



MEDGUARD

Professional Healthcare Supplies

User Manual



User Manual Rev. 1.6

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WARNING 

The paper mouthpiece, the nose clip and the disposable turbine with mouthpiece in the equipment should be considered disposable products.

Before using your spirobank ...

- Read this manual carefully, plus all labels and other product information supplied.
- If not fitted, install the operating battery taking care to connect the “+” and “-” battery poles correctly, as shown in the battery compartment.
- Set the device configuration as required (date, time, predicted values, device language etc.) as described in Paragraph 2.4.

WARNING 

The winspiro Express PC software supplied with the device MUST be installed correctly to the PC before connecting spirobank to the PC. At the end of the installation, connect the device to the PC and the hardware will be "recognised" by the PC. The device can then be used with the winspiro Express software.

Keep the original packaging!

In the event that your device requires attention then always use the original packaging to return it to the distributor or manufacturer.

In this case, please follow these guidelines:

- Return the complete device in the original packaging, and
- The transport (plus any customs or taxes) costs must be prepaid.

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MIR has a policy of continuous product development and improvement, and the manufacturer therefore reserves the right to modify and to update the information contained in this User's Manual as required. Any suggestions and or comments regarding this product should be sent via email to: mir@spirometry.com. Thank you. MIR accepts no responsibility for any loss or damage caused by the User of the device due to instructions contained in this Manual and/or due to an incorrect use of the product.

Note that due to printing limitations the screenshots shown in this manual may differ from the display of the machine and/or from the keyboard icons.

Copying this manual in whole or in part is strictly forbidden.

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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1. INTRODUCTION

1.1 Intended Use

Indications for Use: The Spirobank spirometer is intended to be used by a physician or by a patient under the instruction of a physician or paramedic.

The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates; it can be used in any setting.

1.1.1 User Category

The **spirobank** spirometer calculates a series of parameters relating to human respiratory function.

Typically the doctor “prescribes” a spirometry test and is responsible for analysing and controlling the results obtained.

1.1.2 Ability and experience required

The correct use of the device, the interpretation of the results and the maintenance of the device all require qualified personnel. In the event that the device is operated by the patient, then sufficient training must first be given to the patient by the doctor or by the trained paramedic under the supervision of the doctor.

WARNING

The manufacturer cannot be held responsible for any damage caused by the user of the device failing to follow the instructions and warnings contained in this manual.

If the user of the device is a person considered to be cognitively impaired, then the operation of the device must be made under the supervision and responsibility of whoever is legally charged with the supervision of this person.

1.1.3 Operating environment

spirobank has been designed for use in a doctor's office, in a hospital or directly by the patient during day-to-day activities for the monitoring of physical conditions. All information necessary for the proper use of the device in electromagnetic environments (as required by the EN 60601-1-2 Standard) is available from the manufacturer.

The procedures for using the device at home are described on the display which shows all of the instructions (messages, suggestions etc.) step-by-step, which allows the subject to correctly perform tests and obtain correct results, to be analysed by the doctor.

The instrument is not intended for use in an operating theatre nor in the presence of flammable liquids or detergents, nor in the presence of flammable anaesthetic gases (oxygen or nitrogen).

The instrument is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.

The user and/or the doctor are responsible for ensuring that the device is stored and used in appropriate environmental conditions; in this regard reference is made to the specifics described in paragraph 1.6.2 below.

WARNING

If the device is exposed to unsuitable environmental conditions, this could cause the device to malfunction and to give incorrect results.

1.1.4 Who can or must make the installation

The device requires installation by qualified personnel. Normally the doctor configures the instrument before giving it to the patient for use at home.

1.1.5 Subject effect on the use of the device

A spirometry test should only be carried out when the subject is at rest and in good health, and thus in suitable testing conditions. A spirometry test requires the **collaboration** of the subject since the subject must make a complete forced expiration, in order to have a meaningful test result.

1.1.6 Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the subject's clinical condition. A detailed clinical history of the subject is also required together with the results of any other test(s) suggested by a doctor.

Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.

Any symptoms that the subject has at the time of the test must be carefully considered before a spirometry test is made. The user is responsible to assess both the mental and the physical capacity of the subject in order to make a correct test, and the user, in the evaluation of test results, must also assess the degree of collaboration of each test carried out.

A spirometry test requires the full collaboration of the subject. The results depend on the person's capability to inspire and to expire all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are "not acceptable".

The acceptability of a test is the responsibility of the user. Special attention should be given to testing elderly subjects, children and handicapped people.

The device should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

1.2 Important safety warnings

spirobank has been examined by an independent laboratory which has certified the conformity of the device to the European Safety Standards EN 601-1 and guarantees the EMC Requirements within the limits laid down in the European Standard EN 60601-1-2.

spirobank is continually controlled during its production and therefore the product conforms to the established security levels and quality standards laid down by the Council Directive 93/42/EEC for MEDICAL DEVICES.

After removing the device from its packaging, check that there is no visible damage. In case of damage do not use the device, return it to the manufacturer for repair.

WARNING

The safety and the correct performance of the device can only be assured if the user of the device respects all of the relevant safety rules and regulations.

The manufacturer cannot be held responsible for damage caused by the failure of the user correctly to follow these instructions.

The device must be used only and exclusively as a spirometer following the indications given by the manufacturer with particular attention to the paragraph on **INTENDED USE**, and utilizing only original spare parts and accessories. Use of non-original parts such as the turbine flow sensor or other accessories may cause errors in measurement and/or compromise the correct functioning of the device, and is therefore not permitted.

The device should not be used beyond the declared life span. The life span is strictly related to the life of the internal lithium backup battery (CR2032) and in normal conditions this should be around 10 years. The device constantly monitors the state of charge of this battery and a message informs the user when the battery is discharged. Contact Technical Service to have this battery changed.

