Electroacupuncture Unit

ES-130

OPERATION MANUAL

CE 0123

ITO PHYSIOTHERAPY &REHABILITATION

CONTENTS

■Warning Symbol Marks

Following warning symbol marks are used in this manual.

⚠DANGER

indicates a danger of death or serious injury of an operator or patient if the operator ignores this symbol and uses the ES-130.

⚠WARNING

indicates a possibility of death or serious injury of an operator or patient when the operator ignores this warning and uses the ES-130.

⚠CAUTION

indicates a possibility of death or serious injury of an operator or property damage when the operator ignores this caution and uses the ES-130.

■For Correct and Safe Use

CONTRAINDICATIONS

1) Over or in the region of carotid sinus
2) Thorax of individuals with cardiac disease
3) ES-130 should not be used to people or in conjunction with the devices listed below
   a) Individuals with cardiac pacemakers or other devices implanted
   b) Pump-oxygenators and other electronic devices designed for sustentation
   c) Electrocardiographs and other electronic medical devices used for monitoring patients
4) Over or into abdomen, trunk, pelvis or low back during pregnancy
5) Over or into infected areas
6) Over or into areas of laceration or open wounds
7) Over or into areas of impaired sensory
8) Individuals with active hemorrhage or bleeding disorders such as hemophilia
9) Over the heart
10) Individuals with contagious disease such as tuberculosis

⚠WARNINGS

1) Excessive stimulation causing muscle contraction should not be applied over the body.
2) Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
3) Stimulation should not be applied transcerebrally.
4) Stimulation should not be applied over swollen , or over skin surface with atrophic contracture, etc.
5) Stimulation should not be applied over, or in proximity to, cancerous lesions.
6) Do not use the device on mentally unstable patients.
7) Do not use over areas of known thrombosis or thrombophlebitis.
8) A warning on the following potential hazards.
9) Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
10) Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy EQUIPMENT may produce instability in the STIMULATOR output.

Caution should be used for patients with suspected or diagnosed heart problems.

2) Caution should be used for patients with suspected or diagnosed epilepsy.

3) Caution should be used in the presence of the following:
   a. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   b. Individuals with menstruating ;
   c. Patient has febrile disease;
   d. Patients with abnormal blood pressure or suspected vascular disease.

4) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrodes.

5) The irritation can usually be reduced by using an alternate electrode, or alternate electrode placement.

6) Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

7) Stimulators should be kept out of the reach of children.

8) Stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

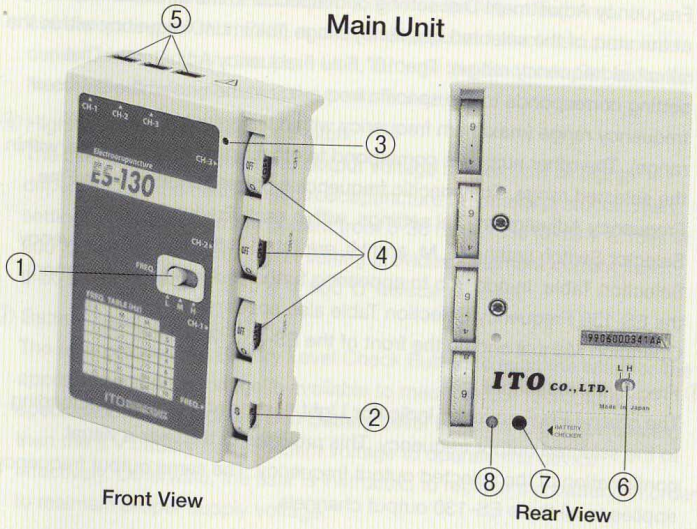
9) ES-130 should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user under extreme risk of injury.

10) ES-130 should not be used for other patients determined unsuitable by licensed individuals (EX. acupuncturists etc.). Practitioners using this device should be properly trained for the safe use of this modality.

Rx ONLY

11) If an allergic reaction to the electrode is noticed, discontinue use.

