TEST REPORT

FCC Part 15 Subpart C Section 15.209

MANUFACTURER'S NAME	EnteroMedics Inc 2800 Patton Road St. Paul MN 55113 USA
PRODUCT NAME	Maestro® Rechargeable System

MODEL/SERIAL NUMBER(S) TESTED

Description	Model #	Serial #
Neuroregulator	2002	003007
Anterior Lead	2200A-47E	021316
Posterior Lead	2200P-47E	021314
Transmit coil	2403-60	10596
Mobile Charger	2402	D05010

PRODUCT DESCRIPTION	Implantable pulse generator with leads for delivering blocking signals to vagus nerve with mobile charger (6.78 MHz) rf communication
TEST REPORT NUMBER	NC1405671.1
TEST DATE(S)	04 June 2014

TÜV SÜD America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C Section 15.209 “Radiated emission limits; general requirements”, with consideration to DA 09-2425 FCC Waiver granted to EnteroMedics.

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

Issue Date: 23 June 2014

Greg S Jakubowski
Senior EMC Technician

Joel T Schneider
Senior EMC Engineer

Not Transferable

EMC TEST REPORT

Test Report No. NC1405671.1 Date of issue: 23 June 2014

Product Name Maestro® Rechargeable System

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Product Description Implantable pulse generator with leads for delivering blocking signals to vagus nerve with mobile charger (6.78 MHz) rf communication

Manufacturer

EnteroMedics Inc
2800 Patton Road
St. Paul MN 55113
USA

Test Result ■ **Positive** ☐ **Negative**

TÜV SÜD America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV SÜD America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV SÜD America Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. TÜV SÜD America's Wild River Lab maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as an Electrical Testing Laboratory.

TÜV SÜD America Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NARTE, and VCCI.

REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	20	23 June 2014	Initial Release

DIRECTORY

Contents

EMC TEST REGULATIONS:
The tests were performed according to the following regulations:
FCC Part 15 Subpart C §15.209

ENVIRONMENTAL CONDITIONS IN THE LAB

	Actual
Temperature:	: 25° C
Atmospheric pressure	: 99 kPa
Relative Humidity	: 45%

POWER SUPPLY UTILIZED
Power supply system : 4 VDC battery

TEST EQUIPMENT
All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

MEASUREMENT UNCERTAINTY
The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ±4.8 dB. All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

SIGN EXPLANATIONS
☐ - not applicable
■ - applicable

General field strength limits 0.009 – 30 MHz
FCC 15.209(a), FCC 15.209(c)

Test summary
The requirements are: ■ - MET ☐ - NOT MET
Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.2.2.
No unwanted emissions exceed the level of the fundamental.

Test location
☐ - Wild River Lab Large Test Site (Open Area Test Site)
■ - Wild River Lab Small Test Site (Open Area Test Site)

Test distance
■ - 1 meter
■ - 3 meters
■ - 10 meters
■ - 30 meters

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Due
WRLE02418	6502	EMCO	Loop Antenna	2215	16 Aug 14
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	15 Jul 14
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y

Cal Code B = Calibration verification performed internally.

Test limit

Frequency (MHz)	Field strength μV/m	Measurement distance (m)
0.009-0.490	2400/F(kHz)	300
0.490 - 1.705	24000/F(kHz)	30
1.705 - 30	30	30

The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector, with consideration to DA 09-2425 FCC Waiver granted to EnteroMedics. Relaxed fundamental limit is 36.02 dBμV/m, 63.3 μV/m at 30 meters. The implantable is tested in human simulator.

Test Data

Frequency (MHz)	Field strength dBμV/m – 1m	Field strength dBμV/m – 3m	Field strength dBμV/m– 10m	Field strength dBμV/m– 30m	Field strength μV/m– 30m	Limit w/waiver μV/m– 30m
6.78	102.9 (qp)	79.2 (qp)	55.2 (qp)	34.2 (qp)	51.3	63.3
13.56	42.3 (qp)	20 (qp)	Noise floor	-20* (qp)	0.1	30

***extrapolated using 40 dB/decade falloff as indicated by the measurements**

Radiated emissions in the frequency range of 10 kHz to 30 MHz, including the fundamental transmit signal, are measured using a receiver capable of quasi-peak/average/peak measurements and a magnetic loop antenna. The transmitter and loop antenna are rotated through 3 orthogonal axes in order to determine the maximum emission levels. If the signal cannot be measured at the specified limit distance, measurements are recorded at multiple distances nearer to the device and the final level mathematically extrapolated. Measurements between 150 kHz and 30 MHz are made with a 9 kHz resolution bandwidth. Measurements between 9 kHz and 150 kHz are made with a 200 Hz resolution bandwidth.