In the event of any incident or accident of any kind resulting from the use of the device, the user is required to inform the manufacturer without delay, this procedure is laid down in Article.9 of the European Regulations No. 46/1997, which implemented the EC Directive No. 93/42.

1.2.1 Danger of cross-contamination

Two different types of turbine sensors can be used with the device, one is reusable and one is single-patient disposable. A disposable mouthpiece is required in order to connect a subject to the spirometer. In order to avoid exposing the subject to the critical danger of cross-contamination, the reusable flow sensor must always be cleaned before each spirometry test, and a new disposable mouthpiece must always be used for each subject. The use of an anti-bacterial filter is at the discretion of the doctor. If a single-patient disposable turbine is used, then a new one must be used for each patient.

1.2.2 Turbine

WARNING



Disposable turbine

If you are going to perform the spirometry test with a disposable turbine it is important to use a new turbine for each new patient. The characteristics, accuracy and the hygiene of the disposable turbine can only be guaranteed if it has been conserved beforehand in its original sealed packaging.

The disposable turbine is made of plastic and its disposal after use should adhere to the local regulations and norms in force.



Reusable turbine

The correct functioning of the re-usable turbine can only be guaranteed if it has been cleaned in the correct manner and is free from foreign bodies which could alter its movement. If the turbine has not been cleaned sufficiently this could cause cross-contamination from one patient to another. Periodic cleaning should only be done when the instrument is for personal use and will only be used by one patient. The cleaning of the turbine should be performed according to the instructions contained in the User's Manual.

The following information applies to both turbine models.

The turbine must never be held under a jet of water or air and must never come into contact with high temperature fluids.

Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities such as hair, sputum, threads etc. within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

1.2.3 Mouthpiece

Any disposable mouthpieces included with the device are supplied only as a guide to the correct type and dimensions of the mouthpiece required for this device, they are clean but not sterile. To purchase appropriate mouthpieces, generally either paper or plastic, but in any case single use/disposable, we suggest that you contact your local distributor who supplied the spirometer.

WARNING

Use a bio-compatible mouthpiece to avoid any problems to the patient; unsuitable materials could cause a bad functioning of the instrument, and therefore the test results could be incorrect.

The user is responsible for obtaining the correct type of mouthpieces for the device. Those required are a standard type with an outside diameter of 30 mm, they are commonly used and in general easily procured.

To avoid environmental contamination caused by the disposal of used mouthpieces, the user must follow all the relevant local regulations.

1.2.4 Device

WARNING

The maintenance operations detailed in this manual must be fully and accurately carried out. If these instructions are not followed this can cause measurement errors and/or an incorrect test interpretation.

Any modifications, adjustments, repairs or reconfiguration must be made by the manufacturer or by personnel authorised by the manufacturer. Never attempt to make a repair oneself. The set-up of configurable parameters should only be made by qualified personnel. However, an incorrect set-up of the parameters does not put the patient at risk.

High-frequency emissions from “electronic” devices may interfere with the correct operation of the instrument. For this reason, certain minimum clearances (a few metres) should be observed when high-frequency appliances such as a TV, radio, portable phone, etc. and other electronic units are operated at the same time in the same room.

The instrument may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, or in the presence of computed tomography (CT) equipment.

If the PC and/or the printer connected to spirobank come into contact with the area containing patient data, ref. directive EN 60601-1-1, it is necessary that they conform to the directive EN 60601-1.

For the recycling of the spirobank, the accessories, any plastic consumable materials (mouthpieces) as well as the battery, use only the appropriate containers or return all such parts to the dealer or to a recycling centre. All applicable local regulations must be followed.

If any of these rules are not followed then MIR will decline all responsibility for any direct or indirect damages, however caused.

Use only the battery type indicated in the § Technical specifications.

Remove the battery from the device if it is not used for a long period (several months).

The instrument may be powered through a PC by a USB cable.

Keep the device out of reach of children and of any person with mental handicap.

1.3 Unforeseen errors

In case device internal memory data are damaged, when the device is switched on, the following message appears:

Error on RAM memory
Recovery data
Please wait

If data have been successfully recovered, the device completes the standard switch on process, otherwise please contact an authorised technical assistance point or the manufacturer.

In the case of a problem with the device, a message indicating the nature of the problem will appear on the screen, together with a warning “beep”.

Operation of the device beyond its declared life (see § 1.6 Technical Specifications) could provoke a loss of data in the memory of the device (SRAM memory).

Errors in measurement or in interpretation can also be caused by:

- use by non-qualified or non-trained personnel, lacking ability or experience
- user error
- use of the instrument outside the guidelines described in this User Manual
- use of the instrument even when some operational anomalies are encountered
- non-authorized servicing of the instrument.

1.4 Labels and symbols

1.4.1 Identification label

SN A23-04P.00000
REF spirobank
MIR via del Maggolino 125
00155 Roma, Italy



The label shows:

- Serial number of the device

- Product name
- Name and address of the manufacturer
- CE mark in compliance with the Directive 93/42 EEC.
- Electrical safety symbol
- Warning symbol for the WEEE

1.4.2 CE mark for medical devices



This product is certified to conform to the Class *I/a* requirements of the 93/42/EEC medical device directive.

1.4.3 Electrical safety symbol



In accordance with the **IEC 60601-1** Standard, this product and its component parts are of **type BF** and therefore protected against the dangers of direct and indirect contact with electricity.

1.4.4 Warning symbol for the USB port



For connection to other devices such as PC.

Use only the serial cable supplied by the manufacturer and observe the safety regulations of **IEC 60601-1-1**.

