

## **USER MANUAL**



### DY400-4 LED Curing Light

- \*The unit must be installed by a qualified engineer.
- \*Only for user by dental professionals.
- \*Read this operation manual carefully before installation or operation.

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### CONTENTS

**SECTION I. INTRODUCTION** 

**SECTION II. FEATURES** 

**SECTION III. SYMBOL** 

SECTION IV. MAIN TECHNICAL INDEX

SECTION V. COMPONENTS

SECTION VI. INSTALLATION

SECTION VII. OPERATION

SECTION VIII. SAFETYPRECAUTIONS

SECTION IX. MAINTENANCE

SECTION X. TROUBLE SHOOTING

SECTION XI. STORAGE & TRANSPORT ENVIRONMENT

SECTION XII. WARRANTY STATEMENT

#### **REMARKS**:

The pictures here are for reference only. Real products shall prevail.

The parameters and pictures in this manual are subject to change without prior notice.

Thank you for purchasing our device. Before operating the device, please fully read the manual and this manual should be saved for later use.

DENJOY DENTAL CO., LTD will take the responsibility for the security, reliability, capability under the following conditions:

1. The installation, debugging, maintenance should be adjusted by the approbatory technician by our company or obtained related nation quality level license professions.

2. The power supply shall be in conformity with the relevant provisions of the state and the use requirements of device itself.

3. The device should be operated by licensed dental professionals with medical applied skill. The whole operation process should follow user's manual strictly.

DENJOY DENTAL CO., LTD has right to improve shape and structure of the device, change any information and technical specification of this manual all the time, and no need to notice the user in advance.

#### **CONTACT INFORMATION**

The device is manufactured by: DENJOY DENTAL CO., LTD Address: F4, Building A4, Lugu Medical Device Park, No.229 Guyuan Road, Changsha, 410205 P. R. China Website: www.denjoy.cn Phone: +86 731 85126543 Fax: +86 731 88885317

Authorized European Representative: Company name: CMC Medical Devices & Drugs S.L. Address: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Please contact sales representative directly from whom you have bought this device for user's record and further after-sale service.

## Denjoy®

#### **SECTION I. INTRODUCTION**

Thank you for purchasing our **DY400-4** LED curing light! Two types available: DY400-4(5W) and DY400-4 (7W).

**LED Curing Light DY400-4** is a perfect combination of the highly-efficient LED tube, the micro-control electric circuit and the rechargeable lithium battery. It is used for polymerize composite material. Because of high-efficiency, outstanding function, convenient operation, and longevity, it becomes the latest top curing light in the global market.

#### **SECTION II. FEATURES**

#### 1. Latest LED technology with longevity

Continuous operating time: Avg. 40m with fully charged battery. The life of lamp: charging for 10,000 times

Light Intensity: (Different meters have different readings)

For DY400-4(5W), 1000-1400 mw/cm<sup>2</sup> for reference.

For **DY400-4(7W)**, Light Intensity: 2000-2400 mw/cm<sup>2</sup> for reference.

#### 2. Beep sound design

Beep at every 5 seconds to remind user of remaining curing time!

#### 3. Cord/Cordless interchangeable

Cordless or cord use are both available!

When running out of battery, the unit can be still used directly with power charger.

#### 4. Curing Program



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(1) Curing Program 1: Full power till end
(2) Curing Program 2: Soft start in first 5S to full power till end
(3) Curing Program 3: Soft start in first 5S to half power till end

#### 5. Curing Time

For **DY400-4(5W)**: 5/10/15/20/25/30/35/40S For **DY400-4(7W)**: 5/10/15/20S

\* Except for full power grogram, the curing time for other programs should be started from 10 seconds. User should follow the original instructions of the composite when curing.

#### 6. Battery Sign

When flashed on the panel, the battery needs to be

charged at least 2.5 hours. Directly connecting the charger with the handpiece can also charge the battery. When full battery sign

on the LCD panel appear and stop flashing, this indicates that

the battery is fully charged.

#### 7. Specially made battery: reliable and powerful

a. To support continuous time for 40 minutes and curing time at 35S and 40S. When the user sets curing time at 30S/35S/40S often, if there is no reliable and powerful battery as strongest supporter, the lamp is easily aging to shorten the life. **(For DY400-4 5W)** 

b. To ensure the inactive time of 200 hours. If the unit is nonuse, the unit will have electricity power inside for the duration of about three months.

c: To guarantee the stability of performance

#### 8. Specially design for eye-protection cover

Autoclaved Eye-protection cover tip



Convenient for curing on the molar teeth.

