




CONTENTS 

CONTENTS

Before using the device 1

Intended Use of the Device.....1

Precautions.....2

Package Overview10

Product Overview11

Powering On/Off the Device15

Charging the Device18

First Time Configuration.....20


Operating instructions 27

Navigating the Screens.....27

User Settings.....37

Managing the Bluetooth Connection.....39

i

 CONTENTS

Measuring operation 50

Before Measuring50

Taking a Measurement52

Event Tagging58

The Result Screen60

Calibrating Your Device 65

ADVANCED FEATURES (BY APP) 69

App Introduction.....71

Maintenance 77


Error Messages.....77

Cleaning the Device.....80

Technical data 81


Specifications.....81

ii

CONTENTS 


Electromagnetic Compatibility Information85

iii

BEFORE USING THE DEVICE 

Intended Use of the Device

The Freescan device is intended to record, and transfer single-channel electrocardiogram (ECG) rhythms. It provides Atrial Fibrillation (AFib) and Arrhythmia (Tachycardia and Bradycardia) detection, and also measures adult's blood pressure and heart rate (when prescribed by a physician) The Freescan device is clinical investigated according to the requirement of ISO 81060-2:2013.

IMPORTANT:  • People in the following conditions may get inaccurate blood pressure readings: pregnant, irregular heartbeat, atrial fibrillation, currently taking cardiovascular drugs or ever receiving cardiovascular surgeries.








• The presence of a cardiac pacemaker may impair the AFib detection

1

 BEFORE USING THE DEVICE









Precautions

CAUTIONS

-  Read all of the information in the user manual and other provided instructions before operating the unit.
-  Do not self-diagnose or self-medicate on the basis of the Freescan measurements without consulting your doctor.
-  Do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
-  Keep this user manual carefully for the life of this product.
-  Do not drop this monitor or subject it to strong impact.
-  Do not attempt to disassemble this device.
-  Do not scratch or rub the screen with a hard object.

2





BEFORE USING THE DEVICE 

-  Harsh chemicals may cause damage to the cabinet and the touch sensor. Do refer to "Cleaning the Device" on page 83 for device cleaning.
-  Use only CE marking USB chargers for device charging.
-  Keep away from child and pets for it may get polluted or something similar.
-  Keep away from the flame.
-  Blood pressure accuracy will be affected if the pulse sensor is damaged.
-  If the user experiences any symptom of an allergic reaction when using Freescan, stop using the product and seek medical attention immediately.
-  If the user encounters any error message on the device, please refer to "Error Messages" section on page 69 for further instruction.
-  The device should be charged at least every 3 months to keep the Li-Polymer battery in good condition.

3

 BEFORE USING THE DEVICE







WARNINGS

-  Do refer to "Before Measuring" on page 53 before taking a measurement.
-  Do not plug or unplug the power cord into the electrical outlet with wet hands
-  Do not change the battery. If the battery can no longer be charged, please contact Customer Service.
-  Overcharging the battery may reduce its lifetime.

4

BEFORE USING THE DEVICE 

IEC60601-1 3rd SAFETY WARNINGS

-  When using Freescan, do not connect the power cable of the computer to multiple portable socket outlets or power boards which are connected to other devices. Do not place the multiple portable socket-outlet or power board on the floor while Freescan is in use.
-  Do not disassemble Freescan. Freescan contains no serviceable parts. Servicing shall be performed by qualified service personnel.
-  Only use accessories supplied, or specified for use, with this system.
-  For assistance, if needed, in setting up, using or maintaining the equipment, please contact the retailer or Customer Service for help.
-  No modification of this device is allowed.
-  Do not conduct static electricity on ECG sensor.

5

 BEFORE USING THE DEVICE

NOTES

Disposal: Follow the national requirement to dispose unit.

- Within the European Union:



EU-wide legislation, as implemented in each Member State, requires that waste electrical and electronic products carrying the mark (left) must be disposed of separately from normal household waste. This includes monitors and electrical accessories, such as signal cables or power cords. When you need to dispose of your display products, please follow the guidance of your local authority, or ask the shop where you purchased the product, or if applicable, follow any agreements made between yourself.

The mark on electrical and electronic products only applies to the current European Union Member States.

6

BEFORE USING THE DEVICE 

- Outside the European Union:
If you wish to dispose of used electrical and electronic products outside the European Union, please contact your local authority so as to comply with the correct disposal method.

Important information required by the FCC:

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

7

BEFORE USING THE DEVICE

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.
- These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.

BEFORE USING THE DEVICE




- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

BEFORE USING THE DEVICE




CAUTION required by the FCC:

- Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.




SYMBOL DESCRIPTION

	Attention.
	"BF" symbol, indicate this product is according to the degree of protection against electric shock for type BF equipment.
	Away from the flame.

BEFORE USING THE DEVICE

	Caution, read the instruction before use.
IP22	Water and dust protection classification.
	Disposal of electrical & electronic equipment (WEEE): this product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment.
EC REP	This symbol shall be accompanied by the name and the address of the authorised representative in the European Community.
	This symbol shall be accompanied by the name and the address of the manufacture.
REF	Symbol for "catalogue number".

BEFORE USING THE DEVICE

LOT	Symbol for "batch code".
SN	Symbol for "serial number".
	CE certification LOGO.
	FCC certification LOGO.
	Direct current.

