Percutaneous Jaundice Detector
User Manual

Date of revision: February 9, 2023

Version: V1.1

Product information

Product name: Percutaneous jaundice detector

Model: GD-001

Working and storage environment

Ambient temperature: 10℃~40℃

Ambient humidity: ≤80％

Operating atmospheric pressure: 70~106kpa

Storage temperature: -20℃~55℃

Storage humidity: ≤93%

Atmospheric pressure for storage: 50~106kpa

Ownership and copyright

Responsibility of the Manufacturer

Changsha Xiaobaituan Technology Co., Ltd. is responsible for the safety, performance and reliability of the detector only under the following circumstances:

1. Operate the detector according to the User Manual.
2. The use and storage environment of the detector shall comply with the requirements listed in the User Manual.
3. Use qualified accessories and consumables manufactured by the Company.
4. The detector shall be repaired and maintained by the personnel approved by Changsha Xiaobaituan Technology Co., Ltd. Anyone other than the personnel above shall not disassemble or modify the detector without authorization.

⚠Please read and understand the User Manual carefully before using the detector, and keep the Manual in an accessible position for further reference. Any detector damage caused by the failure in operating it in accordance with the Manual is not included in the scope of warranty service provided by the Company.

Please use the detector only under doctor's instructions.

ALAN Dental Equipment

Contents

1. Basic information

1.1. Descriptions of Production Information

Name of registrant: Changsha Xiaobaituan Technology Co., Ltd.

Address: Room 704, Building 12, Zhitingyuan Community, No. 816, Zhenhua Road, Tongsheng Sub-district, Yuhua District, Changsha City

Contacts: Room 704, Building 12, Zhitingyuan Community, No. 816, Zhenhua Road, Tongsheng Sub-district, Yuhua District, Changsha City

Entrusted Production License No.: X.Y.J.X.S.C.X. No. 20200191

Medical device registration certificate No.: X.X.Z.Z. 20222071276

Product technical requirement No.: 20222071276

Service life: 3 years

Name of the entrusted manufacturer: Changsha Joymed Medical Technology Co., Ltd.

Domicile: 6F, Building 1, West Zhitingyuan Community, No. 816, Zhenhua Road, Yuhua District, Changsha City

Manufacturer address: 6F, Building 1, West Zhitingyuan Community, No. 816, Zhenhua Road, Yuhua District, Changsha City

Contacts: 4008337400

After-sales service company: Guangdong Xiaobaituan Technology Co., Ltd.

Address: 3 A02 of Room 904, Block 4, Jinying Green Island International Center Community, No. 133 Jihua West Road, Chancheng District, Foshan City, Guangdong Province

Contacts: 0757-85331319

1.2. Scope of Application

The detector is applicable to detection of neonatal percutaneous jaundice.

1.3. Contraindications

Photosensitive patients shall use the product with care. Those with skin lesion of tested skin shall not use the product.

1.4. Precautions

Before using the detector, please carefully read the following precautions. Failure to observe these precautions may result in deviation in test results or damage to the detector.

- The detector shall be used in an environment free from vibration, dust, corrosive or inflammable and explosive gases (narcotic gases, gasoline), extremely high or low temperature, humidity, etc., and with sufficient space for operation.
- Ambient temperature exceeding the technical specification range will affect the detector accuracy, resulting in equipment damage or shortening its service life.
- Do not use the detector in places with strong electromagnetic field. Portable and mobile RF communications equipment may affect the detector's performance.

- When using the detector, make the optical probe perpendicular to the detection point, so that the entire end of the probe is close to the skin appearance; otherwise the detection value will fluctuate.
- The detector emits strong light in course of detection so it is recommended to place it on the forehead or sternum for detection. It is strictly prohibited to directly emit light into eyes.
- Do not place the detector on unstable or inclined surfaces. Otherwise, the detector or base may fall or tip over and cause injury. Do not make the detector fall while handling it.

1.5. Descriptions of Symbols and Marks of Accompanied Files

Marks/symbols	Meaning
	Attention! View accompanied documents
	BF type applied part

1.6. Information of Software Version

Software release version: 1

2. Product Introduction

2.1. Product Overview

The product is a percutaneous jaundice detector (hereinafter referred to as the detector), which is composed of a detector unit and a display screen.

