

sensidose



MyFID[®] Dosing Device

For Parkinson Disease.
Manual for setting
a fixed dosing schedule.

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Before starting the programming of MyFID®

MyFID® dosing device needs charging before starting the programming. Therefore, start with inserting the charger in an electrical outlet and the charging cable in the MyFID® and wait for the screen to boot. Wait one minute and start the device with the on button. The programming can continue whilst MyFID® is being charged.

Follow the instructions in this manual for seamless programming of the device. For questions about programming contact Sensidose AB at info@sensidose.se or look for information at www.sensidose.se.

The dose escalation schedule when initiating a patient on Levodopa is preprogrammed in the MyFID® and cannot be changed. For details about the dose escalation schedule see approved SPC. Regarding the fixed dosing schedule there are three possibilities:

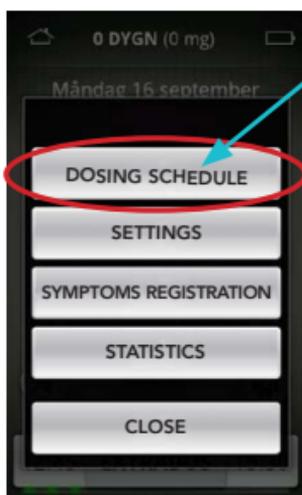
- 1) Add a patient. Use this option the first time MyFID® is programmed.
- 2) Remove a patient. Use this option when you want to remove all existing data. Note that all data previously saved are lost when this option is selected.
- 3) Change schedule. Use this option when the dosage schedule for an already programmed patient is changed. If the screen goes off during programming press the green "On / Off" button to wake it up.

1. Setting a new dosing schedule

1.1 Opening the settings menu

SETTINGS

Press on the setting icon and the following menu appears.



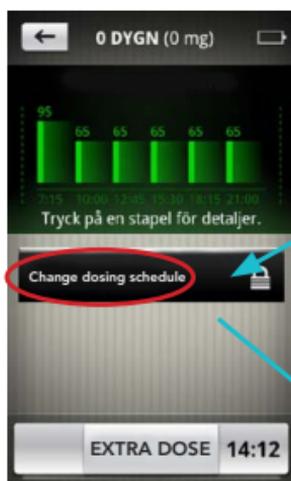
Press Dosing schedule.



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1.2 Changing the dosing schedule

1.3 Starting a new patient



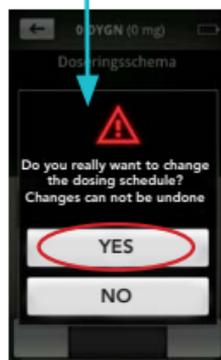
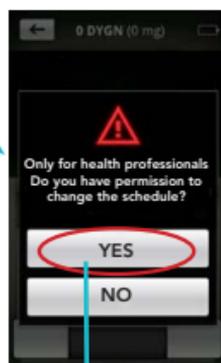
PRESS CHANGE DOSING SCHEDULE

In order to change the dosing schedule you have to answer YES to the question "Do you have permission to change?" followed by "Do you really want to change the dosing schedule?". Note that changes cannot be undone.

Only qualified healthcare professionals have permission to modify the dosage schedule in MyFID®. You must confirm twice that you have permission to make a change.



Choose New Patient.



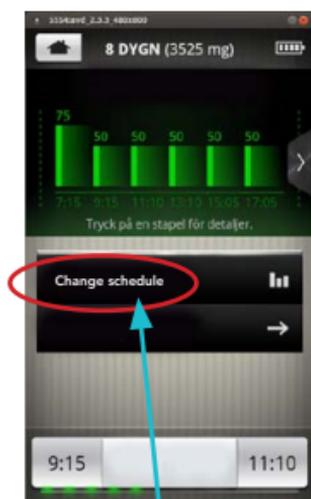
1.3 Starting a new patient

1.4 Setting a fixed schedule



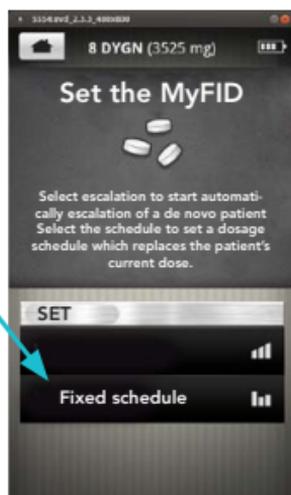
Add the new patient and write the patient's name. This name will appear on the front page and personalize the MyFID®. Do not use birth date or other sensitive information to identify the patient.