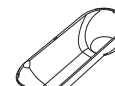
BEFORE USING THE DEVICE

Package Overview

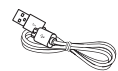
Before using the device, ensure the following items are included to the package. If any of the items are missing or are damaged, please contact the distributor.



Freescan device



Device cover



USB cable



User manual



Quick start guide

BEFORE USING THE DEVICE

Product Overview

Front View

14

BEFORE USING THE DEVICE

1	ECG sensor A1 / Start button	<ul style="list-style-type: none"> Detect the lead I ECG. On the Ready screen, press to start the measurement. Refer to "Taking a Measurement" on page 55.
2	Display	Display the menus, settings, results of the measurements, system status, etc.
3	Up button	On the Ready screen, press to enter the measurement History screen or long press to change the user.
4	Pulse indicator	Blinking green only during the measurement and the pulse has been detected.
5	Set / Power button	<ul style="list-style-type: none"> Press to power on / off the device. Refer to "Power Off the Device" on page 19. On the Ready screen, press to enter the Menu screen.
6	Down button	On the Ready screen, press to initiate the Bluetooth pairing or long press to change the user.

15

BEFORE USING THE DEVICE

Rear View

16

BEFORE USING THE DEVICE

1	Pulse sensor	For detecting the pulse (refer to "The Sensors" on page 55.)
2	ECG sensor A2	For detecting the lead I ECG (refer to "The Sensors" on page 55.)
3	ECG sensor B	For detecting the lead I ECG (refer to "The Sensors" on page 55.)
4	Micro USB port / Reset hole	Remove the cover to access the Micro USB slot or Reset hole.

17

BEFORE USING THE DEVICE

Powering On/Off the Device

Power On the Device

Press and hold the **Power (O)** button to turn on the device. The FREESCAN logo is displayed shortly and then the Ready screen appears.

Note:

- If the "low battery" () indicator appears on the screen, please charge the battery (refer to "Charging the Device" on page 21) or press the **Set / Power** button to ignore the indicator.
- If the "no battery power" () indicator appears, the device will power off immediately.

18

BEFORE USING THE DEVICE

Power Off the Device

Press and hold the **Power (O)** button for 2 seconds. The icon is displayed shortly before powering off.

Note: If no button is pressed within 60 seconds, the device will power off automatically.

19

BEFORE USING THE DEVICE

Reset

Please proceed with the reset procedures if an unexpected system error occurs. To reset the device, do the following:

- 1 Open the Micro USB / Reset hole cover.
- 2 Insert a pin tool (for example, a paper clip) into the reset hole. The device will reset the settings and power off.

Note: Resetting the device does not affect the measured records and user profile.



BEFORE USING THE DEVICE

Charging the Device

When the low battery (🔋) appears on the display, it indicates the battery power is less than 20%. If this happens, we highly recommend you to charge the battery immediately.

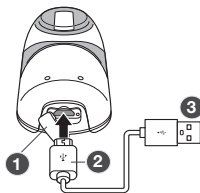
To charge the battery, do the following:

- 1 Open the Micro USB / Reset hole cover.
- 2 Plug one end of the USB cable into the Micro USB port on the device.
- 3 Plug the other end of the USB cable into the USB port of computer.

Note: The intended use of USB port is for charging the battery, which is required to follow IEC60601-1:2012 MOPP and IEC 60601-1-11:2010 requirement.

WARNING! For safety reason, do not charge the battery during sleep time or when nobody is around.

BEFORE USING THE DEVICE



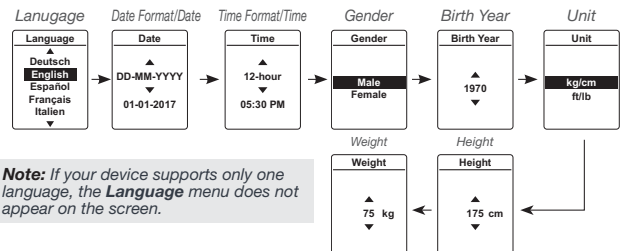
- 4 The device will power on automatically and show the "Charging" (🔌). Wait until the charging is complete and the "Full Battery" (100%) indicator appears on the Ready screen.

Note: With full battery the device is capable to take at least 150 measurements.

BEFORE USING THE DEVICE

First Time Configuration

When you power on the device for the first time, you need to go through the initialization process. Please refer to the following sequence:



Note: If your device supports only one language, the **Language** menu does not appear on the screen.

BEFORE USING THE DEVICE

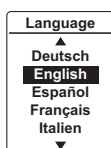
Set the Language

If your device supports multi-language, you need to choose the display language:

Note: If your device supports only one language, please move to section "Set the Date" on page 25.

- 1 Press the **Up** (▲) or **Down** (▼) button to select the language.
- 2 Press the **Set / POWER** (○) button to confirm the selection.

Note: If you select a wrong language and get lost, please restart the device and refer to "Navigating the Screens" on page 30 to find the location of the **Language** menu.



BEFORE USING THE DEVICE

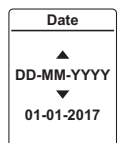
Set the Date

Note: The date setting sequence depends on the chosen date format. In the following example the sequence is "DD-MM-YYYY".

- 1 Press the **Up** (▲) or **Down** (▼) button to select the date format.

Note: The "DD" indicates a day, "MM" a month, and "YYYY" a year format.