1.4.5 Warning symbol for the WEEE



As laid down in the European Directive 2002/96/EEC requirements regarding the disposal of electrical and electronic devices (WEEE), at the end of its useful life this device must not be thrown away together with normal domestic waste as it contains materials which would cause damage to the environment and/or represent a health risk. Instead it must be delivered to a WEEE authorised collection centre, where the device will then be disposed of correctly.

An alternative is to return the device without charge to the dealer or distributor, when a new equivalent device is purchased.

Due to the materials used in the manufacturing of the device, disposing it as a normal waste product could cause harm to the environment and/or health.

Failure to observe these regulations can lead to prosecution.

1.5 Product description

spirobank is a pocket spirometer. It can operate in stand alone mode and it can be connected to a PC using USB connection.



spirobank is specifically designed to measure a range of respiratory parameters. A quality control check is carried out internally on the measured parameters and the device has an internal memory to store data of the last session.

spirobank is a powerful and compact measurement device, intended for use by a respiratory specialist or by a suitably trained generalist. The spirometer calculates the main respiratory parameters.

The flow and volume measurement sensor is a digital turbine, based on the infrared interruption principal. This principal ensures the accuracy and the reproducibility of the measurements, without requiring a periodic calibration.

The features of this kind of sensor are listed below:

- Accurate measurement even at very low flow rates (end of expiration)
- Not influenced by gas humidity nor density
- Shockproof and unbreakable
- Inexpensive to replace.

The turbine flow measurement sensor is available both in reusable and in single-patient disposable versions.



REUSEABLE TURBINE



DISPOSABLE TURBINE

The following precautions must be observed to ensure that the characteristics of the turbine remain unaltered over time:

- for the disposable turbine: must always be substituted between patients.
- for the reusable turbine: always clean the turbine between patients, to ensure the maximum level of hygiene and safety for the patient.

For a correct interpretation of a spirometry test, the measured values must be compared either to the so-called **normal or predicted values** which are calculated from the anthropometric details of the patient or, alternatively, to the **personal best values** from the clinical history of the subject.

The personal best values can vary considerably from the predicted values, which are taken from “healthy” subjects.

spirobank can also be connected to a PC (or to another computerised system) to configure the system. All spirometric test results plus the related subject details stored inside the device can be transferred from the device to the PC and then viewed on the PC (Flow/volume curves, spirometry parameters).

The connection to the PC is made through the USB port.

spirobank gives an automatic interpretation of each spirometry test carried out, and assigns a “traffic light” feedback (green, yellow or red) for a rapid reading of the interpretation.

spirobank is able to make FVC and VC tests and calculates an index of test acceptability (quality control) plus the reproducibility of the spirometry tests carried out. The automatic test interpretation follows the latest 11 level ATS (American Thoracic Society) classification. Each test can be repeated as required. The best parameters are always available for review. The normal (predicted) values can be selected from several normal “sets”. For example, within the European Union the majority of doctors use the ERS (European Respiratory Society) predicted values.

The device has two batteries:

- Main power: 9V battery (1 battery is required)
- Memory back up: lithium battery type CR2032 of 3V. The battery life is about 10 years, depending on the use of the device

1.6 Technical specifications

A comprehensive description of the main features of the device, the flow and volume measurement turbine follows:

1.6.1 Features of the spirometer

Measured parameters:

SYMBOL	DESCRIPTION	Units
*FVC	Best FVC	L
*FEV1	Best FEV1	L
*PEF	Best PEF	L/s
FVC	Forced Vital Capacity	L
FEV1	Volume expired in the 1 st second of the test	L
FEV6	Volume expired in the initial 6 seconds of the test	L
FEV1/FVC	FEV1/FVC x 100	%
PEF	Peak expiratory flow	L/s
FEF2575	Average flow between 25% and 75% of the FVC	L/s
ELA	Estimated lung age	year
FIVC	Forced inspiratory volume	L
EVC	Slow expiratory vital capacity	L
IVC	Slow inspiratory vital capacity	L

* = best values

Flow/volume measurement system	Bi-directional digital turbine
Temperature sensor	semiconductor (0-45°C)
Measurement principle	Infrared interruption
Volume range	10 L
Flow range	± 16 L/s
Volume accuracy	± 3% or 50 mL
Flow accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 cmH ₂ O/L/s

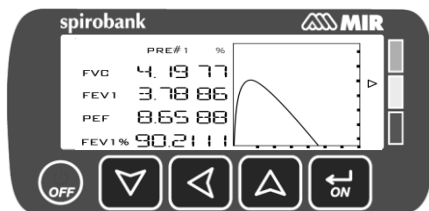
1.6.2 Other features

Memory	Memory capacity for the last session
Display	graphic LCD type SFTN,128x48 Pixel
Keyboard	Membrane keyboard with 5 keys
Interface	USB, Bluetooth
Duration of the CR2032 3.6 V lithium battery (memory backup)	Circa 10 years, under normal conditions of use
Power supply	1 battery 9V DC (type PP3), or through USB connection
Dimensions	162x49x34 mm
Weight	160 grams (including battery)
Type of electrical protection	Class II device
Type of electrical protection	BF
Grade of protection against water ingress	IPX1 device, protected against water drops
Safety level in the presence of inflammable anaesthetic gas, oxygen or nitrogen	Device not suitable
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity :MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C; Humidity: MIN 10% RH; MAX 95%RH
Applied norms	Electrical Safety Standard IEC 60601-1 Electro Magnetic Compatibility IEC 60601-1-2

2. FUNCTIONING OF THE SPIROBANK


2.1 Keyboard

The **spirobank** keyboard is composed of 5 keys:



Key functions are as followed:

1		Off
2		esc/ok previous page OSD key
3		Scroll left OSD key
4		Scroll up



		OSD key
5		On/Scroll down OSD key

Switching on spirobank

To switch on **spirobank** press  and then release.










