NOVAERUS

Defend 1050 User Manual
(NV1050)

FDA Cleared
510(k) Class II Medical Device

Novaerus, US Inc.
35 Melrose Pl.
Stamford, CT 06902
Phone: 1.866.515.5181
www.novaerus.com

Document No. NOV-MNL-103

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1. Intended Purpose

The Novaerus Defend 1050 (NV1050) is a free-standing, portable recirculating air cleaning system designed for additional frontline protection in healthcare settings such as operating rooms, intensive care units, in vitro fertilization labs, emergency rooms, waiting and treatment areas, neonatal units, and other critical environments including those performing aerosol-generating medical procedures (AGMP).

Please read and follow all instructions in this manual.

2. Labeling Symbols

Symbol	Meaning
	Caution, Consult User's Manual
	Caution, High Voltage
	Date of Manufacture
	Manufactured for or by
	Serial Number
	This product has been tested by UL to nationally recognized safety and sustainability standards.
	Mains Power Switch On (Power)
	Mains Power Switch Off (Power)
	Accompanying documents must be consulted

	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.

3. Classification of Equipment

Item	Classification
Protection of Harmful Ingress of Water	IPX0 (No protection, indoor use only)
Mode of Operation	Continuous
Oxygen Rich Environments	Not intended for oxygen rich environments

4. Warnings

General Warnings

CAUTION:	This High Voltage (HV) Device is not suitable for use within atmospheres that contain potentially combustible or explosive dusts, vapors or gases (including oxygen rich environments).
CAUTION:	This device should not be exposed to environmental sterilization processes such as fogging and misting. Both the water vapor and chemical agents may cause internal damage to device componentry thus invalidating the warranty. The active carbon filter may also absorb the chemical vapor, thereby minimizing the sterilization effects in the environment, whilst also reducing the operating life of the filter.
CAUTION:	The product is not meant to be carried or lifted by the handle. Castors are provided for mobility, risk of instability if power cord stops wheels from moving, ensure cord is lifted above the wheels.
CAUTION:	Use two or more people to move and handle this unit. Failure to do so can result in back or other injury. Carefully remove the packaging materials and any shipping tape before using.
CAUTION:	This equipment contains high voltage

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CAUTION:	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
CAUTION:	This equipment should be inspected frequently and collected dirt removed from it regularly to prevent excessive accumulation that may result in flashover or a risk of fire.
CAUTION:	No modification of this equipment is allowed.
CAUTION:	Do not modify this equipment without authorization of the manufacturer.
CAUTION:	Do not restrict the air flow of the product.
CAUTION:	Do not open the tamper proof screws on the casing of the unit. No serviceable parts are contained within. The units should be opened by qualified Novaerus personnel only.
CAUTION:	Do not use other filters except those supplied by Novaerus. The use of other brand or no-brand filters with the NV1050 will invalidate the claims that can be made for the performance of the NV1050. Novaerus also reserves the right in such situations to refuse warranty claims.
CAUTION:	Do not position the equipment where it is difficult to operate the power switch.
CAUTION:	For continued protection against risk of fire, replace the fuse with the same type and rating, Fuse rated at 120 VAC, 6.3 Amps.
CAUTION:	Do not use outdoors or near water.
CAUTION:	Not to be used by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction. Children should be supervised to ensure that they do not play with the appliance.
CAUTION:	To reduce the risk of electric shock, this equipment has a grounding type plug that has a third (grounding) pin. This plug will only fit into a grounding type power outlet. If the plug does not fit into the outlet, contact qualified personnel to install the proper outlet. Do not alter the plug in any way.
CAUTION:	If the power cord is damaged in any way it must be replaced by a special cord or assembly available from the manufacturer or its service agent.
CAUTION:	Please remove plastic packaging from filters before use.

5. Technical Specifications

Floor standing, 2-wheeled base + handle, 5 speed fan setting with 6.6 ft power cord

Area Coverage:
200 – 1,000 ft^2 (4 air changes per hour)
400 – 2,000 ft^2 (2 air changes per hour)

Volume Treated:
1,600 – 8,000 ft^3 (4 air changes per hour)
3,200 – 16,000 ft^3 (2 air changes per hour)

Electrical Rating:
Single phase, 100-120 VAC, 60 Hz
Fuse rated at 120 VAC, 6.3 Amps, Listed

Power Consumption:
Maximum 396W

Construction + Color:
Precision-cut fabricated metal casing in a white anti-bacterial powder coat finish.

Dimensions:
36.2" (h) × 19.3" (w) × 23.2" (d)

Weight
Approx. 118.6 lbs

Electrical Connection:
Switched and fused with a grounded, molded and detachable power cord.