- 2 Press the **Set** (○) button to confirm the selection.
- 3 Press the **Up** (▲) or **Down** (▼) button to set the day.
- 4 Press the **Set** (○) button to confirm the selection.
- 5 Press the **Up** (▲) or **Down** (▼) button to set the month.
- 6 Press the **Set** (○) button to confirm the selection.



BEFORE USING THE DEVICE

- Press the **Up** (▲) or **Down** (▼) button to set the year.
- Press the **Set** (○) button to confirm the selection.

Set the Time

- Press the **Up** (▲) or **Down** (▼) button to select the time format between 12-hour and 24-hour.
- Press the **Set** (○) button to confirm the selection.
- Press the **Up** (▲) or **Down** (▼) button to set the hours, minutes, and period (AM or PM).
- Press the **Set** (○) button to confirm the selection.

26

BEFORE USING THE DEVICE

Configure Your Profile

Set Birth Year

- Press the **Up** (▲) or **Down** (▼) button to set the your birth year.
- Press the **Set** (○) button to confirm the selection.

Set Gender

- Press the **Up** (▲) or **Down** (▼) button to set the your gender.
- Press the **Set** (○) button to confirm the selection.

27

BEFORE USING THE DEVICE

Set Unit

- Press the **Up** (▲) or **Down** (▼) button to set the preferred unit for your height and weight.
- Press the **Set** (○) button to confirm the selection.

Set Height

Note: The height unit depends on previously chosen unit format. In the following example the preferred unit is "cm".

- Press the **Up** (▲) or **Down** (▼) button to set the your height.
- Press the **Set** (○) button to confirm the selection.

28

BEFORE USING THE DEVICE

Set Weight

Note: The weight unit depends on previously chosen unit format. In the following example the preferred unit is "kg".

- Press the **Up** (▲) or **Down** (▼) button to set the your weight.
- Press the **Set** (○) button to confirm the selection.

IMPORTANT: The display values of blood pressure will be affected by your profile settings and date settings (for calculating your age). Make sure you input the correct values.

29

OPERATING INSTRUCTIONS

OPERATING INSTRUCTIONS

Navigating the Screens

After powering on the device and complete the initial configuration, you can access the Ready, Scanning, Bluetooth, History, or Menu screen.

Ready Screen	Scanning Screen	Bluetooth Screen	History Screen	Menu Screen

30

OPERATING INSTRUCTIONS

Ready Screen

After you have completed the initial configuration, the Ready screen opens by default. On the Ready screen, you can see the following items:

1 System date	Current system date.
2 Upload	This indicator appears only when there are measurements not yet uploaded to the smartphone, and flicks if the memory is enough for less than 10 measurements.

31

OPERATING INSTRUCTIONS

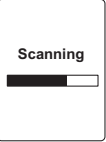
3	Calibration	This indicator only appears if the device has not been calibrated yet.
4	System time	Current system time.
5	Battery	Indicate the battery status: <ul style="list-style-type: none"> █: Battery power is 100%-81%. ▒: Battery power is 80%-61%. ░: Battery power is 60%-41%. ░░: Battery power is 41%-21%. ░░░: Battery power is 20%-1%. □: No battery power. ⚡: Battery is charging.
6	Bluetooth pairing	This indicator only appears if the device has been paired with a smartphone.
7	Multi-Users	Support up to 2 users.

32

OPERATING INSTRUCTIONS

Scan Screen

You will see the Scan screen during blood pressure measurement. To access the screen, press the **Start** (Ⓢ) button any time while the device is powered on.



To measure the blood pressure and understand more about the sensors, please refer to "Taking a Measurement" on page 55.

33

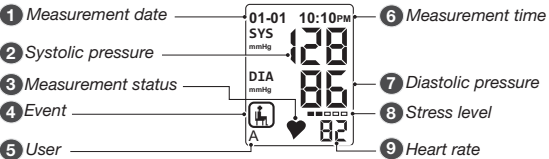
OPERATING INSTRUCTIONS

History Screen

On History screen, you can view the measurement records. To access the History screen, press the **Up** (▲) button on Ready screen. You will see the latest record first.

Do any of the following:

- Press the **Up** (▲) or **Down** (▼) button to scroll the records.
- Press the **Set** (Ⓢ) button to exit the History screen.



34

OPERATING INSTRUCTIONS

1	Measurement date	Indicate the date when the measurement was taken.
2	Systolic pressure	Indicate the highest arterial pressure during contraction of the left ventricle of the heart. The measurement unit is millimeters of mercury (mmHg).
3	Measurement status	Describe the measurement result: <ul style="list-style-type: none"> Successful Unstable Irregular heartbeat (Refer to "Measurement Status" on page 66.)
4	Event	<ul style="list-style-type: none"> Display the respective event icon tagged to the result (refer to "Event Tagging" on page 61). "Empty" if the event tagging is turned off.
5	User	Display the record of the specified user.

35

OPERATING INSTRUCTIONS

6	Measurement time	Indicate the time when the measurement was taken.
7	Diastolic pressure	Indicate the minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood. The measurement unit is millimeters of mercury (mmHg).
8	Stress level	Display the stress level from "1" (the lowest) to "5" (the highest). Each bar represents 1 level. The example shown in the illustration, the stress level is "2". <p>Note: Stress level is determined by heart rate variability (HRV). If your stress level is 4 or above frequently, try to relax yourself more often. Stress level is not a medical index and is for reference only.</p>
9	Heart rate	Display the heartbeat rate in a period of time.