Radiated Emissions 30 - 1000 MHz

FCC 15.209(c), FCC 15.209(f)

Test summary

The requirements are: ■ - MET ☐ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.3.

Test location

Wild River Lab Small Test Site (Open Area Test Site)

Test distance

3 meters

Test Equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Due	
OWLE03202	EM-6917B	Electro-Metrics	Biconicalog Periodic	101	20-Sep-13	20-Sep-14
WRLE02668	8447D	Hewlett-Packard	Preamplifier	1937A02209	Code B 06-Aug-13	Code B 06-Aug-14
WRLE03294	8566B	Hewlett-Packard	Spectrum Analyzer	2349A03098	26-Jun-13	26-Jun-14
WRLE02673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	26-Jun-13	26-Jun-14
WRLE02684	85650A	Hewlett-Packard	Quasi-Peak Adapter	2521A01006	26-Jun-14	26-Jun-14
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y	

Code B = Calibration verification performed internally. Code Y = Calibration not required when used with other calibrated equipment

Limit

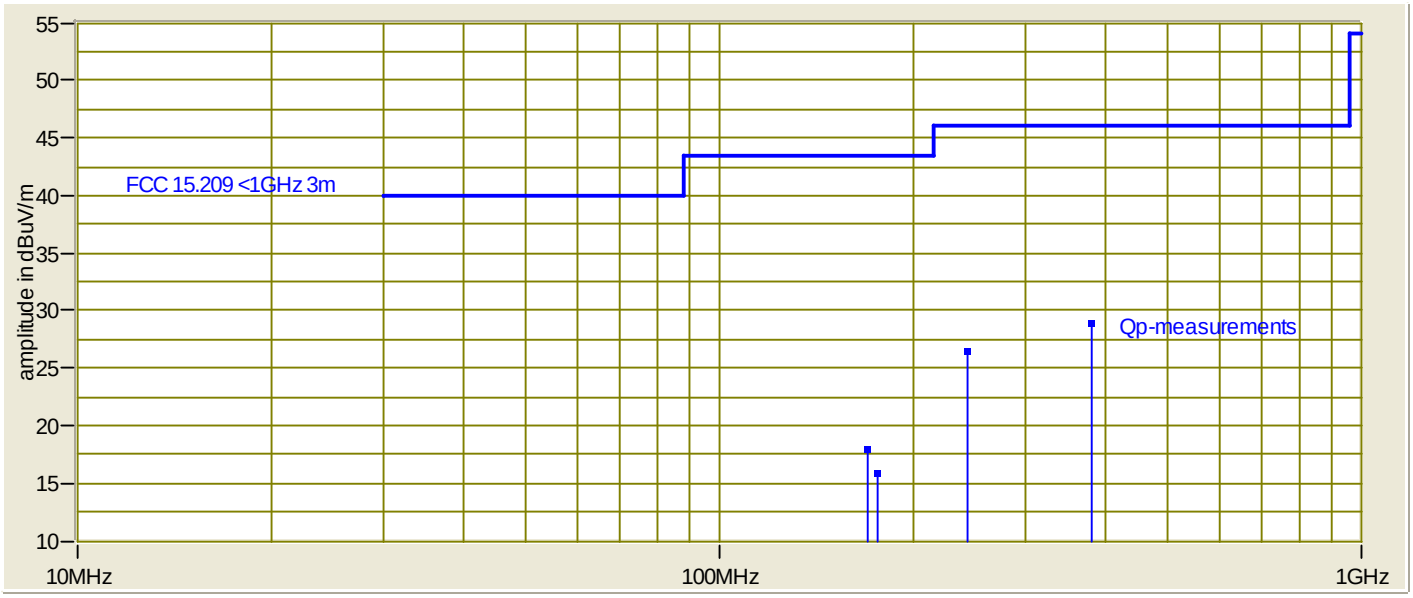
Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30 - 88	100	3
88 - 216	150	3
216 - 960	200	3
Above 960	500	3

The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, *e.g.*, see §§ 15.250, 15.252, 15.255, and 15.509–15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees. When performing measurements at a distance other than that specified, the results shall be extrapolated to the specified distance using an extrapolation factor of 20 dB / decade (inverse linear-distance for field strength measurements).

Test data

See next page.