Fan Airflow Volume:
Speed 1 = 107 CFM
Speed 2 = 187 CFM
Speed 3 = 267 CFM
Speed 4 = 400 CFM
Speed 5 = 553 CFM

Noise Level:
Speed 1 = 48 dBA
Speed 2 = 56 dBA
Speed 3 = 62 dBA
Speed 4 = 70 dBA
Speed 5 = 78 dBA

Filters:
Stage 1: M5 30/30 filter
Stage 2: HEPA H13 filter, MGA grade
Stage 3: G4 carbon pleated filter

Operating Conditions
50 – 95 °F, 10 - 75% Relative Humidity

Shipping / Storage Conditions
41 – 122 °F, Maximum 95% Relative Humidity

Quality + Safety:
Manufactured under ISO 9001, ISO 14001 & OHSAS 18001.
IEC 60601-1, Third Edition
IEC 60601-1-2, Fourth Edition
UL 867 Safety for Electrostatic Air Cleaners
FDA K200321.510(k) Class II Medical Device

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6. Instructions for Use

a. Transporting the Defend 1050

When transporting the Defend 1050, care should be taken when moving the unit to the desired location.

The transporter should be positioned close to the back of the unit holding the transport handle firmly with both hands. The transporter should place one foot against the base of the Defend 1050 for anchorage and pull the handle slowly towards them, stepping back on to their other foot.

Stabilize the Defend 1050 at a comfortable angle, depending on the transporters individual height, where minimal pressure is exerted against the body to ensure stability.

Once the destination has been reached, allow the unit to gently return to the upright position. The transporter should place one foot against the base of the unit and gently extend their forearms, allowing the unit to rest on its front feet.

The Defend 1050 should be placed in a dry location and connected to a suitable grounded outlet. The product is intended to be used as a floor standing unit only.

Once the product is installed, turn the power switch on the back of the unit to the ON position. The device is now ready to operate, please use the control panel to activate the unit to the desired speed.

Control Panel and Location

The control is located on the top panel of the Defend 1050 near the front of the unit.

The control panel layout is shown in Figure 1. The control features are listed below:

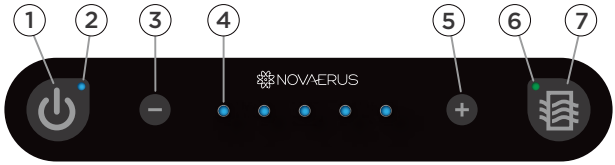

Figure 1: Defend 1050 Control Panel layout.

1. ON/OFF power button
2. LED light indicator for ON/OFF power state
3. Airflow speed selection button, reduce airflow
4. LED lights (5 lights) indicating the active airflow speed
5. Airflow speed selection button, increase airflow
6. LED light indicator of pressure drop check across HEPA filter
7. Pressure drop check button across HEPA filter

b. Power control

The control button on the furthest left-hand side of the control panel is for switching the device ON/OFF; the power button. The power button is clearly illuminated with a blue LED to indicate when the device is on. The blue LED is illuminated when in the 'ON' mode and non-illuminated when the device is in the 'OFF' mode.

c. Air flow control

The control allows the user to select the device airflow using selection button '+' on the right-hand side for incrementing the air flow setting to a higher airflow, and '-' on the left-hand side for decreasing the air flow setting to a lower air flow. The air flow setting level is clearly indicated by illuminating a series of blue LEDs in sequence (from left to right) according to the speed setting (e.g. two LEDs for speed II, three LEDs for speed III). The Defend 1050 has 5 selectable air flow speeds.

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d. Save airflow to memory

There is an ability to save a selected airflow to memory so the device will revert to the last known speed on power-on. The last known speed can be saved to memory by holding the ON/OFF (1) and '-' (3) buttons for three seconds. To revert to factory settings and to clear the air speed memory the ON/OFF (1) and '+' (5) buttons are held for three seconds.

e. HEPA Filter replacement test

The HEPA filter replacement test indicator is for information purposes only. The filter replace button, for testing the filter back pressure, is on the furthest right-hand side of the panel. Upon pressing the filter back pressure test, the device shall override the air flow setting to speed 5 air flow for testing the filter for a period of approx. 30 seconds. The test button shall remain backlit illuminated blue LED while the device is testing the air pressure.

The device will indicate that the HEPA filter needs to be inspected for replacement by illuminating the test button in orange or a continuous LED light in orange.

The device will indicate that the HEPA filter does not need to be inspected by illuminating the test button in green or a continuous light in green.

