When you pass the *GSM Controller* to the patient, ask them to read and understand the consent form and accept or reject consent to store their personal information in the *GSM Controller.*

- If the patient rejects consent the *GSM Controller* will emit a tone and you should take it back from the patient. The enrolment process is terminated at this point and the patient cannot use the *GSM Controller* until consent is obtained.

- If the patient accepts consent the enrolment process continues as per the flow shown in Figure 16.

- If the patient requires help inputting data then assist as required. See the section *'Using the GSM Controller'* for details on inputting data.

- The patient should enter their phone number as normal with the leading "0". If the patient does not have a phone number get the patient to leave the fields blank or at their default setting.

- When the fingerprint data has been successfully learnt, the patient will be told to hand the *GSM Controller* back to you. You will then confirm and enrol the patient.

- Once you have enrolled the patient, you need to create their prescription on the *GSM Controller*.

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CREATE THE PATIENT'S PRESCRIPTION

This section of the manual is about creating a prescription for the enrolled patient on the *GSM Controller.*

Step 1. Set the Prescription Parameters

Follow the steps shown in Figure 17 to set up the patient's prescription.
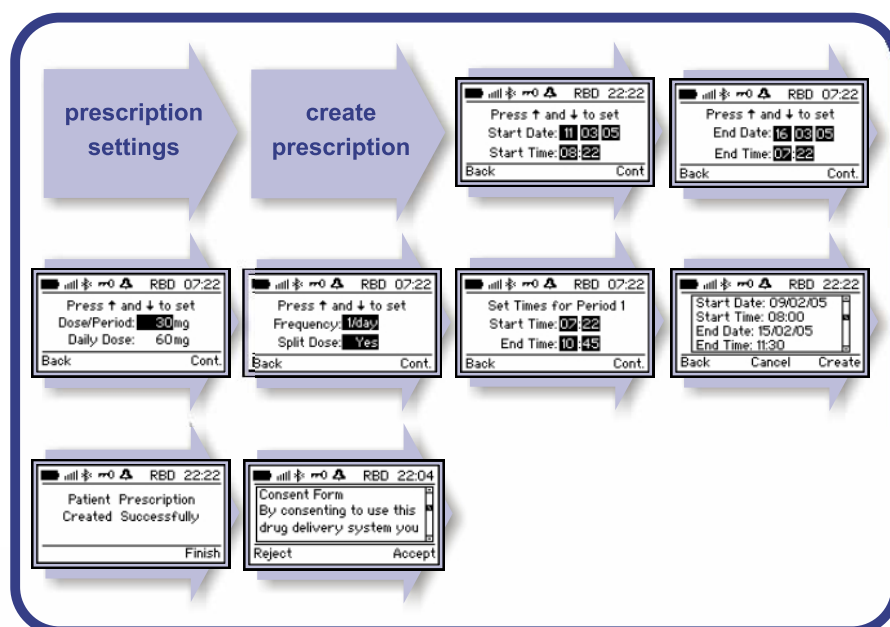

Figure 17. Create the Patient Prescription

Dose Frequency and Periods

You can specify the following dose frequencies:

● Free, where doses can be taken at any time during the day.

● "n"/Day, where "n" is the number of individual dosing periods where a dose can be taken. Each dose period has a fixed start and end time. The 'Dose Period Start and End Time' screen will repeat "n" times to allow you to specify "n" dose periods.

Split Dosing

You can specify the following dose patterns:

- "Split" set to "Yes", where the patient will be able to take any portion of the dose up to the **dose period** maximum, within any dose period.

- "Split" set to "No", where the patient will only be able to take the fixed prescribed dose within one of the dose periods.

Dose Size Per Period

- The dose size (in mg) to be set is per dose period and the daily dose size will be calculated and updated automatically and shown back to you on the screen *for information only.*

See '*Appendix 1: Dosing Examples'* for examples of how patient prescription requirements transfer to *GSM Controller* prescription settings.

