

PKA 84

PEDIATRIC AUDIOMETER

User Manual



OCTOBER 5, 2016



WWW.LORECa.COM

Table of Contents

Table of Contents	1
Introduction	2
Intended Use	2
Precautions.....	3
Basic Functions	5
Description of Control Panel.....	5
Description of Stimuli Panel	6
Auditory Behaviour	7
Auditory Behaviour -Test Overview.....	7
Description of Various Tests	8
Auditory Behaviour Index for Infants	10
Reflex Audiometry by Neonates.....	11
Maturation of Auditory Response.....	12
Technical Specifications	14
Unpacking / Inspection	17
Contents of Shipment.....	16
Reporting Imperfections	18
Trouble Shooting	19
Appendix: General Maintenance Procedures	20
Recommended Literature	21
Return Report	22

Introduction

Intended Use

The PKA handheld pediatric screening audiometer is designed to be a device for screening for hearing loss primarily amongst children. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. However, for children not responding well, various test possibilities allow the tester of having at least some evaluative result. Thus, a “normal hearing” result should not allow for ignoring other contra indications in this case. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

Precaution

Notice - Be sure to use only stimulation intensities, which will be acceptable for the patient.

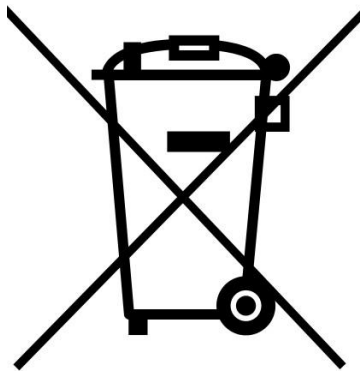
Notice - The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers require a recalibration.

Notice - It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

Notice - Always remove the batteries when the instrument is left unused for more than a month.

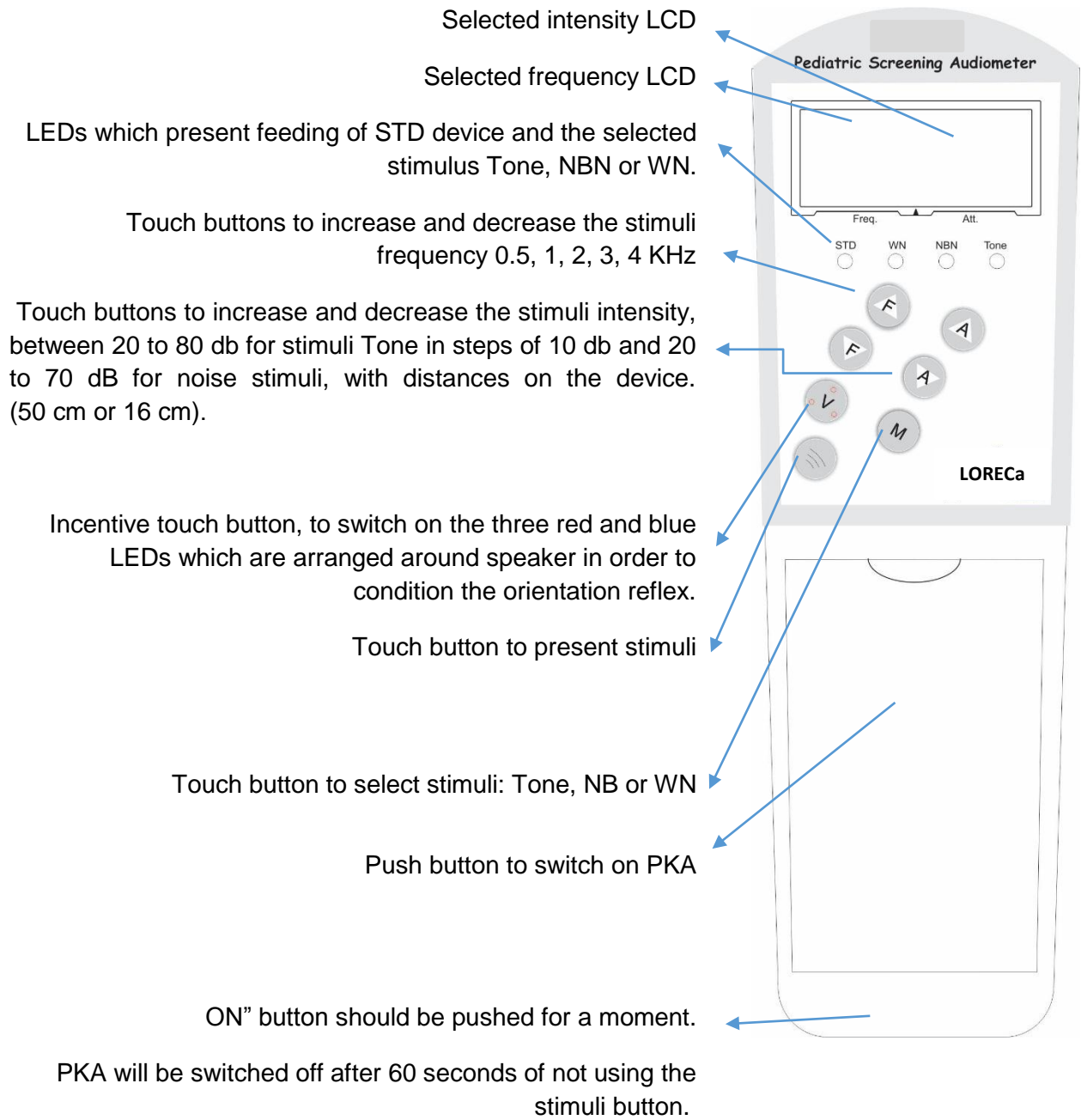
Notice - Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Notice - Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings. Disposal of batteries must be made according to national regulations.

