



Christian Medical College Vellore Biomedical Engineering



First Hospital Biomedical Engineering Department Accredited by NABL – CMC Experience

Arul Prakash
CMC Vellore



Background

Christian Medical College Vellore

- Started as one-bedded clinic-cum-dispensary in 1900 by Dr. Ida Sophia Scudder.
- Today, we have multiple campuses in and around Vellore and one campus in Chittoor, AP with a total count of more than 3300 beds.
- CMC is committed to serve the marginalized with best care at affordable cost without compromising in technology or state of art medical equipment.
- CMC is the pioneer in many areas of healthcare including education, research, surgeries, technology & equipment etc.



Biomedical Engineering

1971 – Started as a small section

1982 – Became an independent Department

2020 – Became central Department with 7 Sections

- Manage 4 campuses with **15,000** medical equipment
- Calibrate more than **3000** equipment in-house every year

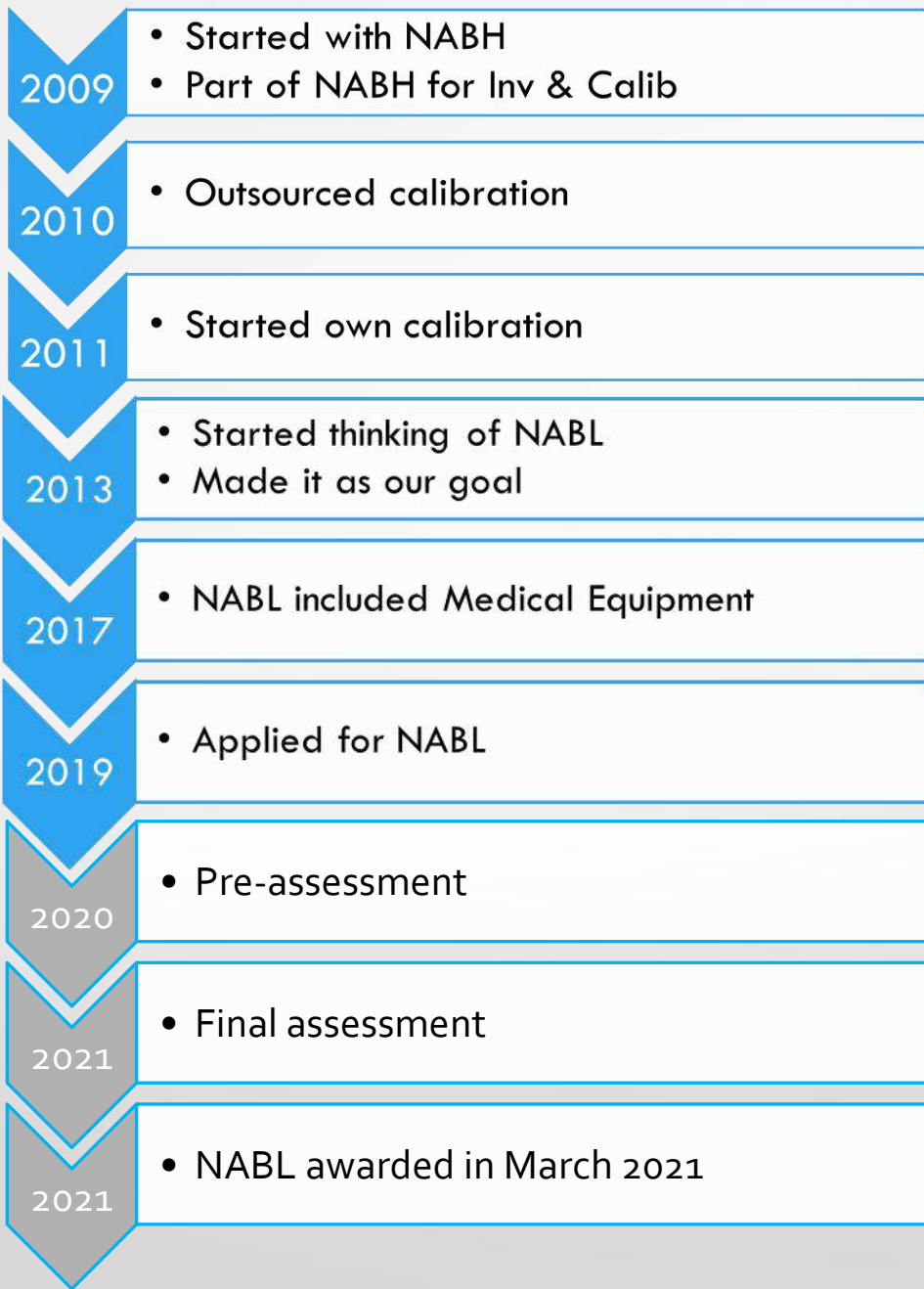
Why Calibration?