Switching off spirobank

To switch off **spirobank** press  for at least two seconds.


CONFIRM: to confirm and pass to the next phase, use  or 

Symbols and Icons

The icons used in the various function screens and their meanings are shown in the following table:

ICON	DESCRIPTION
	To access the set up (Service Menu) of spirobank
	To manage or enter new patient data from the main screen
	To enter new patient data
	To modify data of the current subject
	To carry out a spirometry test
	To carry out a VC spirometry test
	Visualize tests for current subject
	To select male patient
	To select female patient
OK	Visualize data for a test in archive
ESC	To exit from the selected screen and return to the main screen

WARNING

IF no key is pressed the instrument after 1 minute will ‘beep’ and if no key is pressed after a further 10 seconds it will automatically switch off. If spirobank is powered by a USB connection to a PC, the aforementioned function is disabled and the device is switched off using .

The instrument can be switched off at any time by pressing and holding the  key.

2.2 Battery Level

The symbol




shown in the second screen when the unit is turned on indicates that the battery is charged. The following symbol indicates Low Battery:

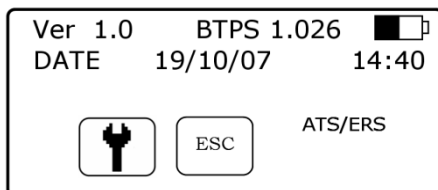




If the battery is discharged the following message appears:


BATTERY DISCHARGED

2.3 Information

Switch on **spirobank** by pressing . The display will show:











- Version 1.0 (version of firmware ie internal software)
- BTPS (Body Temperature Pressure Saturated)
- Power source (USB or battery symbol)
- Current date and time
-  icon (Access to the Service Menu)
-  icon (Return to the main screen)
- standard spirometry in use

Press  to go to the main screen.

2.4 Service menu

Switch on **spirobank** by pressing and holding . Press  to access the service menu. The "Service Menu" screen contains the following fields:

- Select Language (English default)
- Turbine Calibration
- Select Predicted
- Delete Test Data
- Change Date/Time
- Date Format
- Units Format
- Select Turbine
- Select Standard
- Info Firmware

Select the required option using  or  and the  symbol on the left of the screen; press  to access options; select the required setup using the  or , then press  to return to the Service Menu, press  to return without modifications.

Select Language

Press  to access the Menu, use  or  to select the required language and press  to save the change and return to the Service Menu.





Turbine Calibration

Insert the following password to access the calibration function:


For the correct use of this function, please see Paragraph 2.4.1.

Select Predicted Values

Enter Menu with , then use  or  to select the required value and press  again to return to the Service Menu.

Adult	Paediatric
ERS	Knudson
Knudson	Knudson
USA	Knudson
ERS	Zapletal
MC-Barcelona	Zapletal

Delete Memory







Enter Menu with , then enter the password




if the password inserted in correct, the following message appears:

Test data has been cancelled





Change Date/Time

In the date and time setting, the  arrow indicates the field to modify. Use  or  to modify the selected option; use  to pass to the the following option. Lastly, press  to return to the Service Menu. To return to the Service Menu display without making any changes press .





Date Format

Use  or  to select the required format and  to enter and return to the Service Menu.





Units Format

Access with  and select imperial or metric as required with  or . Press  again to return to the Service Menu.

Turbine Setup

Access with  and select the turbine in use (disposable or reusable) with  or . Press  again to return to the Service Menu.


Select Standard

Access with  and select the required standard using  or . Press  to return to the Service Menu.


WARNING


With the standard NAHNES III is not possible to select or to modify the predicted values.

Info Firmware

Access through  to view the version number of the following components, where available:





- **spirobank**

After approximately 10 seconds **spirobank** automatically displays the Service Menu, otherwise press .

Having set the parameters as required from the Service Menu press  to access the main screen:

Which indicates:

- Patient ID code* and ethnic group
- Birth date (dd/mm/yyyy)
- Height (cm)
- Weight (kg)
- Sex (S)
- Function icons

ID#:	0001	CAUCASIAN			
Birth date	cm	Kg	S		
04 / 11 / 1967	182	70	♂		
					

* the ID code is created automatically when new patient data is entered and is always 1.


2.4.1 Turbine Calibration

WARNING

The turbine flow sensor does not require calibration but needs only a regular cleaning. If a calibration must be made then the following guidelines should be carefully noted.
Calibration can be made only on the reusable turbine.

Calibration of the turbine is performed using a calibration syringe to make an FVC test for the expired parameters and an FIVC test for the inspired parameters.

Before the calibration procedure, make a FVC test using a calibration syringe (for example 3 litres) and it is vital to make a complete expiratory and inspiratory phase.

To access the calibration function, select "Turbine Calibration" from the Service Menu with the horizontal scroll key and then press . The following screen appears:

SYRINGE	FVC	FIVC
---------	-----	------

300 ◀	308	333
correction	0%	0%
FOR FACTORY CALIBRATION		
INSERT FVC = 0		

The Old FVC and the Old FIVC values now shown are from the previous calibration.

The values in % indicate the correction factor. These are pre-set to 0 by default.

Use ▼ or ▲ to set the desired values, use ← to go to the following value.

If the difference in percentage between the expected value and the measured value is greater than 10% then it is not possible to continue the calibration procedure, this means that the turbine is damaged or requires cleaning.

To clarify: using a 3 litres syringe, the expected FVC value is 3.08 L, the expected FIVC instead is in function of the ambient temperature.

Press ◀ to turn to the service menu without applying any calibration factor.

