



Development Environment for Medical Devices in
Japan and the US: ***Impact on Current Activities and the
Roles of Clinical Engineering***
Sunday, June 11, 8:00 a.m. - 9:00 a.m.

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CEO, DocBox Inc

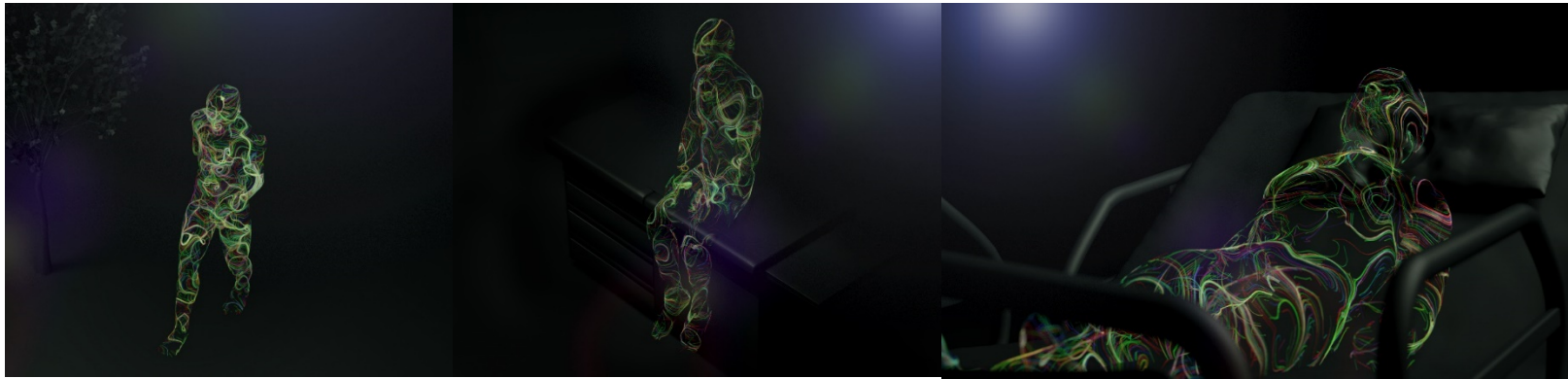
Health Technology Management Challenges

- Limited Skilled Staff
- Limited Resources
- Cost Conscious Healthcare
- High Volume
- Diverse set of environments (Hospitals → Clinics)

What does data have to do with HTM?

- Traditional Maintenance Management Systems
 - Inventory
 - Repairs
 - Software Updates
 - Preventative Maintenance
- HTM has been traditionally very labor intensive with retrospective documentation
- Emerging Markets will leapfrog stand alone technology and require bedside integration
- Traditional Markets are being pushed to be more efficient