- ✓ Ensure Accuracy
- ✓ Ensure Reliability
- ✓ Ensure Availability
- ✓ Reduces Risks & Ensures Safety Of Patients & Operators
- ✓ Enhances Performance
- ✓ Increases Efficiency
- ✓ Extends Life Of Equipment
- ✓ Quality Of Care Increases
- ✓ **MANDATE** - Accreditations, Studies, Research & Projects
- ✓ **REQUIRED** – Grants, Funds, Donations



Journey

Our Journey to NABL





How we did it...

Preparation for NABL

- Master Analyzers, Testers, PC And Software
- Inventory Of Medical Equipment
- Technical Manuals / Calibration Procedures
- Qualified Technical And Trained Personnel
- ISO/IEC 17025:2017 Training
- Uncertainty Training
- Quality Manual / SOP's
- Inter Lab Comparison
- MRM / Audit Reports



Facilities & Capabilities



Defibrillator
Analyzer for
Defibrillator
& Pacemaker



Vital Signs
Simulator for
Monitor,
Pulse
oximeter,
Fetal Monitor



Electrosurgical
Analyzer for
Electrosurgical
Units



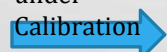
Gas Flow
Analyzer for
Ventilator,
Anaesthesia
Workstation,
BiPAP, CPAP



Infusion Device
Analyzer for
Syringe,
Infusion & Feed
Pumps



Electrical
Safety
Analyzer for
All Device
under
Calibration



Facilities & Capabilities



Information Board Calibration File upload PM Calibration Report HABL documents Equipment Manual Temperature Monitor QM DOC UPLoad

☐ INVENTORY NO
☐ DEPARTMENT
☒ EQUIPMENT CATEGORY VENTILATOR - CRITICAL CARE
☒ CALIBRATION REQUIRED

Find On Date 19-03-2022 B/W Date 19-03-2022

Equipment and calib status Due Valid - 144 Due Expired - 12

Inventory No.	Department	Location	Equipment	Model	Serial No.	Calibdate	Nextdue	Cal. Remarks	REPORT/Cal. Status	AMC
MSO-K0080101	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	94275	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080102	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	94281	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080296	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-S	45011	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080115	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	91523	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080117	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	91521	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080103	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	94282	09-02-2022	09-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080104	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	94283	10-02-2022	10-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080098	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-S	45014	10-02-2022	10-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080098	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-S	45013	10-02-2022	10-02-2023	Calibration Pa.	REQUIRED	
MICU-D0080097	MICU	MICU	VENTILATOR	RAFAEL SI	10878	10-02-2022	10-02-2023	Calibration Pa.	REQUIRED	Yes
MSO-K0080100	M.S.OFFICE	KANNIGAPU	VENTILATOR	SERVO-H	94278	10-02-2022	10-02-2023	Calibration Pa.	REQUIRED	
MICU-D0080251	MICU	MICU	VENTILATOR	CI	14081	14-02-2022	14-02-2023	Calibration Pa.	REQUIRED	
MSO-K0080294	M.S.OFFICE	KANNIGAPU	VENTILATOR	CI	5284	14-02-2022	14-02-2023	Calibration Pa.	REQUIRED	
MSO-S0080029	M.S.OFFICE	BME STAND	VENTILATOR	GS	22556	14-02-2022	14-02-2023	Calibration Pa.	REQUIRED	
MICU-L0080285	MICU	MICU	VENTILATOR	RAFAEL CO	15526	14-02-2022	14-02-2023	Calibration Pa.	REQUIRED	Yes
MSO-K0080144	M.S.OFFICE	KANNIGAPU	VENTILATOR	GS	22299	14-02-2022	14-02-2023	Calibration Pa.	REQUIRED	

