

ICS NCA-200

AIR CALORIC STIMULATOR

User Manual

Doc no. 920001301-EN/06
Part no. 920001301-EN



otometrics
MADSEN • AURICAL • ICS

Copyright notice

No part of this Manual or program may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written consent of GN Otometrics A/S.

Copyright[©] 2011, GN Otometrics A/S

Printed in Denmark by GN Otometrics A/S, Denmark

All information, illustrations, and specifications in this manual are based on the latest product information available at the time of publication. GN Otometrics A/S reserves the right to make changes at any time without notice.

GN Otometrics A/S

GN Otometrics North America

50 Commerce Drive, Suite 180

Schaumburg, IL 60173-5329

USA

Phone: 847-534-2150 Fax: 847-534-2151

www.otometrics.com

Version release date

5. December 2011

Trademarks

The GN Otometrics logo is a trademark of GN Otometrics

CHARTR is a trademark of GN Otometrics

Technical support

Please contact your supplier.

FORWARD

Otometrics specializes in the manufacture of instruments for electro-oculography, electronystagmography and videonystagmography. Our products are of high quality and can be expected to provide excellent diagnostic information for many years. We back these instruments with a warranty and service commitment. Please contact Otometrics or an authorized distributor should you require assistance.

TABLE OF CONTENTS

Section	Page
I. Introduction	1
II. Installation	2
III. Operation	4
A) Front Panel Controls.....	4
B) Rear Panel Connectors	9
C) The Delivery Head Controls.....	11
D) Charging the Memory Backup Capacitor.....	12
IV. Operating Procedures	14
A) Preparation for Testing.....	14
B) Testing Procedure.....	15
V. Safety Features	16
VI. Cleaning and Maintenance	18
NCA-200 Coolant Refill Procedure	18
VII. Warranty.....	20
VIII. Specifications	21

I. INTRODUCTION

The NCA-200 Air Caloric Stimulator is a convenient and accurate instrument to be used for evoking eye movement responses (nystagmus) during VNG/ENG examinations. The system provides thermal stimulation through the use of a carefully controlled flow of air. The air temperature is adjustable from 12°C to 50°C. The system provides for presetting two temperatures -- one for the warm and one for the cool caloric stimulation. Precise temperature control is maintained through the use of a thermistor located within 60 mm of the point of airflow delivery. The innovative design of the otoscopic delivery head allows observation of the point of stimulation, assuring valid and repeatable responses.

Intended Use:

An air caloric stimulator is a device that delivers a stream of air to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produce involuntary eye movements that are measured and recorded by a nystagmograph.

Caution:

This device should be used by a trained professional.

II. INSTALLATION

After unpacking the instrument, remove any packing debris from around the control console and the delivery head. Make certain that the delivery cable has not been twisted or kinked.

The system is designed to be used at any convenient level such as a table, cart or bench surface. A clear 18" x 18" area is required. Figure 1 shows a typical VNG/ENG examination room layout.

Connections to the computer-based CHARTR 200 VNG/ENG can be made. In order to understand how these connections are made, please refer to section IIIB (Rear Panel Connectors).

The capacitor that provides power to maintain the temperature and time setpoints on the unit may need to be recharged prior to the unit being used. Please refer to section IIID for instructions on how to do this.

NOTE: Before applying line power to the NCA-200, verify that the unit is set up for the appropriate line voltage. Please refer to section IIIB (Rear Panel Connectors).

