

**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 -
2021

- Semi-automation implemented - “ANSUR” software

2022

- Accredited by NABL in Medical device calibration with 6 advanced analyzers covers 9 category of equipment and 24 parameters
- 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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TEST REPORT

DEVICE UNDER TEST - PATIENT MONITOR (SGL, RR, NIBP, SPO2, SpO2, TEMP)

LOCATION: 1st floor, 1st block, Sector, T-101, Road, Kolar, 532004. NAME OF CONNECTION: PA, SPS, SPS2

QUANTITY NUMBER: 1 CLASS OF PROTECTION: IP 20 IP

SERIAL NUMBER: 6-11-2501A 2554 APPLIED PART TYPE: PA, SPS, SPS2

SERIES & MODEL: 10012501A 10012501A ACCESSORIES: 10012501A 10012501A

TEST EQUIPMENT		DATE	BY
Safety Analyzer	EST-000001	16/11/24	10012501A
SPO2 CALIBRATION	10012501A	16/11/24	10012501A
PATIENT TRANSDUCER (SGL)	00000001	16/11/24	10012501A
SPO2 SENSOR	10012501A	16/11/24	10012501A

PHYSICAL VERIFICATION TEST

Preventive Maintenance Done YES NO

Label and signs checked YES NO

Display & keyboard test done YES NO

Battery test done YES NO

Current date and time verified YES NO

ELECTRICAL SAFETY TEST

Measured value: 0.00 YES NO

Protective Earth Resistance: 0.00 YES NO

Equipment Leakage Current: 0.00 YES NO

Patent Auxiliary Leakage Current: 0.00 YES NO

RESISTANCE VERIFICATION TEST

TEST	ACT	SET	ACT	SET	ACTUAL	SET	ACTUAL	SET	ACTUAL	SET	ACT	SET	ACT	SET	TRIP
100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

REMARKS: Working good

DATE TESTED: 16/11/24 NEXT DATE: 03/12/24

ISSUED BY: [Signature]

RECEIVED BY: [Signature]

DATE: 16/11/24

TIME: 10:30

PLACE: [Signature]

NOTE: RR, Apnea/Respiratory, RR flow/ventilator power supply cord, SPS/leakage Power supply cord, RR flow application
 The standards used are traceable to National/International standards.
 10MA16C004/004/000018

Stage 2

Semi-Automation (ANSUR)

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

DUT Information

Device Under Test

Serial Number	
Model	
Location	
Make	
Equipment	
Inventory Number	
Temperature	
Humidity	
Due Date	
Contact Number	
Date of Received	
Date of Issue	
UPLA - CC322220	

Navigation icons: Home, Back, Forward, Refresh, Search, Print, Close

Stage 3

Full Automation (OneQA)

- Complete Auto data capture
- Standardized and customizable templates
- No Manipulation
- Auto decision and evaluation

Home > DUT Info

Process

PATIENT MONITOR

PROCEDURE: ACTED ACTIVITY: RESULTS

TEST SETUP

Test activity

Enter description

Done

Start

Test Date

Test Time

Test Type

Procedure

Auto Monitor

EVOLUTION OF CALIBRATION REPORT IN BME

Stage 1

Stage 2

Stage 3

REPAIR ORDER		DATE		TIME	
NO.		DATE	TIME	DATE	TIME
DESCRIPTION					
BY					
FOR					
DATE					
TIME					
STATUS					
REPAIR ORDER NO.					
DATE					
TIME					
STATUS					
REPAIR ORDER NO.					
DATE					
TIME					
STATUS					
REPAIR ORDER NO.					
DATE					
TIME					
STATUS					
REPAIR ORDER NO.					
DATE					
TIME					
STATUS					
REPAIR ORDER NO.					
DATE					
TIME					
STATUS					

CALIBRATION CERTIFICATE

CONDITIONS OF USE AND ACCEPTANCE

Calibration Report

CALIBRATION PASSED

Calibration Setup

Signatures

Calibration Result

SHARON F

CALIBRATION CERTIFICATE

CALIBRATION REPORT: VENTILATOR - ADULT

Summary

Test Devices

Asset Information

Electrical Safety Settings

Pre-use Inspection

Performance Verification

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

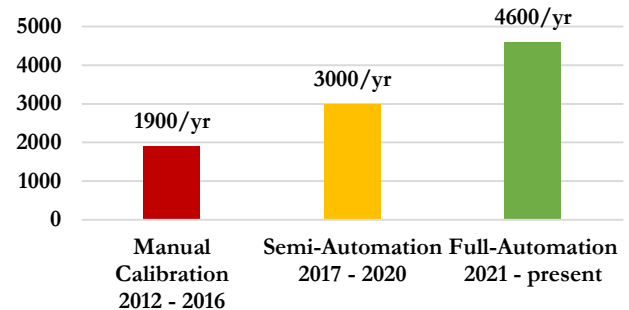
- **One Time** Initial Investment
- **ROI** can be retrieved from the **first year itself**
- **Minimizes the Man-power**
- **One software** for all Master analyzers
- **Single license** for 100+ users
- Accessibility through **cloud**
- **Not a PC-dependent** software license
- Software upgradation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

Cost Analysis

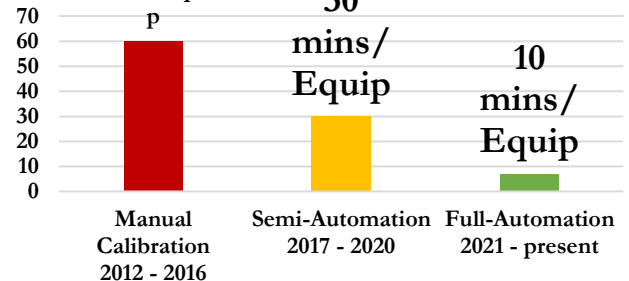
Total Value of Analyzer	Rs. 41,32,047.00
Depreciation (Cost / 7 yrs.)	Rs. 5,90,292.43
Annual Maintenance / yr.	Rs. 82,640.94
Operators Salary / yr.	Rs. 8,40,000.00
Over Head Charges / yr.	Rs. 1,90,865.00
Total Expenses / yr.	Rs. 17,03,798.37
Cost saved in calibration / yr.	Rs. 38,98,280.00
Cost Recovered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

Manual vs Automation

Average Equipment Calibrated in nos



Average Time Consumed for Calibration per equipment in mins



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**

2024

- **Full automation in Lab Equipment calibration**
- **Proficiency Testing Provider for Medical Devices**

THANK YOU