### 9. Equipped with radiating fan to ensure the continuous operation for a long time! (Just for DY400-4 7W)

It can guarantee the stability of performance to avoid over-heat. Not many manufacturers make the unit with radiating fan inside!

### 10. Build-in meter on the front of charging base to check the intensity.

It is fairly obvious to know the light intensity just to see how many light indicators become bright simultaneously. Inset the light guide to intensity test hole after plug charger into the outlet of power.

The meter will measure the intensity of LED curing light by lighting-up the LED indicators. The operator can use the reading to adjust the curing time.

#### 11. Sleeping Mode

When the unit is no longer in using for 2 minutes, the handpiece will turn into sleeping mode to save power.

#### SECTION III. SYMBOL

The following symbols may appear in this manual, on the label, or on it's accessories. Some of the symbols represent standards and compliances associated with the LED Curing Light and its use.

i	Consult accompanying documents				
$\wedge$	Caution				
EC REP	Authorized Community	Representative	in	the	European

Denjo	<b>y</b> <sup>®</sup> Rev. 01/08/21 VER SMS-GH04 20140828-EN
CE	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC
135°C \$\$\$	Sterilizable up to the temperature specified at most
$\sim$	Date of manufacture.
	Manufacturer
SN	Specifies serial number
Ŕ	Type B applied part
	Refer to instruction manual / booklet
$\Box$	The device should not be used after the end of the shown or the day.
X	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

#### SECTION IV. MAIN TECHNICAL INDEX

- 1. Classification: Class I
- 2. Power source:

a) Power supply-Power Charger:

Input: 100-240V, 50/60Hz Output voltage: 5V DC

Output current: 1A

b) Internal power supply-Lithium battery



#### **SECTION V. COMPONENTS**

(1) Curing Program: Soft start to full power (4) Curing Time

- (2)Curing Program: Full power (5) Beep Sound Sign
- (3)Curing Program: Soft start to half power (6) Battery Sign



#### Standard Accessories

Handpiece	1 PC	Charging Base	e 1 PC
Light Guide	1 PC	Charger	1 PC
Eye-protection C	over 3 PCS	User Manual	1 PC

1) Eye-protection Cover

2) Light Guide

3) LCD Panel

4) Function Switch for Curing Time

- 5) Function Switch for Turning on the Unit and Curing Program
- 6) Charger Port 9) Charger Port
- 7) curing Switch 8) Charging interface 10) Light Intensity Indicator







1.Voltage: 3.7V

Charging time: Approx. 2.5 hours

2. Continuous Operating time: Avg. 40m with fully charged battery

3. LED lamp

Model: 5W and 7W, Wavelength: 400-515nm (Blue light)

4. Dimension: W300×H120×D150mm

5. Net Weight: about 700g

#### SECTION VI. INSTALLATION

#### 1. Charge battery

For best performance—charging time is at least 2.5 hours! (Charging time is at least 4 hours for the first time). When full

battery sign **IIII** on the LCD panel appear and stop flashing, it

shows that the battery is fully charged.

#### 2. Install the eye-protection cover

Directly insert it onto the front of the handpiece. It still can be rotated when proper installed.

#### 3. Install light guide

Directly insert the light guide to the handpiece, make sure it has been totally insert and fixed steadily. It still can be rotated when proper installed.

After use, the user is free to pull out the light guide with care and keep it in the package.

#### 4. Connect power charger

This unit is available to use directly with power charger when battery run out of power.

Directly connect the power charger to the connector which is located on the bottom of handpiece, then plug the charger into the outlet. (AC100-240V).

#### **SECTION VII. OPERATION**

• Power switch and function switch

#### 1. Turn on the unit.

Extended press the power button can turn on the unit. LCD



panel is working.

#### 2. Set curing program

Short press function switch for suitable curing program.

(1)Curing Program 1: Full power

(2) Curing Program 2: Soft start to full power

③Curing Program 3: Soft start to half power

#### 3. Set curing timer

Press function switch CYCLE to select curing time

When choosing Curing Program 2

3 **461**, the cutting time should start from 10 seconds.

#### 4. Start to operate

Press curing switch to start curing program. "Beep" sound will be heard every 5 seconds. To interrupt a program, just press curing switch again. When the program is finished, the unit will turn off the light immediately.

#### 5. Low Battery Sign

When low battery sign is flashing on the panel, the battery needs to be charged immediately or connecting the charger with the handpiece for continuous use.

#### 6. Turn off the power

10

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When the unit turns into sleeping mode automatically, it will shut down all the function except the battery sign, beep sound sign and curing program sign on LCD panel to save the power.