LAYOUT OF CHARTR ENG TEST ROOM

MINIMUM ROOM SIZE
8 FT. WIDE X 12 FT. LONG

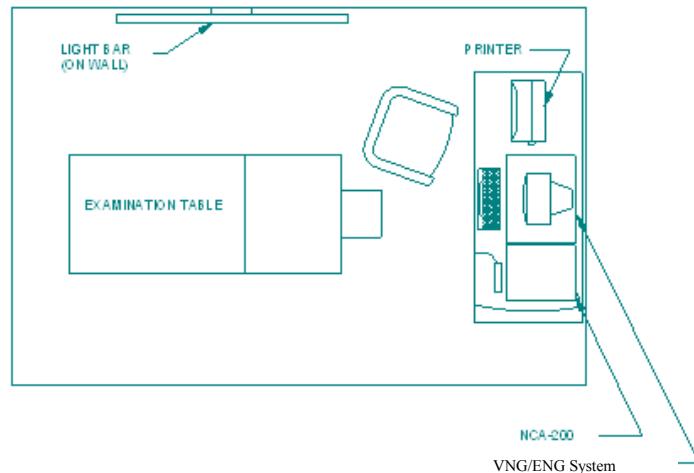


Figure1: Typical room layout for performing the VNG/ENG test

III. OPERATION

A. Front Panel Controls

This section describes all operational controls located on the front panel of the NCA-200 (Figure 2).

1. Power Switch

This is a push on/push off switch that applies line power to the unit. Power-on is indicated by the illumination of the digital display.

2. Digital Display

When setting temperature with the Warm Temp/Cool Temp set controls, the display indicates temperature with a "C" to indicate degrees Celsius.

"S" indicates time in seconds, presented when the flow time is being displayed. The default settings on power-up provide selection of the cool stimulus and display of the cool stimulus temperature.

3. Warm (orange) or Cool (blue) Temperature Select Controls

The warm or cool temperature select buttons allow the operator to select the stimulus (warm or cool) by depressing the associated pushbutton. Temperature selection will be indicated by the illumination of a green light adjacent to the temperature select button. The digital display will present the actual corresponding temperature. Once a temperature has been selected, it takes no more than 60 seconds for the system to come to equilibrium at the new temperature.