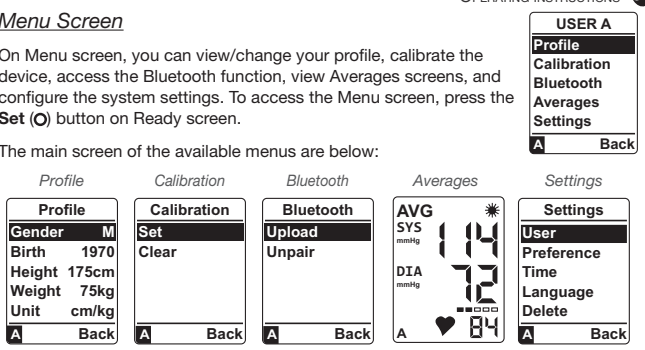
36

OPERATING INSTRUCTIONS

Menu Screen

On Menu screen, you can view/change your profile, calibrate the device, access the Bluetooth function, view Averages screens, and configure the system settings. To access the Menu screen, press the **Set** (Ⓢ) button on Ready screen.

The main screen of the available menus are below:



37

OPERATING INSTRUCTIONS

Main Menu	Description
Profile	<p>Select this option to modify your gender, birth year, height, weight, or height/weight unit. For more information, refer to "Configure Your Profile" on page 27.</p> <p>Note: If you try to change the profile data when the device has been calibrated, a warning screen appears. To change the profile data, please go to the Calibration screen and clear the calibration first.</p> <div style="border: 1px solid black; padding: 5px; width: fit-content;"> Clear calibration before profile update. </div>
Calibration	Select this option to calibrate your device. For more information, refer to "Calibrating Your Device" on page 68.
Bluetooth	Select this option to upload the records or configure the Bluetooth settings. For more information, refer to "Managing the Bluetooth Connection" on page 42.

38

OPERATING INSTRUCTIONS

Averages	Select this option to view the average values of the measurements based on 8 categories. For more information, refer to "Averages Screen" on page 45.
Settings	Select this option to configure the event tagging, adjust the beep/time setting, or reset the device to its default settings. For more information about the event tagging, refer to "Event Tagging" on page 61.

Note:

- After performing the **Reset All** function, all measured records will be cleared.
- To navigate between the menu items, Average screens, or select the parameters, press the Up (▲) or Down (▼) buttons.
- To enter the submenu or confirm your selection, press the **Set (O)** button.
- To exit the menu, select **Back** and press the **Set (O)** button to confirm.
- If the device supports only one language, the language option is not visible in **Settings** menu.

39

OPERATING INSTRUCTIONS

User Settings

With Settings menu, you can update/add user in the device. By default, USER A is created. You can modify the user name by pressing the **Set (O)** button on USER A. A new user could be created simply by pressing the **Up (▲)** or **Down (▼)** button to the empty user list, then pressing the **Set (O)** button to create a new user.

Menu

Settings

User

User A

40

OPERATING INSTRUCTIONS

Note: If all users are created in User Setting, the user can perform a quick user switch by long pressing the Up (▲) or Down (▼) button on Ready screen.

41

OPERATING INSTRUCTIONS

Managing the Bluetooth Connection

With Bluetooth menu, you can manually upload the measurement data or configure the Bluetooth settings. Before uploading the records, make sure the smartphone app is properly installed and the Bluetooth function is enabled on the smartphone.

To pair the Freescan device with a smartphone, perform the following:

- In the Freescan Bluetooth menu, select **Upload** and press the **Set (O)** button. You will see the Bluetooth connection screen.
- On the smartphone app (myFreescan), press the **Settings** tab. Choose "Freescan Pairing".
- In the **Pair Freescan** page, click the **Discover Freescan** button and pick your Freescan device.

Bluetooth

Upload
Unpair

A Back

42

OPERATING INSTRUCTIONS

- The pairing screens appear on both app and device. Then on the device, press the **Up (▲)** or **Down (▼)** button to select **Accept**.
- Press the **Set (O)** button to accept the connection.

1234-5678

Accept
Reject


Note:

- The Bluetooth pairing process needs to be done only once.
- If no response from the smartphone app is received for 90 seconds, a "Bluetooth not found" error message will appear. Refer to "Error Messages" on page 80.

43


OPERATING INSTRUCTIONS

6 Once connected, your device starts uploading the data. The progress of the transferred data is displayed on the screen.



7 When all the records have been uploaded, the **OK** screen appears.

8 View your measurement data from the smartphone app.

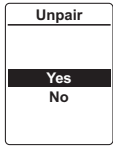


44

OPERATING INSTRUCTIONS

To unpair with the smartphone, perform the following:

- 1 In the Bluetooth menu, select **Unpair** and press the **Set (O)** button.
- 2 In the Unpair screen, press the **Up (Λ)** or **Down (∇)** button to select **Yes**.
- 3 Press the **Set (O)** button to unpair the BT pairing with the smartphone.




Note: Unpairing will make the device “forget” the smartphone it has been paired with. To upload data later, you will have to pair with the smartphone again.

45

OPERATING INSTRUCTIONS

Manually Upload Data to Smartphone app

Freescan device does not automatically upload new measurement data to smartphone app. It is required a manual upload triggered from the smartphone app (press the **Update** tab (Ⓢ) on the app).