#### 7. Use Build-in meter

For better curing performance, user should check the light intensity of LED before use. It is fairly obvious to know the light intensity just to see how many light indicators become bright simultaneously.

Inset the light guide to intensity test hole after plug charger into the outlet of power.

The meter will measure the intensity of LED curing light by lighting-up the indicators. User can use the reading to adjust the curing time.

If five indicators become bright simultaneously, it stands for the intensity is at least1000 Mw/cm2. If only three indicators become bright simultaneously, it stands for the intensity is a little lower! In this situation, the user had better charge the unit at once!



X The reading comes from the meter is as reference for dentist to adjust the appropriate curing time. Dentists still need to follow the curing procedures which are provided by composite manufacturer.

X The light source must aim at the fixed position when operated. The working distance must be within 3mm from the fixed position. The depth of the polymerization of material is not less than 2mm. Curing layer by layer is recommended if the material is very thick!



#### SECTION VIII. SAFETYPRECAUTIONS

a). Before operation, you have to read usage manual carefully.

b).  $\triangle$  CAUTION: This curing unit produces high output curing

energy!

Do not place light directly on or toward unprotected gingival or skin.

The light source has to shoot directly in the polymerization of resin material when it is in clinical use. Improper radiation which may affect the curing result should be avoided.

c).  $\triangle$  CAUTION: Do no look directly at the light emitted from this curing unit. Do not use this device without suitable protective eye ware for the operator, assistant and patient. Suitable protective eye ware blocks all energy below 550nm.

d). A CAUTION: Persons having a history of photosensitive reactions or who are using photosensitizing drugs should not be exposed to light from this unit.

CAUTION: Equipment not suitable for use in the presence of flammable anesthetic mixture with air or nitrous oxide.

f). To keep the safety operation, we suggest that check your local AC power supply voltage before you buy this product oversea.

g) The curing light should be placed in the original packing box in a dry and clean cupboard, in case of its drop onto the floor.

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#### SECTION IX. MAINTENANCE

1. This unit can not be dismantled privately; otherwise the unit will be damaged wholly.

2. For non-use for a long time, the unit should be cleaned and then put away it inside the original package.

3. Be sure there is no any resin or material sticking on the surface of the light guide

4. If the materials are sticking on the light guide, immediately clean it with cloth. Keep it clean for better light output and curing performance

5. The light guide should be sterilized after each use. It can be safely autoclaved at  $121^{\circ}$ C, 1060hPa for 30minutes.

6. The other accessories such as oval protector ...etc., which is close to patients should be scrubbed by pure water or antiseptic and follows the standard disinfection procedure to disinfect the materials.

7. Please use the original charger, any other charger may result in the damage of the battery and the controlled electric circuit; even the machine will be greatly damaged.

#### SECTION X. TROUBLE SHOOTING

Question 1: The battery sign can show charging condition when charging, but the unit can not be charged fully.

Solution: Check whether the handpeice is connected well with the charging base or not. Reconnect the handpiece with the charging base, making sure that connection is well and stable.

Question 2: The unit can not be turned on and LCD screen does not work.

Solution:

1. Possible cause: low battery. Charge with power charger at once for a short time, then turn on the unit again to check.

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2. Possible cause: power button

Please try to press power button 0 extendedly

Please check the power button is in good order.

Question 3: Curing program and curing time can not be adjusted.

Solution: Check that function buttons are in good order.

Question 4: Solidification effect is not good.

Solution: Check that the light intensity is high enough for curing. Check that the curing program is correct.

Question 5: The unit can not be charged and the battery sign does not show charging condition.

Solution:

1) Check that the charger or charging base is connected with handpiece properly.

2) Check that the metal dome (interface) on the handpiece is loose or damaged.

3) Check that the metal dome (interface) on the charging base is loose or damaged.

Question 6: It is unable (or hard) to insert the light guide to the handpiece.

Solution: Check that the size of light guide is suitable for handpiece.

#### SECTION XI. STORAGE & TRANSPORT ENVIRONMENT:

#### **Operation environment**

Ambient temperature:  $5^{\circ}C \sim 40^{\circ}C$ Relative humidity range:  $\leq 80\%$ Atmospheric pressure:  $70kPa \sim 106kPa$ 

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#### Storage environment

Ambient temperature: -40°C ~ 55°C Relative humidity range:  $\leq 80\%$ Atmospheric pressure: 50kPa $\sim$ 106kPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, and corrosive gasoline and volatile without poor ventilation.

Transportation is applicable to all common method.

#### SECTION XII. WARRANTY STATEMENT

This instrument described below has been fully inspected and confronts to the current products specification.

