



### MAKING THE GSM CONTROLLER SAFE

This section of the manual describes making the *GSM Controller* safe for use with another patient.

#### Step 1. Make Safe Selection

Please note that making the **GSM Controller** safe will remove all patient information from its memory. The *GSM Controller* is then ready to be used again for another patient.



Figure 23. Making the *GSM Controller* Safe

## APPENDIX 1: DOSING EXAMPLES

This appendix gives examples of dosing regimens to aid you in setting up a patients prescription on the *GSM Controller*.

### Case 1: Free Dosing with Split Dose

**Requirement:** Patient A needs a prescription that allows him to 'free dose' i.e. take a dose whenever he wishes. He can split his daily dose however he wishes. His prescription starts on the 18<sup>th</sup> July 2005 and runs until the 27<sup>th</sup> August 2005 inclusive. His dose size is 120 mg of Methadone per day.

| Prescription Setting                       | Input Value                         |
|--|-------------------------------------|
| Start date and time                        | 18/07/05 00:00 (start time default) |
| End date and time                          | 27/08/05 23:59 (end time default)   |
| Frequency                                  | Free                                |
| Split Dose                                 | Yes                                 |
| Dose size per period                       | 120 mg                              |
| Daily dose size (automatically calculated) | 120 mg                              |



### Case 2: 3 Dose Periods per day no Split Dose

**Requirement:** Patient B has been restricted to dosing within three discreet time periods in a day. She can only take doses between the times 07:00 - 09:00; 12:30 - 14:30; and 18:00 - 22:00. She can not split her dose and must take it in one go. Her prescription starts on the 09<sup>th</sup> September 2005 and finishes on the 20<sup>th</sup> September 2005. In each dose period she can take 30 mg of Methadone.

| Prescription Setting                       | Input Value                         |
|--|-------------------------------------|
| Start date and time                        | 09/09/05 00:00 (start time default) |
| End date and time                          | 20/09/05 23:59 (end time default)   |
| Frequency                                  | 3/day                               |
| Split Dose                                 | No                                  |
| Dose size per period                       | 30 mg                               |
| Daily dose size (automatically calculated) | 90 mg                               |
| Dose period 1 start and end time           | 07:00; 09:00                        |
| Dose period 2 start and end time           | 12:30; 14:30                        |
| Dose period 3 start and end time           | 18:00; 22:00                        |

## IMPORTANT INFORMATION

### Storing and Maintaining the Secure Key

When the Secure Key is not in use, ensure that it is stored **with the cap on** in a safe dry location within the operating parameters defined in the WARNINGS section of this leaflet.

The Secure Key should be stored securely by the pharmacist at all times when not in use.

Transport and/or store between temperatures of 0°C and 40°C, relative humidity of 30% and 75% RH and air pressure of 700kPa and 1060kPa.

### Using the Secure Key

The Secure Key should be used between temperatures of 10°C and 40°C, relative humidity of 30% and 75% RH and air pressure of 700hPa and 1060hPa.

## Troubleshooting

If you require assistance to solve any of these situations contact your system administrator.

| Problem   | Solution  |
|---|---|
| Screen is <b>blank</b>  | <ul style="list-style-type: none"><li>Battery may be flat, try connecting the charger.</li></ul>  |
| Screen shows ' <b>Incorrect PIN</b> '   | <ul style="list-style-type: none"><li>An incorrect PIN has been entered. Re-enter your PIN.</li><li>If an incorrect PIN is entered 3 times, the <i>GSM Controller</i> will be disabled and the screen 'Pharmacist Locked' will be displayed. Please contact your system administrator for help.</li></ul> |
| Screen shows ' <b>Finger Not Recognised</b> '   | <ul style="list-style-type: none"><li>An incorrect Fingerprint Scan has been entered. Re-enter your Fingerprint Scan.</li><li>Finger scanned incorrectly. Scan at correct angle and speed.</li><li>Finger wet, dirty or too cold. Wash finger with warm water, dry finger, then retry scan.</li></ul>     |
| Incorrect time and date   | <ul style="list-style-type: none"><li>Reset Time and date as per section Step 4. Setting the Time and Date on page 16.</li></ul>  |
| Screen shows ' <b>Error No. XX</b><br><b>Please Contact your Equipment Provider</b> ' | <ul style="list-style-type: none"><li>An error has occurred in the <i>GSM Controller</i>. Please contact your equipment provider for help.</li></ul>  |