Main Unit



Front View

Rear View

① Frequency Range Selector Switch
Output frequency range is selected by the user from L setting which represents the low ES-130 frequency range (1-20 Hz), M setting which represents the medium ES-130 frequency range (20-150 Hz), or H setting which represents the high ES-130 frequency range (150-500 Hz).

② Fine Frequency Adjustment Dial
After setting the Frequency Range Selector Switch, the user then rotates the Fine Frequency Adjustment Dial to select the specific desired output frequency within the selected frequency range. The user-selectable Fine

Frequency Adjustment Dial settings are S, 2, 4, 6, 8, and 10. The “S” Fine Frequency Adjustment Dial setting corresponds to the specific frequency at the start of the selected frequency range (minimum frequency within the selected frequency range). The“10” Fine Frequency Adjustment Dial setting corresponds to the specific frequency at the end of the selected frequency range (maximum frequency within the selected frequency range). The other numbers correspond to other specific frequencies within the selected range. The specific frequencies corresponding to the Fine Frequency Adjustment Dial settings, within each Frequency Range Selector Switch setting (L, M, and H), are listed in the ES-130 Frequency Selection Table. In addition to appearing further below in this document, the ES-130 Frequency Selection Table also appears in the ES-130 Operation Manual and on the front of the ES-130 Main Unit.

③ Frequency Indicator Light

The green LED Frequency Indicator Light flashes at a rate corresponding to the selected output frequency. This provides to the user a visual confirmation of the selected output frequency. The same output frequency applies to all three ES-130 output channels.

④ Output Level Adjustment Dials

The Output Level Adjustment Dial settings are OFF, 0, 2, 4, 6, 8, and 10. The OFF position locks the Output Level Adjustment Dial at zero output, avoiding any unintentional output from the corresponding channel. The 0 position unlocks the Output Level Adjustment Dial, but still keeps the output at zero. The 2 position is the lowest output current for that channel. Positions 4, 6, and 8 are linear increases in output current. Finally, the 10 position is the maximum output current for that channel.

⑤ Output Terminals

The user attaches one Electrode Cable to each Output Terminal, corresponding to CH1, CH2, and CH3. The pulsed electroacupuncture current is carried from the Main Unit, through the Electrode Cable, to the Needle Electrodes placed at the treatment area.

⑥ High/Low Intensity Selector Switch

The user selects between two output voltage ranges (low or high), depending on the desired electroacupuncture treatment protocol. The L setting provides treatment current from 0-36 mA ±15% (0-18 V ± 15% @ 500 Ω resistance load). The H setting provides treatment current from 0-60 mA ± 15% (30V ± 15% @ 500 Ω resistance load).

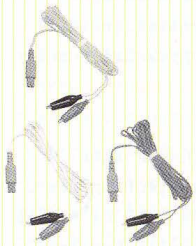
⑦ Battery Level Check Button

The user presses the Battery Level Check Button to examine whether the appropriate supply voltage is available to meet the ES-130 output specifications. If the green LED Battery Level Indicator Light illuminates, then the 9 V battery has sufficient voltage to operate the device effectively. Otherwise, the user is instructed to replace the battery, in order to maintain proper supply voltage.

⑧ Battery Level Indicator Light

This green LED illuminates when the Battery Level Check Button is pressed and the battery has sufficient voltage to operate the device effectively. The green LED does not illuminate when the Battery Level Check Button is pressed and the battery has insufficient voltage (< 8.0 V) to operate the device effectively, thus indicating to the user that replacement of the 9 V battery is necessary.

Electrode Cables



Each of the three Electrode Cables is composed of one connector and two clips for attaching the acupuncture needles (positive and negative connections). Any of the three Electrode Cables can be attached to any of the three Output Terminals, but are provided in three different colors (green, yellow, and white) to assist in distinguishing among placement of needle electrodes, when multiple channels are used. The part number for replacement Electrode Cables is 180434, 180433 and 180432.

Carrying Bag

The carrying bag is intended to carry, protect, and house the main unit and cable accessories when not in use. For replacement, the Carrying bag part number is 260182.

