



CareFusion

Micro Diary

Operating Manual



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Introduction

The Micro Diary spirometer is a compact, battery operated, and fully portable data recording spirometer designed specifically to collect FEV1, PEF, FVC or FEV6, and symptom scores in epidemiological studies and drug trials.

The Micro Diary connects to a PC for configuration and uploading of stored data using the Micro Diary System Windows™ based software. This software allows the unit to be easily customised for a particular trial and includes many built in safeguards to ensure the integrity of the accumulated data.

The unit can be configured to take spirometry readings and symptom scores, entered either numerically, on an analogue scale, or from a scroll down list of responses. The results are stored together with the time and date of testing. Various identifiers such as trial centre, unit number, and description are also stored.

Different sequences of questions and spirometry tests may be configured for 4 individual time zones. Each sequence is activated by the subject turning the unit on, within the relevant time zone, or by answering an optional alarm. After completing a sequence the unit turns off automatically. Having completed a time zone sequence, a supplementary sequence will be activated if the unit is turned on again within the time zone or between zones. Note that once a time zone sequence has been completed,

the sequence cannot be repeated until the following day. During a sequence the last spirometry test or questionnaire response can be erased by pressing 'del'.

The recorded tests can be uploaded to a computer for future analysis or printing, via a USB interface.

The spirometer uses the CareFusion Digital Volume Transducer, an extremely stable form of volume transducer, which measures expired air directly at B.T.P.S (Body Temperature and Pressure with Saturated water vapour) thus avoiding the inaccuracies of temperature corrections. This transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.



Indications for Use

The Micro Diary Spirometer is used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs. Specifically, the Micro Diary Spirometer measures the following lung function parameters: FEV1, FVC, FEV6, and PEF. The device also records the test data for later review and has the ability to transfer these records to a compatible computer.

Target Population

The device can be used on patients who require lung function measurements. It can be utilized for patients from 4 years and older, providing that they are able to follow the medical practitioner's instructions.

Environment of Use

The environment of use is the hospital or a doctor's or medical practitioner's office or clinic or the patient's home.

Environment

Please observe the following precautions:

- Avoid exposing the Micro Diary to direct sunlight.
- Avoid operating the spirometer in dusty conditions or near to heating appliances or radiators
- Do not keep the spirometer in a damp or expose it to extreme temperatures
- Operate the equipment under normal environmental temperatures which are defined in this manual (see section "Specification of the Micro Diary")
- The transducer should not be held towards a strong light source during operation of the spirometer.

Contraindications, Warnings and Cautions.

Contraindications

- Acute disorders affecting test performance (e.g Vomiting , nausea, vertigo)
- Recent eye surgery (increases in intraocular pressure during spirometry)
- Oral or facial pain exacerbated by a mouthpiece

Caution:



CAUTION: Read the manual before use

WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anaesthetic mixtures or in oxygen rich environments.

CAUTION: Mouthpieces are single patient use. If used on more than one patient there is a risk of cross-infection. Repeat use may degrade materials and lead to an incorrect measurement.



PLEASE NOTE: The product you have purchased should not be disposed of as unsorted waste. Please utilise your local

WEEE collection facilities for the disposal of this product.

Package Contents

The Micro Diary is packaged in a convenient carrying case and comes complete with the following items (Fig.1):

1. Micro Diary microcomputer unit.
2. CareFusion Digital Volume Transducer.
3. Lithium coin cell, CR2450
4. USB cable



Figure 1: The Micro Diary

Configuration

Before using the Micro Diary the required sequence of questions and spirometry tests must be defined using the PC software (Please see Help files on software for guidance). Micro Diary PC Software may be downloaded using the link:

<http://www.micromedical.co.uk/update/download.asp>

(The PC Software is intended for use by Clinicians and Trial co-ordinators only).

Once defined, the sequence can be loaded into the Micro Diary. This can be done with a direct connection to a USB port of the PC: plug the unit into a USB port on the PC, using the cable provided, and turn the unit on with the 'enter' key depressed to display the operations menu. Once the operations menu is displayed, release the 'enter' key. Scroll to option 1, PC Connection, using the up and down keys and then press 'enter' (the other options are described in section Menu Options). From the PC software, download the program to the unit and switch off by pressing 'del'.