This instrument is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase.

Products warranty or service will not be extended if (1) the product is repaired, modified, misused, disassembled, or using the parts are not provided by the manufacturer, (2)The serial number at the bottom of product is defaced or missing.

The guarantee for accessories is 6 months. All accessories of the device are damaged or needed to be renewed, the user can purchase new accessories from the seller.

#### WARNING

The device is not repairable by user and contains no user serviceable parts. No modification of this equipment is allowed. The user must check that the equipment functions safely and see that it is in proper working condition before being used. The manufacturer does not require such preventive inspections by other persons.

Please contact sales representative directly from whom you have bought this device for user's record and further after-sale service.



Guidance a	Guidance and manufacturer's declaration - electromagnetic					
	emiss	sions				
The [DY400-4]	The [DY400-4] is intended for use in the electromagnetic environment					
specified below.	specified below. The customer or the user of the [DY400-4] should assure					
	that it is used in such an environment					
Emissions	Compliance	Electromagnetic environment -				
test		guidance				
RF emissions	Group 1	The [DY400-4] uses RF energy				
CISPR 11		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	Class [B]	The [DY400-4] is suitable for use in				
CISPR 11		all establishments other than				
Harmonic	Class A	domestic, and may be used in				
emissions		domestic establishments and those				
IEC 61000-3-2		directly connected to the public				
Voltage	Complies	low-voltage power supply network				
fluctuations/		that supplies buildings used for				
flicker		domestic purposes, provided the				
emissions		following warning is heeded:				
IEC 61000-3-3		Warning: This equipment/system				
		is intended for use by healthcare				
		professionals only. This equipment/				
		system may cause radio				
		interference or may disrupt the				
		operation of nearby equipment. It				
		may be necessary to take				
		mitigation measures, such as				
		re-orienting or relocating the				
		[DY400-4] or shielding the location.				



Guidance a	and manufactur	er's declaration	- electromagnetic					
	е	missions						
The [DY400-4]	is intended for	use in the electro	magnetic environment					
specified below.	The customer o	r the user of the [	DY400-4] should assure					
	that it is used i	n such an enviro	nment					
Immunity Test IEC 60601 Compliance Electromagnetic								
	Test level	level	environment -					
			guidance					
Electrostatic	±6 kV	±6 kV contact	Floors should be					
discharge	contact	±8 kV air	wood, concrete or					
(ESD)	±8 kV air		ceramic tile. If floors					
IEC 61000-4-2			are covered with					
			synthetic material, the					
			relative humidity					
			should be at least					
			30 %					
Electrical fast	±2 kV for	±2 kV for	Mains power quality					
transient/burst	power	power supply	should be that of a					
IEC 61000-4-4	supply lines	lines	typical commercial or					
	±1 kV for		hospital environment.					
	input/output		The electrical fast					
	lines		transient burst (EFT) is					
			generated by the					
			switching of inductive					
			loads. Separation					
			between the					
			equipment and other					
			loads shall be					
			considered before					
			installation. Mains filter					
			is required, if					
			necessary.					

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Surge	±1 kV line(s)	±1 kV line(s)	Mains power quality					
IEC 61000-4-5	to line(s)	to line(s)	should be that of a					
	±2 kV line(s)		typical commercial or					
	to earth		hospital environment.					
Voltage dips,	<5% U⊤	<5% U⊤	Mains power quality					
short	(>95% dip in	(>95% dip in	should be that of a					
interruptions	U <sub>T</sub> )	U⊤)	typical commercial or					
and voltage	for 0.5 cycle	for 0.5 cycle	hospital environment.					
variations on			If the user of the					
power supply	40% U⊤	40% U <sub>T</sub>	[DY400-4] requires					
input lines	(60% dip in	(60% dip in	continued operation					
IEC	U <sub>T</sub> )	U <sub>T</sub> )	during power mains					
61000-4-11	for 5 cycle	for 5 cycle	interruptions, it is					
			recommended the					
	70% U <sub>T</sub>	70% U <sub>T</sub>	[DY400-4] be powered					
	(30% dip in	(30% dip in	from an uninterruptible					
	U <sub>T</sub> )	U <sub>T</sub> )	power supply or a					
	for 25 cycle	for 25 cycle	battery.					
	<5% U <sub>T</sub>	<5% U <sub>T</sub>						
	(>95% dip in	(>95% dip in						
	Ū <sub>T</sub> )	U <sub>T</sub> )						
	for 5s	for 5s						
Power	3 A/m	3 A/m	Power frequency					
frequency			magnetic fields should					
(50/60Hz)			be at levels					
magnetic field			characteristic of a					
IEC 61000-4-8			typical location in a					
			typical commercial or					
			hospital environment.					
NOTE $U_T$ is the a	i.c. mians voltag	e prior to applica	tion of the test level.					