* A battery isn't attached to the standard accessories. Purchase the battery locally. Use a DC9V battery.

■General Description of Product

The ES-130 device is an Electroacupuncture Device composed of a Main Unit and three separate Electrode Cables. The Main Unit is powered by a standard 9 V battery, and the handheld ES-130 device is supplied with a Carrying Bag.

■Intended Use

The indication for use of ES-130 is an ELECTROACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use Only: As an electroacupuncture device, the ES-130 is restricted to the sale by or on the order of an acupuncture practitioner licensed by the law of the state in which he/she practices.

⚠**Use of this machine should be limited to properly trained individuals.**

■Compatible Needle Electrodes

When using the ES-130, use only the electrodes (0.20 mm minimum diameter) that have been determined to be compatible with the ES-130 Electroacupuncture Device.

(1) Output channel: 3 channels (individually adjustable)

(2) Maximum output voltage @ 500 Ω load (setting on back of device):

18V ± 15% when High/Low Selector Intensity Switch = L

30V ± 15% when High/Low Selector Intensity Switch = H

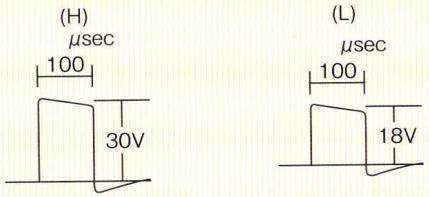
(3) Maximum output current:

Output selector 14mA ± 20% (rms, when resistance load is 500 Ω)

(4) Frequency for treatment: 1-500Hz

(5) Pulse width: 100μ sec

(6) Output waveform: biphasic rectangular waveform



(7) Power source: DC9V battery

(8) Classification: Internally powered equipment

Type BF

(9) Size: 96 mm (H) x 63 mm (W) x 27 mm (D)

(10) Weight: 160g (Including battery)

In use	Temperature:	10–40℃
	Humidity:	30–85%
	Barometric pressure:	700–1060hPa
Storage and Transportation	Temperature:	10–60℃
	Humidity:	30–95%
	Barometric pressure:	700–1060hPa

⚠CAUTIONS

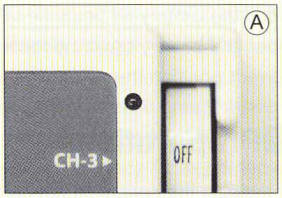
1) Remove batteries before storing unit for an extended period of time.
2) Avoid twisting or pulling wires, as this may cause damage.
3) When storing the machine, be sure to pay attention to the following:
   a) Keep unit away from water.
   b) Store unit in a climate controlled environment with proper ventilation.
   c) Watch the state of stability of the machine, avoiding vibration or impact (including when it is transported).
   d) Do not place the machine in a storage of chemicals or a place where gases are emitted.
4) Do not use any accessories or components designed for other machines as this may cause the unit to malfunction.
5) Keep unit away from fire.
6) Combined use with other treatment equipment could affect the diagnostic equipment.
7) Test the battery prior to each use.
8) Check the dials and controls to make sure that those components are functioning correctly.
9) Make sure that all wires are intact and plugged in correctly.

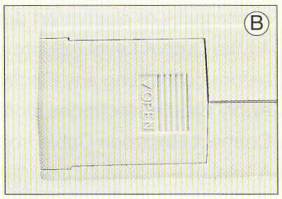
10) Output of the RED alligator clip is positive and the BLACK is negative.
11) Misuse or violent force may cause damage to the machine.
12) Clean unit with a damp cloth.
13) Do not use chemicals or cleaning agents.
14) When the machine is going to be operated again after it has been laid out for a while, make sure to verify in advance that the components of devices work normally and safely.
15) Inspect the main unit and the accessories regularly on a daily basis in order to make sure that the main unit maintains the specified performance, and search for any deterioration or abrasion on the accessories at the same time.
16) Make sure to check the accessories at all times. If any of them are found defective, replace it with new ones to prevent danger.
17) Avoid current densities exceeding 2mA/cm^2 when using this device. Use extreme caution to reduce the chance of thermal bums due to high current density.