Featuring small size, light weight, convenient use and maintenance, the product has been widely used in Neonatology Department and Pediatric Department of hospitals at all levels.

2.2. How It Works

The detector detects the concentration of bilirubin in the subcutaneous tissue of newborns through the light wave difference between blue light (450nm) and green light (550nm).

2.3. Technical Parameters

Items	Parameter
Model	GD-001
Unit weight	≤ 250g
Overall dimensions	179mmx55mmx38mm (L×W×H)
Display	38.8mmx24.5mm
Ambient temperature and humidity	+10℃~+40℃/≤80%RH
Storage temperature and humidity	-20℃~+55℃/≤93%RH
Waterproof and dustproof	IP20
Software release version	1

2.4. Performance Parameters

Items	Parameter
Detection range	≥ (0~25mg/dL) or (0~425 μmol/L)
Detection error	±1.5mg/dL or ±25.5μ mol/L
Repeatability	≤10%
Preparation time	≤12s

2.5. Configuration List of Products

S/N	Category	Unit	Qty.	Remarks
1	Unit	Pcs	1	
2	AA battery	-	2	
3	Certificate of Conformity	Pcs	1	

S/N	Category	Unit	Qty.	Remarks
4	User Manual	Pcs	1	
5	Warranty Card	Pcs	1	
6	Check disk	Pcs	1	

2.6. Unit

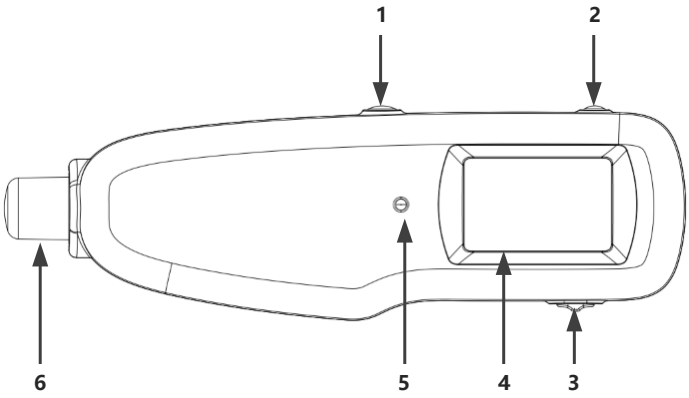

Figure 2-1 Front Panel of the Unit

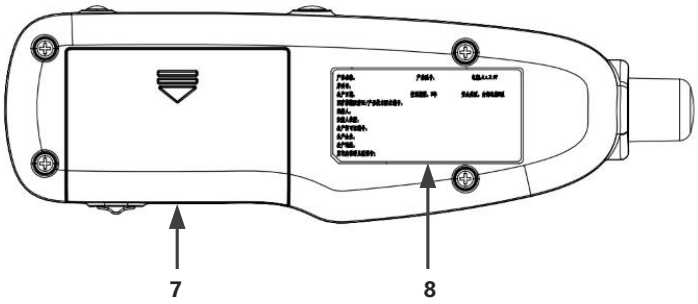

Figure 2-2 Rear Panel of the Unit

The main structure of the detector is shown inFigure 2-2 Rear Panel of the Unit-1 and Figure 2-2.

S/N	Name	Remarks
1	Reset button	Clear the current detection values to get prepared for next test; and delete and view stored data together with the on/off switch and set button (Set button)
2	Set button	Delete and view stored data together with the on/off switch and reset button (Reset button)
3	On/off button	Delete and review the stored data by toggling on/off power together with the reset button and set button
4	Display screen	Display detection values, etc.
5	Ready indicator	It means that the detection can be carried out once it is on
6	Measuring	Press the detection site for detection

S/N	Name	Remarks
	probe	
7	Battery cover	Open it to insert/remove batteries into/from the battery compartment
8	Nameplate	Identify product information