## Pharmacist Secure Key

IM\_102539 V1.0

### Safety Information

**ALWAYS FOLLOW INSTRUCTIONS CAREFULLY. IF IN DOUBT CONTACT YOUR SYSTEM ADMINISTRATOR.**

|                 |  |
|-----------------|--|
| Cleaning        | Keep the <i>Secure Key</i> clean by wiping with a clean cloth or kitchen towel dampened with diluted household detergent and/or warm water once a week.<br>DO NOT IMMERSE.   |
| <b>WARNINGS</b> | <p><b>NOTE:</b> The <i>Secure Key</i> is of a unique design and will be labelled clearly with a statement that it is suitable ONLY for use with the <i>GSM Controller</i>.</p> <hr/> <p>The <i>Secure Key</i> is not protected against ingress of water or dust (IPX0).</p> <hr/> <p>Do not immerse or expose to rain or spray.<br/>Do not use in very dusty areas.</p> <hr/> <p><b>FOLLOW CLEANING INSTRUCTION ABOVE.</b></p> <hr/> <p>Do not use in the presence of flammable gasses.</p> <hr/> <p>Users are advised to check the integrity of the <i>Secure Key</i> enclosures, at least once each month. However, no parts require maintenance or inspection other than by users. Consult your system administrator if any damage is suspected.</p> <hr/> <p>The <i>GSM Controller</i> must only be connected to mains electricity using the <i>Power Supply</i> provided in the pack. This must be connected to a 100-240 Volt AC supply 50Hz/60Hz for charging the battery in the <i>GSM Controller</i>.</p> <hr/> <p>Do NOT connect items to the <i>GSM Controller</i> that are not specified as part of the system.</p> <hr/> <p><i>The Secure Key, GSM Controller, Secure Methadone Canister and Power Supply</i></p> |

## Safety Information

### WARNINGS

may emit or be affected by electromagnetic interference. Do not keep or use close to pacemakers or other sensitive electronic medical equipment.

The *Secure Key*, *GSM Controller*, *Secure Methadone Canister* and *Power Supply* conform to the requirements of Electromagnetic Compatibility Standard EN ISO 60601-1-2.

Transport and store between 0°C and 40°C and between 30% and 75% relative humidity. For use at normal atmospheric pressures (700 hPa to 1060 hPa).

The *Secure Key* and the *GSM Controller* are sealed units and no parts can be repaired, or require maintenance other than normal cleaning etc. by the user.

**DO NOT ATTEMPT TO OPEN.** Opening will void any guarantee offered by the manufacturer.

Contact with low voltage circuits within the *Secure Key* is possible through the rear connector when connected to the *GSM Controller*. Handle carefully and do not touch internal electronic components.

Minimum dose size delivered by the *Secure Methadone Canister* is 1ml +/- 10%.

The *GSM Controller* is of a modular construction and is intended to be used in conjunction with the *Secure Methadone Canister*. It is necessary to observe static handling precautions when initiating or receiving a *GSM Call*. Please ensure that the *GSM Controller* is placed on the *Secure Methadone Canister* prior to use.

*These symbols appear on the device packaging and indicate:*



This symbol indicates that the devices are a type B applied part with respect to electric shock protection (EN 60601-1).



This symbol means CAUTION - Consult accompanying documents.



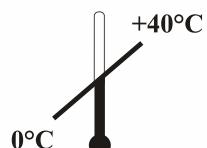
This symbol means that this device conforms to the requirements of the European Medical Device Directive 93/42/EEC and has been certified as such by European Notified Body No. 0086 (British Standards Institution).



This symbol means DC (direct current). Connect the socket marked to *Power Supply*.



This symbol means AC (alternating current).



This symbol specifies the transport and storage temperature range for the Device that the marking appears on.

## Weight & Dimensions

*All measurements given are approximate.*

L = Length, W = Width, and D = Depth

|   |  |
|---|--|
| <b>Secure Key (REF 101766)</b><br>L = 65 mm, W = 23mm and D = 15mm<br>Weight = 75g  |  |
| <b>GSM Controller (REF 101763)</b><br>L = 110 mm, W = 62mm and D = 27mm<br>Weight = 100g                                  |  |
| <b>Secure Methadone Canister (REF 101764)</b><br>(No bottle fitted)<br>L = 315 mm, W = 120mm (cylinder)<br>Weight = 4.5Kg |  |
| <b>Power Supply (REF 101765)</b><br>L = 100mm, W = 50mm and D = 50mm<br>Weight = 90g                                      |  |
| <b>Disposable Pump (REF 101768)</b><br>L = 85mm , W = 100 mm<br>Weight = 50g  |  |

## Classification Information

- Type of protection against electric shock - Type B (Applied Part).
- Mode of operation - Continuous.
- Degree of protection against ingress of water - IPX0 Not protected.
- Degree of protection against electric shock when SMC system is connected to specified plug top charger - Class II.
- Degree of safety of application in the presence of a Flammable Anaesthetic mixture with air or with oxygen or nitrous oxide - Not Protected.
- All parts of this Drug Delivery system are suitable for use within the patient environment.

At the end of their service life all non disposable devices must be returned to GW Pharma Limited.





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