■Battery

INSTALLING AND REPLACING BATTERY

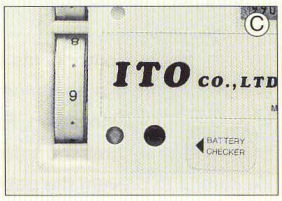
1. Turn off all Output Level Adjustment Dials (see A).
2. Slide the bottom battery cover open (see B).
3. Insert the battery into the battery compartment and then close this bottom cover (see B).
   ＊Use only a 9 volt battery, 6F22.





HOW TO CHECK BATTERY

Turn on one of 3 channels and then push the Battery Level Check Button on the reverse side of the unit, using the point of a ball point pen or similar object (see C):



Battery Level Indicator Light = ON, then battery power is sufficient.
Battery Level Indicator Light = OFF, then battery power is not sufficient and battery must be replaced to operate ES-130 within the manufacturer specifications.

The output voltage reduces linearly as the battery is depleted, resulting in less treatment to patient when the Battery Level Indicator Light does not illuminate. Before using the ES-130, check the battery power using the Battery Level Check Button.

⚠ **CAUTIONS**

Avoid environmental contamination by disposing of batteries according to local law. When the battery is inserted in the reverse position it is hard to close the battery lid because of its structure. In that case do not attempt to close the battery cover by force, but instead reverse the battery to the correct position then close the battery cover.

■Preparations

1. Instruct the patient to advise the operator when he or she feels any abnormality or discomfort during the treatment.
2. All the Output Level Adjustment Dials should be set to the "OFF" position before connecting any Electrode Cable to the patient.
3. Apply needle electrodes (compatible acupuncture needles) to patient.
4. Connect Electrode Cable from each output channel to needle electrodes.
5. A total of 6 individual treatment sites may be stimulated at the same time (2 sites from each output channel). Limit the operation time to within 30 minutes.
6. Monitor device components and the patient during the treatment to ensure that there is no abnormality. Should any irregularity be detected, take an appropriate action. For example, shutting down the operation in a manner that secures the safety of the patient.
7. Be careful to prevent the patient from touching the machine or meddling with the dials and other controls. Such action could lead to an injury.
8. The alligator clip or its wire is very fragile so handle with care. Attach alligator clips to acupuncture needles when delivering electroacupuncture stimulation.
9. When desired, fix position of Electrode Cables by using medical adhesive tape. Allow room so that wire can move freely if patient moves during treatment.

10. Set the High/Low Intensity Selector Switch to "L" setting during treatment protocols using acupuncture needles of short insertion depth, as stimulation on "H" power may be too strong for patient. Minimum insertion depth is 10 mm. Reserve the "H" setting of the High/Low Intensity Selector Switch for treatment protocols using acupuncture needles of long insertion depth.
11. Use only cleared acupuncture needles recognized in each area that are larger than 0.20mm in diameter, and compatible with the ES-130 device.
12. Select pulse frequency for treatment from the Frequency Table printed on the unit.
13. Set the Frequency Range Selector Switch (L, M, H) and the Fine Frequency Control Dial (S, 2, 4, 6, 8, 10) according to the table shown below.

ES-130 FREQUENCY TABLE

Frequency Range Selector Switch Setting				
L	M	H		
1	20	150	S	Fine Frequency Adjustment Dial Setting
1.3	23	170	2	
1.5	30	210	4	
2.5	43	270	6	
5.5	80	380	8	
20	150	500	10	

First, the Frequency Range Selector Switch is set to L (low frequency range of 1-20 Hz), M (medium frequency range of 20-150 Hz), or H (high frequency range of 150-500 Hz). The Fine Frequency Adjustment Dial can then be set to S, 2, 4, 6, 8, or 10. Each combination of Frequency Range Selector Switch setting and Fine Frequency Adjustment Dial setting results in a specific output frequency (between 1-500 Hz) as shown in the table above.