Guidar	Guidance and manufacturer's declaration - electromagnetic						
	emissions						
The [DY4	The [DY400-4] is intended for use in the electromagnetic environment						
specified be	specified below. The customer or the user of the [DY400-4] should assure						
	that it is used in such an environment						
Immunity	IEC	Complian	Electromagnetic environment -				
Test	60601	ce level	guidance				
	Test level						
			Portable and mobile RF communications equipment should be used no closer to any part of the [DY400-4], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.				
Conducte	3V(rms)	3V	Recommended separation				
d RF	150KHz		distance				
IEC	to 80MHz		$d=1.2\sqrt{P}$				
61000-4-6			$d=1.2\sqrt{P}$ 80 MHz~800 MHz				
	3 V/m		$d=2.3\sqrt{P}$ 800 MHz~2.5 GHz				
	80MHz to	3 V/m	where $p$ is the maximum output				
Radiated	2.5GHz		power rating of the transmitter in				
RF			transmitter manufacturer and <i>d</i> is				
IEC			the recommended separation				

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61000-4-3			distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:

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.

<sup>a</sup> 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 [DY400-4] is used exceeds the applicable RF compliance level above, the [DY400-4] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [DY400-4].

 $^{\rm b}$  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 [DY400-4]

The [DY400-4] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [DY400-4] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [DY400-4] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power	Separation dis	tance according to fre transmitter m	equency of
of transmitter W	150 kHz to 80 MHz d=1.2 √p	80MHz to 800MHz d=1.2√p	800MHz to 2.5GHz d=2.3√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 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.



### Guidance and manufacturer's declaration - electromagnetic emissions

The [DY400-4] is intended for use in the electromagnetic environment specified below. The customer or the user of the [DY400-4] should assure that it is used in such an environment

Radiate	Test	Ban	Service a)	Modulat	Mod	Dist	IMMU
d RF	Frequ	d a)		ion b)	ulati	anc	NITY
IEC610	ency	(MH			on	е	TEST
00-4-3	(MHz)	z)			b)	(m)	LEVE
(Test					(W)		L
specific							(V/m)
ations	385	380	TETRA	Pulse	1,8	0,3	27
for		-39	400	modulati			
ENCLO		0		on b)			
SURE				18 Hz			
PORT	450	380	GMRS	FM c)	2	0,3	28
IMMUNI		-39	460,	± 5 kHz			
TY to		0	FRS 460	deviatio			
RF				n			
wireless				1 kHz			
commun				sine			
ications	710	704	LTE Band	Pulse	0,2	0,3	9
equipme	745	_	13,	modulati			
nt)	780	787	17	on b)			
				217 Hz			
	810	800	GSM	Pulse	2	0,3	28

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<b>,</b>	870	<u></u>	800/900.	werk Siv	<u>3-GHU</u>	4 2014	<u> J828-EIN</u>
		960	TETRA	on b)			
	930		800,	, 18 Hz			
			iDEN 820,				
			CDMA				
			850,				
			LTE Band				
			5				
	1720	1	GSM	Pulse	2	0,3	28
	1845	700	1800;	modulati			
	1070	-	CDMA	on b)			
	1970	1	1900;	217 Hz			
		990	GSM				
			1900;				
			DECT;				
			LTE Band				
			1, 3,				
			4, 25;				
			UMTS				
	2450	2	Bluetooth,	Pulse	2	0,3	28
		400	WLAN,	modulati			
		-	802.11	on b)			
		2	b/g/n,	217 Hz			
		570	RFID				
			2450,				
			LTE Band				
			7				

Denj	oy®	Rev	v.01/08/21	VER SM	<u>IS-GHO</u>	<u>4 2014</u>	<u>0828-EN</u>
	5240	5	WLAN	Pulse	0,2	0,3	9
	5240	100	802.11	modulati			
	5785	-	a/n	on b)			
		5		217 Hz			
		800					

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.

The MANUFACTURER should consider reducing the minimum separation distance, based on

RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

### $E = \frac{6}{d} \sqrt{P}$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the

IMMUNITY TEST LEVEL in V/m.



tem Name:	
Model Name:	
Serial No.:	
Date of Purchase:	
Name:	
Address:	
Phone:	
Email:	
Name of Distributor:	
Authorized Distributors:_	
Stamp and Signature	