Once you have created the prescription for the patient, the *GSM Controller* is ready to dispense medication in conjunction with a *Secure Methadone Canister* filled with the appropriate Methadone solution.

Remove the *Secure Key* and give the *GSM Controller* to the patient with the contents of the *GSM Controller* box.

VIEW PATIENT DETAILS

This section of the manual describes viewing patients details on the *GSM Controller.*

Select the 'Patient Settings' menu item from the Home menu. You will now have a Patient Settings menu. Then select the 'View Patient Info' menu item.

The following patient details will be displayed in a scrollable list:

- Dose size per period
- Daily dose size
- Next available dose time
- Next available dose date
- Patient contact telephone number.

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MANAGE PATIENT PRESCRIPTIONS

This section of the manual describes maintaining the patients prescriptions on the *GSM Controller*, including viewing and deleting prescriptions.

Step 1. Viewing Prescriptions

Select the 'Prescription Settings' menu item from the Home menu. You will now have a Prescription Settings menu. Then select the 'View Prescription' menu item.

You will have a scrollable list of prescriptions for the patient, listed by date and time. To view a prescription select one and press the View key.
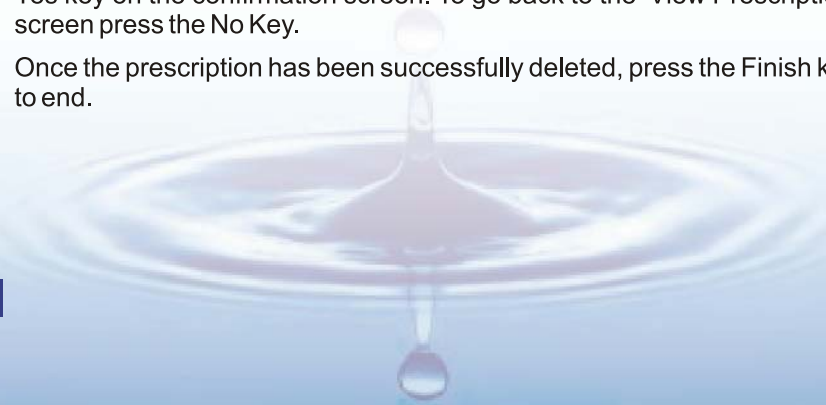
The following prescription details will be displayed in a scrollable list:

- start date and time
- end date and time
- dose size
- dose frequency and split dose
- dose periods start and end times

Step 2. Deleting Prescriptions

From the scrollable list of prescriptions from the 'View Prescription' menu item you can also select prescriptions to delete.

- To delete a prescription select one from the scrollable list of prescriptions and press the View key. Then on the 'View Prescription' screen press the Delete key.

- You will confirm that you want to delete the prescription by pressing the Yes key on the confirmation screen. To go back to the 'View Prescription' screen press the No Key.

- Once the prescription has been successfully deleted, press the Finish key to end.

MANAGING CO-WORKER PROFILES ON THE SECURE KEY (PRIMARY PHARMACIST)

This section of the manual describes managing co-worker profiles on the *Secure Key* via the *GSM Controller*. This section is only for the designated primary pharmacist in a pharmacy.

Select the 'Pharmacist Settings' menu item from the Home menu. You will now have a Pharmacist Settings menu. Then select the 'View Profiles' menu item. You will have a scrollable list of co-worker profiles, listed by initials and profile status. To manage a profile select one and press the Select key. You will now have a view of the profile you wish to manage.

Profile Status	Description
Active	Profile is currently active and in use. You can suspend an active profile by updating the status to suspended.
Suspended	Profile has been suspended because of an authentication failure. You can reactivate a suspended profile by updating the status to active.
Expired	Profile expiry date has been passed. You can not update the status of an expired profile, the profile must be created again to become active.

Step 1. Updating Co-worker Profile Status

To update the status of a profile, from the profile view screen press the Change button.