Patients are the Source of Clinical Data



Transformation of the Data for HTM

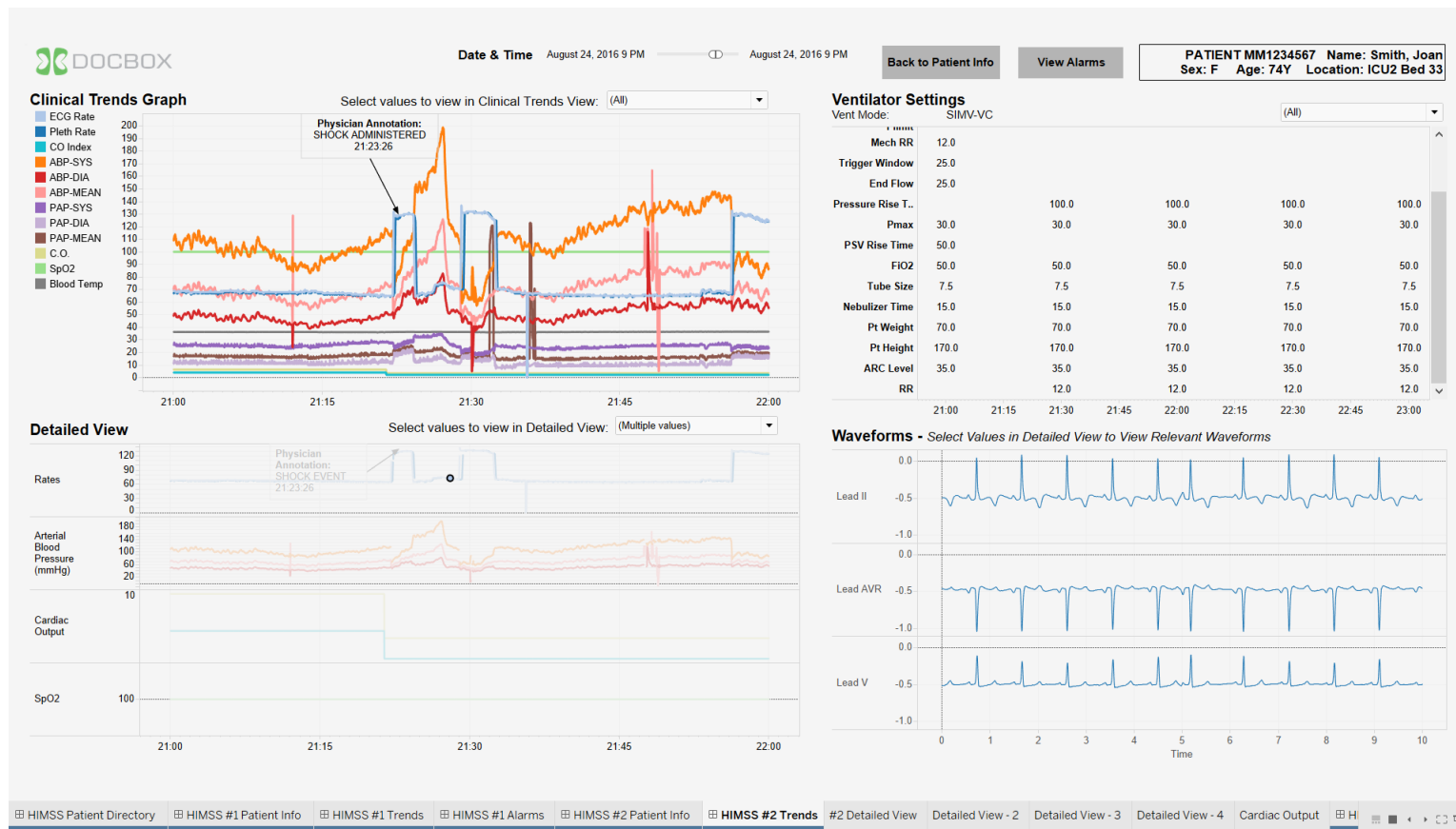
- Detailed Adverse Event Analysis
- Automated Device Maintenance and Errors
- Remote monitoring of technology
- Automated Inventory Tracking
- Analytics for Technology Planning and Use
- Use based Preventative Maintenance

Pilot Work

- 10 Beds in Cardiac ICU at Medanta the Medicity in Gurgaon, India
- Tracked Monitors, Ventilators, Infusion Pumps
- 3 months (March to May 2017)
- Retrospective review
- Preliminary Results

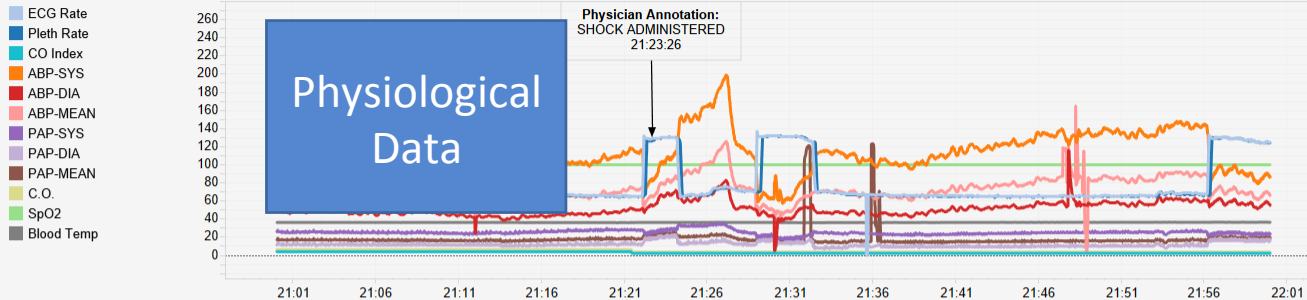
Retrospective Clinical Data Analysis

Adverse event and device failure investigations



Time synchronized, multisource, multivendor data set

Clinical Trends Graph



Select values to view in Clinical Trends View:

(All)