The Micro Diary is now ready to perform the defined sequence of questions when the unit is turned on. The subject is instructed to complete the sequence of questions and spirometry tests. Once complete, the unit will turn off automatically.

If the subject turns the unit on but leaves the unit before completing the sequence, the unit will automatically turn

off after several minutes. Data collected on a partially completed sequence will not be stored and the subject must turn the unit on again and complete the whole sequence before the results are stored.

If an alarm is set then the unit will turn on automatically at the required time, sound an audible alarm, and display:



The subject should then press 'enter' to initiate the sequence. If no response is given the unit will turn itself off after a few minutes (configurable) and repeat the alarm every 11 minutes (configurable) until the end of the time zone.

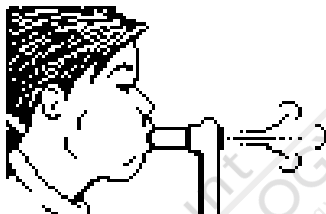
When turned on, the subject will be requested to perform a spirometry manoeuvre or to enter the answer to questions in the order specified in the program.

In order to familiarise the subject with the spirometry manoeuvre a test may be performed without the results being stored. To do this, turn the unit on in the 'options' menu, as described above. Then scroll to option 3, training Blow and press 'enter'. A spirometry manoeuvre will be requested as outlined in the next section. Pressing 'del' will return the unit to the options menu.

Operation

Spirometry Recording

When taking a spirometry measurement the following will be displayed:



The subject should then perform a spirometry manoeuvre using a clean mouthpiece connected to the transducer. After completion the display will show the results together with a spirometry manoeuvre quality check:

GOOD BLOW

FEV1	4.10 L
FVC	4.70 L
PEF	8.80 L/S



DO NOT HESITATE

FEV1	4.10 L
FVC	4.70 L
PEF	8.80 L/S



FASTER BLOW

FEV1	4.10 L
FVC	4.70 L
PEF	8.80 L/S

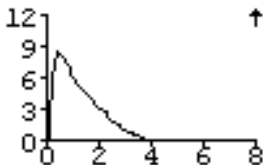


LONGER BLOW

FEV1	4.10 L
FVC	4.70 L
PEF	8.80 L/S



The results and quality checks displayed to the user may be configured with the PC software. The software may also be configured to automatically reject any manoeuvre that fails any of the quality checks. The unit will 'beep' once at the end of the manoeuvre or three times if an alarm has been set and the result is below the acceptable level. The arrow at the bottom right of the screen indicates that the 'down' arrow key may be used to obtain more results. Using the 'down' arrow key will display the flow/volume curve, if configured by the PC software:



The Quality checks can result either in discarding the blow or not. See the Quality Assurance Options page from the help files.

When an acceptable test has been performed, pressing 'enter' will move on to the next test or symptom score entry and save the spirometry results. When performing a series of tests it is possible to configure the unit to record only the best blow.

The unit may also be configured to alarm when the spirometry manoeuvre is below a set value or below a set percentage of the recorded best effort. When a manoeuvre is below the required level an alarm will sound continuously and the display will flash the reading, which has triggered the alarm.

If for any reason the subject is not satisfied with their effort, pressing 'del' will cause the test to be repeated and the results will not be stored until 'enter' is pressed.

Repeatedly pressing 'del' will erase, in turn, all the tests performed and may be used to erase a whole sequence if, for example, the subject decides that they are not able to complete a set of tests at that time.

Please note that the results to be displayed, and stored, are individually selected by the program. It is therefore possible, for example, to store FEV1 and FVC but display no results if a blind study is to be undertaken. In this case the Micro Diary will move on to the next question or spirometry test immediately after the test is performed unless the effort is below the minimum requirement in

which case the alarm will sound and the display will flash the reading that triggered the alarm.

Symptom Score entry

Numerical data and responses to questions may be entered in five different ways.

Question with Numeric Answer:

**How many times have
you taken your
medication today?**

5

The question is displayed at the top of the screen and the default response is shown flashing below. Note that when an 'up' or 'down' key is first used, the default number stops flashing. Subsequent use increments the number up or down.

In order to avoid the possibility of the subject simply pressing 'enter' repeatedly to accept all default values in a series of questions, the 'enter' key is only recognised after an 'up' or 'down' key is used at least once.