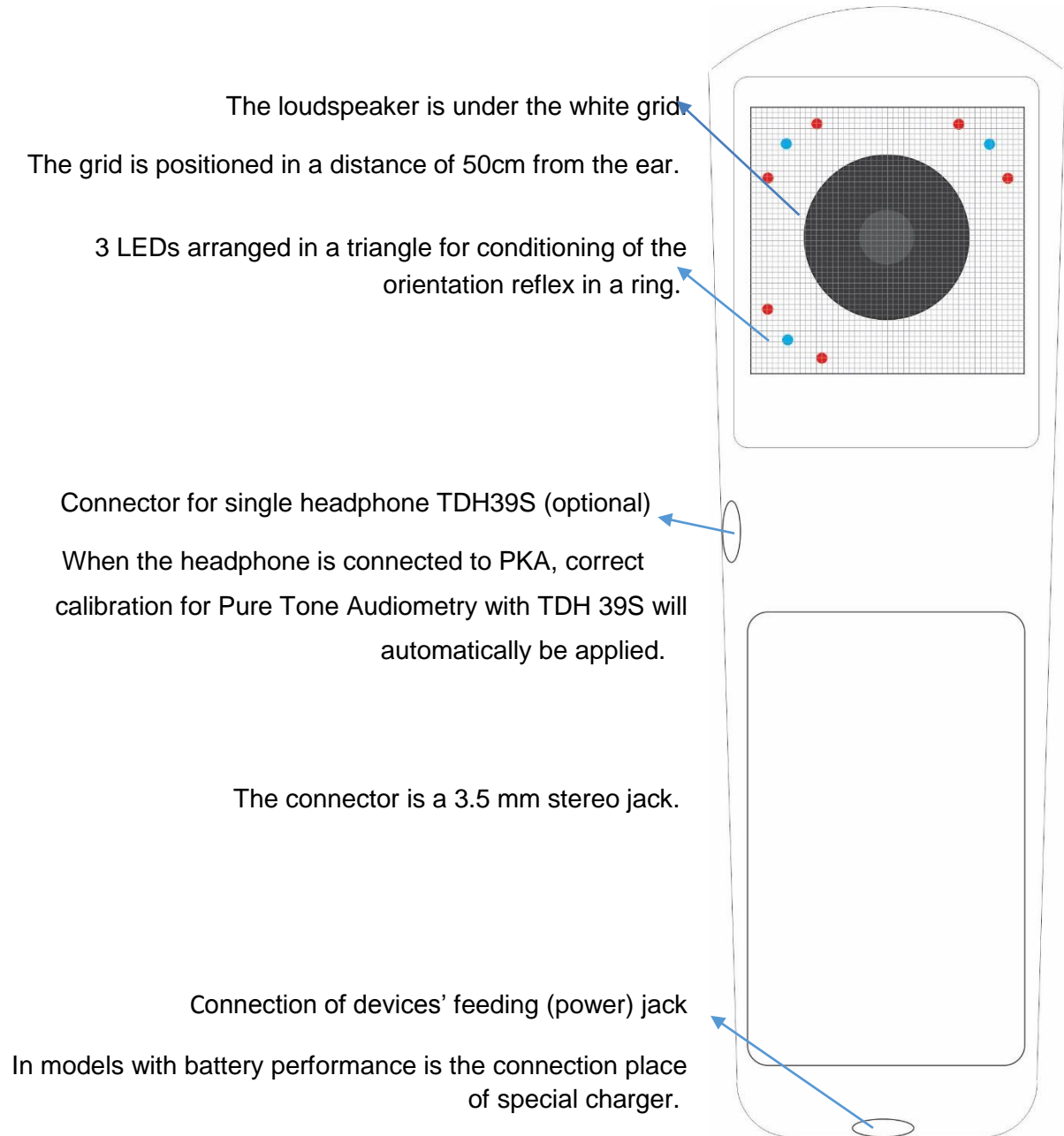


Basic Functions

Description of Control Panel



Description of Stimuli Panel



Auditory Behavior

Auditory Behaviour -Test Overview

	Waking up	Respiration. Aud	APR	COR	VRA
Recommended age group (month)	0 - 3	0 - 4	0 - 12	4 - 15	6 - 30
Preferred Frequency:					
500 Hz				x	x
1000 Hz				x	x
2000 Hz		x	x	x	x
3000 Hz	x	x	x	x	x
4000 Hz	x	x	x	x	x
Tone Duration (Sec)	1.5-2	1-2	0.5-1	0.5-1	0.5-1
Time between Stimulation (sec)	30	20	10-20	10-20	10
MRL1 (sound cabin) (dBHL)	40-80	40-80	40-80	30-60	20-40
Distance to test ear (cm)	10-50	10-50	10-50	50-100	50-100
Condition of child:					
- sleeping	x	x			
- half asleep	x	x	x		
- awake		x	x	x	
- playing				(x)	(x)
- playing alert				x	x
Recom . no. of PKAs for the test:	1	1	1	2	2

Description of Various Tests

As found by Professor Sanford E. Gerber complex signals like White Noise (WN) assure better responsiveness on neonates and up to the age of approximately seven months than e.g. pure tones and Narrow Band Noise. Therefore PKA has the possibility of stimulating with WN.

The APR Test:

The Auropalpebral Reflex is a startle reflex of the eyelid elicited by relatively strong sounds, approximately 80 - 100 dB SPL (PKA is calibrated in dB HL).

The test can be performed on neonates from the day of birth and it is not based on co-operation with the newborn child. Other responses than the APR can be arousal from sleep, crying or diminished activity.

The COR Test:

The Paediatric Audiometer PKA can perform Conditioned Orientation Audiometry based on a technique described by Suzuki and Ogiba (1961). The phenomenon called "Orientation Reflex" is not a learned response, but a natural reflex movement elicited by sound or visual stimulation.

If the visual stimulation elicits a reflex which is conditioned by a tone, the child will look towards the visual stimulation, e.g. flashing light, as soon as the tone is heard. If the conditioning is effective the child will look in the direction of the sound source even before the visual stimulation is presented. The COR method requires cooperation from the child.

The VRA Test:

The Paediatric Audiometer PKA can perform the Visual Reinforcement Audiometry (Liden and Kankunen, 1969), which is an extension and modification of COR, where the co-operation with the child is less important. Liden and Kankunen accept not only the sound localisation orientation reflex, but also four other reactions: reflex reactions (body and face), search reactions, orientation reactions and spontaneous reactions.