Physiological Alarms

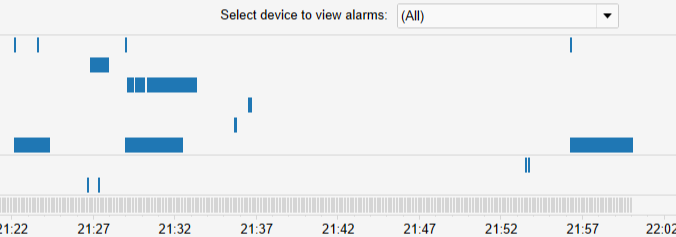
Patient Monitor 1

- * NON-SUSTAIN VT
- ** ABPs HIGH
- ** ABPs LOW
- ** Tblood LOW
- *** ASYSTOLE
- *** VTACH

Ventilator 1

- patient disconnected
- plimit reached

Alarm Data



Physiological Alarm Total Durations

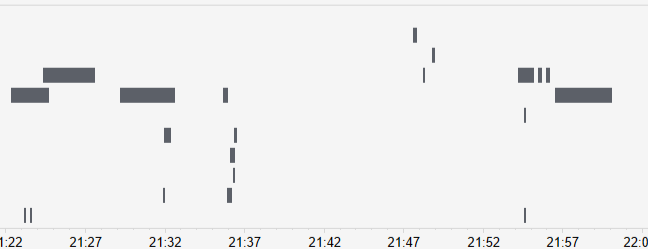
Alarm Message	Device	Seconds	Hours
patient disconnected	Ventilator 1	2.0	0.001
plimit reached	Ventilator 1	2.0	0.001
*** ASYSTOLE	Patient Monitor 1	3.0	0.001
* NON-SUSTAIN VT	Patient Monitor 1	5.0	0.001
** Tblood LOW	Patient Monitor 1	7.0	0.002
** ABPs HIGH	Patient Monitor 1	66.0	0.018
** ABPs LOW	Patient Monitor 1	223.0	0.062
*** VTACH	Patient Monitor 1	522.0	0.145

Technical Alarms

Patient Monitor 1

- ABP ARTIFACT
- ABP NON-PULSATILE
- ABP OVERRANGE
- ABP REDUCE SIZE
- CANNOT ANALYZE ST
- ECG NOISY SIGN.
- PAP ARTIFACT
- PAP NON-PULSATILE
- PAP OVERRANGE
- PAP REDUCE SIZE
- Resp LEADS OFF

Technical Alarms



Technical Alarm Total Durations

Alarm Message	Device	Seconds	Hours
PAP OVERRANGE	Patient Monitor 1	1	0.000
ABP OVERRANGE	Patient Monitor 1	2	0.001
ECG NOISY SIGN.	Patient Monitor 1	2	0.001
SpO2 POOR SIGNAL	Patient Monitor 1	2	0.001
ABP ARTIFACT	Patient Monitor 1	5	0.001
Resp LEADS OFF	Patient Monitor 1	5	0.001
ABP NON-PULSATILE	Patient Monitor 1	6	0.002
PAP NON-PULSATILE	Patient Monitor 1	12	0.003
PAP REDUCE SIZE	Patient Monitor 1	14	0.004
PAP ARTIFACT	Patient Monitor 1	25	0.007
SpO2 LOW PERF	Patient Monitor 1	31	0.009

Fleet Management and Technology Planning



DocBox Operations and Logistics Analysis
Time Period of 19/08/2016 - 01/09/2016 (14 Days)

Device Utilization Analysis

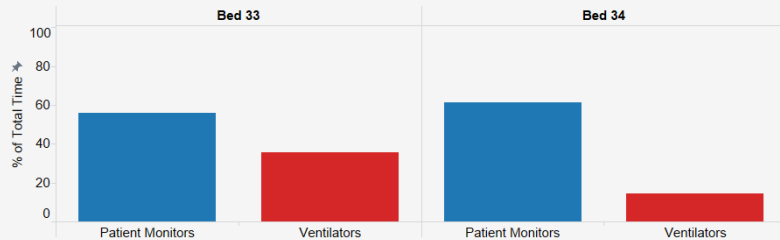
Total Number of Unique Devices Used per Bed

Bed	Patient Monitors	Syringe Pumps	Ventilators	Grand Total
Bed 33	1	4	2	7
Bed 34	1	5	2	8
Grand Total	2	9	4	15

Total Device Utilization (hrs) per Bed

Bed	Patient Monitors	Syringe Pumps	Ventilators	Grand Total
Bed 33	188.3	134.1	119.6	441.9
Bed 34	206.6	116.2	48.1	370.9
Grand Total	394.9	250.3	167.7	812.8