2.7. Display screen

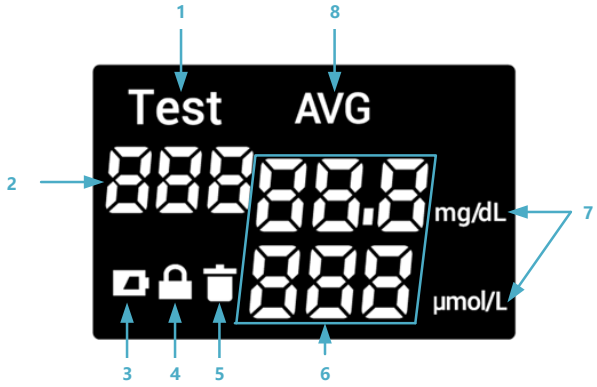

Figure 2-3 Schematic Diagram of Display Screen

Display screen is as shown in Figure Figure 2-2 Rear Panel of the Unit3

S/N	Name	Remarks
1	Test display	Indicate that the Reset button has been pressed
2	Display of detection serial number	Indicate the serial number of the current detection value
3	Battery display	Display battery symbol when the battery level is low
4	Display of parameter lock	Display the parameters set by user have been saved
5	Data clear display	Indicate that the test data has been cleared entirely
6	Display of detection value	Display detection values
7	Unit of detection display	Display units (mg/dL, µmol/L)
8	Display of average detection value	Display under the detection state of average detection value and indicate average times

3. Operating Instructions

3.1. Steps

1) Unpack the detector to check its intactness;
2) Take out of the unit and open the battery cover to put the battery inside;

Note:

Ensure correct installation of battery anode and cathode; please replace the battery in time if the battery level is low; take out of the battery if the detector will not be used for a long time; dispose used batteries in accordance with local regulations instead of discarding them at will.

3) Remove the probe sleeve and clean the measuring probe with medical alcohol, as shown in Figure 3-1;

Figure 3-1

4) Turn the on/off switch to "ON", and the LCD screen will display "0.0" in several seconds (as shown in Figure 3-2).

Figure 3-2

5) Press the Reset button and the Ready indicator will light up in a few seconds. See Figure 3-3 for what the screen displays.

Figure 3-3

6) When the ready indicator is on, make the measuring probe perpendicular to the measured part and press gently until a flash appears.

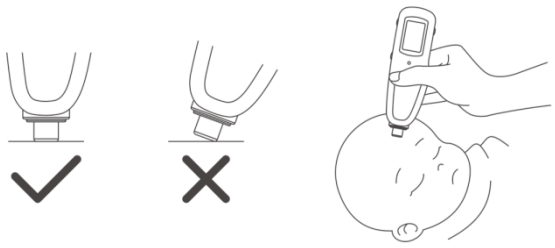

Figure 3-4

a) Make the probe perpendicular to the measured part during use, as shown in Figure 3-4; otherwise significant detection error will occur;

b) When the product is used for newborns, the probe must be perpendicular to the measured part, so that the entire end surface of the probe will be close to the skin appearance without any gap; otherwise the test result is invalid.

Warnings:

Please do not press the measuring probe in the direction facing the newborn's eyes, to avoid damaging their eyes due to strong light

7) See Figure 3-5 for the detection results displayed by the display screen;

Figure 3-5

8) Make detection again according to Steps 5)~6). The display screen will display the contents in Figure 3-5, but the serial number will increase, as shown in Figure 3-6.

Figure 3-6

9) After finishing detection, turn on/off switch to "OFF" to shut down the detector.

10) Put the unit back into the box.

3.2. Descriptions of Functions

3.2.1. Unit of detection display

After detection is finished, the display screen can simultaneously display two units of "mg/dL" and "μmol/L".

3.2.2. Storage of test records

The detector will automatically store the detection data after detection is finished. The detector can store up to 25 pieces of data.

3.2.3. Delete data

After powering off the detector, press and hold the Reset button and Set button at the same time, turn on/off switch to "ON", press and hold the Reset button and Set button for longer than 5 s, and the detector will enter data deletion mode. At this time, the screen will display the contents shown in Figure 3-7, indicating that the stored data has been deleted.

Figure 3-7

Detection can be made by starting up the detector.

Note:

All data will be deleted through the step above so please oeprate with care.

3.2.4. View data

After shutting down the detector, press and hold the "Set" button, turn the on/off switch to "ON", press and hold the "Set" button for 5 s at least, and the display will enter data viewing mode.

The screen displays the last stored value. Press the Reset button to scroll up the stored data or Set button to scroll down, as shown in Figure 3-8.

Figure 3-8

If there is no any data stored in the detector, enter the data viewing mode, and the display screen will display the contents shown in Figure 3-9.