Inventory Year Calibdate location View
2019 01-02-2019 01-02-2020 REC'D-D008048.pdf





Documentation & Training

Christian Medical College Vellore

18-02-2022

CALIBRATION CERTIFICATE

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CHRISTIAN MEDICAL COLLEGE VELLORE
DEPARTMENT OF BIOMEDICAL ENGINEERING
IDA SCUDDER ROAD, VELLORE, TAMIL NADU, INDIA-632004.
PHONE:0416 2282661,2283418
EMAIL: hme @ cmcvellore.ac.in <mailto:hme@cmcvellore.ac.in>

DESCRIPTION	MAKE	MODEL	S.N.O	CAL DATE	EXP DATE
ELECTRICAL SAFETY ANALYSER-ECT-6000402	FLUKE	ESA 612	180245	20-09-2021	20-09-2022
ELECTRICAL SAFETY ANALYSER-ECT-6000402	FLUKE	ESA 612	221054	20-09-2021	20-09-2022
VENTILATOR ANALYSER-ECT-6000402	FLUKE	VT FLU510P	302013	20-09-2021	20-09-2022

Conditions of Issue of Certificate:

- The standards used are traceable to National/International standards
- This certificate refers only to the item calibrated and shall not be reproduced in full/partial without the written approval of the issuing laboratory
- This certificate is not valid unless it is Digitally signed by the authorized signatory.
- Any error in this certificate should be brought to our knowledge within 15 days from the date of issue of this certificate.
- The result reported is valid at the time of and under stated conditions of measurement.

VENTILATOR-ADULT-18: Page 1 of 5

Christian Medical College Vellore

18-02-2022

Fluke Biomedical Amstar CALIBRATION

Calibration Report

CALIBRATION PASSED

QC Performed	18-02-2022	Amstar Components Used	Version 2.1.4
Date:	18-02-2022	Amstar	Version 2.1.4
Record:	VENTILATOR-ADULT-18: Plug-in: AVPI	Version 2.4.11	
Template:	VENTILATOR-ADULT-18: Plug-in: VTAPlus	Version 1.1.3	
Complete Version:	1.0.20	Version 2.1.12	

Calibration Setup

Selections

Service Events Performed	Standards Performed
	User defined IEC 62353 (C,L,T)

Device under test

Serial Number	RE33	Exp Date	18-02-2023
Manufacturer	HAMILTON	Equipment	VENTILATOR
Model	CALIBRO	Credent Number	3646
Location	CCU	Temperature	28.4 C
Inventory Number	CARD-100000040	Humidity	37.9

MTI Data

Instrument	Serial Number	Firmware Version
ESA612B	221054	v2.03
VT Plus	3023013	1.06.09 P

Signatures

MAGESH B

BBEABDF-4CBF-6B42-8C27-06D57E3BD9B1

Calibration Result

Element	Type	Fail
I. PREVENTIVE MAINTENANCE	Recorded Value	Checked
Result:		
PREVENTIVE MAINTENANCE DONE	Pass	
LABELS AND SERIAL	Pass	
EXTERNAL NO	Pass	
DRAGAGE	Pass	
POWER CORD	Pass	
WHEELS	Pass	
FAN FILTER COVER	Pass	
AND BOWL	Pass	
OL CELL	Pass	
II. FUNCTIONAL VERIFICATION	Recorded Value	Checked
Result:		
CHECK TECHNICAL	Pass	
LOC		

VENTILATOR-ADULT-18: Page 2 of 5

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CHECK TECHNICAL	Pass	
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VENTILATOR-ADULT-18: Page 2 of 5

- CALIBRATION & TEST REPORTS ARE AUTO GENERATED
- ALL THE DOCUMENTS WERE COMPUTERIZED
- STAFF UNDERGONE NECESSARY TRAININGS
- ILC & AUDITS WERE PERFORMED
- MRM & LAB MEETINGS CONDUCTED