Beginning Treatment

1. Select either High (H) or Low (L) intensity by means of the High/Low Intensity Selector Switch found on the back of the device. Use the Low (L) setting for electroacupuncture treatment of low insertion depth and the high (H) setting for electroacupuncture treatment of high insertion depth.
2. Select pulse frequency for treatment from the ES-130 Frequency Selection Table printed on the unit. Set the Frequency Range Selector Switch and the Fine Frequency Adjustment Dial according to the table shown on the previous page.
3. Slowly rotate the Fine Frequency Adjustment Dial clockwise to the desired setting. The Frequency Indicator Light will flash at the rate corresponding to the frequency chosen.
4. Carefully turn on the Output Level Adjustment Dial from the locked OFF position.
5. Set the Output Level Adjustment Dial to an output which is comfortable for the patient, or according to your methods of practice.

⚠CAUTIONS

1. First, understand the diagnosis and the prescription of the patient, and check for any specific cautions or instructions that should be known.
2. Inform the patient of the "Treatment Procedure" and instruct him or her to immediately notify you of any pain.
3. Set the output power to an intensity that allows the patient to undergo a pleasant treatment.
4. Some patients under anesthesia may not know the adequate amount of treatment for them, which could often result in an excess of stimulation.
5. Ask the patient how he or she feels from time to time, not only immediately after the outset of the treatment, but also while the treatment lasts.

Before starting treatment, be sure that the patient is relaxed so that he or she can undergo the treatment comfortably, free from tension.

Concluding Treatment

1. After concluding treatment, turn off all intensity Output Level Adjustment Dials. Be sure each Output Level Adjustment Dial is turned to the locked OFF position.
2. Remove Electrode Cables from needle electrodes.
3. Removed needle electrodes from patient.
4. Examine the patient's skin for any unusual reactions.
5. Once the treatment is finished, return the dials and other controls to their original positions, turn off the power, dispose of electrodes/acupuncture needles safely according to your established medical sharps procedures, and store the ES-130 device and accessories in an appropriate location.

Device Maintenance

⚠WARNINGS

1. To secure safety, check the ES-130 device on a regular basis. For any information, please contact your dealer or the manufacturer.
2. Do not attempt to repair or modify the machine by yourself, lest an accident may result. If the machine malfunctions, shut down the operation and contact your dealer or the manufacturer.
3. Adhere to all applicable local regulations concerning environmental impact when disposing of consumables, residue, or the system itself or accessories at the end of their service lives.

Cleaning Instructions:

Never clean the unit and accessories using a cloth moistened with thinner, gasoline, polishing power, hot water, or chemical agents. Only use a cloth moistened with lukewarm water or a neutral detergent and sufficiently wrung out.

Item	Description	Checking Method
Appearance and markings	Whether the machine has any damaged parts.	Check visually
Operation	Ensure that the machine works properly when operated as instructed in the operation manual.	Check by operating the machine
Accessories	(1) Whether they have any damaged part. (2) Check to see whether the wires have any breakage.	Check visually

EMC

- Medical electronic devices are designed to ensure electromagnetic compatibility (EMC).
- These devices must be installed and used in accordance with the EMC information provided on the following pages.
- Portable and mobile RF communications devices may affect medical electronic devices.
- Electrode Cable (lead wire) length is 2.0 m.
- If accessories other than those supplied as spare parts by the manufacturer are used, the emission of this unit may increase and immunity may be reduced.
- Do not place this unit next to or on top of another device when using it. If it has to be placed next to or on top of another device, check that this unit and the device function properly before use.

Guidance and manufacturer's declaration – electromagnetic emissions

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group1	This unit 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	This unit 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%U_T (>95% dip in U_T) for 0.5 cycle 40%U_T (60% dip in U_T) for 5 cycles 70%U_T (30%dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of this unit requires continued operation during power mains interruptions, it is recommended that this unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this unit. including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/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 this unit is used exceeds the applicable RF compliance level above, this unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this unit.

[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 this unit

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 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 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.

CE 0123

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Printed in Japan

C0a230968-0911 B1006TS-X