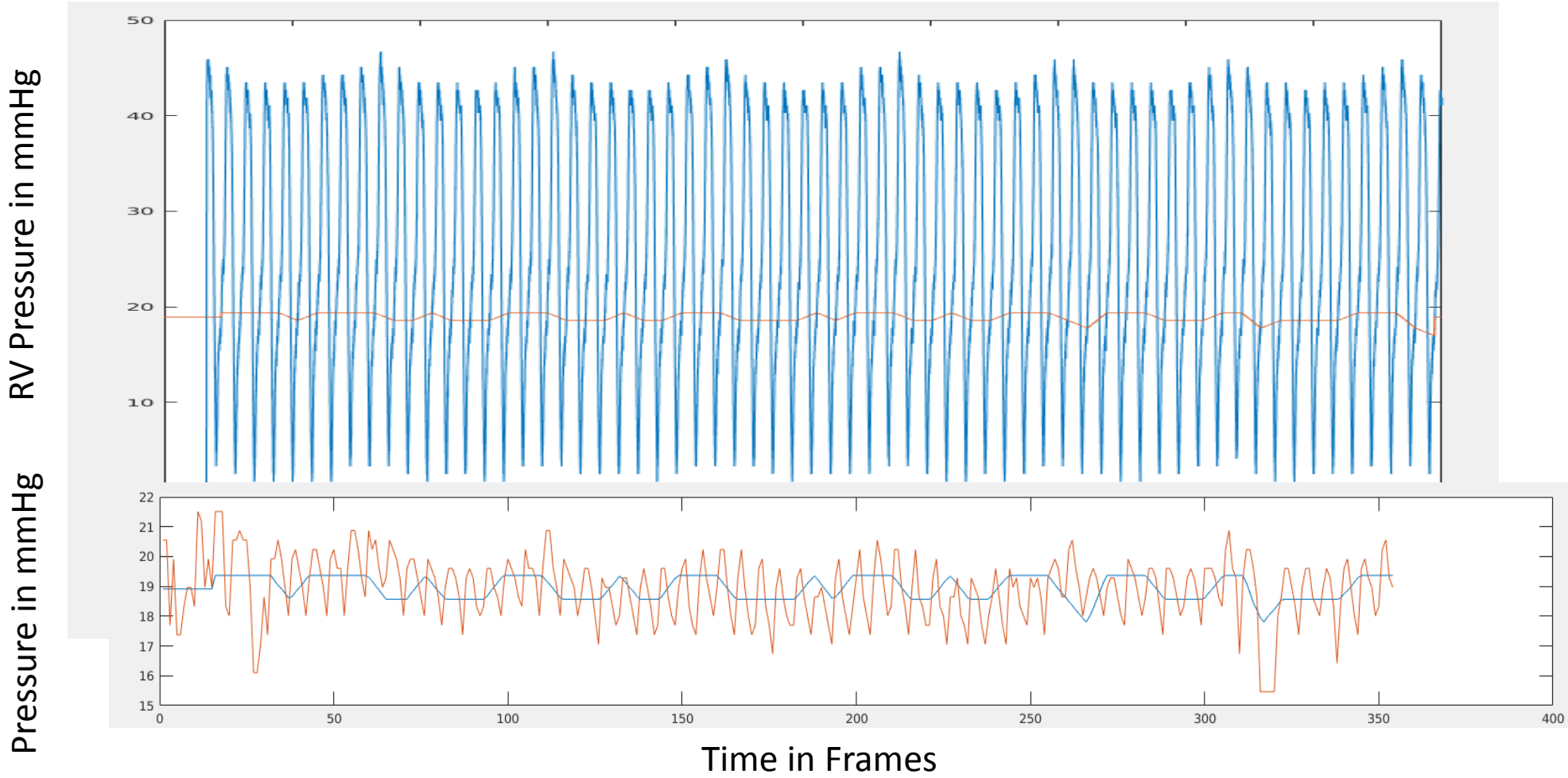
In ZIV Hospital 17-Jan-2019: Assessing LA and LVEDP by LV