Measurement summary for limit1: FCC 15.209 <1GHz 3m (Qp)						
FREQ	LEVEL (dBuV)	CABLE / ANT / PREAMP / ATTEN (dB)	FINAL (dBuV / m)	POL / HGT / AZ (m)(DEG)	FINAL (uV / m)	LIMIT (uV / m)
379.71 MHz	24.48 Qp	6.36 / 21.81 / 23.81 / 0.0	28.84	H / 1.00 / 355	27.7	200
244.088 MHz	28.35 Qp	4.74 / 17.18 / 23.85 / 0.0	26.43	H / 1.00 / 90	21	200
169.486 MHz	22.75 Qp	3.92 / 15.05 / 23.86 / 0.0	17.86	V / 1.00 / 180	7.8	150
176.3 MHz	20.23 Qp	4.03 / 15.48 / 23.86 / 0.0	15.88	V / 1.00 / 0	6.2	150
Scanned DUT 30-1000MHz, 0 - 360°, 1 - 4m high, V & H						
No other significant emissions detected						



Equipment Under Test (EUT) Test Operation Mode:

The device under test was operated under the following conditions during immunity testing :

☐ - Standby

☐ - Test program (H - Pattern)

☐ - Test program (color bar)

☐ - Test program (customer specific)

☐ - Practice operation

■ - Normal operating mode

Configuration of the device under test:

■ - See Appendix A and test setup photos

☐ - See Product Information Form(s) in Appendix B

DEVIATIONS FROM STANDARD:
None.

GENERAL REMARKS:
None

Modifications required to pass:
■ None
☐ As indicated on the data sheet(s)

Test Specification Deviations: Additions to or Exclusions from:
■ None
☐ As indicated in the Test Plan

SUMMARY:
The requirements according to the technical regulations are
■ - met and the device under test does fulfill the general approval requirements.
☐ - **not** met and the device under test does **not** fulfill the general approval requirements..

EUT Received Date:	04 June 2014
Condition of EUT:	Normal
Testing Start Date:	04 June 2014
Testing End Date:	04 June 2014

TÜV SÜD AMERICA INC

Tested by:
Greg S Jakubowski
Senior EMC Technician

Approved by:
Joel T Schneider
Senior EMC Engineer

Appendix A

Constructional Data Form

Form

EMC Test Plan and Constructional Data Form

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.
NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company:	EnteroMedics Inc		
Address:	2800 Patton Road		
	St. Paul, MN 55113		
	USA		
Contact:	Scott Lambert	Position:	Engineering Director
Phone:	651-270-4487	Fax:	651-634-3212
E-mail Address:	slambert@enteromedics.com		

General Equipment Description -- ***NOTE: This information will be input into your test report as shown below.***

EUT Description	IRadio components of the Maestro® Rechargeable System		
EUT Name	Maestro® Rechargeable System		
Model No.:	2002 2402 2403-60 2200A-47E 2200P-47E	Serial No.:	003007 D05010 10596 021316 021314
Product Options:			
Configurations to be tested:	Low Power / Normal		

Equipment Modification (*If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.)*

Modifications since last test:	New tuning design and RF power amplifier drive signal timing for the MC
Modifications made during test:	Not Applicable

Test Objective(s): ***Please indicate the tests to be performed, entering the applicable standard(s) where noted.***

- ☐ EMC Directive 2004/108/EC (EMC)
  - Std: FCC Part 15 Subpart C Section 15.209 for the RNR and MC, Part 15 Subpart B (EN 55011)for the RNR only(as required) and MC under charge
- ☐ Machinery Directive 89/392/EEC (EMC)
  - Std:
- ☐ Medical Device Directive 93/42/EEC (EMC)
  - Std:
- ☐ Vehicle Directive - 2004/104/EC (EMC)
  - ☐ Other Vehicle Std:
- ☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC)
- ☒ FCC: Class ☐ A ☐ B Part 15
- ☐ VCCI: Class ☐ A ☐ B
- ☐ BSMI: Class ☐ A ☐ B (Separate Report)
- ☐ Canada: Class ☐ A ☐ B
- ☐ Australia: Class ☐ A ☐ B
- ☐ Other:
- ☐ Ag Directive *2009/64/EC (EMC)

Form

EMC Test Plan and Constructional Data Form

Third Party Certification (contact TÜV for quote), if applicable (*Signature on last page required).	
☐ Attestation of Compliance (AoC)*	☐ EMC Certification (used with Octagon Mark)*
☐ Statement of Compliance (SoC, previously CoC)* - All aspects of the essential requirements were assessed	
Protection Class (Req'd for AoC, SoC, EMC Cert. N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III (Press **F1** when field is selected to show additional information on Protection Class.)	
☒ FCC / TCB Certification	☐ Taiwan Certification
☐ Industry Canada / FCB Certification	☐ Korean Certification
☐ e-Mark Certification	

Attendance

Test will be: ☒ Attended by the customer ☐ Unattended by the customer

Failure - *Complete this section if testing will not be attended by the customer.*

If a failure occurs, TÜV SÜD America should:

☐ Call contact listed above, if not available then stop testing. (After hrs phone): _____

☐ Continue testing to complete test series.

☐ Continue testing to define corrective action.

☐ Stop testing.

EUT Specifications and Requirements

Length: Multiple Devices Under Test Width: _____ Height: _____ Weight: _____

Power Requirements

Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)

Voltage: 4.0 VDC (MC and RNR battery) (If battery powered, make sure battery life is sufficient to complete testing.)