Ready for NABL

- Master Analyzers, Testers, PC And Software 
- Inventory Of Medical Equipment 
- Technical Manuals / Calibration Procedures 
- Qualified Technical And Trained Personnel 
- ISO/IEC 17025:2017 Training 
- Uncertainty Training 
- Quality Manual / SOP's 
- Inter Lab Comparison 
- MRM / Audit Reports 

On 3rd March, 2021 BME was awarded NABL accreditation

IEC 17025: 2017- General Requirements for the Competence of Testing & Calibration Laboratories

“First in-house Biomedical Engineering Department to get NABL Accreditation”

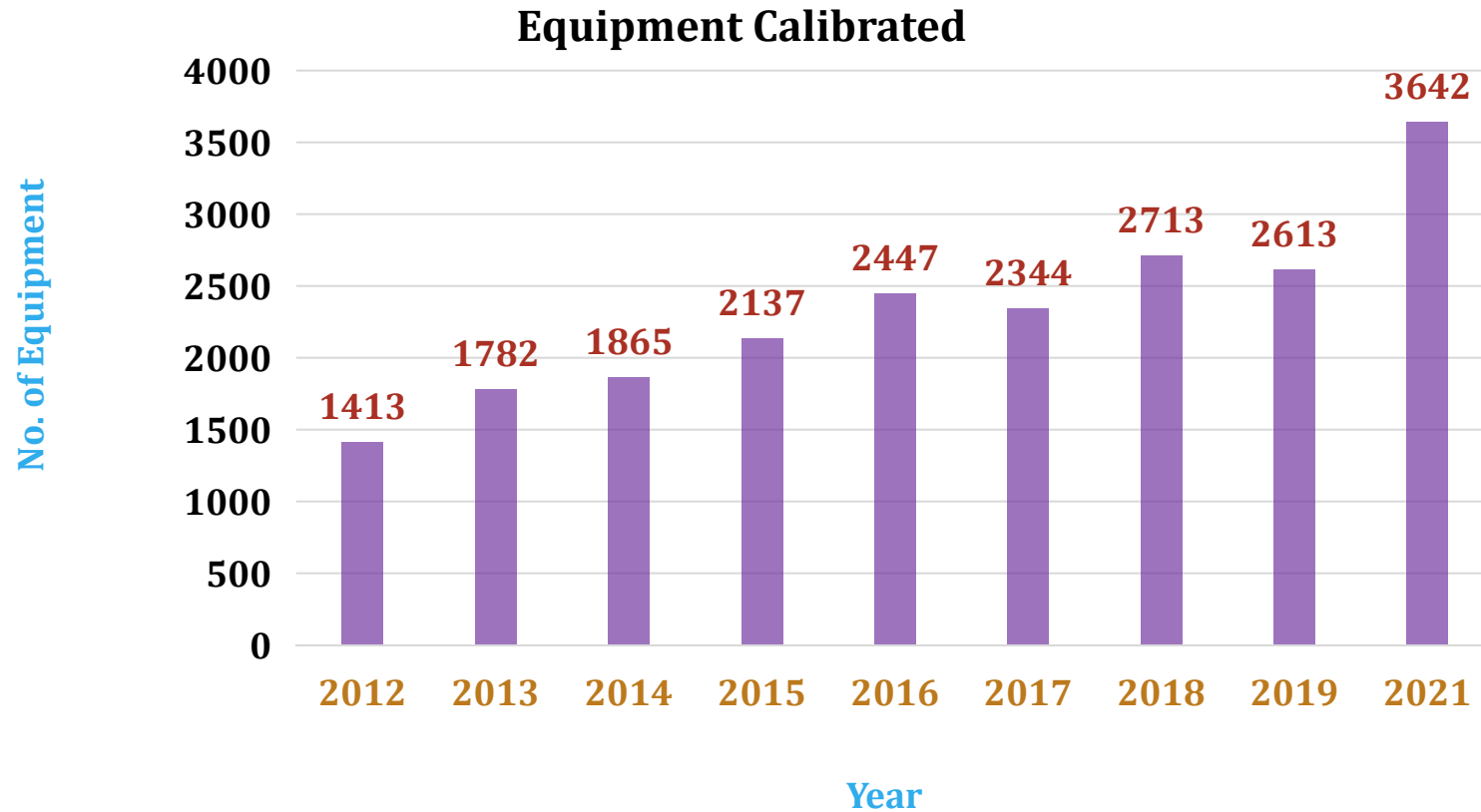
Scope of Accreditation

- DEFIBRILLATOR
- ECG RECORDER
- ELECTROSURGICAL UNIT
- FETAL MONITOR
- MULTIPARA MONITOR
- SYRINGE INFUSION PUMP
- VOLUMETRIC INFUSION PUMP
- VENTILATOR-CRITICAL CARE
- ELECTRICAL SAFETY
 - FUTURE SCOPE - BIPAP, CPAP, HUMIDIFIERS, WARMERS, INCUBATORS ETC.
 - FUTURE SCOPE – BIOCHEM, PATH, VIRO, MICRO



Cost Benefits

Calibration Statistics



**** Projected Equipment to be calibrated in 2022 = 5183**

**** During COVID-19, only 1967 equipment were calibrated in 2020 due to restrictions**

Cost Benefit Analysis - 2021

Equipment Category	Quantity Being Calibrated	Calibration Charges in INR	Cost Saved in INR
Defibrillator	94	800.00	75,200.00
ECG Recorder	36	600.00	21,600.00
Electrosurgical Unit	92	800.00	73,600.00
Fetal Monitor	60	600.00	36,000.00
Infusion Pump	827	600.00	4,96,200.00
Light Source	48	400.00	19,200.00
Multipara Monitor	760	1,200.00	9,12,000.00
Pulse Oximeter	263	400.00	1,05,200.00
Syringe Pump	1186	600.00	7,11,600.00
Ventilator	133	1,200.00	1,59,600.00
Radiant Warmer	63	1,200.00	75,600.00
Feed Pump	40	600.00	24,000.00
BiPAP	30	880.00	26,400.00
Grand Total	3642		27,36,200.00