% of Time Devices Utilized per Bed from 19 AUG to 01 SEP



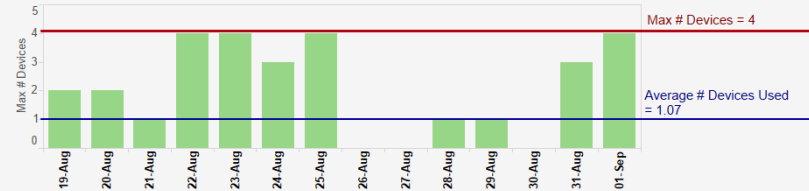
NOTE: Because only a single patient monitor and a single ventilator can be used at a time at each bed, the graph above indicates the % of time that these devices are used per bed over the 14 day time period. Syringe pumps are not included in this graph because the simultaneous use of multiple syringe pumps is very common during patient care.

Average Hrs of Device Utilization per Bed per Day (hr/day)

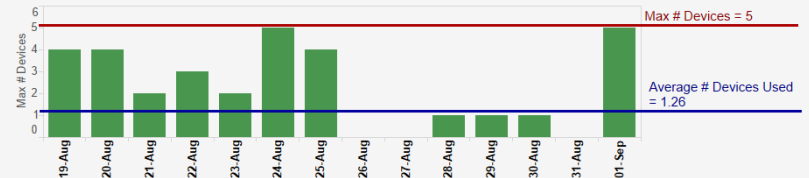
Bed	Patient Monitors	Syringe Pumps	Ventilators
Bed 33	13.45	9.58	8.54
Bed 34	14.76	8.30	3.44

NOTE: The average # of devices below is a calculation of the average number of devices used simultaneously at a bed per day.

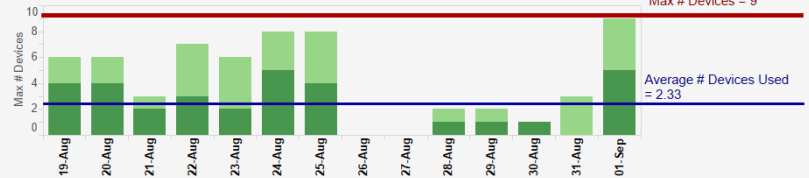
Max Number of Simultaneously Used Devices per Day at Bed 33



Max Number of Simultaneously Used Devices per Day at Bed 34



Potential Maximum Number of Simultaneously Used Devices per Day at ICU2 (Bed 33 & Bed 34)



NOTE: The potential maximum number of simultaneously used devices in ICU 2 was determined by adding together the max number of simultaneously used devices per day at Bed 33 and simultaneously used devices per day at Bed 34. This is a "potential" max number of simultaneously used devices in ICU 2 because it is assuming the max number of simultaneous device use per day at both Bed 33 and Bed 34 occurred at the same time.

Counts and Tracking of Total Devices Used
Tracking of Unique Devices Utilization Across Facility
Total Device Utilization Hours
Maximum Count of Devices Used

