South East Coast Ambulance Service NHS
NHS Foundation Trust

Emergency Access to Medicines in event of an Omnicell XT Cabinet Failure or Malfunction Standard Operating Procedure

Contents

1. Scope

1.1. South East Coast Ambulance Service NHS Foundation Trust (the Trust) is committed to providing high quality patient care.

1.2. The Trust stores medicines including controlled drugs (CDs) at a number of ambulance stations within an Omnicell cabinet, which utilises biometrics to gain access.

1.3. To access medicines stored in the Omnicell a power supply is required. This SOP describes the actions to be taken if there is a power failure to the Omnicell or an Omnicell malfunction and how emergency access to medicines can be gained via use of keys by individuals who have received training in the process.

1.4. A video of this process is available by clicking on the following link below Omnicell Emergency Access-20220429_081420.m4v (sharepoint.com)

1.5. This procedure is applicable to all clinicians in the Trust who use an Omnicell and sets out the scope of practice to which clinicians must adhere if the Omnicell was to fail.

2 Procedure in the event of power failure to an Omnicell cabinet

2.1. In the event of power failure to an Omnicell cabinet, a report should be made immediately to an Operational Team Leader (OTL). Should one not be available the nearest duty Bronze Manager should be contacted.

2.2. The cause of the failure should be immediately investigated.

2.3. Internet connectivity disruption will appear as a frozen or blank display screen (i.e. when the screen is touched there is no response). If this occurs, a reset of the Omnicell system is required.

2.4. To reset the Omnicell:

- Gently pull the keyboard down using the handle located above the keyboard.
    - In the alcove behind the keyboard there is a small LED, which maybe flashing red on the left hand side-wall of the alcove.
    - Under the LED, there is a small switch. Press the switch downwards while supporting the weight of the keyboard with your other hand. Hold the switch for 5 seconds, the Omnicell should start to “reboot” itself and show activity on the display screen.
- Replace the keyboard to its original location and monitor the Omnicell to ensure it completes the restart and becomes active again.

2.5. If the above action fails to successfully reboot the Omnicell, an engineer should be called.

Omnicell Technical Support - **01903 768486** (Please note this number is only for Omnicell technical problems and not for advice around procedures which are Trust related).

2.6. In the event of a power failure, the Omnicell will cease all activity. It has a back-up battery, however, this will only last for a maximum of 15 minutes. Make attempts to ascertain the cause of the power failure and the estimated duration of the power failure.

2.7. If the power failure is restricted to the Omnicell and not to the building, then attempt to restart the Omnicell as detailed in section 2.4. If this fails, call an engineer.

2.8. If the power failure is due to an electricity failure in the local area but is expected to be restored in a reasonable period, then consider whether to make a general broadcast to crews to explain that restock is unavailable at the station and to divert to an alternative station.

2.9. If the power failure is estimated to be for a prolonged period of time, then arrangements must be made to manually unlock the Omnicell and stay with it until such time that it is secured and power is restored. Alternatively, the drugs may be moved to the Bristol Maid cabinets in the Omnicell room.

3. Performing a manual unlock of Omnicell

3.1. In the event of a prolonged power failure or an Omnicell malfunction that requires technical engineer support, a manual unlock of the Omnicell cabinets will be required to relocate the medicines within the Omnicell to secure Bristol Maid cabinets.

3.2. Before commencing a manual unlock, ensure that the emergency controlled drug (CD) registers are available for use. All CD transactions must be documented by staff using the correct CD register during this period. Ideally there should be a CD register for each CD, to facilitate smooth reconciliation.

3.3. CD registers should be kept in a secure place with a copy of this SOP. The location should be known by all OTLs, and separate from the Omnicell itself, to avoid problems in accessing the registers.

3.4. Please refer to the SOP “Record Keeping and Controlled Drug Entries” for guidance on documenting entries in controlled drug registers.

3.5. The Omnicell override keys are kept in a secure location known by all station OTLs.

3.6. Only an OTL or a delegated registered clinician is permitted to perform a manual unlock on the Omnicell. The details of the clinician performing the manual unlock of the Omnicell must be recorded within the Datix description.