Novaerus recommends replacing the HEPA filter every twelve-month (12) period to ensure optimal performance, or when the filter test check output indicates to do so; whichever comes first. Discoloration on the HEPA filter may indicate that the filter has exceeded its life expectancy. The expected lifetime of these filters is approximately twelve months (12) under normal clean air conditions (such as that of a hospital ward).

7. Service and Maintenance Instructions

a. Service

No serviceable parts are contained within the Defend 1050 unit. The units should be opened by qualified Novaerus personnel only. The unit is designed with tamper-proof screws to ensure that it cannot be easily opened by anyone other than service personnel.

b. Maintenance – Replacement of Filters

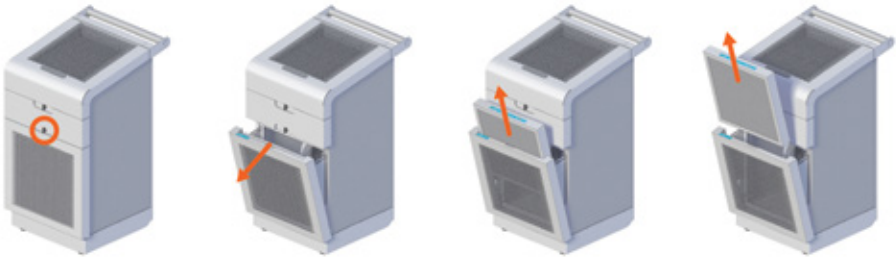
Before replacing filters, ensure the power is switched off at the rear mains switch. Ensure all filter doors are securely closed before switching the unit back on via the rear mains switch.

Pre-filter

The intake pre-filter is located behind the front panel of the unit. The pre-filter should be inspected monthly and be replaced when dirty.

The pre-filter can be removed by unlocking the latch, simply pulling the framing of the filter outwards and replacing with a new filter.

The metal wire-frame grid should be facing towards the rear of device as shown in the image below. An airflow arrow on the side of the filter shows the correct direction for the installation of the intake pre-filter screen.



Marking on the Defend 1050 unit corresponding with the required filter.

Markings on the filter to aid placement and correct orientation.

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It is recommended to replace this filter after three (3) months of continuous use. It is recommended that the user inspect the intake pre-filter screen monthly during the first 2 months of use to determine the most appropriate cleaning period for its facility. If dust and debris has collected on the intake screen sufficient enough to cause a significant decrease in airflow, more frequent replacement of this filter may be required.

Only Novaerus supplied replacement filters should be used. Please contact Novaerus Customer Service for replacement filters.

Carbon Filter and HEPA Filter

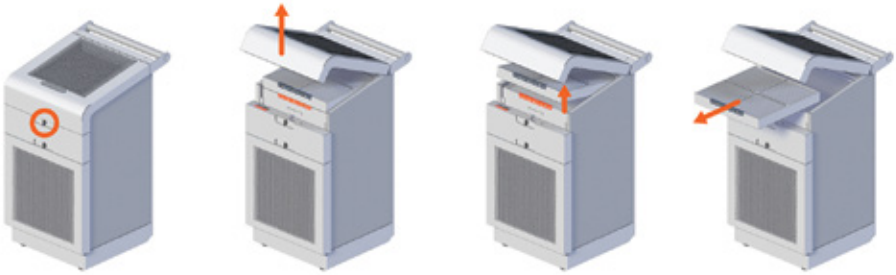
The Carbon and HEPA filters are located in the top of the unit and are accessible by opening the top panel. The Carbon filter should be removed before gaining access to the HEPA filter.

Marking on the Defend 1050 unit correspond with the required filter.

The Carbon and HEPA filters are fitted with a handle that can be used to pull the filter out of its housing in the Defend 1050 unit.

Carbon Filter

The Carbon Filter can be accessed from the top panel. The orientation of the filter is indicated on the filter frame itself, see illustration below.



Markings on the filter to aid placement and correct orientation.

The expected lifetime of the Carbon filter is approximately four months (4) under normal clean air conditions (such as that of a hospital ward). It is recommended to replace this filter after four (4) months of continuous use.

Only Novaerus supplied replacement filters should be used. Please contact Novaerus Customer Service for replacement filters.

HEPA Filter

The HEPA filter can be accessed from the top panel, see illustration below. The orientation of the filter is indicated on the filter frame itself, see illustration below. The Carbon filter should be removed before gaining access to the HEPA filter.

Markings on the filter to aid placement and correct orientation.

Novaerus recommends replacing the HEPA filter every twelve-month (12) period to ensure optimal performance, or when the filter test check output indicates to do so; whichever comes first. Discoloration on the HEPA filter may indicate that the filter has exceeded its life expectancy. The expected lifetime of these filters is approximately twelve months (12) under normal clean air conditions (such as that of a hospital ward).

Only Novaerus supplied replacement filters should be used. Please contact Novaerus Customer Service for replacement filters.

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8. Filter Disposal

The pre-filter, HEPA and carbon filters are throw-away, dry type air filter units.

The following instructions are for filter disposal for filters used in non-hazardous environments:

To properly dispose of a used non-hazardous air filter:

- Before you begin, turn off the unit
- Have a plastic bag on hand
- Carefully remove the used air filter from the Defend 1050 unit
- Place the filter gently into the bag, without shaking it. This will prevent the filter from releasing dust and particles into the air
- Tie or tape the bag shut
- Take the bagged air filter and place it in the waste disposal

For filters used in environmentally hazardous and/or biomedical hazardous air streams, follow the occupational safety and health administration guidelines in the country of origin.

9. Cleaning

The unit should be visually inspected for accumulation of dirt and dust on the vent grills that are located in front and above the unit chassis on a monthly basis.

It is recommended that the unit be cleaned using a vacuum cleaning brush from the outside of the unit to remove any dirt and dust that may have accumulated on the grills.

Clean the body of the Defend 1050 regularly to prevent dust from collecting.

1. Wipe away dust from the body of the device with a soft dry cloth.
2. Clean the air outlet with a soft dry cloth.

10. Troubleshooting

Should the unit sustain severe damage and an increase in noise from the internal parts is observed, discontinue use of the unit and contact a representative of the Novaerus technical team for assistance. This product is not intended to be repaired in the field.

To ensure the Defend 1050 unit's optimal functionality when replacing the filters, the power must be switched off at the rear mains switch before attempting to open the filter doors. Ensure all filter doors are securely closed before switching the unit back on via the rear mains switch.

Should the unit power up to an unwanted airspeed, the memory can be cleared by holding down the ON/OFF button and the '+' button for three seconds.

11. Product Certifications

IEC 60601-1, Third Edition
IEC 60601-1-2, Fourth Edition
UL 867 Safety for Electrostatic Air Cleaners
FDA K200321.510(k) Class II Medical Device

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12. APPENDIX A. Guidance and Manufacturer's Declarations

Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems

Guidance and manufacturer's declaration – electromagnetic immunity		
The NV1050 is intended for use in the electromagnetic environment specified below. The customer or the user of the NV1050 should assure that it is used in such an environment.		
Emissions test	**Compliance**	
RF Emissions CISPR 11 EN 55011: 2009 + A1: 2010	Group 1	The NV1050 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11 EN 55011	Class B	The NV1050 is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Complied	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complied	

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems

Guidance and manufacturer's declaration – electromagnetic immunity			
The NV1050 is intended for use in the electromagnetic environment specified below. The customer or the user of the NV1050 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 2, 4, 6 & 8 kV contact +/- 2, 4, 8 & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst EN 61000-4-4	+/- 2kV for power supply lines +/-1 kV for input/output lines	+/- 2kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	+/- 1kV differential mode +/- 2 kV common mode	+/- 0.5 & 1kV differential mode +/- 0.5, 1 & 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

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Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NV1050 requires continued operation during power mains operation, it is recommended that the NV1050 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c.mains voltage prior to application of the test level.			

Table 203 – Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The NV1050 is intended for use in the electromagnetic environment specified below. The customer or the user of the NV1050 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms outside industrial, scientific and medical (ISM) and amateur radio bands. 6 Vrms in ISM and amateur radio bands 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz	6 Vrms 150 kHz to 80 MHz 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9V/m,217HzPM 710 MHz 9V/m,217HzPM 745 MHz 9V/m,217HzPM 780 MHz 28V/m, 18 Hz PM 810 MHz 28V/m,18HzPM 870 MHz 28V/m,18HzPM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the NV1050, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [1.17] Sqrt P d = [1.17] Sqrt P...80MHz to 800 MHz d = [2.33] Sqrt P...800 MHz to 2.5GHz. 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

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	28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	in meters (m), field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], 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: 

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NV1050 is used exceeds the applicable RF compliance level above, the NV1050 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the NV1050.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1]V/m.

Table 204 – Recommended separation distances between portable and mobile RF communications equipment and the equipment and system – for equipment and systems that are not life supporting

Recommended separation distances between portable and mobile RF communication equipment and the NV1050.			
The NV1050 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NV1050 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NV1050 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 = [1.17] Sqrt P	80 MHz to 800 MHz d = [1.17] Sqrt P	800 MHz to 2.5GHz d = [2.33] Sqrt P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

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