Question with Decimal Numeric Answer:

**What is your
temperature**

37.5

The display shows the question number with the default response (set by the PC software) to one decimal place. The subject adjusts the response, as described above, and then presses 'enter'. Note that it is not possible to enter the default value whilst the display is flashing. Pressing the 'up' or 'down' once will stop the flashing and subsequent use will increment or decrement the value. This feature ensures that the subject actively reviews the value and does not repeatedly press 'enter' for a sequence of questions in order to save time.

Question with Short Written Answer:

**Which treatment did
you take last night?**

None
Steroid
Bronchodilator

When this type of question is displayed the user uses the 'up' and 'down' arrow keys to select the correct response and then presses 'enter'. If there are more answers than can be displayed on the screen, an arrow will be displayed to indicate that further answers are available. As before,

the default response flashes until the 'up' or 'down' arrow keys are first used.

Question with Long Written Answer:

What exercise have
you had today?

1/4

I have stayed seated
all day

What exercise have
you had today?

2/4

I have moved around
the house but not
upstairs

What exercise have
you had today?

3/4

I have moved around
the house including
climbing some stairs.

**What exercise have
you had today?**

4/4

**I have walked for more
than 15 minutes today.**

When the answers are too long to fit on one line, paged responses may be used. Using the 'up' and 'down' keys will scroll between the programmed responses. Pressing the 'enter' key will select the required response.

Question with Analogue Scale Response:

**How bad is your chest
pain today?**

No Pain

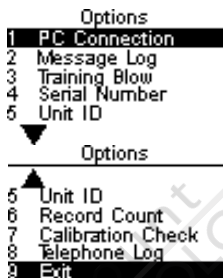
Terrible



Question requiring an answer on an analogue display can also be displayed. The user uses the 'up' and 'down' arrows to move the solid bar to the right and left. When the required level is displayed press 'enter' to store the result.

Menu Options

To obtain the options menu hold down the 'enter' key, turn the unit on, and when the sounder is heard release the 'enter' key.



Use the up and down arrow keys to select the required option and then press enter.

Select option 9, Exit, when you have finished using the options.

1 PC Connection

When this option is used connect the Diary unit to a PC running the software supplied to a USB port using the cable supplied. The Diary is then controlled by the PC in order to upload saved data or to reprogram the unit.

2 Message Log

The feature is not used in the Diary system.

3 Training Blow

Use this option to allow the user to familiarise themselves with performing a spirometry test. None of the tests performed in this mode of operation will be stored.

4 Serial Number

Use this option to identify the serial number of the unit.

5 Unit ID

Use this option to display the programmed Unit ID and the Full ID. These identifiers, loaded into the Diary at the time of programming.

6 Record Count

A record count and the percentage of memory used is available with this option.

7 Calibration Check

Use this option to perform a calibration check. A calibration syringe will be required.

8 Telephone Log

This function is not used in the Micro Diary.

Maintenance

Battery Management

The Diary is powered by a 3 Volt Lithium coin cell accessed via a slide cover on the rear of the instrument. When the battery is low a warning icon will be displayed and the battery should be replaced:



The recorded data is stored in non-volatile memory and no data will be lost when the battery expires. It is recommended that the battery is replaced at the commencement of each new study.

Battery replacement

For access to the battery first remove the battery cover by sliding sideways as indicated

Disassembly

Prise out the old coin cell using a suitable, non-metallic implement



Assembly

Replace the battery paying particular attention to its orientation. The part number etched on its outer face should be uppermost and visible when the battery is inserted.

Press until clicked into place

Slide the battery cover back into place.

Calibration Check

The Micro Diary is calibrated to read in litres at body temperature, barometric pressure saturated with water vapour (BTPS).

The calibration should remain stable indefinitely, unless the transducer is physically damaged, and the unit should not require re-calibration. However, to ensure the correct functioning of the unit we do recommend that a calibration check is performed periodically.

To perform a calibration check turn the unit on with the 'enter' key pressed and select 'Calibration Check' from the menu options, see section Menu Options

Connect a 3L syringe to the Micro Diary with the minimum of adapters and the syringe volume should be injected into the transducer evenly, without pausing.

