

A MODEL CENTRE FOR FULLY AUTOMATED IN-HOUSE CALIBRATION LAB BIOMEDICAL ENGINEERING OF CMC VELLORE (NABL ACCREDITED)

India's 1st NABL Accredited Healthcare Biomedical Engineering Calibration

Lab

Presented by – BME Team



OBJECTIVES AND ROADMAP

Ensure the safety of patients, Minimize downtime, Extend lifetime and increase efficiency, Reduce maintenance cost, Ensure accuracy, reliability, and availability

2010

• NC - in pre-assessment of NABH - medical equipment calibration

2011

- Calibration of equipment outsourced
- Charges were high for minimum quantity of equipment
- Calibration performance Not at desired level

2012

• BME planned the in-house calibration facility with 6 analyzers

2013 -2016, • BME executed the calibration in a Manual process

2017

• Semi-automation implemented - "ANSUR" software

2021

- Accredited by NABL in Medical device calibration with 6 advanced analyzers covers 9 category of equipment and 24 parameters
- 2022
- Associated with the development process of OneQA with Fluke and Started the calibration in Full automation



EVOLUTION OF CALIBRATION PROCESS IN BME

Stage 1

Manual Calibration

- · Manual data entry
- · No control on Procedure.
- · Manipulation possible.
- No digital copy
- · Multiple manual evaluation

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| BI SET HR NO 60 | TOLERA TOLERA | SET 57 30 30 30 30 | ACT FR 165 30 30 | ME SET 200/150 150/150 120/80 | #18-1000; #09-41# #LPS #F ACTUAL 51/DIA 201 / IQ-E IQ-F 795 (IQ-F 798 | 1. /s 2 ph, 9f - 2 ms, Appl REGRAM PC SE 1FO2 98 | pA, 000 pA, Hel par MANCE ALSE O T FR 55 | VERIFIC XVMETE ACT SPOT | ATION R IAL INC EE 95 | SET 123/80 120/00 | 18 | P ACTUA | - 50µA | SET Calsius 30 35 | MP |
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| El 587 HR 30 60 120 160 | TOLERA TOLERA TOLERA TOLERA TOLERA TOLERA TOLERA TOLERA TOLERA | 15 SET 15 30 30 60 100 second | ACT FR SD SO | Refrage - Clin Sarth residence - Sarth residence | ## 1200, 1000 - C1 ## ## 200 ## ACTUAL \$1/004 \$1/004 \$1/004 \$1/004 \$1/004 \$1/004 \$1/004 \$1/004 \$1/004 | 1. (# 2) 1. (# | 95 45 180 130 Tide | 90 - 1000 VERIFIC VERIFIC VERIFIC VACTO SPOJ 90 - 87 - 73 - 90 - 85 - 85 - 85 - 85 - 85 - 85 - 85 - 8 | ATION R IAL IAL IAC | 185 N/A 1857 187 120/80 120/00 25/00 10/2 14/4 15/30 | 18 min | P ACTUA IBP2 | 1893 | 76 SET Celsius 30 35 37 40 42 | AC Calls |
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| El 587 HR 50 60 120 160 180 | TOLERA TO | 987 88 15 20 80 100 ance - 1999 | ## ACT FR 145 SO SO SO SO SO SO SO S | Refrage - Clin Sarth residence - Sarth residence | ### 1200, ### 12 | 1. (# 2) 1. (# | 95 180 1390 1590 1590 1590 1590 1590 1590 1590 15 | 90 87 72 90 95 110 110 110 110 110 110 110 110 110 11 | ATION R IAL | 185 N/A 1857 187 120/80 120/00 25/00 10/2 14/4 15/30 | 18 min | P ACTUA IBP2 | 1893 | 76 SET Celsius 30 35 37 40 42 | AC Calls |
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Stage 2

Semi-Automation (ANSUR)

- Partial Auto data Capture
- · Limitations in template
- Corrections due to partial manual entry
- Partial Evaluation

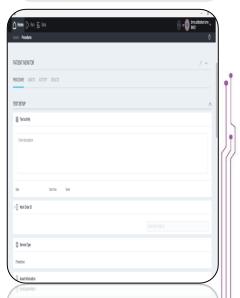


Full Automation (OneQA)