If % FVC and FIVC are more than 10%, the device cannot correct such a value; in this case:

- Check the correct functioning of the **spirobank** with a new turbine and/or
- Clean the turbine.

To erase the calibration in use and reset to the factory calibration, input 0 in the New FVC and New FIVC fields.

Note

Each time a calibration is made, the new correction factors are added to the previous correction factor. Therefore, before making a new calibration make sure to delete the calibration in use as described above.

For an accurate and reliable calibration, the syringe volume must be at least 3 L.

WARNING

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.

The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.

For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature, as the air inspired is at ambient temperature.

For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.

The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.

If a 3L syringe is used to make the calibration and if the spirobank is calibrated correctly then the FVC (syringe) value will be:

3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).

If the ambient temperature is 20°C, the FIVC (syringe) value will be:

3.00 (FIVC) x 1.102 (BTPS) = 3.31 L (FIVC at BTPS).




The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.






**For instance, if the calibration procedure is carried out with measured data:
FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting
correction factor becomes:**

EXPIRATION	.00%
INSPIRATION	.00%


This does not represent an error, but is a logical consequence of the explanation detailed above.

2.5 Subject Data








Switch on **spirobank** by pressing , or if already switched on, press  ( icon); to access the “PATIENT DATA MANAGEMENT” screen, the following table describes the functions and icons.

Icon	Key	Description
		To enter new patient data
ESC		Go to the main screen
		To modify data of current subject

To enter new patient data

From the “Patient Data Management” menu press  to access the data input screen.

First screen (date of birth, weight, height, sex)

Use  or  to select date of birth, use  to set month, repeat to set year; continue setting data by entering patient height, weight and sex using the same  key. The arrow  shown to the right of the field indicates the numerical value that is being changed. After this operation use  to go to the following screen; or  to return to the previous data.

Second screen (ethnic group)



Set an ethnic group: this function allows the correction of the predicted values for a subject with the ethnic group to which he or she belongs. The function “without correction” can also be used.

ATS/ERS Standard		NAHNES III Standard	
Group	% correc.		
Without correction	100%	Caucasian	
Caucasian	100%	African-American	
Oriental	100%	Mexican-American	
Hong Kong Chinese	100%	Others	
Japanese	89%		
Polynesian	90%		
North Indian	90%		
South Indian	87%		
Pakistan	90%		
African Descent	87%		

For ATS/ERS standards, the correction is applied to the predicted values of the following parameters:



FVC, FEV1, FEV3, FEV6

For NAHNES III standards, the correction is based on several theoretical formulas (as described in the publication).

press  to complete the setting of the parameters, the main screen then appears. In the event of an error during the setting of patient data press  to return to the previous screen.

To interrupt data input press , which then goes back to the main screen.

Modifying patient data

In the “Patient Data Management” menu press  which corresponds to the  icon. Modify data in the following screens by using the keys as described for entering new patient data.

To return to the main screen without changing any data press .

2.6 Displaying data from memory

From the main screen press  ( icon), to check data of the last session. Press  to return to the main screen without searching.

2.7 Online operating mode (connected to a PC)

Connect the unit to a PC using the USB cable.

In this modality the device can make the following activities:

- Print last session
- Calibrate the reusable turbine in use
- Upgrade the internal software of the device
- Create an archive of the tests made

For more information see the on line manual of the software winsporoPRO Express.

2.8 Spirometry Testing

WARNING

To make a correct spirometry test the device has to be disconnected from the PC.

To make a correct spirometry test we recommend to follow carefully the following instructions:

- Insert the mouthpiece into the protruding part of the turbine, by at least 0.5 cm;
- Fit the nose clip onto the nose of the subject to ensure that air cannot escape through the nostrils;
- Hold **spirobank** at either end in two hands, or alternatively hold it in one hand as you would a cell phone. In either case, the display should be facing the user;
- Insert the mouthpiece well into the mouth beyond the teeth, being careful to ensure that air cannot escape from the sides of the mouth;


- It is suggested to make testing in a standing position and during an expiration to lean forward, to help the expiratory action with a compression of the abdomen.

WARNING 

Do not touch the keys during a test to avoid switching off the machine or stopping a test too soon.

The test available with **spirobank** is FVC (Forced Vital Capacity)

The device displays the information regarding the turbine selected in the initial setting (reusable or single-patient disposable), and then the relevant test information follows.

Or press  to turn to the main screen.

2.8.1 FVC Test

The phases as described on the screen must be followed, specifically:

EXPIRE quickly

INSPIRE slowly

It is possible (and may be helpful) to start the test by breathing for a few moments at rest. When ready to start *inspire slowly as much air as possible* (made easier by holding arms wide apart) and then *make a complete expiration as fast as possible*. Then with the mouthpiece still held firmly in the mouth, complete the cycle by inspiring again as quickly as possible. This final inspiration may be left out if the inspiratory parameters (FIVC, FIV1, FIV1%, PIF) are not of interest.

The optional initial inspiration phase can also be performed before inserting the mouthpiece in the mouth.

After inspiring slowly and deeply, the following expiration must be made with the maximum effort by expiring all of the air as fast as possible.

After 6 seconds of expiration the instrument will emit a continuous beep, this helps the user to understand when the minimum expiry time has been reached.

WARNING 

For accurate spirometry testing it is indispensable that all of the air contained in the lungs is expired.

The test may be repeated several times by repeating the cycle without taking the mouthpiece out of the mouth, in which case **spirobank** recognises the best test (FVC+FEV1) and will automatically show the results of this best test.

At end of the test press  as shown on the screen.

During testing **spirobank** emits "beeps", the frequency of which is directly proportional to the inspired and expired air velocity. This is useful to the doctor to understand when the velocity of the air is approaching zero, and therefore the patient has almost exhausted all of the inspired or expired volume.