Use the Up and Down Arrow keys marked "▲" "▼" to cycle through the available profile status and press the Update key to update the status. To go back to the view profile screen press the Back key.

Once the profile status has been successfully updated, press the Finish key to end.

Step 2. Deleting Co-worker Profiles

To delete a profile, from the profile view screen press the Delete button.

You will confirm that you want to delete the profile by pressing the Yes key on the confirmation screen. To go back to the profile view screen press the No key.

Once the profile has been successfully deleted, press the Finish key to end.

REPLENISHING THE CANISTER

This section of the manual describes replenishing the *Secure Methadone Canister* in a pharmacy environment.

Canister Requirements

When replenishing the canister, you must use the Disposable Pump (REF 101768) with 500ml amber bottles as supplied with the Martindale or Rosemont products.

What do I do with the empty Bottle and Disposable Pump?

Bottles with *Disposable Pumps* attached that are no longer needed or are empty must be disposed of using normal disposal procedures for controlled substances.

Step 1. Unlocking the Canister

Insert your *Secure Key* and authenticate yourself to the *GSM Controller*. Place the *GSM Controller* on top of the canister and follow the flow diagram in Figure 18.
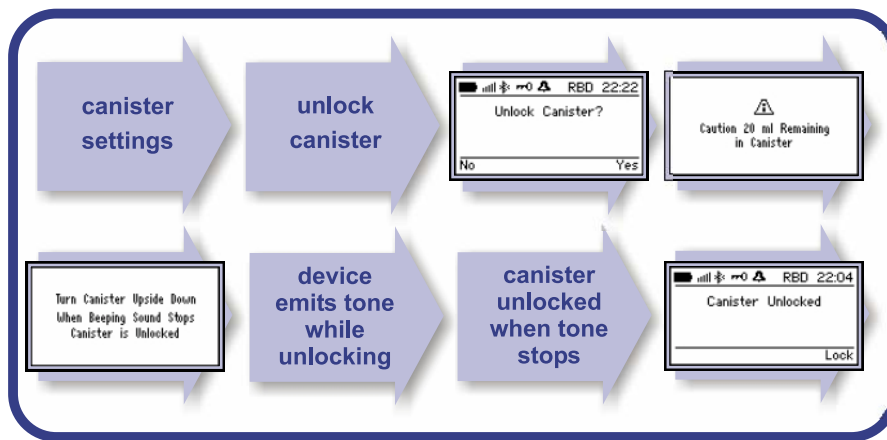

Figure 18. Unlocking the Canister

Step 2. Opening the Canister and Removing the Bottle

Once upside down and unlocked, take the short half of the canister off the main body of the *Secure Methadone Canister* and remove the used bottle and *Disposable Pump* from the canister. See Figure 19. for details.

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Step 3. Fitting a Disposable to a New Bottle of Methadone

- Remove the cap from the new bottle of Methadone and push the *Disposable Pump* onto the top of the bottle. When the *Disposable Pump* clicks it is successfully fitted onto the bottle. Do not twist the pump when attaching it to the bottle.

- Fit the bottle and pump assembly into the *Secure Methadone Canister* ensuring the nozzle is correctly aligned to the slot on the long half of the canister. Fit the short half of the canister onto the main body of the canister. See Figure 20 for details.

- The *GSM Controller* will automatically detect the *Secure Methadone Canister* and will lock it. While the *Secure Methadone Canister* is locking the *GSM Controller* will emit a tone.

- When the tone has stopped the *Secure Methadone Canister* is locked and you can turn it upright again. Ensure that you hold both halves of the *Secure Methadone Canister* whilst turning it over.

- At this point the *GSM Controller* will tell you that the canister is locked and ask if you want to prime the canister. See the next section on priming the canister.

Figure 20. Fit the Bottle into the Canister

Step 4. Priming the Canister

Choosing when to Prime the Canister

You can choose to prime the canister either immediately after the canister has been replenished and locked, or at some other point independently.

