

Category: Handling and Maintenance of equipment of Phase I unit

Title: Procedure to use Infusion pump

SOP No. DCP/Ph1/004

Date first effective: 01 Jan 2025

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Department of Clinical Pharmacology, 1st Floor, New MS Building,
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Category: Handling and Maintenance of equipment of Phase I unit

Title: Procedure to use Multipara monitor

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1. Purpose

The purpose of this SOP is to describe the responsibilities of the study team towards use and maintenance of the equipment 'multi-para monitor' which monitors pulse rate, oxygen saturation percentage (SpO₂), blood pressure, temperature and ECG of the participant.

2. Scope

This SOP is limited to describing procedure to use 'multi-para monitor' in participants admitted in phase 1 unit and its maintenance.

3. Responsibilities

Principal investigator [PI], Co-Investigator(s), study coordinator or any other medically qualified member as delegated by PI will be responsible to follow the procedures to determine the vital parameters of the participants admitted in phase 1 unit. It is also need to be ensured that the equipment is appropriately cleaned, maintained in good working order, and available for research personnel as requested.

4. Detailed Instructions

4.1 Approach to participant

- The investigator or the delegated person will refer to the protocol to ensure specific requirements of vital parameters in the participant.
- The investigator or the delegated person will explain the procedure to the participant.
- The investigator or the delegated person must ensure participant comfort and the participant is warm enough
- The investigator or the delegated person should wash their hands according to Hand Hygiene Policy.

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4.2 Equipment Set-up

- Obtain all supplies needed (monitoring clips, temperature probe, sterile gloves, chest lead electrode, jelly and gauze)
- The investigator or the delegated person must ensure that all the probes to be used on the participants are clean and in good condition
- Assemble and check that all equipment functions properly. Connect power charger to unit and electrical outlet. (The battery must be charged of the multipara monitor)
- The various probes (oxygen saturation, BP cuff and ECG) should be connected with their port in the multipara monitor on the side panel.
- To measure oxygen saturation and pulse rate connect oximeter probe to unit and participant. A large clip oximeter sensor is available, which need to be attached to participant finger.
- To measure blood pressure, select the blood pressure cuff and connect to the unit depending on the participant arm girth to the unit and the button of the BP to be pressed.
- To record ECG, the chest leads are connected to the sticky ECG pads placed on the patient's chest.

4.3 Equipment Use

- Turn on unit STANDBY/ON by pressing the center round button
- To measure oxygen saturation, place SpO₂ sensor clip/probe on patient. If sensor does not show reading, remove sensor, hold closed for several seconds. When light flashes, re-apply to area of choice
- To monitor blood pressure, the blood pressure cuff has to be applied around the arm. After clicking the button marked with arm with cuff, wait for few minutes for the cuff to inflate. The blood pressure will be displayed on the monitor. Make sure that the pulse oximeter/IV line and blood pressure cuffs are not attached to the same upper limb.
- Attached the chest lead at three points (right 2nd Intercostal space, left 2nd intercostal and left below rib at mid clavicular line) after applying disposable ECG pads. The probe is then attached to the leads, the monitor will automatically capture the ECG and

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display in the monitor. A print out of the ECG can be obtained by pressing the print button if the machine is enabled with an inbuilt printer.

- The investigator or the delegated person will record the vital parameters on the relevant source data, in the participants medical notes or in the case record form.
- The investigator or the delegated person should wash their hands according to hand hygiene policy when they have finished interaction with the participant.

4.4 Maintenance

- Inspect condition of unit and electrical cord/plug to ensure safe operation weekly. Equipment determined to be unsafe will be removed from service immediately.
- Inspect unit and all components (e.g. sensors, probes, cables, ECG paper roll and battery) before and after each use for, damage, cracks, looseness, or wear and replace when necessary
- Any additional maintenance/service should be performed by authorized personnel

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