In the maintenance section an explanation is given as to how this feature can also function as a very simple check system for the correct operation of the mobile "rotor" of the turbine.

For the FVC test to be judged as acceptable, besides breathing as deeply as possible, it is also required that the forced expiratory time (FET) is sufficiently long to allow for the complete expiration of all air contained in the lungs.


Six seconds from the start of the forced expiratory test, **spirobank** emits a continuous beep. This is useful to the doctor to understand if the patient has reached the minimum expiry time, as per the requirements of the major international pneumology associations.

2.8.2 VC Test

Expiratory Slow Vital Capacity: VC

Press  on the main screen *inspire slowly* as much air as possible and then *expire slowly* as much air as possible.

Inspiratory Slow Vital Capacity: IVC

Press  on the main screen *expire slowly* as much air as possible and then *inspire slowly* as much air as possible.

To end the test press OK.

To correctly carry out this test, follow the indications as described on the display.

2.8.3 Reading messages

A series of measured parameters, based on the international reference standards are shown at the end of each test. A series of test messages are displayed, followed by the measured parameters.

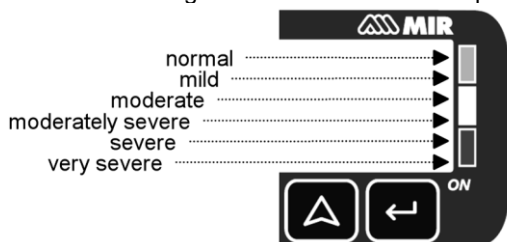
A description of these messages and the parameters now follow in the order in which they appear.

If no key is pressed for circa 6 seconds then the unit moves automatically to the next message or parameter.

2.8.4 Spirometry test interpretation

Spirometry test interpretation is based on the Forced Vital Capacity (FVC) test and is based on the ATS standard. For a faster comprehension this interpretation is illustrated by a traffic light code (green, yellow, red). For each test made, an arrow on the right of the screen indicates the worst level of interpretation of the test session.

The connection between the traffic light colour and the test interpretation is shown below:



Through an analysis applied to some of the indices and parameters calculated in the FVC test, **spirobank** produces a variety of **quality control comments** useful to understand the reliability of the test made.

This control quality check assigns a letter for the current session as described below:

PRE Test

A = At least two acceptable manoeuvres, with the highest two FEV1 values matching to within 100 mL and the largest two FEV6 values within 100 mL.

B= At least two acceptable manoeuvres, with the FEV1 values matching to within 101 to 150 mL

C= At least two acceptable manoeuvres, with FEV1 values matching to within 151 to 200 mL

D= only one acceptable manoeuvres, or more than one, but the FEV1 values not matching to within 200 mL (with no interpretation).

F= No acceptable manoeuvres (with no interpretation).

Acceptable manoeuvre means: good start and satisfactory exhalation (duration and flow)

Where several *comments* related to the single test are calculated, **spirobank** will only show the most important to facilitate the test interpretation.

ERROR IN Vext and PEF

If the extrapolated volume Vext is greater than 500 mL or greater than 5% of the FVC, or if the PEFT (time to peak flow) is greater than 300 ms, then the following comment is shown:

INITIAL EXPIRATION TOO SLOW

FET error

If FET is under the predicted threshold the following message appears:

EXPIRY TIME INSUFFICIENT <6s

FLOW ERROR

If the last flow point of the F/V curve is greater than 200 mL/s, this indicates that the expiration was not complete and thus the following comment is shown:

BLOW OUT ALL AIR IN LUNGS

Between two tests, **spirobank** evaluates the repeatability of the following parameters:

PEF repeatable when the difference between the two largest PEF is ≤ 0.67 L/s;

VC repeatable when the difference between the two largest VC is ≤ 150 mL;

If FVC is > 1.0 L then:

FEV1 repeatable when the difference between the two largest FEV1 is ≤ 150 mL;

FVC repeatable when the difference between the two largest FVC is ≤ 150 mL;

if FVC is ≤ 1.0 L then:

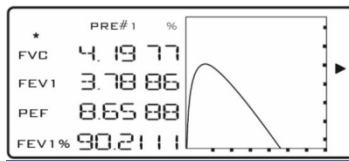
FEV1 repeatable when the difference between the two largest FEV1 is ≤ 100 mL;

FVC repeatable when the difference between the two largest FVC is ≤ 100 mL;

2.8.5 Viewing the spirometric parameters

I° case: ATS/ERS standard

Following an FVC test, the spirometry test results are shown. The first screen displays the main parameters *FVC, *FEV1, *PEF, *FEV1%, the percentage of the predicted values, the Flow/Volume curve plus a traffic light summary of the test interpretation (in the upper right), as illustrated below.



*= best values

In case of “repeatability” a symbol ® is shown in the graphic area

The following screens show other values compared to the predicted values.

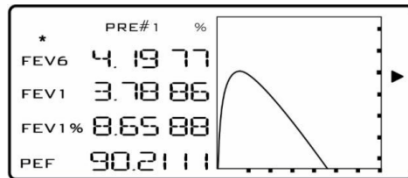
Parameters shown:

FVC, FEV1, FEV1/FVC, PEF, FEF2575, ELA.

*= best values

II° case: NAHNES III standard

Following an FVC test, the spirometry test results are shown. The first screen displays the main parameters *FEV6, *FEV1, *FEV1/FEV6%, *PEF, the percentage of the predicted values, the Flow/Volume curve plus a traffic light summary of the test interpretation (in the upper right), as illustrated below.



*= best values

In case of “repeatability” a symbol ® is shown in the graphic area

The following screens show other values compared to the predicted values.