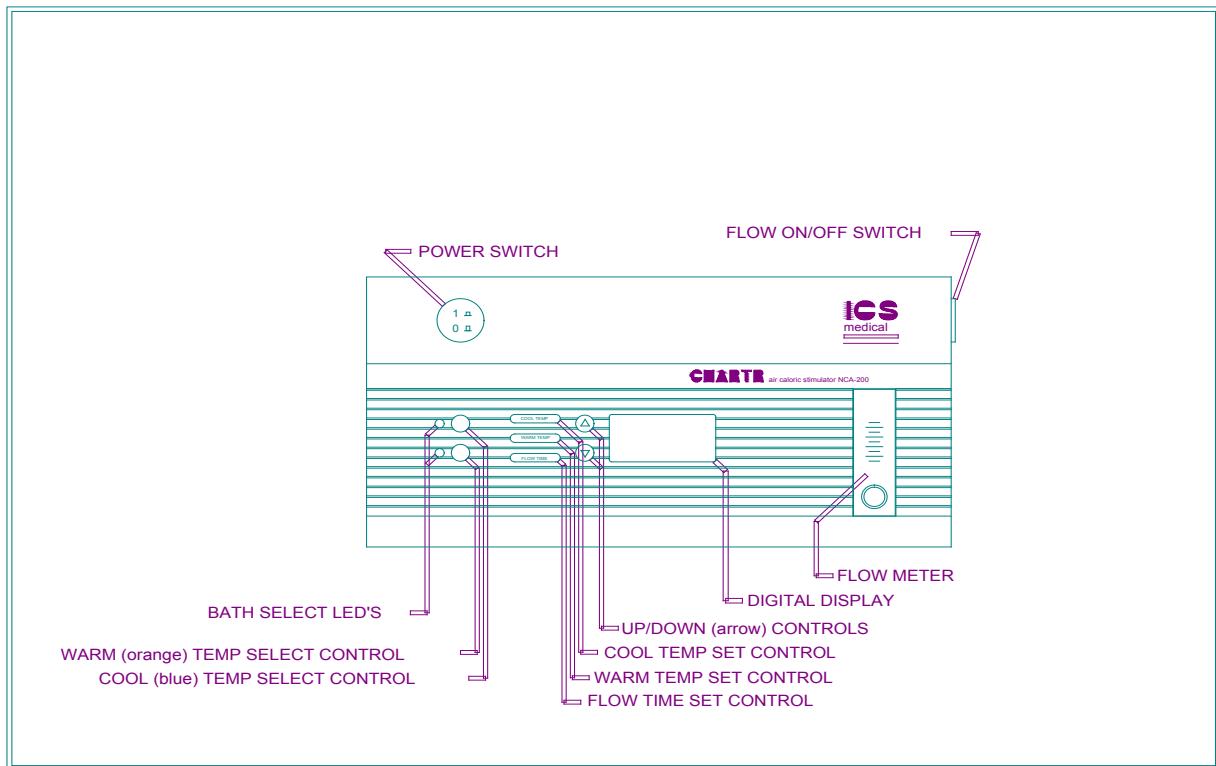


Figure 2: Front view of the NCA-200 showing panel controls.

Selections made with these buttons can be used to override computer selections.

4. Warm Temp/Cool Temp Set Controls

These buttons provide a display of the “set” temperature and allow it to be changed. Pressing the Warm Temp button causes the set temperature for the warm stimulus to be displayed. The Cool Temp button presents the set temperature for the cool stimulus. Five seconds after pressing the button or after making the last changes (see point 6 below), the display returns to the temperature of the selected stimulus.

5. Flow Time Set Control

This provides a display of the period of time for stimulation and allows it to be changed. By pressing the button marked Flow Time, the display changes to the current setting for flow time in seconds. Five seconds after pressing the Warm Temp or Cool Temp or Flow Time button, or making the last changes to set temperatures (see point 6 below), the display returns to the temperature of the selected stimulus.

6. Up or down (arrow) controls

Immediately after selecting the Warm Temp, Cool Temp, or Flow Time controls, the up or down (arrow) controls can be used to adjust the set temperature or the flow time. A single push of either the up or down button will increase or decrease the temperature by 0.1°C or the flow time by one second (the available time range is from 1 to 99 seconds). By holding the up or down button for more than 3/4 of a second, the temperature or the flow time will change at the rate of 3 units a second in the selected direction.

Once set, the operating parameters will be stored in memory registers so they will not need to be re-entered each time the unit is turned on. The display will automatically return to the temperature of the selected stimulus 5 seconds after the last push of a button. Tapping either stimulus select button (the blue or orange buttons) will immediately switch the display to the selected stimulus temperature.

The standard temperatures used are usually 24°C (cool) and 50°C (warm).

7. Flow Meter

The flow rate can be adjusted by using the control at the base of the flow meter. The flow meter is usually set to deliver 8 LPM of air.

8. Flow on/off switch

This switch enables the user to start or stop the airflow to the delivery head. With the air flow turned off, the delivery head may be used as an otoscope.

B. Rear Panel Connectors

The rear panel is the location of connectors to external control or recording devices (Figure 3).