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. 27,36,200.00
Cost Recovered / yr.	Rs. 10,32,402.00

EXPENSES INCLUDES

ENGINEERS SALARY

MASTER ANALYZERS INVESTMENT

OVER HEAD CHARGES

- **ANNUAL CALIBRATION**
- **INTER-LAB COMPARISON**
- **ANNUAL ACCREDITATION FEE**

** Test charges are calculated based on the tariff by Anna University, NHHID*

Projected Cost Benefit Analysis - 2022

Equipment Category	Quantity Being Calibrated	Calibration Charges in INR	Cost Saved in INR
Defibrillator	127	800.00	1,01,600.00
ECG Recorder	52	600.00	31,200.00
Electrosurgical Unit	135	800.00	1,08,000.00
Fetal Monitor	85	600.00	51,000.00
Infusion Pump	1065	600.00	6,39,000.00
Light Source	156	400.00	62,400.00
Multipara Monitor	1068	1,200.00	12,81,600.00
Pulse Oximeter	398	400.00	1,59,200.00
Syringe Pump	1553	600.00	9,31,800.00
Ventilator	231	1,200.00	2,77,200.00
Radiant Warmer	63	1,200.00	75,600.00
BiPAP	203	880.00	1,78,640.00
CPAP	38	880.00	33,440.00
Feed Pump	72	600.00	43,200.00
Grand Total	5183		38,98,280.00

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

** Test charges are calculated based on the tariff by Anna University, NHHID*



After NABL

We Know

- What We Are Doing
- How It Is Done
- How To Calculate

We Are

- Confident
- Learning Everyday

Our

- Machines Are Reliable
- Results Are Comparable

Manufacturers


- Accept Our Reports
- Request For Product Evaluation
- Change / Update Designs

Calibration Labs

- Inter-Lab Comparisons (ILC)

Commercials

- Tenders
- Private And Govt. Hospitals



**We encourage hospital biomedical teams to think of
NABL accreditation**

**We will be able to do inter lab comparisons and
improve our standards**

**TOGETHER WE CAN BUILD A CULTURE OF SAFETY
IN HEALTHCARE - MEDICAL EQUIPMENT**



THANK YOU!