Auditory Behaviour Index for Infants

Age	Reaction on noisemaker (approx. dB SPL)	Reaction on warbled pure tones (dB HL)	Reaction on Speech (dB HL)	Expected Response
0–6 weeks	50-70 dB	78 dB(±6)	40-60 dB	Eye-widening, eye-blink, stirring or arousal from sleep, startle.
6-16 weeks	50-60 dB	70 dB(±10)	40dB (±2)	Eye-widening, eye-shift, eye blink, quieting: beginning rudimentary head turn by four month.
4-7 months	40-50 dB	51 dB(±9)	21dB (±8)	Head turn on lateral plane towards sound: listening attitude.
7-9 months	30-40 dB	45 dB(±15)	15dB (±7)	Direct localisation of sounds to side, indirectly below ear level.
9-13 months	25-30 dB	38 dB(±8)	8dB (±7)	Direct localisation of sounds to side, directly below ear level indirectly above ear level
13-16 months	25-30 dB	32 dB(±10)	5dB (±5)	Direct localisation of sounds.
16-21 months	25 dB	25 dB(±10)	5dB (±1)	Same.
21-24 months	25 dB	25 dB(±10)	5dB (±1)	Same.

Reflex Audiometry by Neonates

The reflex pattern elicited by sound can be divided into the following types of reflexes (Relke and Frey 1966). The sound intensity is 75 – 90dB.

Breathing Reflex

The breathing rhythm is changing when the sound is heard and should stabilise after 5-10 seconds.

Auropalpebral Reflex (APR)

The open eyelids will be closed fast and clear.

Moving Reflex

The neonatal child will move heavily after a quiet period.

Crying Reflex (Scream)

The face of the child will indicate discomfort and shortly after followed by weeping or a scream.

Astonishment Reflex

Crying and body movements stop momentarily as if the child is asking: “What is going on”?

Waking up Reflex

The breathing rate is accelerating; the child starts moving, wakes up and opens the eyes.

Maturation of Auditory Response



Newborn to 2 months of age

Arousal from sleep. MRL₂ in quiet surroundings 50-70 dB.

MRL in noisy surroundings: 90

2 Minimum response level, dB HL. The MRL levels are recorded in sound cabins. In noisy surroundings the levels will have to be correspondingly higher



3-4 months of age

Rudimentary head turn, horizontally.

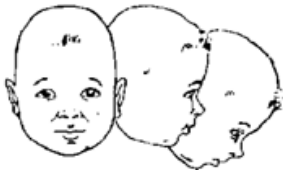
MRL: 50-60 dB



4-7 months of age

Sound localisation to the side only, not above or below eye level.

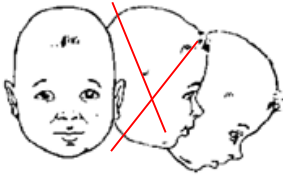
MRL: 40-50 dB



7-9 months of age

Sound localisation to the side
Indirect below. (Not above).

MRL: 30-40 dB.



9-13 months of

Sound localisation to the side
and direct below.

MRL: 25-35 dB.



13-16 months of age

Sound localisation to the side,
below and indirect above.

MRL: 25-35 dB.



16-21 months of age

Direct sound localisation to
the side, below, indirect
above.

MRL: 25-35 dB.



21-24 months of age

Locates directly sound at any
angle.

MRL: 25-30 dB.

Technical Specifications

Standards:

Audiometer: EN 60645-1, Type 5

Sound Pressure Level of the loudspeaker: ISO 389-7

Sound Pressure Level of the headphone: ISO 389-1

EMC: EN 60601-1-2

Frequencies:

500, 1000, 2000, 3000, 4000 Hz.

Stimuli:

Warble Tone, NB, and WN.

Intensities:

Distance 50 cm: 30 – 80 dB HL in 10 dB steps for Warble Tone and WN.

20 – 70 dB for NB

Distance 16 cm Increases the indicated intensity by 10 dB.

Warble Frequency:

5 Hz, $\pm 5\%$.

Stimulation using TDH39S:

Pure Tone: 500, 1000, 2000, 3000 and 4000 Hz.