3.7. Once the override keys and CD registers have been located, the manual unlock process can be initiated. Once the Omnicell is unlocked it cannot be left unattended as it will not be secure.

3.8. To manually unlock the Omnicell - follow the steps detailed below in order:

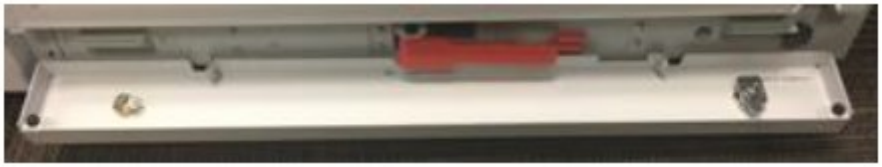
To access the cabinet **doors**, insert key 4210 into the keyhole on the right side of the cabinet (fig.1). Rotate the key 90 degrees clockwise. This will open the cabinet. You can access the inside lock (fig.2) which will open the subsequent door/doors on the left hand side. It will open the entire column to the left.

fig.1

fig.2

3.9. To access the cabinet **drawers**, unlock the two camlocks, 8001 on the front-left, 8011 on the right of the cover in this order. You cannot remove 8011 until the cover is open.

3.9.1. Pull the red handle to engage the override



3.9.2. Slide the stop lever to the right to keep the override engaged.

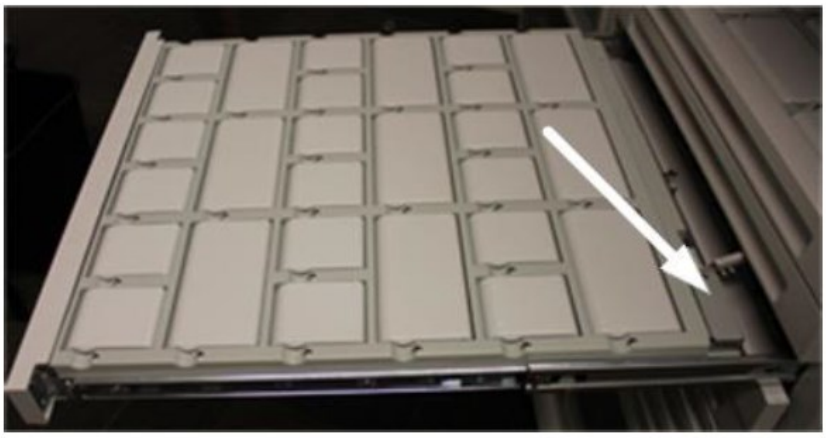
3.9.3. You should now have access to the clear fronted cabinets.

3.9.4. For access to the metal bin engage the override as laid out in previous steps. Slide the drawer outwards until it stops.

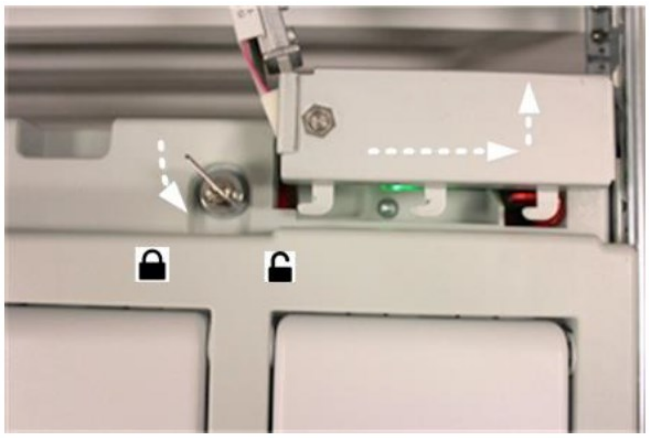
3.9.5. Loosen the slotted release screws on both sides on the drawer until they stop turning (approx. 4 anticlockwise turns). This allows the front releases to be pulled forward. This will require a flat headed screwdriver. The screws are not tightly fastened, so it may be loosened by hand if a screwdriver is not available.

3.9.6. To remove a double-deep drawer you must loosen the slotted screw on the bottom rail. Then pull all four of the front releases at the same time

3.9.7. While pulling on the front releases, pull the drawer out to the second stop. This exposes the cable arm cover. This requires a little force, ensure you do not use extreme force. If the cable arm cover fails to be fully exposed, check the rails are retracted fully.