Device Utilization by Procedure

Device Utilization Analysis

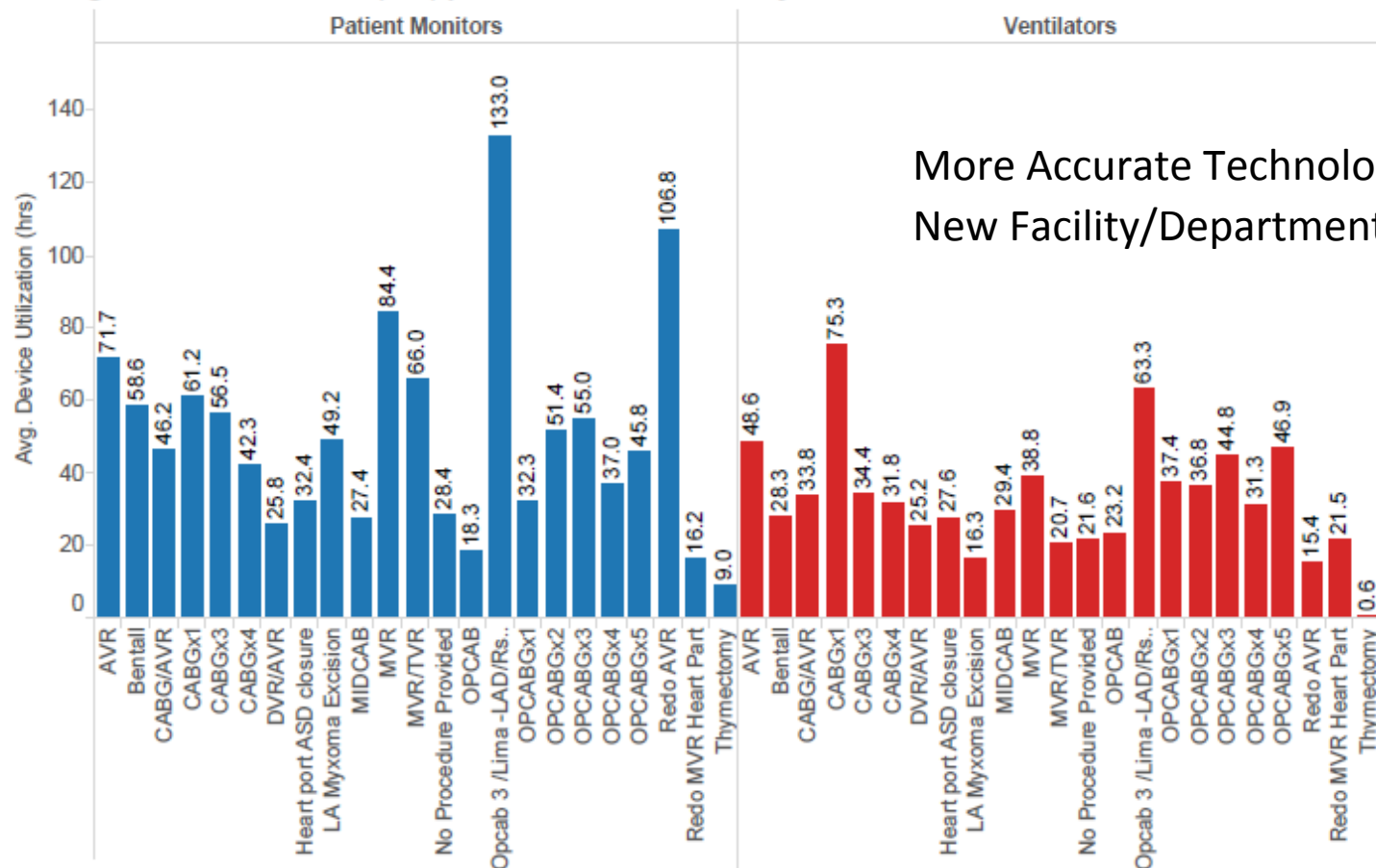
Total Device Utilization (hrs) in ICU2 (10 beds)

Patient Monitors	Ventilators	Syringe Pumps
7,045	5,048	229

Average Device Utilization (hrs) per Patient Admission

Patient Monitors	Ventilators	Syringe Pumps
41.44	31.16	5.59

Average Device Utilization (hrs) per Patient Admission by Patient Procedure



Alarms and Device Management

- Automated monitoring of medical device alarms via report or dashboard

Top 10 Technical Alarms by Total Time Alarming		Device	Alarm Description	Time Alarming (hrs)
ABP	Reduce Size	Patient Monitor	Reduce size of arterial pressure wave	525.26
Resp	Leads Off	Patient Monitor	Respiratory leads off patient	491.16
Cannot Analyze QT		Patient Monitor	Cannot analyze QT signal	485.64
Cannot Analyze ST		Patient Monitor	Cannot analyze ST signal	420.27
Batt	MALFUNCTION	Patient Monitor	Battery malfunction	396.66
SpO2	Sensor Off	Patient Monitor	SpO2 sensor off	300.24
ECG	Leads Off	Patient Monitor	ECG leads off patient	299.49
SpO2	Low Perf	Patient Monitor	Low perfusion at SpO2 sensor	164.39
SpO2	No Sensor	Patient Monitor	No SpO2 sensor connected	134.28
backup audio failure		Ventilator	The backup audio system has failed.	131.56

- Use Base Preventative Maintenance
- Use Base Technology Management and Planning
 - How many devices do I need?
 - Where are the missing devices?
 - Are there devices in the fleet that aren't being used?

Preliminary Conclusions

- Clinical Point of Care Data can be utilized as a way to optimize HTM resources
- Data can be used for PM scheduling
- Data can be used for retrospective clinical data analysis
- Data can be used for capital equipment planning
- Systems can be automated for device maintenance requests

Future Plan

- Completing Pilot Cost Analysis
- Daily Technical Alarm Reports for Biomed
- Continued Tracking of Devices
- Expand to more beds
- Bi-Weekly/Monthly Reports to COO and Chief of Anesthesia