46

OPERATING INSTRUCTIONS

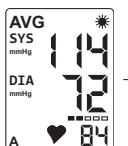
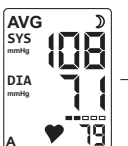
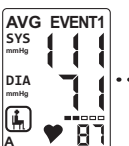

Note: During the manual upload procedure, make sure the Bluetooth on your smartphone is turned on and also the Freescan device is paired with the app. Ensure the distance of device and smartphone are within 5 meters.

47

OPERATING INSTRUCTIONS

Averages Screen

On Averages screen, you can see the average values of all measurements based on the 8 categories as shown on the following sequence and table:

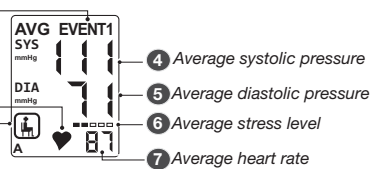
Morning Average	Evening Average	Event1 Average	Event6 Average
			

48

OPERATING INSTRUCTIONS

Morning Average (☀)	Measurements taken during 3 AM to 2:59:59 PM
Evening Average (🌙)	Measurements taken during 3 PM to 2:59:59 AM
Event1 Average to Event6 Average	Measurements associated with Event1 to Event6 (refer to “Event Tagging” on page 61).

As a reference to the items on the Averages screen, please refer to the following illustration:



49

OPERATING INSTRUCTIONS

1 Average category	Indicate the average category type: <ul style="list-style-type: none"> • Morning Average. • Evening Average. • Event1 Average to Event6 Average.
2 Measurement status	Describe the average measurement result: <ul style="list-style-type: none"> • Successful • Unstable • Irregular heartbeat (Refer to "Measurement Status" on page 66.)
3 Event	<ul style="list-style-type: none"> • Display the respective event icon tagged to the result (refer to "Event Tagging" on page 61). • "Empty" if the event tagging is turned off.

50

OPERATING INSTRUCTIONS

4 Average systolic pressure	Indicate the average highest arterial pressure during contraction of the left ventricle of the heart. The measurement unit is millimeters of mercury (mmHg).
5 Average diastolic pressure	Indicate the average minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood. The measurement unit is millimeters of mercury (mmHg).
6 Average stress level	Display the average stress level from "1" (the lowest) to "5" (the highest). Each bar represents 1 level. The example shown in the illustration, the average stress level is "2".
7 Average heart rate	Display the average heartbeat rate in a period of time.

51

OPERATING INSTRUCTIONS

Note: If the average data is not available for the specific category, then dash lines appear instead of the data as on the following example.

52

MEASURING OPERATION

MEASURING OPERATION

Before Measuring

- 1 Sit comfortably before a desk with your back supported.
- 2 Make sure your legs are uncrossed and your feet are flat on the floor.
- 3 Rest your left hand on the desk. If you are wearing a long sleeve, be sure to pull the sleeve up.
- 4 Place the back of your left wrist on a support, such as the desk edge or a rest pad. Make sure your left wrist is between your heart and leg.

53

MEASURING OPERATION

- 5 Bend the left palm outward naturally. Keep your left hand relaxed.
- 6 Rest for 5 minutes before the first measurement. Rest for 1 minute between two measurements.
- 7 Use your right fingers to find the pulse on the left wrist. Continue with "Taking a Measurement" on page 55.

IMPORTANT: Make sure it is the left wrist that is measured. Measuring the right wrist will result in wrong readings.

54

MEASURING OPERATION

Taking a Measurement

The Sensors

The device has four sensors, that are used to measure your blood pressure. To take a measurement, all the four sensors must be contacted properly with both your left and right hands.

1 ECG sensor A1	Contact with the right finger.
2 Pulse sensor	Contact with the radial artery on the left wrist.

55



MEASURING OPERATION

3	ECG sensor B	Contact with the left wrist.
4	ECG sensor A2	Contact with the right fingers.

Measurement Gestures

After you have found the pulse on your left wrist, do the following:

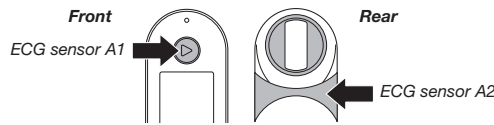
- Choose your favorite gesture between "A" or "B".

56

MEASURING OPERATION

- Power on the device.
- Rest your left wrist on a support. Make sure your left wrist is between your heart and leg, and your whole left arm is relaxed.
- Hold the device with the right hand so that the right fingers are in contact with the ECG sensor A1 and ECG sensor A2.

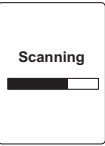



57

MEASURING OPERATION

- Do the following at the same time. The device enters the scanning mode.
 - Press the **Start** (Ⓢ) button.
 - Press the pulse sensor and the ECG sensor B on the pulse location on your left wrist.

Scanning





IMPORTANT: The sensors are fragile. Please handle it carefully.

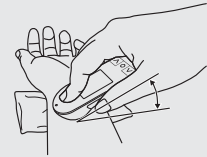
58

MEASURING OPERATION

- Observe the pulse indicator. The LED blinks green in the same frequency of your heart rate when your pulse is detected.

Note:

- If the LED doesn't blink, try to adjust the measuring angle or pressure.