Parameters shown:

FEV6, FEV1, FEV1/FEV6%, PEF, FEF2575, FVC, FEV1/FVC

*= best values

3 CONNECTION TO A PC THROUGH USB PORT

WARNING

Before connecting spirobank via USB to a PC, winspiro Express must be installed to interface with the device.

It is important prior to initiating the following procedure to know the version of the operating system installed on the PC used for the connection (from control panel click on “System”, where the operating system installed on the PC can be checked).

If winspiro Express is already installed on the PC then a new installation is not required.

To make the connection, insert the mini USB connector supplied with **spirobank** as shown in the picture and attach the other connector to the USB port of the PC.

When making an initial connection, the PC will (depending on the version of the operating system) either make an automatic driver installation or request some information. To avoid errors in this phase please read the winspiro Express User Manual very carefully.

To check the connection between the device and the PC, ensure that the led on the device is illuminated.



3.1 Upgrade Internal software

spirobank software can be upgraded when connected to a PC. Upgrades can be downloaded by registering on www.spirometry.com. For further information on upgrading software see the "winspiro Express" software manual.

4 MAINTENANCE

spirobank is an instrument that requires very little maintenance. The operations to perform periodically are:

- Cleaning and controlling of the reusable turbine.
- Changing the disposable turbine before each test.
- Changing the battery.

The maintenance operations described in this User Manual must be carried out carefully. Failing to observe the instructions may cause errors in measurement or in the interpretation of the measured values.

Modifications, adjustments, repairs, and reconfiguration must be carried out by the manufacturer or by authorised persons.

In case of problems do not attempt to repair the unit.

The setting of configuration parameters must be carried out by qualified personnel. In any case the risks pertaining to incorrect configuration settings do not constitute a danger for the patient.

4.1 Cleaning and controlling the reusable turbine

The turbine utilized by **spirobank** belongs to one of two categories: disposable or reusable. These both guarantee precise measurements and have the great advantage of requiring no periodic calibration. In order to maintain the characteristics of the turbine a simple cleaning is required prior to each use (**only for the reusable turbine**).

Cleaning of the disposable turbine is not required, as it is supplied clean in a sealed plastic bag. It must be disposed of after use.

WARNING

It is good practice to control from time to time that dirt or foreign bodies are not deposited inside the turbine, such as threads or hair. Any such deposits could brake

or block the rotation of the turbine blade and thus compromise the measurement accuracy.

Verify the free movement of the turbine.

- Switch on **spirobank** as if to make a spirometry test (for example **FVC**)
- Hold **spirobank** in one hand and move it gently from side to side so that air passes through the turbine
- If the rotor within the turbine is turning correctly then you will hear a regular **beep** that indicates that the turbine is moving within the specific low flow range indicated by the beeping
- If moving the turbine from side to side at a constant velocity, the regular beeps or no beeps at all are heard, then proceed with the cleaning of the turbine.

To clean the **reusable** turbine, first remove it by pulling it gently from the **spirobank** turning it anti-clockwise and pulling lightly. It can be helpful to push it gently from underneath with one finger.

Immerse the turbine in a cold detergent solution and move it within the liquid to remove any impurities which may be deposited inside. Leave the turbine immersed for the time specified in the instructions of the solution.

To avoid any kind of damage to the reusable turbine please do not use any alcoholic or oily substances, do not immerge the turbine in hot water or hot solution.

Never place the turbine under a direct jet of water or any other liquid. Where no cleaning solutions are available it is however indispensable to clean the turbine in clean water.

MIR suggest the use of Perasafe, manufactured by Dupont, which has been tested with positive results on all MIR sensors.

Rinse the turbine by immersing it in clean water (**not hot**).

Shake off the excess water from the turbine and leave it to dry, standing it vertically on a dry surface.

Once the turbine has been cleaned insert the turbine in its place and follow the instructions indicated by the closed lock symbol printed on the plastic casing of the **spirobank**.

To insert the turbine correctly push it and then turn it clockwise until reaching the stop, which ensures that the turbine has been blocked inside the casing.

To ensure the turbine is functioning correctly repeat the controls described above; if it doesn't work correctly, replace with another one.

If the disposable turbine is used do not clean it but change it after each test.

4.2 Changing the Batteries

If the message "**BATTERY DISCHARGED**" appears on the **spirobank** display, or if the instrument does not switch on, then the battery must be changed as follows:

- Remove the battery cover by pressing and pushing it away from the device.
- Disconnect and remove the battery.
- Replace with a new battery, ensuring the connector is correctly connected.

- Close the battery compartment by replacing the back cover and sliding it towards the inside of the device.

WARNING 

Use only 9 V type PP3 battery or equivalent. When inserting the battery in the battery slot, take care to connect the “+” and “-” as shown inside (see figure below).



The device also has an internal lithium battery for the RAM memory and the average life is approximately 10 years. If the display shows the following message:

Warning change lithium battery

Call a service centre or the manufacturer for replacement.

5 PROBLEM SOLVING

A list of problems follow that may arise when working with the **spirobank**. Diagnostic messages are also shown on the display to indicate the type of malfunction:

5.1 Causes and Solutions

- **spirobank does not switch on**
Check that battery is correctly inserted in the compartment on the back of the instrument. If it is correctly positioned then replace it with new one.
- **During operation the machine switches itself off and on again**
Change the battery.
- **At the end of spirometry testing the test data is incorrect**
Clean the turbine and then control it; use a new turbine.
- **All data in memory lost due to an unforeseeable event**
All data in memory has been deleted. Contact the technical service centre.

WARNING 

Before contacting the centre for technical assistance, please download the test memory from the device to the PC using the Winspiro Express software. This procedure is necessary as the test data could be lost whilst repairing the device and could also be of a confidential nature and therefore subject to laws on data privacy.