Figure 3-9

3.2.5. Calibration function

After shutting down the detector, press and hold "Reset" button, turn to on/off switch to "ON", press and hold "Reset" button for 5 s at least, and the detector will enter calibration state interface (as shown in Figure 3-10).

According to the difference between the measured value and the nominal value of the calibration plate, press the "Set" button or the "Reset" button to adjust the increase and decrease. After selecting the calibration value to be set, press the measuring probe in front to save the current adjustment calibration value. At this time, the indicator light "Ready" will be on, and the screen will display the symbol that the calibration value has been locked, indicating that the calibration value has been set (as shown in Figure 3-11).

Figure 3-10

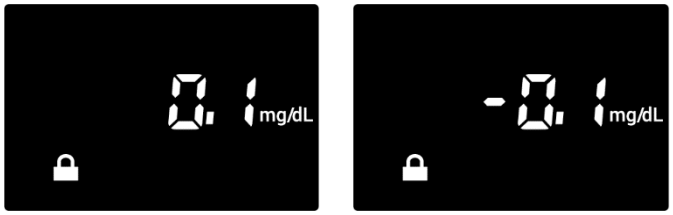

Figure 3-11

Note: The setting range of calibration value: -9.9 ~ 9.9.

3.2.6. Detection function of average value

3.2.6.1 Settings of average times

After shutting down the detector, press and hold the probe, turn the on/off switch to "ON" to enter the average times setting screen, and the screen will display the average times setting stored last time. Press the "Reset" button to change the average times, which can be set cyclically within the range of 1~9 (as shown in Figure 3-12).

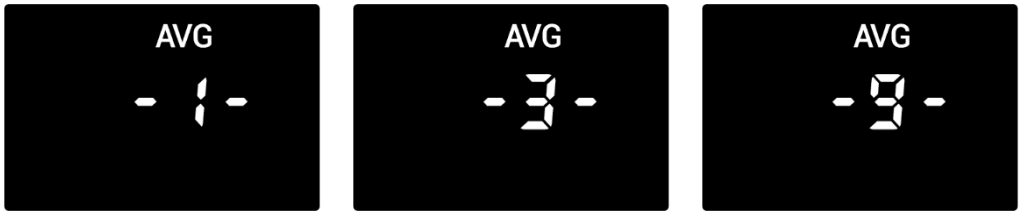

Figure 3-12

After selecting the average times, press the "Set" button to save it, and the "Ready" indicator will be on. Meanwhile, the LCD screen will display the locked symbol, indicating that the average times have been saved (as shown in Figure 3-13).

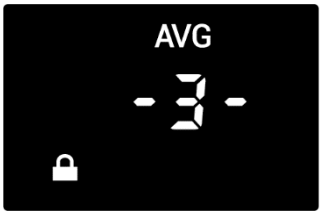

Figure 3-13

3.2.6.2 Detection method of average value

After setting the average detection times, restart the detector and press the Reset button for detection. The number displayed on the right side of the LCD screen is the detection times of average value. After finishing detection for once, the detection result will not be displayed, and the average number of detection displayed on the right side will be reduced by 1 (as shown in Figure 3-14).

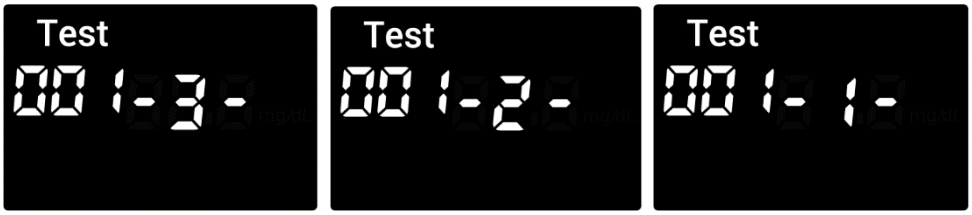

Figure 3-14

After set detection times of average value are completed, the screen will display the average detection result, which is the average value of all detections finished (as shown in Figure 3-5).

4. Prompt and Handling of Fault Alarm

Please refer to the following table in case of any equipment failure alarm or prompt. For any problem that cannot be solved alone, please feel free to contact the customer service specialist in time.

Trouble	Cause	Solution
E01	Unreasonable detection object or position, resulting in signal problems	Please make detection according to the detection object and position
E02	**Detection results beyond the maximum specified range**	**Immediate treatment is recommended!**
	Low battery power	Replace battery.