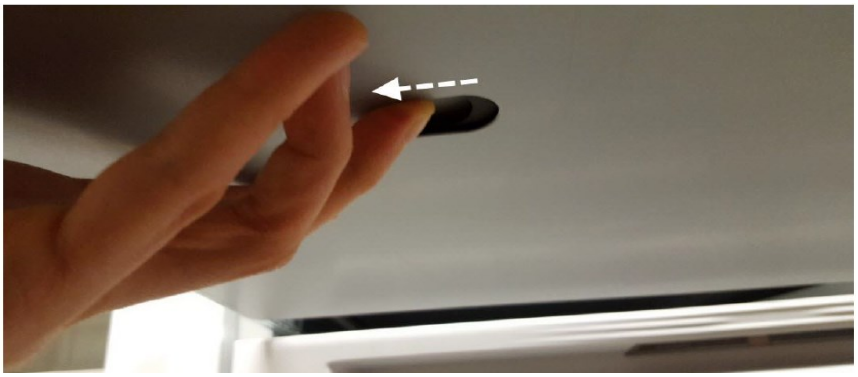


3.9.8. Using the camlock key (8001), unlock the cable cover by rotating the key anticlockwise. Remove the cable arm cover by sliding the cable to the right and away from the drawer allowing the hooks to disengage and to expose the red locking lever

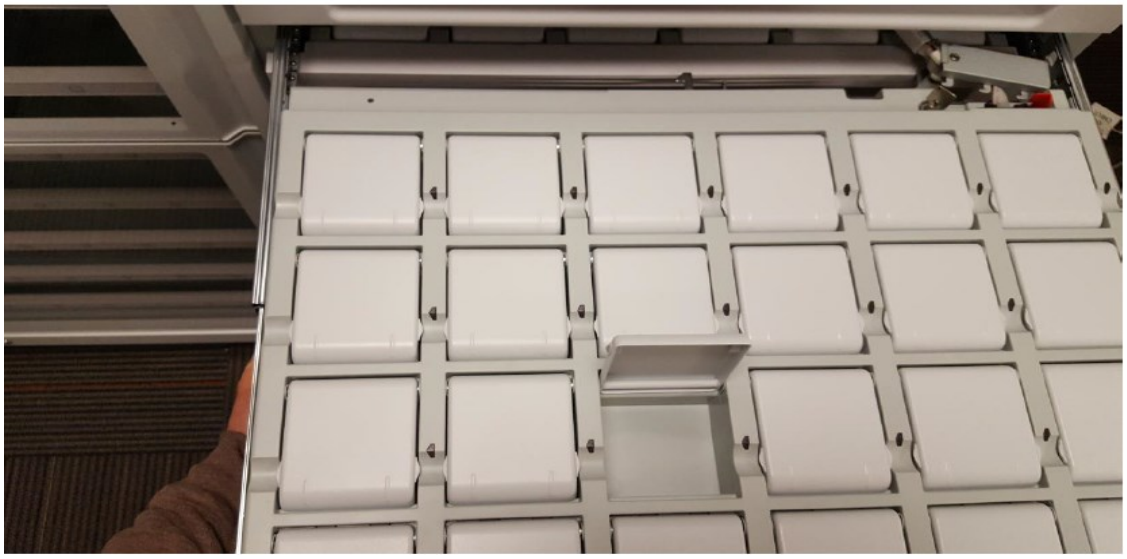


3.9.9. Push the red locking lever to unlock the release mechanism for the bins.

3.9.10. Locate the release mechanism under the drawer. Pull and hold the release mechanism out towards the side of the drawer.



3.9.11. While pulling the release mechanism, all the bins can now be opened.



3.9.12. The Omnicell is now manually unlocked and the CD register can be completed by entering the starting balance for each CD into the corresponding CD Register.

3.9.13. To return the Omnicell to its original state follow these steps in reverse. If the drawer does not shut fully double check that the screw has been tightened on the lower rails.