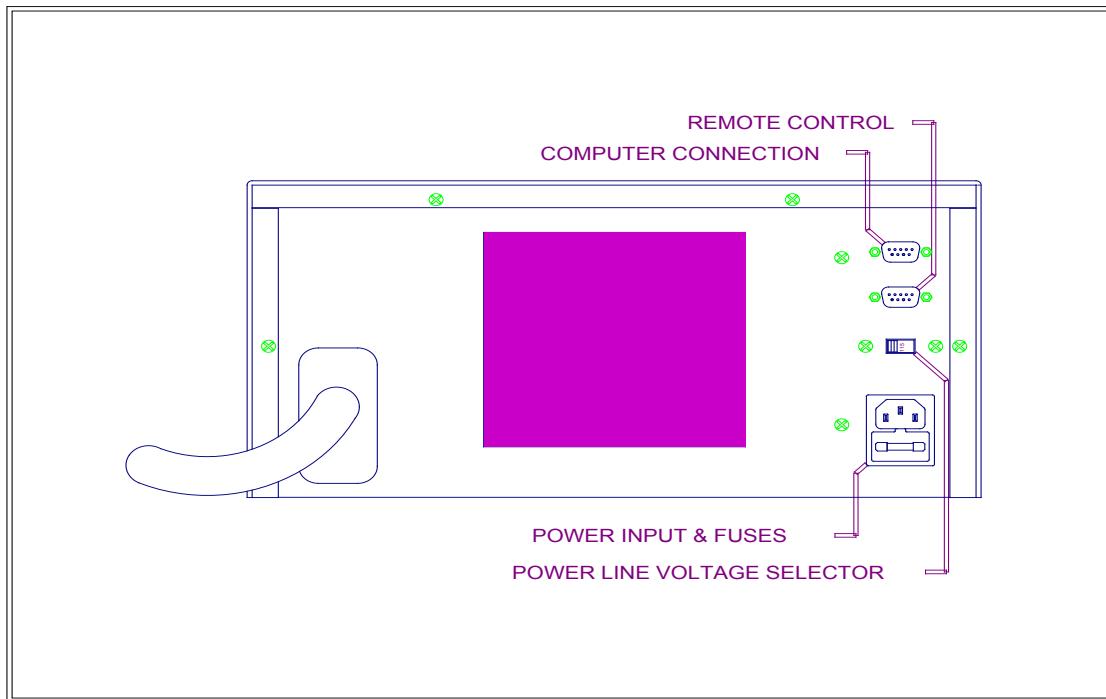


Figure 3: Rear panel view of the NCA-200 with connectors.

1. Computer Connection

The stimulator cable connector goes to the computer connection on the rear panel of the stimulator. Through this connection to the computer, the computer is able to select stimulus temperature through the software.

NOTE: This selection can be made on the unit's front panel (the orange and blue temperature select controls).

2. Remote Footswitch Connection

A footswitch can be connected to the remote control connector at the rear of the stimulator. This would be used to activate the flow timer. If a computer is connected and a caloric test has been selected in the software, the first depression of the footswitch will initiate the flow timer and the recording; subsequent depressions will center the tracing (ENG/VNG) or start the video recording (VNG only). If the computer is turned on but the software is not running, flow time may be activated by holding down the flow time activation switch or the footswitch for 5 seconds. The functions of the footswitch operate in parallel with the flow time activation switch on the delivery head.

3. 115 VAC/230 VAC Operation

If the NCA-200 is to be operated on 115VAC line voltage, the "input voltage" switch must be set to "115" and the line fuses in the power input module must be 5Amp, Slo-Blo, type 3AG fuses. If the NCA-200 is to be operated on 230 VAC line voltage, the "input voltage" switch must be set to "230", and the line fuses in the power input module must be 3 Amp, Time Delay, 5x20 mm fuses.

C. The Delivery Head Controls

The delivery head (Figure 4) can be held in any way that is comfortable for the user. Flow time activation is provided with a trigger button located on the delivery head. The otoscope light can be turned on and off using the button located on the back of the handle below the lens.

NOTE: Turn light off when not in use.

D. Charging the Memory Backup Capacitor

The NCA-200 incorporates a large capacitor to provide power to maintain the temperature and time setpoints while the unit is turned off. The operation of this capacitor is similar to that of a rechargeable battery.

1. Before the NCA-200 is placed in service

Although the capacitor is fully charged at the factory, considerable time may elapse before the unit is actually placed in service. Therefore, it is recommended that the following procedure be followed before the unit is placed in service.

Turn the NCA-200 on. The air pump may be turned off for quieter operation. Leave the NCA-200 turned on for at least 12 hours to fully charge the capacitor. The capacitor cannot be overcharged. A fully charged capacitor is expected to maintain the setpoints for two weeks or more.

2. During routine use of the NCA-200

The capacitor automatically charges whenever the unit is turned on. A couple of hours per day of routine use should be sufficient to keep the capacitor charged.

3. After prolonged interruption of use

If the NCA-200 is out of service for a week or more, follow the procedure for initial charging of the capacitor as described in point 1 above.



Figure 4: Front and Back views of the NCA-200A delivery head and controls.