Trouble	Cause	Solution
Battery symbol is on		
"Ready" indicator is not on after pressing the "Reset" button	No battery power.	Replace battery.
	Hardware faults	Contact the manufacturer
No display after turning the on/off switch to "ON" or the display suddenly disappears during detection	No battery power.	Replace battery.

5. Maintenance & Care

5.1. Cleaning

Clean the detector using a soft cloth dipped in a small amount of water or approved neutral cleaning solvent or solvent. Do not use: Disinfectants proving corrosive to metals include sodium diclofenac (e.g., bleach pellets), hypochlorite (e.g., chlorocarbon mixtures), acetaldehyde (e.g., glutaraldehyde), anionic surfactants (e.g., geramine), iodine (e.g., povidone-iodine), and detergents containing concentrated isopropyl alcohol.

Clean the detection probe by wiping its outer surface with cloth dipped with 75% alcohol directly.

5.2. Maintenance and Inspection

Before use per time, please check the detector and ensure it can operate correctly and safely.

If detecting any malfunction, check or repair the detector before reuse to avoid injuring the patient or user.

6. Disclaimers and Warranties

6.1. Statement of Manufacturer's Responsibility

In case of failure, please contact the professional personnel of the manufacturer. It is forbidden to disassemble, repair the detector or change the detector parameters without authorization.

6.2. Environmental Protection Statement

Dispose the detector and its accessories after expiration of service life in accordance with local laws. Dispose the detector by following the rules below:

- Please contact after-sales service specialist via the after-sales service hotline to learn more about return, restoration or recycling of the detector.
- Dispose wastes according to local guidelines. For any questions about the local waste disposal regulations, please make confirmation with the local authority.

6.3. Warranty Services

The warranty term of the detector is one year, during which, we will provide repair or replacement services for the detector that cannot be used normally by malfunction. The decision belongs to the Company. If the maintenance department finds no problems with the returned equipment, we reserve the right to charge appraisal fees against the detector. The warranty applies to China mainland. The Company is not held liable for any economic loss, loss of profit, general expenses or consequential damages resulting from the sale or use of the detector. The warranty term of the detector cannot be transferred but is applicable to the original purchaser of the detector. Please keep this warranty page properly, which serves as the maintenance certificate.

The Company does not provide free warranty services in any of the following cases:

- The warranty term of detector has expired;
- The detector is damaged by failure in using according to the User Manual;
- The detector is repaired or disassembled by personnel not authorized by the Company;
- The detector becomes faulty or damaged by accidental factors, human factors (such as strong abuse, misuse, negligence, modification, throwing, falling, scratching, etc.);
- The detector becomes faulty or damaged due to force majeure such as natural disasters (earthquake, fire, etc.);

7. Electromagnetic Compatibility

7.1. EMC Clauses

⚠Note:

- The detector complies with the requirements for electromagnetic compatibility of YY0505 standard;
- User shall install and use the detector according to the EMC information provided in the accompanied documents;
- Portable and mobile RF communication equipment may affect the performance of the detector. Avoid strong electromagnetic interference when using the detector, such as near mobile phones and microwave ovens ;
- See appendix for details about the guidelines and manufacturer's declaration.

⚠Warning:

- The detector should not be used close to or stacked together with other equipment. If inevitable, observe and verify that it can operate normally under the configuration used;
- The use of accessories and cables other than the cable sold by the manufacturer as spare parts for internal components may result in the increased emissions or decreased immunity of the detector.

Table 1 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Guidelines and Manufacturer's Declaration - Electromagnetic Emissions		
The detector is intended for use in the electromagnetic environment specified below. Both the purchaser or user shall ensure the applied site satisfies the requirements below for electromagnetic environment:		
Emission test	Conformity	Electromagnetic Environment - Guidelines
Radio Frequency Emission GB 4824	Group 1	[The detector or system] uses RF energy only for its internal functions. Therefore, its RF emissions are very low and less probably cause interference to the nearby electronic equipment.
Radio Frequency Emission GB 4824	Type B	[The detector or system] It is applicable to all installations not directly connected to the public low voltage power supply network for non-domestic and domestic dwellings.
Harmonic Emissions GB 17625.1	Not applicable	
Voltage Fluctuations/Flicker Emissions GB 17625.2	Not applicable	