3.9.14. Once the Omnicell is fixed, or power restored the CDs must be returned to the appropriate drawers. The CD registers must be annotated to show the CDs have been returned to the Omnicell. The balances on the Omnicell electronic CD register MUST be checked to ensure that the restarting CD balance in the Omnicell is correct. This may require a cycle count.

3.9.15. A complete reconciliation of the manual CD register and the Omnicell register for the period of the incident must be carried out to ensure no CDs are missing, and all administrations and waste have been accounted for.

3.9.16. Any discrepancies must be reported to the medicines team and a Datix completed using a DIF1 form.

4. Definitions

4.1. An Omnicell is a cabinet that is used to store medicines at larger ambulance stations within the Trust. Biometric technology is used to recognise each individual attempting to access the unit.

4.2. Datix is the Trust's incident management system.

4.3. DIF1 is the form used to report any incident.

5. Responsibilities

5.1. The **Chief Executive Officer (CEO)** is accountable for Medicines use and governance in the Trust

5.2. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Executive Medical Director has responsibility for the implementation, review, and thus revision where required, of this procedure.

5.3. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Chief Medical Officer and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.

5.4. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.

5.5. The **Executive Director of Operations**, **Chief Medical Officer** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).

5.6. The Executive Director of Operations delegates local responsibilities and accountability for this procedure to the **Associate Directors of Operations**, **Operational Unit Managers, Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics.**

5.7. The **Associate Directors of Operations, Operational Units Managers**, **Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics** delegate their local responsibility and accountability for this policy to their staff including the **Operational Team Leaders (OTLs), Logistics Manager**, and others.

5.8. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.

5.9. **Controlled Drug Accountable Officer** is also the **Chief Medical Officer** and is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision

of Management and Use) Regulations 2013. These responsibilities include keeping records of the investigation of concerns and acting where appropriate.

5.10. The **Medicines Safety Officer (MSO)** is also the **Chief Pharmacist**. The MSO supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

5.11. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust The primary objective of MGG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

5.12. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.

5.13. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.

5.14. The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.

5.15. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug alerts and relevant information relating to medicines is communicated in a timely manner.

5.16. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

6. Education and Training

6.1. In order to carry out this process the user must have read and understood the procedure within this SOP.

6.2. OTL peer training should be provided to new OTLs to familiarise them with this process.

6.3. Any issues or concerns please contact Medicines Governance Team leads.

7. Audit and Review (evaluating effectiveness)

7.1. All Omnicell failures must be reported to the Medicines Governance Team as soon as practicable by email to medicines@secamb.nhs.uk.

7.2. All Omnicell failures must be reported in the organisation using Datix, via a DIF1 form.

7.3. The red controlled drug registers must be appropriately opened and closed at the end of the incident. All transactions must be fully reconciled when the incident is resolved. The senior Operations Manager on duty must ensure no controlled drugs are missing, and all administrations and waste have been accounted for.

7.4. The CDAO (CMO) with support from the Executive Director of Operations and Chief Pharmacist must report outstanding concerns to the Medicines Governance Group and the CDLO (local liaison officer).

7.5. The CDAO with support from the Chief Pharmacist must report outstanding concerns to the CD LIN (local intelligence network) on a quarterly basis.

7.6. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the procedure is not working effectively.

7.7. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

8. Associated Trust Documentation

8.1. SOP Record Keeping and Controlled Drug Entries 2017

8.2. Controlled Drug Policy September 2018

8.3. Medicines Policy

8.4. Administration of Controlled Drugs

8.5. Controlled Drugs Possession Using Body Worn Pouches

8.6. Changing Security Codes for Medicines Storage

8.7. Controlled Drug Stock Checks and Reconciliation

8.8. Handling of Drug Alerts and Recalls

8.9. Medicine Temperature Recording

8.10. Disposal of Controlled Drugs

8.11. Security Management Policy

8.12. Expiry Date Checking and Rotation of Medicines

8.13. Ordering and Distribution of Medicines

8.14. Receipt of Medicines from External Suppliers

8.15. Record Keeping and Controlled Drug Register Entries

9. Financial Checkpoint

9.1. This document has been confirmed by Finance to have no unbudgeted financial implications.

10 Equality Analysis

10.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

10.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions