

DIGITAL BLOOD PRESSURE MONITOR DS-500 INSTRUCTIONS

ENGLISH

This manual is intended to assist the user in the safe and efficient operation of Digital Blood Pressure Monitor DS-500. The product must be used in accordance with the procedures contained in this manual and must not be used for purposes other than those described herein. It is important to read and understand the entire manual. In particular, please read carefully and become familiar with the section entitled "TIPS ON TAKING YOUR BLOOD PRESSURE".

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WARRANTY

This equipment is guaranteed for the period of 2 years after the date of purchase against manufacturing defects when returned along with the proof of date of purchase to the dealer from whom the purchase was made. During this period, the unit will be repaired or replaced free of charge if the failure is attributable to faulty design or manufacture. This warranty does not cover damage or malfunctions caused by improper handling or use contrary to the instructions in this manual. Please contact your dealer for additional warranty provisions which may remain effective after the manufacturer's warranty period has expired.



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 EC-Representative: Nissei Healthcare (UK)LTD. Henfield, BN5 9SJ UK

A116558-1-D

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BASIC PRODUCT INFORMATION

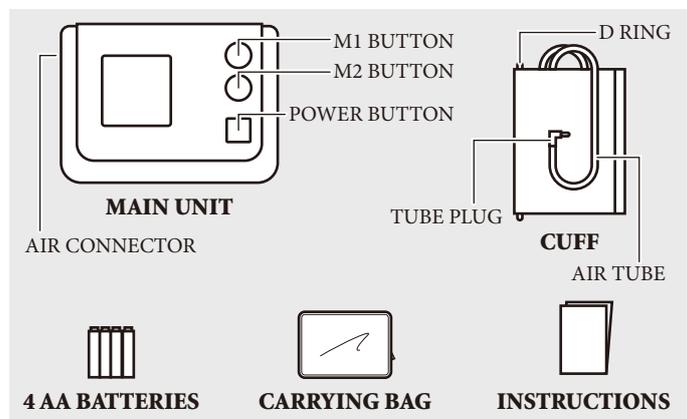
INDICATIONS FOR USE

The DS-500 system is intended for the non-invasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adults, i.e., age 12 and above; this unit is not designed for neonatal use. Also, an inaccurate reading may result if this instrument is used on a child's arm. Consult your physician if you wish to take a child's blood pressure. The product is recommended for use by patients with labile blood pressure or known hypertension in a home care environment as an adjunct to medical management. The cuff will accommodate an upper arm circumference range of approximately 22 to 32 centimeters. Pressure is measured over a range of 0 to 300 mmHg and pulse rate over a range of 40 to 160 beats/minute.

METHOD OF MEASUREMENT

This product employs the oscillometric method for measurement of blood pressure and pulse rate. The cuff is connected to the main unit and wrapped around the arm. Circuits within the cuff sense the small oscillations in pressure against the cuff produced by the expansion and contraction of the arteries in the arm in response to each heart beat. The amplitude of each pressure waves is measured, converted to millimeters of mercury, and displayed on the LCD as a digital value. If the pulse rhythm detected during measurement was irregular, irregular pulse rate rhythm indication be displayed. A memory circuit stores the 30 most recent measurement results with date and time for comparison and computes the average value of stored data.

PARTS NAMES AND PRODUCT COMPONENTS



PRECAUTIONS FOR USE

Do not use this instrument without consultation with your doctor if you are under dialysis therapy or on anticoagulants, antiplatelets or steroids. Use of this instrument under such conditions could cause internal bleeding.

For specific information on your blood pressure, contact your physician. Never make any judgment on your own regarding measurement results.

The material used for the cuff bladder is natural rubber latex and it could cause allergic reactions.

Do not use cuffs other than the original cuff included with this product.

To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape AIR TUBE around your neck.

Use of this device in areas near portable phones, microwave ovens or other devices with strong electromagnetic field may cause malfunctions.

The system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.

Because the unit includes precision parts, care should be taken to avoid extreme temperature variations, humidity, shock, dust, and direct sunlight. Do not drop or strike the unit. Make sure not to expose the unit to moisture. This unit is not water resistant.

Do not disassemble or modify the unit.

Do not inflate the cuff when it is not wrapped around your arm.

PRODUCT SPECIFICATIONS

Model	: DS-500
Operating Principle	: Oscillometric method
Indicator	: 13 digits liquid crystal display
Pressure Indicating Range	: 0 to 300 mmHg (Cuff pressure)
Measuring Range	: 50 to 250 mmHg (systolic) 40 to 140 mmHg (diastolic) 40 to 160 bpm (pulse rate)
Accuracy	: ±3 mmHg (Cuff pressure) ±5% of reading (pulse rate)
Inflation	: Automatic inflation
Deflation	: Automatic (electric control valve)
Exhaust	: Automatic exhaust valve
Power Supply	: 4 pcs. 1.5 volt "AA" (LR6) type batteries
Power Consumption	: 4W (max.)
Memory	: 30 measurements x 2 and averages
Operating Environment	: +10°C to +40°C, 85% relative humidity or below
Storage Environment	: -5°C to +50°C, 85% relative humidity or below
Cuff	: Coverage arm circumference ; 22 to 32cm
Main Unit	: Weight ; Approx. 255g (without batteries) Size ; 152 x 100 x 60 mm (W x D x H)
Key to symbols	⊠ : Type BF equipment ⚠ : Important ; Read operating instructions

This device complies with EMC (IEC60601-1-2), EN1060-1 and EN1060-3.
 Specifications are subject to change without notice due to improvements in performance.

CARE AND MAINTENANCE

Use only a soft, dry cloth to clean the unit. Do not use gasoline, paint thinner, or other strong solvents on the unit. Since the cuff may absorb perspiration and other fluids, inspect it for stain and discoloration after each use. When cleaning the cuff, do not machine wash or scrub it. Use a synthetic detergent and gently rub the surface. Air dry thoroughly. Make sure fluid never gets in AIR HOSE.

When storing the unit, do not place heavy objects on it and do not coil AIR HOSE too tightly. When the unit has been stored at a temperature below the freezing point, keep it for at least 1 hour in a warm place before using. Remove the batteries if the instrument is to be stored for an extended period of time. Keep the batteries out of reach of children.

We suggest that you have your blood pressure monitor checked every 2 years. This operation may only be performed by the manufacturer or by firms authorized by the manufacturer.

INSTALLING BATTERIES AND SETTING THE CLOCK

1. Open the battery compartment cover.

2. Install four "AA" (LR6) type batteries into the compartment.

Make sure that the polarities correspond to the (+) and (-) marks inside the battery compartment. The batteries can be easily installed by pressing their (-) side against the spring.

Do not use rechargeable batteries.

3. Close the battery compartment cover.

Do not force the battery cover into position.

4. Year flashes on the display.

Clock can be set only after the batteries are reinstalled. Adjust the clock so that measurement results are stored with correct date and time.

Use M1 BUTTON to increase the flashing year and M2 BUTTON to decrease the year. Press POWER BUTTON to confirm and move to next step.

5. Month flashes. Adjust the month with M1 BUTTON and/or M2 BUTTON, press POWER BUTTON to confirm.

6. Day flashes. Adjust the day with M1 BUTTON and/or M2 BUTTON, press POWER BUTTON to confirm.

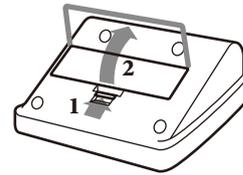
7. Hour flashes. Adjust the hour with M1 BUTTON and/or M2 BUTTON, press POWER BUTTON to confirm.

The clock is in 24 hour mode.

8. Minute flashes. Adjust the minute with M1 BUTTON and/or M2 BUTTON, press POWER BUTTON to confirm.

Clock is set and the unit is turned off.

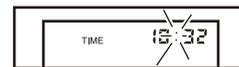
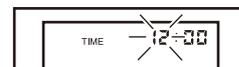
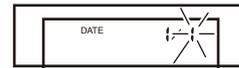
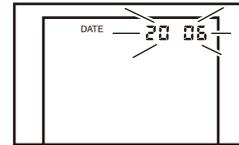
The clock is displayed while the unit is turned off.



BATTERY REPLACEMENT INDICATION

Replace all the batteries when the battery replacement indication appears on the display or nothing is displayed.

The enclosed batteries are for monitoring, and their life may be shorter than that of commercial batteries.



The used electrical and electronic products are not household waste. Follow your national/local recycling rules to dispose of them properly. In the EU countries, please refer to waste management symbol(s) marked on the package or the instrument.

TIPS ON TAKING YOUR BLOOD PRESSURE

Blood pressure is a measurement of the force exerted by the heart in pumping the blood through the arteries and the resistance by the veins in this flow.

Blood pressure varies all the time, influenced by mental and physical factors and is never constant.

In general, blood pressure is highest during the working hours and gradually decreases during the afternoon and evening hours. It is low during sleep and increases at a relatively fast rate after arising from bed.

Causes for Changes in Blood Pressure

- Body movement
- Emotions
- Smoking
- Temperature or noise, etc.
- Conversation
- Eating
- Recent Urination or Bowel Movement
- Changes in the surroundings such as movement or noise, etc.
- Mental Tension
- Drinking Alcohol

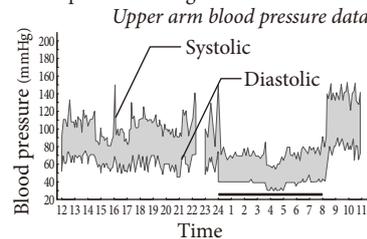
Blood pressure measured at home tends to be lower than when measured in a hospital, clinic or doctor's office.

This is because you are tense at the hospital and relaxed at home. It is important to know your stable normal blood pressure at home.

Let a qualified physician interpret your blood pressure readings.

Depending on your age, weight and general condition, blood pressure can be slightly different. Consult with your doctor on determining what blood pressure is normal for you.

Blood pressure changes shown below.



180~	(severe)	Hypertension				
160~179	(moderate)	Hypertension				
140~159	(mild)	Hypertension				
130~139	High Normal	Hypertension				
120~129	Normal	Hypertension				
~120	Optimal	Hypertension				
SYS mmHg		80	85	90	100	110
DIA mmHg		80	84	89	99	109

Blood pressure classification - WHO (1999)

Before taking blood pressure, rest for approximately five minutes and take your blood pressure while relaxed in a quiet environment.

Measure blood pressure using the correct posture and do not move or speak during measurement.

Avoid exercise, eating, drinking alcohol, smoking and other activities that affect your blood pressure right before a measurement.

Take your blood pressure at the same time every day.

The ambient temperature should be approximately 20°C when you take your blood pressure.

CORRECT MEASURING POSTURE

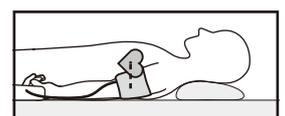
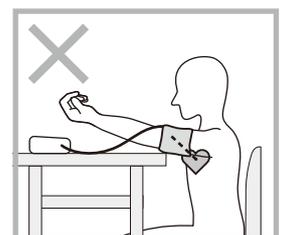
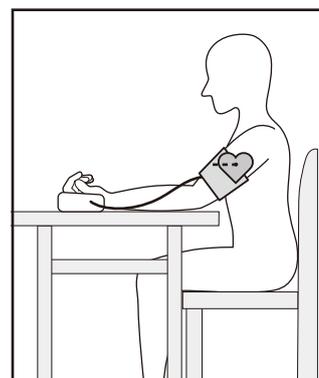
Sit at the table and let the table support your arm as you take the blood pressure measurement.

Make sure that the measurement location on the upper arm is at approximately the same height as the heart, and that the forearm is extended naturally on the table and does not move.

You may lie on your back and take the measurement. Look at the ceiling, stay calm, and do not move your neck or body during the measurement. Again, make sure that the measurement location on the arm is at approximately the same height as the heart.

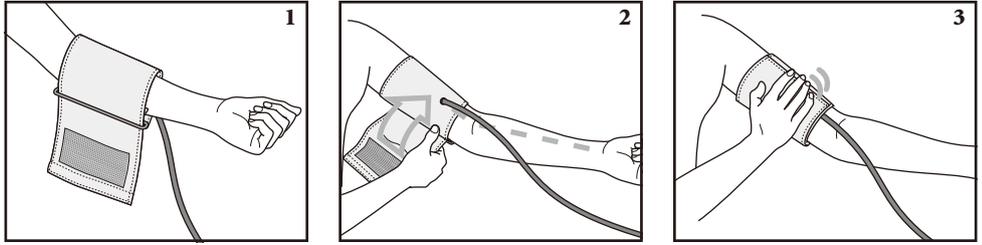
Measured data may vary slightly depending on the posture during measurement.

If the cuff is lower (higher) than the heart, the measured reading tends to become larger (smaller).



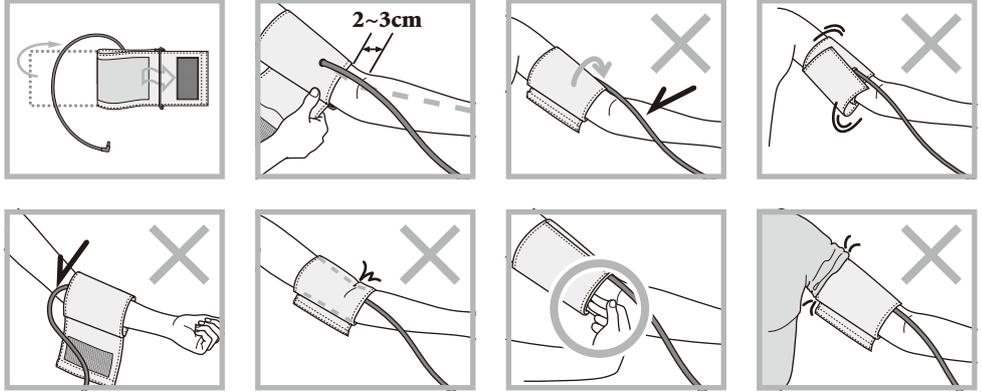
WRAPPING THE CUFF

1. Place the cuff on your left arm with the air hose positioned toward your hand.
2. Wrap the cuff around your arm with the edge of the cuff approximately 2~3 cm above the elbow. AIR TUBE should be on the palm side of the arm.
3. Press the surface of the cuff to make sure that the hook & loop fastens securely.

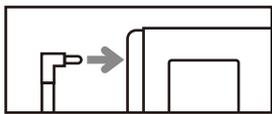


When wrapping the cuff, wrap it loosely enough around the arm so that two fingers can be placed between the cuff and the arm. If the cuff is wrapped more tightly or loosely than this, inaccurate blood pressure readings may result.

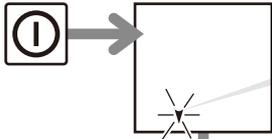
If you are wearing a shirt that might restrict circulation in your upper arm or you roll your sleeve up over the upper arm, the blood flow will be restricted, preventing accurate measurement.



MEASUREMENT PROCEDURES



Insert **TUBE PLUG** into **AIR CONNECTOR**.

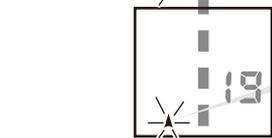
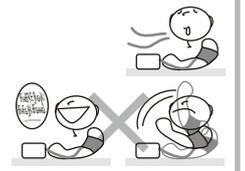


DEFLATION MARK

Press **POWER BUTTON**.
Deflation mark flashes.

Take deep breaths and relax.

Do not move, chat or strain your arm or hand during measurement.

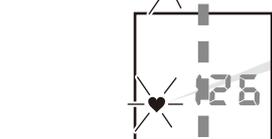


INFLATION MARK

The cuff is automatically inflated to the applied pressure.

To stop measurement

Press **POWER BUTTON** and inflation stops, air is exhausted, and monitor turns off.



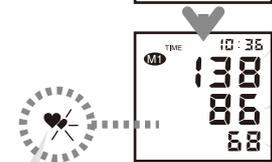
PULSE RATE MARK

Pressure (displayed value) starts to decrease and pulse is indicated by heart mark.

AUTOMATIC REPRESSURIZATION

If the pressure applied is judged insufficient in the early phase of measurement or if movement of the hand or wrist occurs during measurement, the unit will inflate again to a level about 40 mmHg higher. Automatic Repressurization is repeated until a measurement is made. However, this does not indicate a problem.

To manually control pressurization, hold down **POWER BUTTON** immediately after the start of inflation and release it when the pressure reaches the level 50 mmHg higher than the expected maximum systolic pressure. If the pressure value has exceeded 180 mmHg, the inflation will stop when the key is released. Pressure can be increased to approximately 300 mmHg.



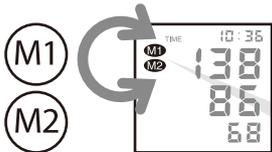
SYS: SYSTOLIC
mmHg

DIA: DIASTOLIC
mmHg

PUL: PULSE RATE
/min

When the measurement is complete, air is automatically released from the cuff. **Blood pressures and pulse rate are displayed. Heart mark flashes when pulse rhythm detected during measurement was irregular.**

IRREGULAR PULSE RHYTHM INDICATION

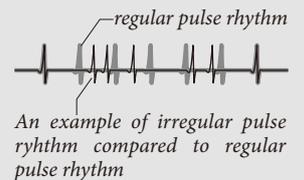


MEMORY BANK NUMBER

Press either one of memory buttons, **M1** or **M2**, and the result is stored in the selected bank.

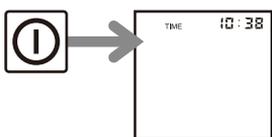
The selected memory bank number is shown on the display. The result is stored in the bank selected when the unit is turned off. Irregular pulse rhythm indication will not be stored, only blood pressure and pulse rate are stored. When a measurement resulted in an error, it will not be stored.

IRREGULAR PULSE RHYTHM INDICATION



A flashing heart mark in the measurement result display indicates irregular pulse rhythm.

Irregular pulse rhythm can be a result of body movement during measurement or arrhythmias. Although continuous appearance of the indication under quiet measurements may suggest arrhythmias, do not make any judgment on your own before consulting with your doctor.



Press **POWER BUTTON** to turn off the power.

If you forget to turn off the unit, it will automatically turn off after 3 minutes.

Do not execute repeated measurements for congestion of blood could result in false measurement. Let your arm rest for at least 5 minutes.

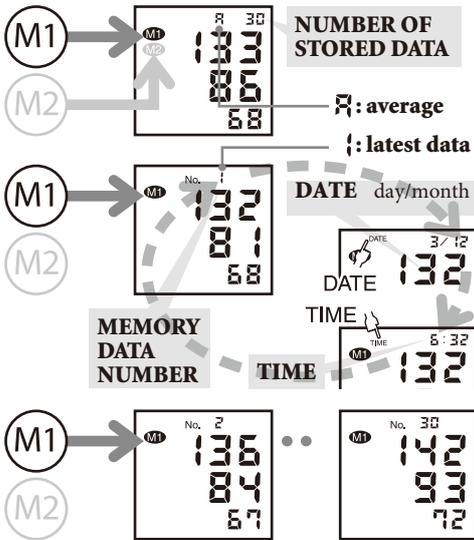
MEMORY FUNCTION

Measured result is stored in either M1 or M2. Each of two memory banks can hold up to 30 results and their average. When the number of measurements exceeds 30, the oldest data will be deleted to record new data. You may decide which bank to store your measurement results to avoid data mixture with someone else's, or may use two banks to save data measured in the morning and evening separately.



RECALLING STORED DATA

Press POWER BUTTON once while measurement result is being displayed after a measurement.



Press memory M1 BUTTON or memory M2 BUTTON to see stored data. The average of the stored result in the selected bank is displayed.

The latest result stored is displayed when there is only a single result and the clock display remains when there are no results stored. The memory data is displayed for approximately 30 seconds. Approximately 30 seconds after memory button is released, the apparatus will turn off.

Press memory button to move to next data. The indication at the top of the display alternately changes from memory data number to date and to time.

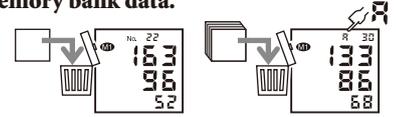
The memory data number 1 is the latest among the stored data in the selected memory bank.

Every depression of memory button switches among the memory data.

As memory button is pressed, the memory data number increases; the bigger the number, the older the result.

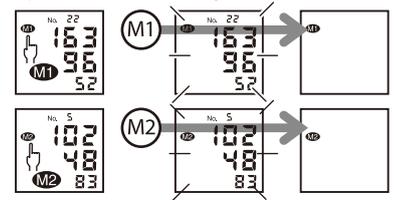
DELETING STORED DATA

Show the individual result to be erased or the average of a memory bank to clear all the memory bank data.



Press and hold down either one of memory buttons: M1 button to erase specified data in memory bank M1, and M2 button to erase specified data in memory bank M2.

The displayed data starts flashing.



Hold down the button until nothing but the memory bank number is displayed.

ERROR DISPLAYS AND TROUBLESHOOTING

ERROR SYMBOL / SYMPTOM	CAUSE / CHECK POINT	REMEDY
	OVER-PRESSURIZATION; The cuff was inflated to the maximum pressure because of movement of body etc.	Do not move during measurement.
	MEASUREMENT ERROR; Measurement could not be made because of moving or talking during measurement.	Remain still and quiet during measurement.
	INFLATION ERROR; TUBE PLUG is not correctly inserted. The cuff is not properly applied.	Reinsert TUBE PLUG and make sure that it is securely inserted. Properly apply the cuff.
	DEFLATION ERROR; Measurement could not be made because of moving or talking during measurement.	Remain still and quiet during measurement.
	NO POWER; Batteries are exhausted. Have the batteries polarities been positioned incorrectly? Are the battery terminals clean?	Replace all batteries with new ones. Reinsert the batteries in the correct position. Clean with a dry cloth.
	LOW BATTERY; Battery is weak.	Replace all batteries with new ones.

ERROR SYMBOL / SYMPTOM	CAUSE / CHECK POINT	REMEDY
	IMPROPER OPERATION; POWER BUTTON was accidentally pressed during battery replacement.	Press POWER BUTTON to turn off the power once and press it again to start a measurement.
	Measurement is interrupted once and cuff is deflated and inflated again.	This does not indicate a problem. Do not move during measurement.
	Cannot complete the measurement.	Have the batteries run down? Replace all batteries with new ones.
	Blood pressure is different each time. The reading is extremely low (or high).	Are you measuring with correct posture? Blood pressure readings constantly vary with time of measurement and nervous condition. Measure with the correct posture. See TIPS ON TAKING YOUR BLOOD PRESSURE.
	Pulse rate is too low (or too high).	Did you move during measurement? Did you take measurement immediately after exercise? Remain still during measurement. Measure again after resting for more than 5 minutes.
	Measurement result is not stored.	Is it the right memory bank? Did you select correct memory bank number after the measurement? Confirm the memory bank number. Make sure desired memory bank is selected before turning off the monitor after a measurement.
	The power is automatically turned off.	Have you left the instrument untouched after the measurement? This does not indicate a problem. The instrument automatically turns off 3 minutes after a measurement or 30 seconds after memory display.

If you cannot get correct measurement with the methods above, do not tamper with the internal mechanism. Contact your dealer. If the unit malfunctions, please return it to the dealer or an authorized service representative for service according to the warranty.

TECHNICAL DESCRIPTION

DS-500 complies with the EMC, electromagnetic compatibility, standard, IEC60601-1-2. Refer to the tables below for specific information regarding compliance to the standard. DS-500, as a medical electrical equipment, needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below. Portable and mobile RF communications equipments can affect the device. The use of accessories other than those specified in this manual may result in increased emissions or decreased immunity of the device. DS-500 should not be used adjacent to or stacked with other equipment.

Table 201 - Guidance and manufacturer's declaration - electromagnetic emissions -

DS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DS-500 should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	DS-500 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	DS-500 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	N/A		
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A		

Table 202 - Guidance and manufacturer's declaration - electromagnetic immunity -

DS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DS-500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _n (>95% dip in U _n) for 0.5 cycle 40% U _n (60% dip in U _n) for 5 cycles 70% U _n (30% dip in U _n) for 25 cycles <5% U _n (>95% dip in U _n) for 5 sec	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Table 204 - Guidance and manufacturer's declaration - electromagnetic immunity -

DS-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DS-500 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, 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of DS-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance N/A d=1.2√P, 80 MHz to 800 MHz d=2.3√P, 800 MHz to 2.5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. ^a Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2.5 GHz	3 V/m	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
^a A field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radios 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 DS-500 is used exceeds the applicable RF compliance level above, DS-500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DS-500.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 206 - Recommended separation distances between portable and mobile RF communications equipment and DS-500 -

DS-500 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DS-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DS-500 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 N/A	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	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.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.