If the computer is turned on but the software is not running, flow time may be activated by holding down the flow time activation switch or the footswitch for 5 seconds.

IV. OPERATING PROCEDURES

A. Preparation for Testing

Turn the unit on by pressing the green power switch at the top left of the front panel. The cool temperature will automatically be selected as indicated by the illumination of the green LED next to the blue temperature select control.

Press the orange temperature select button if the warm temperature is to be selected. The digital display will flash until the set temperature is reached. It takes approximately 60 seconds for set temperatures to be reached when the unit is first turned on. When the set temperature is reached ($\pm 0.5^{\circ}\text{C}$), the temperature display will stop flashing and illuminate steadily. Note that the flashing display does not preclude the user from stimulating the ear. If the set temperature or flow time needs to be changed, see section IIIA for instructions on how to use the front panel controls.

B. Testing Procedure

Using a regular otoscope or the delivery head with air flow turned off, examine the ear canal for the presence of cerumen and also to determine how best to direct the NCA-200 airstream. The ear canal should be essentially free of cerumen. If it is not, this must be removed prior to stimulating. After selecting the proper temperature and the standard 60 second time for caloric stimulation, start the flow of air and then place the speculum of the otoscopic air delivery head directly into the ear and direct the flow of air onto the tympanic membrane.

Momentarily depress the flow time activation trigger button on the delivery head. If the NCA-200 is connected to the CHARTR 200 VNG/ENG or CHARTR VNG/ENG system, subsequent depressions of the flow time activation switch will center the tracing for VNG/ENG or start the video recording for VNG. (If installed, the footswitch will also serve to start and center tracings or start the video recording.) After the selected time interval has elapsed, a beep indicates when the otoscopic air delivery head should be removed. After stimulation, remove the speculum from the ear, dispose of the speculum and carefully place the delivery head in a safe location. Be sure to utilize alerting tasks as the eye movements are being recorded.

V. SAFETY FEATURES

Patient and operator safety are insured by the incorporation of an isolation transformer. Also a heavy duty, three-wire AC line cord and a "Hospital Grade" plug have been provided. **It is imperative that the plug be connected to a "Hospital Grade" receptacle in order to insure a reliable ground.** (In regions outside of the United States of America, the "Hospital Grade" plug will probably be removed from the line cord. In this event it is important to insure that the ground wire of the line cord is reliably connected to an appropriate ground.)

Overtemperature protection is assured through the use of a special secondary sensor that backs up the thermoelectric control unit. In the event of an overtemperature situation, all current to the heating devices is shut off and the unit will beep to alert the user.

Warning Symbols



The NCA-200 is marked with this symbol to indicate compliance with Type BF of the safety standard EN 60601-1.



The NCA-200 is marked with this symbol it is important that the user refer to associated information given in this manual.

Warning Notes

1. For the sake of safety, and in order not to void the warranty, the cabinet should only be opened and serviced by authorized service personnel. In case of defects, please make a detailed description of the defect(s) and contact your distributor. Do not use a defective instrument.
2. Never place the delivery head inner speculum into a patient's ear without first attaching the outer disposable speculum. The speculum should be carefully placed into the patient's ear. Avoid excessive force or deep insertion as it could result in injury.
3. The NCA-200 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the NCA-200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment.
4. Do not use the instrument in the presence of flammable anesthetics (gases).
5. If the instrument is damaged or malfunctioning cease using the system.
6. No parts may be eaten, burnt, or in any way used for purposes other than air caloric irrigation.
7. The NCA-200 can be disposed of as normal electronic waste, according to local regulations.
8. For safety reasons, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.
9. Immediately discontinue device use if skin irritation or discomfort occurs.

VI. CLEANING AND MAINTENANCE

The NCA-200 does require regular maintenance which is the cleaning and refilling of the liquid cooling system. **This is required once every 6 months**, and should be performed by your local Otometrics distributor or the factory. Keep the instrument clean and as free of dust as possible. Remove dust using a soft cloth. To clean the outside case, use a soft, slightly damp cloth with a small amount of mild detergent.

It will also be necessary to dispose the used speculum. The specula were designed for Single Use Only. Additional Specula (part # 8-62-44100 – Qty 25) can be obtained from Otometrics or your distributor.

Two 5 amp fuses (3 amp for 240v operation) are located on the back panel.

NCA-200 Coolant Refill Procedure

NOTE: If the customer is not comfortable following this procedure, contact Otometrics or your local authorized dealer.

1. Unplug the unit from the power source.
2. Remove the four screws from the back panel.
3. Slide the cover back and lift it off the unit.
4. Unscrew the top cover from the white plastic reservoir.
5. Plug the NCA-200 into an appropriate source.

Caution: Throughout this procedure, be careful that you do not spill any water on the internal circuit boards or components. Also, be very careful that you do not come in contact with any of the fuseholders, transformer wires, moving fan blades, etc.

6. Fill the reservoir with only **distilled** water.

7. Turn on the main power switch. Water should circulate from the pump, to the delivery head, then the radiator, and finally return to the pump.
8. Once water is recirculating back into the reservoir, fill the reservoir to within 1/4 inch of its top edge. Replace the reservoir top cover.

Next, tilt the unit to the left by raising the right edge of the unit about 4 inches. Return the unit to a level position. Repeat this process until there are no more air bubbles observed leaving the radiator. If the pump starts sucking air, add more water to the reservoir.

9. Once all the air is purged from the radiator, remove the reservoir top cover and fill the reservoir again to within 1/4 inch of its top edge.
10. Reinstall the reservoir top cover and tighten snugly.
11. Replace the top cover of the unit and the four screws.

VII. WARRANTY

Otometrics warrants this instrument to be free of defects in material and workmanship for a period of one year from the date of shipment from the factory. Defects or deficiencies noted and brought to Otometrics' attention during the warranty period will be corrected, or, at Otometrics' discretion, the instrument will be replaced. Should repairs require transportation to the factory, such shipments will be made prepaid.

Exempted from this warranty are the following:

- A. Instruments not installed in accordance with the instructions in the manual.
- B. Instruments serviced by personnel other than those authorized by Otometrics.
- C. Instruments involved in accidents or which have been misused or improperly maintained. This includes the use of water other than **distilled** water.

Otometrics shall not be liable for consequential damages or other damages beyond the costs associated with the repair and/or replacement during the warranty period of defective instruments.

VIII. SPECIFICATIONS

Temperature range: 12° to 50°C
Cool stimulus: 12° to 37°C (Recommended setting: 24°C)
Warm stimulus: 37° to 50°C (Recommended setting: 50°C)

Temperature readout: Digital

Time to temperature: < 60 seconds

Temperature accuracy: +/- 0.3°C

Time range: 1 to 99 seconds (Recommended setting: 60 seconds)

Flow rate range: 4 - 10 LPM (Recommended setting: 8 LPM)

Air supply: Internally mounted compressor

Remote control capability: Standard for computer-based systems.

Timeout indication: Beeper

Input power: 120 VAC @ 60 Hz or 240 VAC @ 50 Hz

Current: 5A @ 120 VAC, 3A @ 240 VAC

Safety: Primary temperature read-out. Separate over-temperature cut-off.

Stimulus timing activation: Switch on delivery head or footswitch.

Size (W X D X H): 14 x 17.5 x 7.8 inches
35 x 44 x 20 centimeters

Weight: 43 lbs.
20 kg.

Operating Environment

Temperature: +15°C to +35°C (+59°F to +95°F)

Relative Humidity: 30 to 90%, non-condensing

Air Pressure: 600 hPa to 1060 hPa

Operations at temperatures below -20°C or above +60°C may cause permanent damage.

Storing and Handling

Temperature: 0°C to +40°C (32°F to +104°F)

Relative Humidity: <90%, non-condensing

Air Pressure: 500 hPa to 1060 hPa

ACCESSORIES

Specula (Qty 25)	8-62-44100
Lens (Qty 1)	8-35-33300