To obtain the second, third or fourth letter, press two, three or four times. You have to wait a second between taps while the letter is registered. When you have finished press OK.



Choose change schedule.

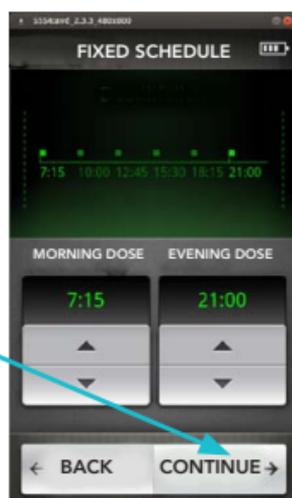
Choose fixed schedule.



1.5 Setting a new dosing schedule



Enter the required total daily dose and the number of dosing occasions and then press CONTINUE.



Enter the time for the first morning dose and last evening dose and then press CONTINUE



Now a graphical presentation of the dosing schedule for the prescribed daily dose is shown. By pressing one of the dosing bars, it is enlarged as seen on the next picture. If no changes are to be made, press directly on CONTINUE.

1.6 Setting the dose and time for product intake

1.7 Setting patient rights



Now, for the selected dose, the amount and time of intake can be adjusted, then press the OK to proceed. If you need to make further changes to another dose, repeat the above. If no changes are to be made, press only on CONTINUE.

Set the amount to be given on each extradose. The press CONTINUE.



Here you need to determine the patient's rights to dosage adjustments, both up or down. You will later in the programming determine the range of the allowed adjustment. Select yes or no if the patient should be able to do dosage adjustments for each dose type and then press CONTINUE.

1.8 Setting request for self assessments



Should the patient do self-assessments of symptoms and answer disease related questions during daily dosing and extradoses?
Select the button or NO

The patients willingness and ability to answer the assessment questions might vary. During some instances it might be better to initially turn this function of, to allow the patient to learn to manage and get used to the dosing device. You can turn on the assessment questioning later when appropriate.

1.9 Setting of limits for dose adjustments



Here you determine the interval within which the patient can adjust the morning dose. Press CONTINUE when done.

Here you determine the interval within which the patient can adjust the daily doses. Press CONTINUE when done.

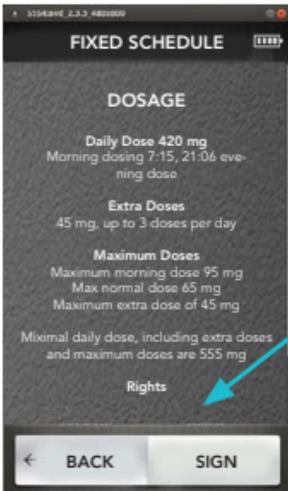


Here you determine the interval within which the patient can adjust the extra dose. Press CONTINUE when done.



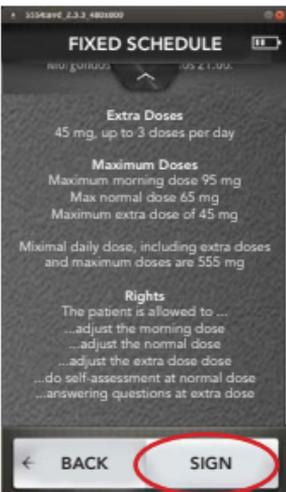
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2.0 Signing the dosing schedule



The screen will show the prescription you have programmed, the total daily dose, extradose, and maximum doses. Scroll up to see all settings.

Note that you have to scroll down to the bottom of the page in order to be able to sign.



Now you will see the rights you have given the patient. If everything is OK press SIGN.

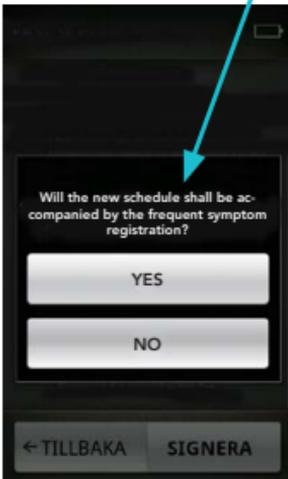
2.0 Signing the dosing schedule

2.1 Setting the frequency of self assessments



Sign using the first two syllables in your first name and the surname (eg, Gunnar Danielsson - GUDA) and press OK.