Table 2 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
The detector is intended for use in the electromagnetic environment specified below. Both the purchaser or user shall ensure the applied site satisfies the requirements below for electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic Environment -
Electrostatic Discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or tile, and if it is covered with synthetic materials, its relative humidity should be at least 30%.
Electrical Fast Transient (EFT) GB/T 17626.4	±2kV for power lines ±1kV for input/output lines	Not applicable	The grid power supply should have the typical quality for use in commercial or hospital environments.
Surges GB/T 17626.5	±1 kV line to line ±2 kV cable to ground	Not applicable	The network power shall be of typical quality for use in commercial or hospital environments.
Voltage dip, short interruption, and voltage variation on power supply input lines GB/T 17626.11	<5 % U_T, lasting for 0.5 cycles (On U_T, >95% voltage dip) 40 % U_T , lasting for 5 cycles (60% dip in U_T) 70% U_T, lasting for 25 cycles (30% dip in U_T) <5 % U_T, lasting for 5s (On U_T, >95% voltage dip)	Not applicable	The network power shall be of typical quality for use in commercial or hospital environments. If the [the detector or system] requires continuous operation during power outages, UPS or battery is recommended.
Power frequency magnetic field (50 Hz /60Hz) GB/T 17626.8	3A/m	3A/m,50/60 Hz	The power frequency magnetic field shall have the level characteristics of power frequency magnetic field for typical site in a typical commercial or hospital environment.

Note: U_T refers to the AC network voltage prior to the application of the test voltage.

Table 3 Guidance and Manufacturer's Declaration–Electromagnetic Immunity

Guidance and Manufacturer's Declaration-Electromagnetic Immunity			
The detector is intended for use in the electromagnetic environment specified below. Both the purchaser or user shall ensure that it is used in such an electromagnetic environment:			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment - Guidelines
RF conduction GB/T 17626.6	3 V (rms) 150kHz~80MHz	Not applicable	Portable and mobile RF communications equipment should not be used with a distance closer than the specified value with any part of the detector, including cables. This distance is calculated from the equation corresponding to the frequency of transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz Where, P -- Max. output rating of the transmitter as provided by the transmitter manufacturer, in W; d ---- Recommended isolation distance, in m.
RF radiation GB/T 17626.3	3V/m 80MHz~2.5GHz	3V/m	The field strength of fixed RF transmitters, which is determined by surveying electromagnetic sites [a], and shall be lower than the compliance level in each frequency range [b]. Interference may occur once the detector is used near the devices marked with the following symbol. 
Note 1: The formula for higher frequency range is used for frequencies between 80MHz and 800MHz. Note 2: These guidelines may not be suitable for all situations, for the electromagnetic propagation is affected by absorption and reflection by buildings, objects and human body.			
a: Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, ham radios, AM and FM radio broadcasts, and television broadcasts, are theoretically unpredictable in its field strengths In order to evaluate the electromagnetic environment of the fixed radio frequency transmitter, the survey of electromagnetic field shall be considered. If the measured field strength of the location in which the detector is located is higher than the applicable RF compliance level above, the detector shall be observed to ensure its normal running. If abnormal performance is observed, supplementary measures may be necessary, such as re-orienting or relocating the detector. [b] In the whole frequency range of 150kHz~80MHz, the field strength should be less than 3 V/m.			

Table 4 Recommended Isolation Distances between Portable and Mobile RF Communications Equipment and the Detector

Recommended isolation distances between portable and mobile RF communications equipment and the detector			
The detector is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. Depending on the max. output power rating of the communications equipment, the purchaser or user can prevent electromagnetic interference by maintaining a min. distance between portable and mobile RF communications equipment (transmitters) and the detector as recommended below.			
Max. Rated Output Power of Transmitter W	Separation distance corresponding to different frequencies of the transmitter/m		
	150 kHz~80 MHz $d = 1.2\sqrt{P}$	80 MHz~800 MHz $d = 1.2\sqrt{P}$	800 MHz~2.5 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 max. output power ratings of transmitters not listed in the table above, the recommended separation distance *d*, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where *P* is the maximum output power rating of the transmitter in watts (W) as provided by the transmitter manufacturer. Note 1: The formula for higher frequency band is used at 80MHz and 800MHz. Note 2: These guidelines may not be appropriate for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and human body.			