A 3 Litre Syringe is available from CareFusion as
Cat.No.36-SM2125

If, after checking, the unit appears to require re-calibration then please refer to your supplier for service.

Cleaning the Transducer

The transducer requires no routine maintenance or servicing. However, if you wish to sterilise or clean the transducer it may be removed by means of the following procedure:

1. Remove the transducer by gently pushing out from the rear of the instrument.
2. The transducer may now be immersed in warm soapy water for routine cleaning or immersed in cold sterilising solutions e.g. Perasafe for a period not exceeding 15 minutes. (Alcohol and chloride solutions should be avoided.) After cleaning/sterilising, the transducer should be rinsed in distilled water and dried.
3. Re-assemble the transducer.

Servicing

If your unit requires service or repair please contact your nearest service dept. See the Customer Contact Information section for more details.

Trouble Shooting Information

Should you encounter problems operating your spirometer, please consult the table below:

Problem	Possible Cause	Solution
Micro Diary cannot be switched on	Batteries are flat	Change the batteries
Every time you switch the instrument on the time is shown as 00:00	The internal battery of Micro Diary is defective	Contact your dealer.
Micro Diary is outside of % when conducting the calibration check	There are leaks in the syringe or connections	Check the syringe and connections for leaks

Electromagnetic Compatibility (EMC)

Changes or modifications to the Micro Diary spirometer that are not expressly approved by Carefusion can cause EMC issues with this or other equipment. The device is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service as per interference exceeding levels specified in EN 50082-1:1992

WARNING: use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation

WARNING: No modification to this device is allowed.

Consumables & Supporting Products

Cat. No.	Description
36-CAB1098	USB A cable for MD03 PC connection.
36-PSA2200	Mouthpieces
36-SSC5000A	PeraSafe Sterilising Powder 81g (to make up 5 litres of solution)
36-VOL2104	Nose Clips (pack of 5)
36-SM2125	3 Litre Calibration Syringe
36-TDX1050	CareFusion Digital Volume Transducer

Specification of the Micro Diary

Measurements:	Forced Vital Capacity (FVC) or Forced Expired Volume in 6 seconds (FEV6) Forced Expired Volume in 1 second (FEV1) Peak Expiratory Flow rate (PEF)
Accuracy:	Meets the accuracy requirements of the ATS/ERS Standardisation of Lung Function Testing: Standardisation of Spirometry - 2005
Storage Capacity:	Typically > 1 year of data recording.
Display:	64 x 100 pixel LCD
Transducer Type:	CareFusion Uni-Directional Digital Volume.
Resolution:	10ml
Volume Range:	0 to 8 litres.
Power supply:	CR2450 Lithium coin cell.
Backup battery life:	>10 years
Main Battery Life:	Approximately 24 hours of continuous use.
Dimensions:	130 X 57 X 37mm.
Weight:	100g
Operating Temperature/ Humidity:	0 to +40 °C / 30% to 90% RH
Storage Temperature/ Humidity:	-20 to + 70 °C / 10% to 90% RH

Symbols



Type B device



In accordance with Directive 93/42/EEC



Disposal in compliance with WEEE



Consult the instructions for use



Date of manufacture



Manufacturer



Serial Number

(Rx only) : Federal U.S. law restricts this device to sale by or on the order of a physician

Customer contact information

UK Customers only

For all Sales Order processing for products, training and spare parts, Service and Technical Support enquiries, please contact the following:

Williams Medical Supplies Customer Service

Sales Enquiries:

Telephone: 01685 846650

Email: sales@wms.co.uk

Factory Repair and Technical Support Enquiries:

Telephone: 01685 845555

Email: test&calibrationworkshop@wms.co.uk

International customers only

For all Sales Order processing for products and Spare parts, Service and Technical Support enquiries, please contact the following:

Carefusion Germany 234 GmbH

Customer Service & Support International

Leibnizstrasse 7

97204 Hoechberg

Germany

Customer Service Sales Enquiries:

Telephone: 0049 931 4972 670

Email: micro.internationalsales@carefusion.com

Factory Repair and Administration Enquiries:

Telephone: 0049 931 4972 867

Email: support.admin.eu@carefusion.com

Technical Support Enquiries:

Telephone: 0049 931 4972 127

Email: support.rt.eu@carefusion.com



Notes



Notes



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