HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Multidisciplinary Policy and Procedure		
Title:	Maintenance and Calibration of Blood Volume Regulators and Balances		
Applies To:	All Blood Bank Staff and Biomedical Engineers		
Preparation Date:	January 06, 2025	**Index No:**	LB-MPP-208
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1. PURPOSE:

1.1 Establishing system and setting responsibilities for measures taken to ensure the integrity, accuracy and reliability of blood volume regulators.

2. DEFINITONS:

N/A

3. POLICY:

3.1 Collected Blood Volume Regulators should be designed for the intended use.
3.2 Calibration and adjustment of blood volume regulators (blood shakers) are performed at regular intervals, on every day of use, and after activities that may alter the calibration.
3.3 Calibration and adjustment procedures conform to the manufacturer's instructions.
3.4 Blood Collection volume regulator (Blood Shaker) should have the following features:
- 3.4.1 Accepts all kinds of blood donor bags.
- 3.4.2 Accurate and Guarantees best mixing of blood.
- 3.4.3 Removal/rechargeable battery (as applicable).
- 3.4.4 Designed to make blood donation safe and simple.
- 3.4.5 Designed to Automatic clamp at the end of the donation.
- 3.4.6 Continuous digital display of collected volume, flow and time during collection.
- 3.4.7 Audible & visual alarms.
- 3.4.8 Slow bleed alarm.
- 3.4.9 End of collection alarm.

4. PROCEDURE:

4.1 **Cleaning:**
- 4.1.1 Before any cleaning operation, switch off the machine and unplug the power cable.
- 4.1.2 Remove the bag tray and clean both tray and external chassis with a clean gauze wet with detergent or disinfectant, being careful of not drop any liquid inside the central hole.
- 4.1.3 Clean the slot of the clamp removing any dirt too.
- 4.1.4 Do not use pure alcohol, varnish removers, or other solvents.

4.2 **Decontamination:**
- 4.2.1 Decontamination is an emergency procedure that should be none only if necessary.
- 4.2.2 A too high concentration of decontamination solution such as bleach can damage the materials of the balance. it is therefore recommended to use it as less as possible.

4.3 **Calibration:**
- 4.3.1 For blood Shaker:
  - 4.3.1.1 Every morning at the day of use, Check blood mixer scales for accuracy by trying different known weights and endorse the results for the shaker calibration in Q.C. form If the result is displayed in ml, multiply the result by 1.053.

4.3.1.2 Continuous observation of the alarm system, digital display, clamp at the end of donation and mixing of blood are documented.

4.3.1.3 Every week, switch the direct current and examine if the machine is working depending on the rechargeable battery (as applicable).

4.3.2 For balances:

4.3.2.1 Check for accuracy by trying different known weights and endorse the results in "Electronic scale (balance) QC form".

4.3.3 Acceptable Criteria:

4.3.3.1 ±2% of standard weight.

4.4 **Investigation** and follow-up of equipment malfunctions, failures, or adverse events include:

4.4.1 Call biomedical engineering for investigation of the malfunction, failure, or adverse event.

4.4.2 Ensure that the equipment is removed from service. Fix label (out of service).

4.4.3 Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

4.5 **Reporting:**

4.5.1 All maintenance and performance testing must be documented on the appropriate forms.

4.5.2 Any deviation from the expected result must be reported to the blood bank physician or designee.

5. MATERIALS AND EQUIPMENT:

5.1 **Forms and Records:**

5.1.1 Daily Blood Volume Regulators Calibration form

5.1.2 Electronic scale (balance) QC form

6. RESPONSIBILITIES:

6.1 Cleaning is performed by blood bank staff in charge daily and according to the equipment need.

6.2 Calibration and adjustment are performed on every day of use and after activities that may alter the calibration by blood bank staff in charge under supervision of blood bank supervisor.

6.3 Scheduled maintenance is performed by biomedical engineering every 6 months according maintenance and calibration plane.

6.4 Unscheduled maintenance is performed by biomedical engineering when needed.

6.5 It is the responsibility of the blood bank physician to review the results of cleaning, maintenance, Calibration and any action taken and documentation of all corrective actions.

6.6 It is the responsibility of blood bank supervisor to maintain records of malfunction and repair during the working lifetime of the equipment.

6.7 It is the responsibility of blood bank supervisor to inform biomedical engineering when unscheduled maintenance is needed.

7. APPENDICES:

7.1 Daily Blood Volume Regulators Calibration form

7.2 Electronic scale (balance) QC form

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.

8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.

8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.

8.4 AABB Technical manual, 18th edition, 2014.

8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

8.6 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

	Name	Title	Signature	Date
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Reviewed by:	Mr. Wafi Abdo	Head of Biomedical Engineers		January 09, 2022
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
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Appendix 7.1 Daily Blood Volume Regulators Calibration form

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

DAILY BLOOD VOLUME REGULATORS CALIBRATION FORM

SHAKER BALANCE: _____ **DATE:** _____

DATE	STANDARD WEIGHT	INTERPRETATION	SIGNATURE	REMARKS
1.				
2.				
3.				
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31.				

Before using the balance, check the listed standard weight within the working day. Acceptable range 2% (490 – 510grams) (466.5 – 485.5ml) (1ml = 1.051g)

CORRECTED ACTION LOG

COMMENTS:

_____

_____

_____

_____

SUPERVISOR SIGNATURE: _____ **DATE** _____

Appendix 7.2 Electronic Scale (balance) QC form

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

DAILY BLOOD BANK BALANCE CALIBRATION FORM

(Date _____)

DATE	STANDARD WEIGHT	INTERPRETATION	Signature	Remarks
1				
2				
3				
4				
5				
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31				

Before use of the balance, check against the standard weight 500 gm in the working day. (Acceptable Range 1% (495-505 gm)

	Corrective Action Log
Date	Comment:

SUPERVISOR SIGNATURE: .....