Measured : 20.06 mmHg **Calculated: 20.09 mmHg**

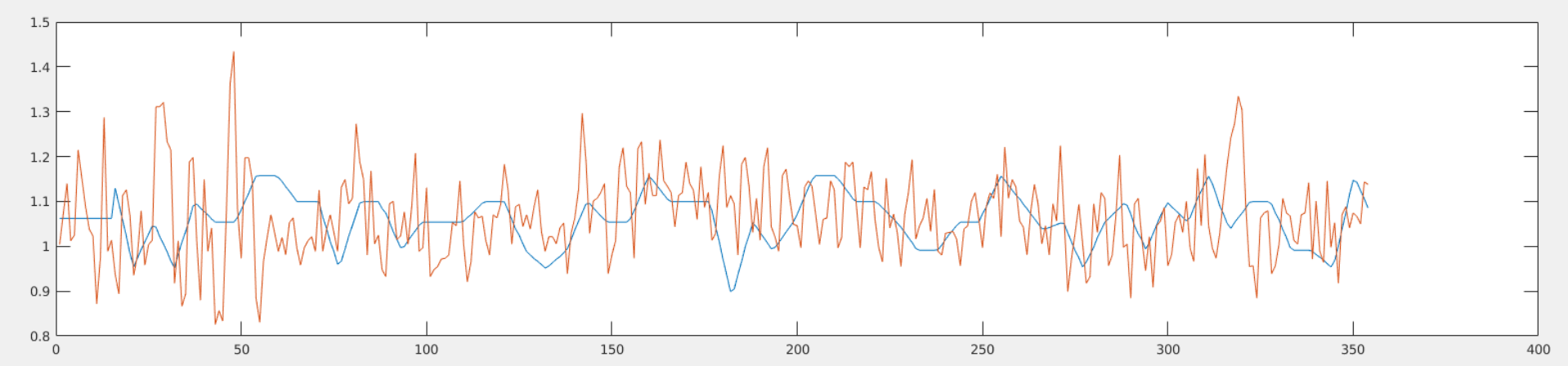
In ZIV Hospital 17-Jan-2019: Assessing RA and RVEDP by RV



Measured : 18.91 mmHg **Calculated: 18.94 mmHg**

In ZIV Hospital 17-Jan-2019:

- **Assessing ventricular End Diastolic Ratio LVEDP/RVEDP in real time:**
  - **Measured : 1.059**
  - **Calculated : 1.065**

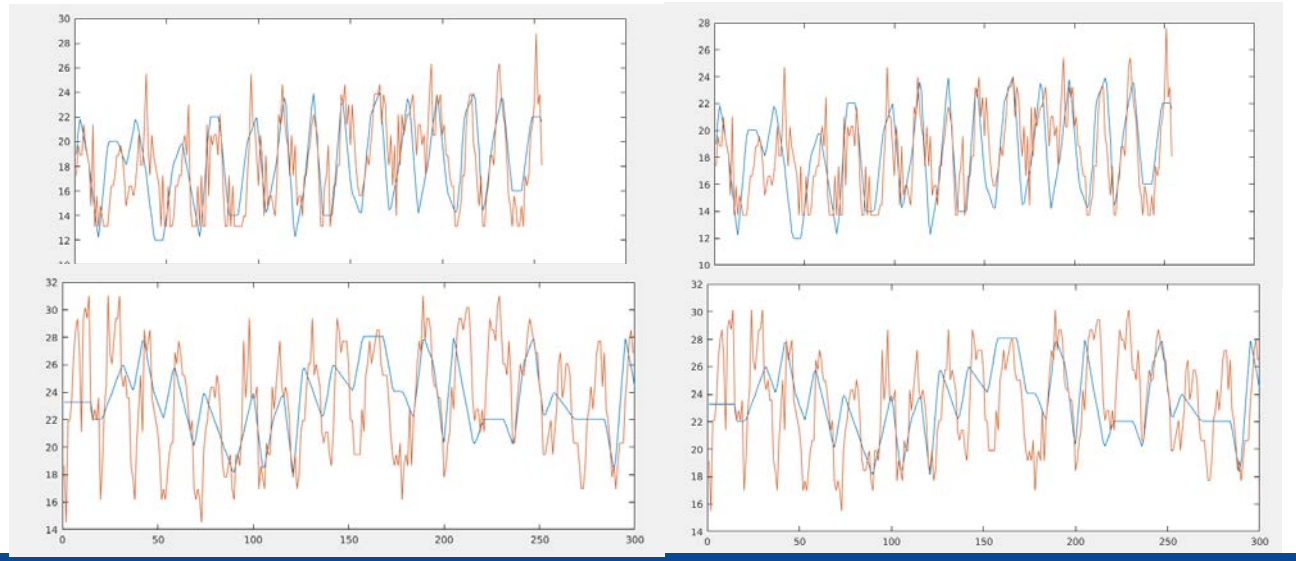


In ZIV Hospital 24-Mar-2019:

Assessing LVEDP with large differences before and after PCI

Cross-Calibration

	Pressure Before	Pressure After	Pressure Measured
US Before	18.24	18.28	18.24
US After	23.36	23.49	23.45



Conclusions

- ICPM provides very high accuracy and reproducibility of calculated pressure data from ultrasound as compared with catheter based pressures recordings.
- Further accumulation of data will allow AI and Machine Learning tools to ultimately remove the requirement for calibration step.

Healthcare Impact

- ICPM introduces new parameters for assessing cardiac health state.
- Fully automated L/RVEDP calculation though Jerk Analysis
- ICPM can detect cardiac pressure changes that occur long before other HF symptoms become visible.
- ICPM has the potential to become an ultimate non-invasive model for assessing CHF, PHT, CHD and more.

Call for Multi-Center Multi-National Study For Elaboration of Invasive and Non-Invasive *Intra Cardiac Pressure Monitoring*

Thank You!

Pi-Harvest Israel