- If you receive the error message E04, try to apply some water to the wrist and finger tips.
- For other error messages, please refer to "Error Messages" on page 80.

59

MEASURING OPERATION

IMPORTANT: You need to keep on pressing the **Start** (Ⓢ) button until the end of step 6.

- After about 10 seconds, your will hear a beep sound and the measurement completes.







Note: If you have enabled event tagging, please continue with "Event Tagging" on page 61. If you have not enabled event tagging, please continue with "The Result Screen" on page 63.


60

MEASURING OPERATION

Event Tagging

After the successful blood pressure scanning, the device prompts you to associate the result with a specific event from 1 to 6.

	Resting	Taking a measurement while resting.
	Waking up	Taking a measurement shortly after waking up.
	Bedtime	Taking a measurement during bedtime.
	After medicine	Taking a measurement after taking medicine.
	After exercise	Taking a measurement after exercise.
	Discomfort	Taking a measurement when feeling discomfort.



61

MEASURING OPERATION

To associate the measuring result with an event, do the following:

- 1 Press the **Up** (▲) or **Down** (▼) buttons to select the desired event.
- 2 Press the **Set** (○) button to confirm the selection.

Note: After associating the measurement with an event, the system displays the Result screen. For more information about the Result screen, refer to "The Result Screen" on page 63.

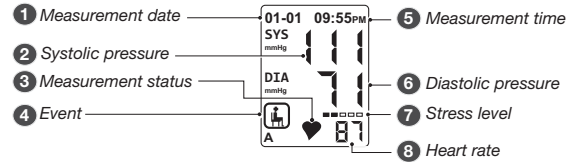
MEASURING OPERATION

The Result Screen

The Result screen appears in the following conditions:

- After associating the measuring with an event, or
- If the event tagging is not enabled, shortly after scanning the measurement result.

On the Result screen, you can see the following items:



MEASURING OPERATION

1 Measurement date	Indicate the date when the measurement was taken.
2 Systolic pressure	Indicate the highest arterial pressure during contraction of the left ventricle of the heart. The measurement unit is millimeters of mercury (mmHg).
3 Measurement status	Describe the measurement result: <ul style="list-style-type: none"> • Successful • Unstable • Irregular heartbeat (Refer to "Measurement Status" on page 66.)
4 Event	<ul style="list-style-type: none"> • Display the respective event icon tagged to the result (refer to "Event Tagging" on page 61). • "Empty" if the event tagging is turned off.

MEASURING OPERATION

5 Measurement time	Indicate the time when the measurement was taken.
6 Diastolic pressure	Indicate the minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood. The measurement unit is millimeters of mercury (mmHg).
7 Stress level	Display the stress level from "1" (the lowest) to "5" (the highest). Each bar represents 1 level. The example shown in the illustration, the stress level is "2".
8 Heart rate	Display the heartbeat rate in a period of time.

IMPORTANT: The device can store up to 200 measurements. When the records limit is reached, the device will overwrite the oldest measurement.

MEASURING OPERATION

Measurement Status

The measurement status may be "successful", indicate a "unstable", or show an "irregular heartbeat".



MEASURING OPERATION

Success	This is a good measurement.
Unstable	<p>The reason for an unstable measurement may be:</p> <ul style="list-style-type: none"> • Your pulse is not stable during the measuring period. The SYS/DIA readings may be less accurate. It is recommended that you rest for a while and measure again. • Your systolic pressure is beyond 60-230 mmHg or your diastolic pressure is beyond 40-140 mmHg.
Irregular heartbeat	Irregular heartbeat is detected. The SYS/DIA readings may be less accurate.

Note: If the "irregular heartbeat" keeps on happening, please consult your physician.

CALIBRATING YOUR DEVICE

CALIBRATING YOUR DEVICE

Freescan can be calibrated with another EN/IEC 60601 certified blood pressure monitor to ensure its accuracy. Please calibrate your Freescan before using it for the first time, after dramatic weight change, surgeries, or critical illness, and calibrate it every 3 months afterward or calibrate more frequently if needed for better accuracy.

IMPORTANT: • Make sure the EN/IEC 60601 certified blood pressure monitor for calibrating Freescan has been calibrated and maintained according to its manufacturer's installation.

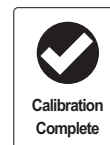
• Please consult the local dealer for Freescan calibration as needed.

To calibrate your Freescan, perform the following:

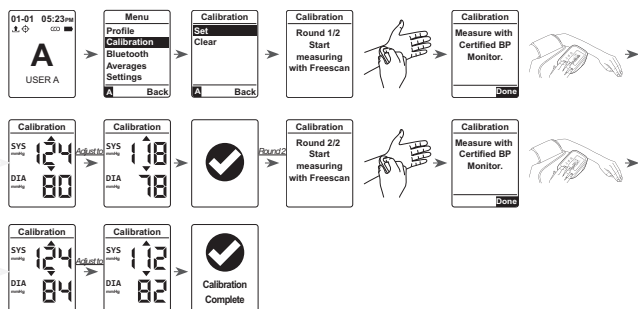
- 1 On Menu screen, choose Calibration.
- 2 In the Calibration menu, select **Set** to start 2 rounds calibration.

CALIBRATING YOUR DEVICE

- 3 Take a measurement using Freescan. Then take a measurement using the certified blood pressure monitor.
- 4 Enter the SYS and DIA values from the certified blood pressure monitor by using the **Up** (▲) or **Down** (▼) button.
- 5 Repeat the procedure again (total 2 rounds calibration) until the calibration complete sign is displayed.