MEDICAL INTERNATIONAL RESEARCH
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DECLARATION OF CONFORMITY CE (annex II excluding par.4)

We hereby declare that the following device:

Type	Spirometer
Brandname	MIR Medical International Research
Device name	spirobank
Class	IIa

Complies with the Essential Requirements of directive 93/42/EC concerning Medical Devices, and its amendments, and its transposition in the Member States.

This statement is made on the basis of the CE Certificate n. MED 9826 issued by Cermet, Notified Body n. 0476.

Rome 01/01/2011

Paolo Sacco Boschetti
The Chairman

Rev.1 – Mod. PO-10DDC_spirobank

LIMITED WARRANTY CONDITIONS

spirobank, together with its standard accessories is guaranteed for a period of:

- 12 months if intended for professional use (doctors, hospitals, etc.)
- 24 months if the product has been purchased directly by the end user.

The warranty is effective from the date of purchase shown on the relevant sales invoice or proof of purchase.

The warranty is effective from date of sale which must be shown on the relevant sales invoice or proof of purchase.

The instrument must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to the manufacturer.

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts or for the labour.

All batteries and other consumable parts are specifically excluded from the terms of this guarantee.

This warranty is not valid, at the discretion of the manufacturer, in the following cases:

- If the fault is due to an improper installation or operation of the machine, or if the installation does not conform to the current safety norms in the country of installation.
- If the product is utilised differently from the use described in the User's Manual.
- If any alteration, adjustment, modification or repair has been carried out by personnel not authorised by the manufacturer.
- If the fault is caused by lack of or incorrect routine maintenance of the machine.
- If the machine has been dropped, damaged or subjected to physical or electrical stress.
- If the fault is caused by the mains, or by a product to which the instrument has been connected.
- If the serial number of the instrument is missing, tampered with and/or not clearly legible.

The repair or replacement described in this warranty is supplied for goods returned at the customers' expense to our certified service centres. For details of these centres please contact your local supplier of the spirometer or contact the manufacturer directly.

The customer is responsible for the transportation and for all transport and customs charges as well as for delivery charges of the goods both to and from the service centre.

Any instrument or accessory returned must be accompanied by a clear and detailed explanation of the defect or problem found. If units are to be returned to the manufacturer then written or verbal permission must be received before any instruments are returned to MIR.

MIR – Medical International Research reserves the right to modify the instrument if required, and a description of any modification made will be sent along with the returned goods.

Pulmonary Function Test Results

Flow / Volume and Volume / Time Loops

Patient Data

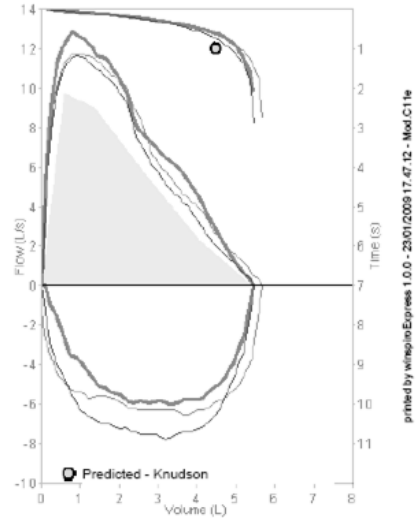
Last name	MARTINI	Age	28
First name	DAVID	Gender	Male
Date of birth	06/05/1975	Height, in	71
Ethnic group	Caucasian	Weight, lb	167

Interpretation

Normal Spirometry

Best values from all loops

Parameters	BTPS	Pred	Measured	%Pred
FVC	L	5,43	5,68	105
FEV1	L	4,49	5,12	114
FEV1/FVC	%	83,2	90,1	108
PEF	L/s	9,77	12,90	132



Date 24/07/2003 14.34.17

Parameters	BTPS	Predicted	Measured #1	%Predicted	Measured #2	Measured #3
Forced Vital Capacity						
FEV6	L	5,30	0,00	0	0,00	0,00
FVC	L	5,43	5,45	100	5,68	5,47
FEV1	L	4,49	5,06	113	5,12	4,85
FEV1/FVC	%	83,2	92,8	112	90,1	88,7
PEF	L/s	9,77	12,90	132	11,91	11,73
FEF2575	L/s	4,71	7,33	156	6,38	5,88
ELA	Years	33	33	100	33	33

Conclusion / Medical report

Signature

 Instrument used
 Spirobank USB S/N 000000

1 / 1



ANNEX 2 INFORMATION FOR CORRECT USE IN AN ELECTROMAGNETIC ENVIRONMENT

Guidance and manufacturer's declaration – electromagnetic emissions

The **spirobank** is intended for use in the electromagnetic environment specified below.
The customer or the user of the **Spirobank** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The spirobank uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The **spirobank** is intended for use in the electromagnetic environment specified below. The customer or the user of the **spirobank** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3] V	Portable and mobile RF communications equipment should be used no closer to any part of the spirobank , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{3} \right] \sqrt{P}$ $d = \left[\frac{3,5}{3} \right] \sqrt{P}$ 80 MHz to 800 GHz $d = \left[\frac{7}{3} \right] \sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[3] V/m	where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE *U*/*T* is the a.c. mains voltage prior to application of the test level.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **spirobank** is used exceeds the applicable RF compliance level above, the **spirobank** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **spirobank**.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the spirobank

The **spirobank** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **spirobank** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **spirobank** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3.5}{3} \right] \sqrt{P}$	$d = \left[\frac{3.5}{3} \right] \sqrt{P}$	$d = \left[\frac{7}{3} \right] \sqrt{P}$
0.01	0.12	0.24	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	5.28	5.28	1.056
100	11.66	11.66	23.32

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.