Click YES if you want the schedule to be accompanied by the more frequent symptom registrations, called Modal days.



1) Modal days. These are days when the patient shall record symptoms and mobility.

- a. Modal days occurs three times / week during the first five weeks of treatment (not during escalation but only on fixed schedule treatment). During these first five weeks there are in total 15 modal days.
- b. Two modal days / week are weekdays and one a holiday (hence three per week).
- c. Modal days occurs randomly such that all the days of the week are covered including both Saturday and Sunday. During the first five weeks there are in total 10 modal days as weekdays; ie two modal days weekly and 5 modal days on holidays (randomly two or three Saturdays or Sundays).

2) On the modal day the patient should be immediately before each dose, ie. when the MyFID alarms and one hour after the dose, rate their mobility on the scale. This should be performed on each dosing occasion regardless of the number of doses the patient use.

2.2 Symptom registration example

Indicate the symptoms that you have had the most trouble with

- Speech difficulties
- Worry / anxiety
- Sweating
- Mood swings
- Weakness
- Problems with balance
- Panic attacks
- Ache

ANSWER

As an example is shown a screen where the patient has indicated presence of two non-motor symptoms.

Following the choice of symptoms the patient will quantify the severity of the chosen symptoms.

Sweating

MILD MODERATE HARD

use the slider to indicate how severe the symptoms are

ANSWER

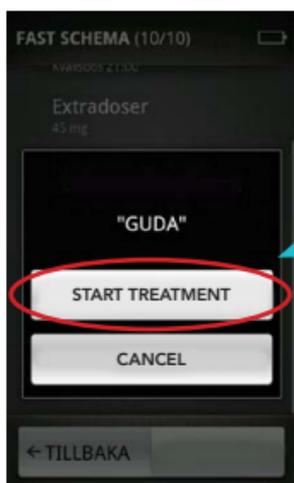
Ache

MILD MODERATE HARD

use the slider to indicate how severe the symptoms are

ANSWER

2.3 Starting the treatment

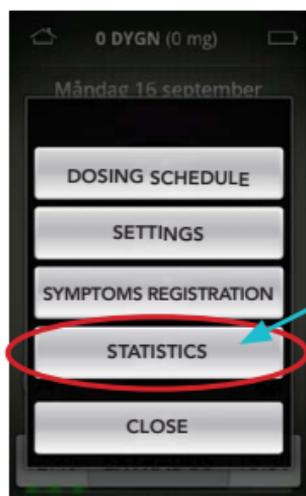


The prescription is now signed. Check that your initials are OK then press **START TREATMENT**.



My Flexible Individualized Dosing

3 Statistics and selection of parameters



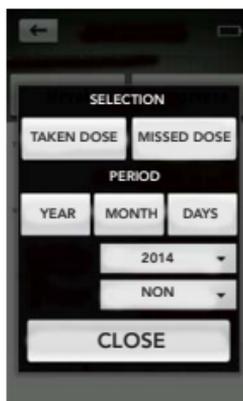
STATISTICS

All information on dosage, missed doses and symptom registered is saved in the MyFID®.

You can retrieve the information in the following manner:

1. On the first page with the clock press the setting icon (gearwheel) and then

2. Press selection



3. Here you select among the different ways to present the information. You can also make

comparisons between different time periods. Once you have made your selection, click on CLOSE. The information will be presented on the screen.

3.1 Exporting statistics



4. In order to save the information on your PC proceed as follows. Connect MyFID[®] to the PC's USB port using the cable from MYFID[®] package. Select on the MyFID[®] which format you would like to transfer the data with CSV is a format that various spreadsheet programs e.g. Microsoft Excel can open. If you select "Export PDF report", you get a standardized

report. This report can be useful to print and bring with you when visiting your doctor or other health care provider. After you have made your selections, click on the icon "Connect USB storage". You will then be able to open the file using Explorer on your PC. The data will be available in a "Removable Disk" under "Computer". Save the report to your computer or print it. When you are finished uncheck "Connect USB storage" and press close. Then remove the cable from the MyFID[®]. For detailed instructions about how to do this with pictures, see www.sensidose.se.



MyFID[®] Dosing Device

15-MA012



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