# of Phases: NA

Current (Amps/phase(max)): 1000 mA maximum current

Current (Amps/phase(nominal)): 200 mA nominal current

Other _____

Other Special Requirements

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)
Home and hospitall

Form

EMC Test Plan and Constructional Data Form

EUT Power Cable

☐ Permanent OR ☐ Removable Length (in meters): ______
☐ Shielded OR ☐ Unshielded
☒ Not Applicable

EUT Interface Ports and Cables

Type	Analog	Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE: *RS232*	☐	☒	☒	☐	*2*	☒	☐	*Foil over braid*	*Coaxial*	*Metallized 9-pin D-Sub*	*Characteristic Impedance*	*6*	☒	☐
Two bipolar leads with IS1 type connectors	☒	☐	☐	☒	2	☐	☒	7 x 7 filar	Dual side by side	3.2 mm pin and sleeve	15 ohms	0.5m	☒	☐
Transmit Coil Cable	☒	☐	☒	☐	1	☒	☐	braid	Coaxial	Lemo RF connector	50	0.6m	☒	☐
Mobile Charger (MC)	☒	☐	☒	☐	1	☐	☒	#26 zip cord	Coaxial	Lemo miniature RF connector			☐	☐
	☐	☐	☐	☐	1	☐	☐		I				☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
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Form

EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables

Type	Analog	Digital	During Test: Active	During Test: Passive	Qty	Shielding: Yes	Shielding: No	Shielding: Type	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
	☐	☐	☐	☐		☐	☐						☐	☐

EUT Software.

Revision Level: RNR Model 2002 Firmware Rev 2.21
MC Model 2402 Rev MC2A Firmware Version E5.01 for Emissions Test
Programmer Cable Model 1600 Firmware Version 0104

Description: MC firmware modified to send continuous telemetry test downlinks to the implant on command. SerialTool script MCTelemEmissions via the CP and programming cable will control the downlink command and monitor communication as required.

Equipment Under Test (EUT) Operating Modes to be Tested -- list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.

1. FCC Part 15 Subpart C Section 15.209 - A special PC program is used to setup continuous low power communications between the CP, MC and RNR. The RNR is linked to the MC via the transmit coil and the MC is linked to the CP via the programmer cable. After communications have been set up the CP and programmer cable shall be disconnected prior to making emissions measurements. The RNR and leads shall be placed in a 1.9ppt saline solution. The RNR shall be spaced 4cm from the transmiit coil..
2. As required -FCC Part 15 Subpart B (EN 55011) - RNR connected to the patient leads in stand alone configuration. The RNR and leads shall be placed in a 1.9ppt saline solution. The RNR shall be spaced 2.5 cm from the transmiit coil The RNR shall be in therapy mode delivering 8ma of therapy to the patient leads. EN 55011 was previously completed but the RNR stand alone operation had not been tested
3. FCC Part 15 Subpart B (EN 55011 - MC connected to the AC Recharger.

Form

EMC Test Plan and Constructional Data Form

Equipment Under Test (EUT) System Components -- List and describe all components which are part of the EUT. For FCC & Taiwan testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc)

Description	Model #	Serial #	FCC ID #
Neuroregulator	RNR Model 2002	003007	None
Transmit Coil	RC 2403-60	10596	None
Anterior Lead	2200A-47E	021316	None
Posterior Lead	2200P-47E	021314	None
Mobile Charger	2402	D05010	None

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc) This information is required for FCC & Taiwan testing.

Description	*Model #*	*Serial #*	*FCC ID #*
Programmer Cable	1600	NA	None
AC Recharger	Model 1620, US	Prototype #21	None
Clinician Programmer	2502 / Dell E5420 Latitude PC	CP502Z	None
CP Power Supply	DA65NM111-00	CN-0N6M8J-48661-25H-GG03-A02	None

Oscillator Frequencies

Manufacturer	*Frequency*	*Derived Frequency*	*Component # / Location*	*Description of Use*
6.78 MHz				Inductive coupling between transmit coil and neuroregulator

Form

EMC Test Plan and Constructional Data Form

Power Supply			
Manufacturer	***Model #***	***Serial #***	***Type***
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____

Power Line Filters		
Manufacturer	***Model #***	***Location in EUT***

Critical EMI Components (Capacitors, ferrites, etc.)				
Description	***Manufacturer***	***Part # or Value***	***Qty***	***Component # / Location***

EMC Critical Detail -- Describe other EMC Design details used to reduce high frequency noise.

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

Authorization (Signature Required if a Third Party Certification is checked on pg 1)

Customer authorization to perform tests according to this test plan. — Date

Test Plan/CDF Prepared By (please print) — Date