

Standard Operating Procedure (SOP)

1. Purpose

To ensure accurate spirometry measurements and maintain infection prevention standards through correct calibration and cleaning of the Vitalograph Pneumotrac device in accordance with ARTP and manufacturer guidance.

2. Scope

This protocol applies to all staff performing spirometry testing within the clinic using the Vitalograph Pneumotrac flowhead.

3. Responsibilities

The Spirometry Practitioner is responsible for:

- Performing daily calibration verification
- Ensuring equipment cleanliness and infection control compliance
- Recording calibration results
- Removing equipment from service if calibration fails

4. Equipment Required

- Vitalograph Pneumotrac flowhead
- Vitalograph spirometry device/software
- 3-litre calibration syringe (ARTP compliant)
- Single-use bacterial/viral filters
- Disposable mouthpieces (if applicable)
- Neutral detergent wipes or approved medical device wipes
- Clean lint-free cloth
- Calibration logbook or electronic record

5. Calibration Verification Procedure

5.1 Frequency

Calibration verification must be performed:

- Daily prior to patient testing or after every 10th patient

- After device relocation
- After cleaning or maintenance
- If environmental conditions change significantly
- If results appear inaccurate

5.2 Preparation

1. Ensure the device has warmed up for at least 10 minutes.
2. Check ambient temperature, humidity, and barometric pressure are correctly entered or automatically detected.
3. Attach a new bacterial/viral filter to the Pneumotrac flowhead.
4. Connect the 3-litre calibration syringe securely to the flowhead.

5.3 Calibration Check Steps

1. Open calibration verification within the spirometry software.
2. Inject the full 3 litres of air smoothly into the flowhead.
3. Perform at least three calibration strokes at varying flow rates:
 - o Low flow (slow)
 - o Medium flow
 - o High flow (fast)
4. Ensure each stroke is smooth without hesitation or leakage.

5.4 Acceptable Range

- Recorded volume must be within $\pm 3\%$ of 3 litres (2.90–3.10 L).

5.5 Action if Calibration Fails

- Repeat the calibration check.
- Inspect connections for leaks.
- Replace filter and repeat.
- Check syringe accuracy and seals.
- Remove device from clinical use if still outside acceptable limits and arrange servicing.

5.6 Documentation

Record the following:

- Date and time
- Operator name
- Calibration results
- Pass/Fail outcome
- Corrective actions (if required)

6. Cleaning and Infection Control Procedure

6.1 Between Patients

1. Remove and dispose of the single-use bacterial/viral filter and mouthpiece as clinical waste.
2. Inspect the flowhead exterior for contamination.
3. Wipe external surfaces using approved medical device disinfectant wipes.
4. Allow surfaces to air dry before next use.

Note: The Pneumotrac flowhead itself should not be immersed in liquid.

6.2 Daily Cleaning (End of Clinic)

1. Disconnect the Pneumotrac from the device.
2. Wipe the external casing with neutral detergent or approved wipes.
3. Ensure no moisture enters electrical components.
4. Allow to fully dry before storage.

6.3 Weekly Inspection

- Check for visible damage or cracks.
- Inspect cable integrity.
- Ensure connections are secure.
- Confirm calibration consistency trends.

7. Storage

- Store in a clean, dry environment.
- Avoid extreme temperatures or humidity.
- Protect from dust and direct sunlight.

8. Infection Prevention and Control

- Use a new bacterial/viral filter for every patient.
- Follow standard precautions and hand hygiene policy.
- Dispose of consumables according to clinical waste regulations.

9. Quality Assurance

- Maintain calibration records for audit purposes.
- Participate in annual spirometry competency review.
- Follow ARTP and manufacturer recommendations.

10. References

- ARTP Spirometry Standards
- Manufacturer Instructions for Use (Vitalograph Pneumotrac)

- Local Infection Prevention and Control Policy

Review of Policy

This policy is reviewed annually or following changes to legislation or guidance. Legislation and guidance links are checked and updated as part of the annual policy review.

Last review date: 04/02/2026

Next review date: 03/02/2027