CALIBRATING YOUR DEVICE



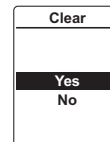
CALIBRATING YOUR DEVICE

IMPORTANT: Please do not talk and keep calm during the whole calibration procedure.

For dramatic weight change, surgeries, or critical illness, it is recommended to **Clear** previous calibration first before **Set** the SYS and DIA after using the certified blood pressure monitor.

To clear the calibration data, perform the following:

- 1 In the Calibration menu, press the **Up** (▲) or **Down** (▼) button to select **Clear**.
- 2 Press the **Set** (O) button to enter its submenu.
- 3 Press the **Up** (▲) or **Down** (▼) button to select **Yes**.
- 4 Press the **Set** (O) button to confirm.



ADVANCED FEATURES (BY APP)

ADVANCED FEATURES (BY APP)

You can use the Freescan device to take the measurement and get the blood pressure result on the device immediately. Through myFreescan smartphone app, you obtain more advanced features: viewing the blood pressure trend, the ECG signal preview, and from ECG signal to evaluate whether the measurement has any atrial fibrillation or arrhythmia detected. To download myFreescan app, please refer to the App Card in the product package to install the mobile app.

Key advanced features in myFreescan app:

- 1 Arrhythmia(Bradycardia and Tachycardia) detection
- 2 Atrial Fibrillation(AFib) detection
- 3 Blood pressure trend
- 4 ECG signal preview

ADVANCED FEATURES (BY APP)

Note: Minimum requirement of the mobile operating system to run myFreescan App:

1. iOS 9.0 and above
2. Android 4.3 and above

ADVANCED FEATURES (BY APP)

App Introduction

Before obtaining the analysis from the myFreescan app, be sure the pairing procedure is completed once (on page 39 "Managing the Bluetooth Connection"). For each new measurement, a manual upload procedure needs to be performed from the smartphone app (refer to page 43).

Note:

- For the advanced features, the app is the result display of cloud computing.
- Be sure that your mobile phone is with internet access to obtain the result.

ADVANCED FEATURES (BY APP)

Blood pressure values

Blood pressure varies extremely and adjusts to internal and external influences, such as physical activity, body weight and age. Too high or too low pressure which could lead to organ damage can be avoided by regulating arterial pressure. In Germany and Switzerland, the blood pressure must be measured in millimetres of mercury (mmHg) by law.

The following classification for systolic and diastolic blood pressure was established in accordance with the World Health Organisation (WHO) and the International Hypertension Society:

ADVANCED FEATURES (BY APP)

	Systolic (mmHg)	and	Diastolic (mmHg)
Optimal	< 120	and	< 80
Normal	< 130	and	< 85
High normal	130 - 139	or	85 - 89
Hypertension (1st degree)	140 - 159	or	90 - 99
Hypertension (2nd degree)	160 - 179	or	100 - 109
Hypertension (3rd degree)	≥ 180	or	≥ 110

ADVANCED FEATURES (BY APP)

This classification of blood pressure categories primarily relates to otherwise healthy people and tells us nothing about the necessity for a medical intervention. "Normal" and "optimal" are descriptions of a condition without further significance for therapeutic intervention.

Atrial fibrillation

Atrial fibrillation (or AFib) is the most common serious abnormal heart rhythm characterized by rapid and irregular beating. Episodes of AFib can come and go, or you may develop AFib that doesn't go away. AFib can lead to blood clots forming in the heart that may circulate to other organs and lead to blocked blood flow. AFib will increase stroke risk by 5 times and death risk by 2 times.

ADVANCED FEATURES (BY APP)

Arrhythmia

An arrhythmia is a problem with the rate or rhythm of your heartbeat. During an arrhythmia, your heart can beat too fast, too slow, or with an irregular pattern. If the heart beats too slow, it is called bradycardia, which can cause insufficient blood flow to the brain and cause heart failure. Bradycardia can usually be corrected with an artificial pacemaker. If the heart beats too fast, it is called tachycardia, which may be a sign of a problem with the heart's electrical system and can cause shortness of breath, chest pain, dizziness. If arrhythmia is detected frequently, further doctoral diagnose is highly recommended.

IMPORTANT:



- It is strongly recommended that you consult your physician, if either the AFib or any arrhythmia symptom detected by myFreescan.
- The presence of a cardiac pacemaker may impair the AFib detection.

ADVANCED FEATURES (BY APP)

IMPORTANT:



- The Freescan device with myFreescan app can provide the detection of AFib, bradycardia and tachycardia. However, the sensitivity and specificity is limited, not all arrhythmia will be detected. The Freescan is not to replace any physician diagnosis; instead, it provides an early detection of some arrhythmia and AFib symptom to proceed further physician's examination.

MAINTENANCE

Error Messages

The following table describes the error messages that you may see on the device's display.

Error	Possible Cause	User Action
E01	Movement detected during measurement.	Keep your body and both hands still.
E02	Start button has been released during the measurement.	Keep the Start (Ⓢ) button pressed until the measurement is complete.