If you are priming the canister directly after replenishing it you will already be in the priming process and you should follow the instructions on the *GSM Controller.*

Warning: not priming the canister will lead to inaccurate dose delivery. The canister MUST be primed before being given to a patient.

Priming the Canister

If you choose not to prime the canister directly after replenishing it then see Figure 21 for details.
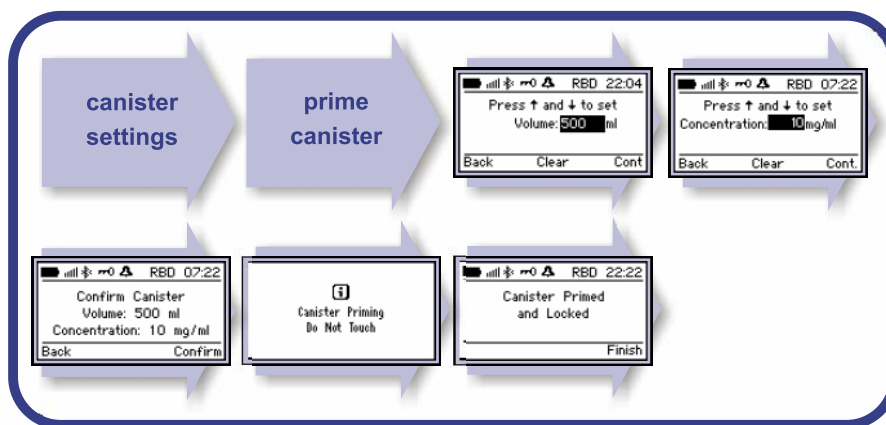

Figure 21. Priming the Canister

● Enter the canister volume in ml into the *GSM Controller*. The default quantity will be 500ml but if you want to clear this to 0 press the Clear key. When you have set the quantity press the Cont. key to continue.

● Enter the canister concentration in mg/ml into the *GSM Controller*. The default quantity will be1mg/ml but if you want to clear this to 0 press the Clear key. When you have set the quantity press the Cont. key to continue.

● Confirm that the canister volume and concentration is correct by pressing the Confirm key.

● The *GSM Controller* will display a canister volume and concentration set screen. Press the Finish key to end.

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BLUETOOTH FUNCTIONS

This section of the manual describes using Bluetooth on the *GSM Controller*.

Step 1. Activating Bluetooth

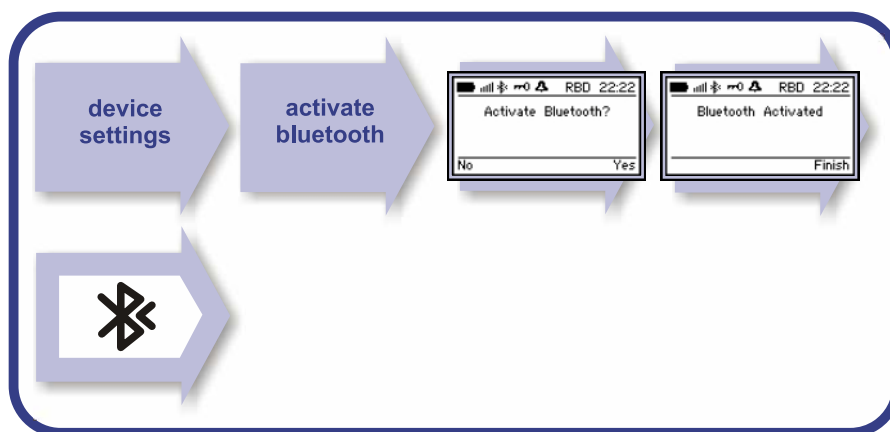Bluetooth functionality has not been implemented as yet. Activating the Bluetooth transceiver causes it to switch on for a 15 minute period.

Figure 22. Activating Bluetooth