Complete Auto data capture

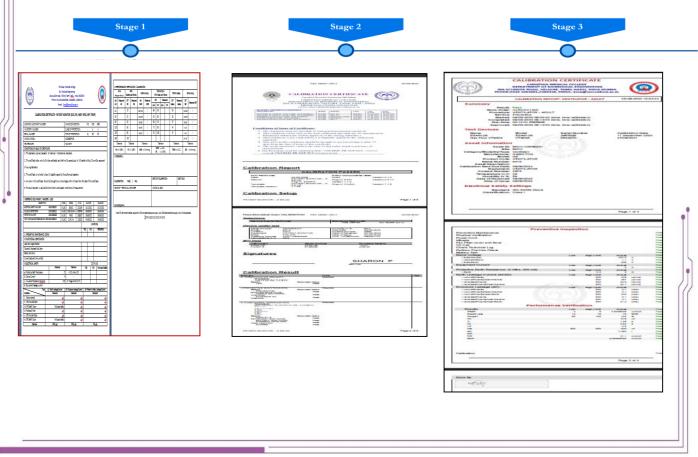
Stage 3

- Standardized and customizable templates
- No Manipulation
- · Auto decision and evaluation





EVOLUTION OF CALIBRATION REPORT IN BME



HIGHLIGHTS AND CHALLENGES



Pre - Automation

- Step by Step procedures & multiple connections & reconnections
- Manual Capture & Verification
- No restricted access
- Manual approval & calculation
- Hand Written Report and manual Upload to Dedicated Data Storage Server
- Template design limitation as per NABL or ISO standards
- Possible Manipulation of reports occurred
- Limited capacity 2000 Equipment/year with Avg 30 mins / eqpt – for calibration



Post - Automation

- Fully Automated procedures & one-time setup with auto advanced sequences
- Auto capture & evaluation
- Complete password-protected
- Automated verification algorithm
- Reports are Auto-generated and integrated with CMMS Software in Cloud-based storage
- Template Custom design to meet the NABL or ISO standards
- Nil manipulation One report per equipment
- Increased Capacity 6000 Equipment/year with Avg 10 mins/eqpt - for calibration



COST EFFECTIVENESS



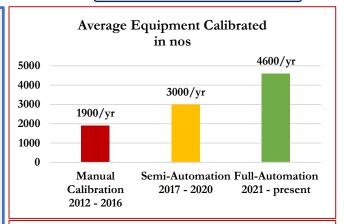
Cost Effectiveness

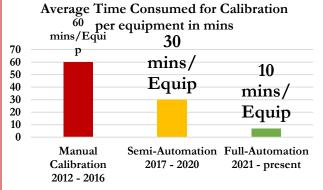
- One Time Initial Investment
- ROI can be retrieved from the first year itself
- Minimizes the Man-power
- One software for all Master analyzers
- Single license for 100+ users
- Accessibility through cloud
- Not a PC-dependent software license
- Software upgradation at free of cost till license validity
- Suitable for medium and large-scale facilities

Cost Analysis

| Cost mining | 310 |
|---------------------------------|------------------|
| Total Value of Analyzer | Rs. 41,32,047.00 |
| | |
| Depreciation (Cost / 7 yrs.) | Rs. 5,90,292.43 |
| Annual Maintenance / yr. | Rs. 82,640.94 |
| Operators Salary / yr. | Rs. 8,40,000.00 |
| Over Head Charges / yr. | Rs. 1,90,865.00 |
| Total Expenses / yr. | Rs. 17,03,798.37 |
| Cost saved in calibration / yr. | Rs. 38,98,280.00 |
| Cost Recovered / yr. | Rs. 21,94,482.00 |

Manual vs Automation







IMPACT AND WAY FORWARD

2023

- 1st Hospital calibration facility in Asia full automation of process and calculations
- NABL awarded accreditation for Mechanical and Thermal parameters
- Full automation in Lab Equipment calibration
- Proficiency Testing Provider for Medical Devices



THANK YOU