Error	Possible Cause	User Action
E03	No Bluetooth connection.	<ul style="list-style-type: none"> Enable the Bluetooth function on your smartphone. Ensure your smartphone is visible for other devices. Ensure the distance of device and smartphone are within 5 meters.
E04	No ECG signal.	<ul style="list-style-type: none"> Use wet wipes to moisturize the wrist and finger tips. Wipe away grease on the electrodes. If this error still happens, please contact the distributor for further assistance.
E05	Pulse signal is poor.	<ul style="list-style-type: none"> Relax your left hand and find again the pulse location using the right hand fingers. Try a different angle / pressure from the right hand. If this error still appears, rest for a while and try to measure again later.

Error	Possible Cause	User Action
E06	Device error.	Please reset the device through the reset hole. If this error reoccurs, please contact the distributor for further assistance.
E07	ECG signal is weak.	Keep at least one meter away from radio sources, such as computer screen. If this error occurs constantly, please contact the distributor for further assistance.

Note:

- To exit the error screen and return to the Scan screen, press the **Start** (Ⓢ) button.
- To exit the error screen and return to the Ready screen, press the **Set** (Ⓞ) button.

Note: If you find any problems in using the device, please contact the distributor for further assistance.

Cleaning the Device

- For safety reasons, turn off the power and unplug the adapter before cleaning.
- By using a single use wipe, clean the device and keep it away from dust and grease.
- Wipe the sensors softly.
- Do not immerse or soak the device.

TECHNICAL DATA

Specifications

General	
Model	21xxxx Series
Classification	Class II, Type BF
Main unit dimension	W1.46 x D3.76 x H0.79 in (W37 x D95.5 x H20 mm)
Main unit weight	60±5 g (2.1±0.2 oz)
Display	Backlight LCD
Memory	200 measurements
Pulse sensor	Silicone rubber pressure sensor
ECG sensor	Coated electrodes with silver color or gold color
Wireless transmission	Bluetooth 4.0 BLE

General (continued)	
Battery type	250 mAh rechargeable Li-Polymer battery
Battery service life	Approximately 150 measurements at room temperature
Battery shelf life	3 years
Charging port	DC 5V, 110mA micro USB connector
Charge protection	Included
Product life	3 years
Warranty	1 year
Blood pressure measurement	
Measurement method	Pulse transition time
Mode of operation	Non-continuous
Measurement site	Radial artery at the wrist
Measurement time	Approximately 10 seconds

TECHNICAL DATA

Blood pressure measurement (continued)

Blood pressure range	40 to 230 mmHg
Blood pressure accuracy	±3 mmHg
Pulse rate range	30 to 180 beats/minute
Pulse rate accuracy	±5% of the value shown

Environment conditions

Operation conditions	<ul style="list-style-type: none"> • 41°F to 104°F (5°C to 40°C) • 15% to 93% RH (non-condensing)
Storage & transportation conditions	<ul style="list-style-type: none"> • -13°F to 122°F (-25°C to 50°C) • ≤ 93% RH (non-condensing)
Environment pressure (for all)	70 to 106 kPa
Altitude range	0 to 3000 meters
Water/dust protection	IP22

TECHNICAL DATA

Regulatory compliance

Performance	IEC 80601-2-30:2013
Electrical safety	IEC 60601-1-2:2006/A11:2011/A1:2013/A12:2014
EMC	IEC 60601-1-2:2007+AC:2010 IEC 60601-1-2:2014+AC:2015
ECG	ANSI/AAMI/IEC 60601-2-47:2012/(R)2016 (Revision of ANSI/AAMI EC38:2007)
Battery safety	IEC 62133:2013

Note: These specifications are subject to change without notice.

TECHNICAL DATA

Electromagnetic Compatibility Information

Table 1: For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions

The 21xxxx Series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the 21xxxx Series should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 21xxxx Series 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	The 21xxxx Series is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

TECHNICAL DATA

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity

The 21xxxx Series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user 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	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, ± 1 kV (line(s) to line(s)) + 0.5kV, +1kV, ± 2 kV (line(s) to earth)	+ 0.5kV, ± 1 kV (line(s) to line(s)) N/A	Mains power quality should be that of a typical home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U _i ; 0.5 cycle 0 % U _i ; 1 cycle 70 % U _i ; 25/30 cycles Voltage interruptions: 0 % U _i ; 250/300 cycle	Voltage dips: 0 % U _i ; 0.5 cycle 0 % U _i ; 1 cycle 70 % U _i ; 25/30 cycles Voltage interruptions: 0 % U _i ; 250/300 cycle NA	Mains power quality should be that of a typical home healthcare environment. If the user requires continued operation during power mains interruptions, it is recommended that the 21xxxx Series be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE: U_i is the a.c. mains voltage prior to application of the test level.

TECHNICAL DATA

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The 21xxxx Series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the 21xxxx Series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms: 0.15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0.15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the 21xxxx Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (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. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

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.

* 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 device is used exceeds the applicable RF compliance level above, the 21xxxx Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 21xxxx Series.

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

TECHNICAL DATA

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the 21xxxx Series

The 21xxxx Series is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the 21xxxx Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 21xxxx Series 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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.

TECHNICAL DATA

Table 5

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The 21xxxx Series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the 21xxxx Series should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 - 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 - 470	GMRS 460, FRS 460	FM c) 8±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							

TECHNICAL DATA

810	800 - 960	GSM 800/900, TETRA 800, ISDN 800, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1720	1700 - 1990	GSM 1800, GSM 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	2	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

TECHNICAL DATA

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.