Intensities of 30 – 80 dB (independent calibration applied when TDH39S is connected).

Sound Source:

Built-in loudspeaker or audiometric headphone TDH39S (independent calibration registers).

Light Stimulation:

3 LED's arranged in a triangle, flash speed 5 Hz (5 pulses per sec).

Tone and Light Stimulation:

Silent presentation switch.

Dimensions:

L x W x H: 22 x 6.7 x 7.5 cm

Warm-up time:

The PKA is ready for instant use and does not require any warm-up time.

Environmental conditions:

The specification for the instrument is valid if the instrument is operated within the following environmental limits:

Temperature: 15°C to 35 °C.

Humidity: 30 %RH to 90 %RH

Transportation and storage of the instrument should be within the following environmental conditions:

Temperature: Transportation: -20° to 50°

Storage: 0° to 50°

Humidity: 10%RH to 95% RH

Non-condensing. Keep dry.

Unpacking / Inspection

Check box and contents for damage:

When the instrument has been received, please check the shipping box for rough handling and damage. If the box is damaged, it should be kept, until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact the nearest service office. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment:

The PKA comes in its own shipping carton, which is specially designed for the PKA. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required, please contact your nearest sales and service office.

Contents of Shipment

Delivered items with PKA:

PKA delivered as standard contains the following:

- PKA Pediatric Free Field Audiometer
- Special adaptor and connection cable 220V
- Calibration Certificate
- Multilingual Instruction for Use

Check numbers on PKA and Manual:

The identification label on the rear plate holds the serial number. This should be checked with the manual number, and written down for later service claims.

Reporting Imperfections

Report immediately any faults:

The cabinet and the accessories should be checked visually for scratches and missing parts. Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number and a detailed report of the problem. In the back of this manual you will find a "Return Report", where you can describe the problem.

Please use "Return Report":

Please realise that if the service engineer does not know what problem to look for he may not find it, so using the Return Record will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction

Annual Calibration:

The PKA has been designed to provide many years of reliable service, but annual calibration is recommended due to possible impact on transducers.

We do also recommend to calibrate the PKA , if something drastic happens to the instrument (e.g. if the instrument was dropped on the floor).

Trouble shooting

PKA does not turn on:

- The screen on the adaptor must be light orange
- Adaptor connections might not be done completely.
- The adaptor jack has not been inserted completely.

No stimuli from the PKAs internal loudspeaker:

Controlling the “dB HL” intensity

No tones in the TDH39 headphone:

The “Tone” presentation signal (10) must be activated by touching the Tone Switch.

If no sound appears check that the headphone is correctly connected to the

“Headphone Connector” on the stimuli panel output and that the jack is fully inserted.

General Maintenance Procedures

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

- It is recommended to let the instrument go through at least one annual overhaul, to ensure that the acoustical, electrical and mechanical properties are correct. This should be made by an authorised workshop in order to guaranty proper service and repair.
- Do not site the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always be careful that no fluid is entering the inside of the instrument or the accessories.
- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or eartips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.
- Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.

Recommended Literature

Jerger, James: Paediatric Audiology, Current Trends

McCormick, Barry: Paediatric Audiology 0 – 5 years, Second Edition (Taylor & Francis)

Northern, Jerry L. and Downs, Marion P.: Hearing in Children (Williams & Wilkins).

Katz, Jack: Handbook of Clinical Audiology, Fourth Edition (Williams & Wilkins).

Löwe, Armin: Pädagogische Hilfen für hörgeschädigte Kinder in Regelschulen.

Löwe, Armin: Kinder-Audiometrie (Carl Marhold Verlagsbuchhandlung).

Return Report

Hospital/ clinic/ company:

Address:

Phone:

Fax or E-mail:

Contact person: Date:

Following item is reported for checking:

Type..... quantity..... serial NO.....

- Return to LORECa for :

Calibration.....

Repair.....

Exchange.....

Other.....

- Defections as described below:

.....

- Repairment locally as described below:

.....

- General problems as described below:

important: accessories used together with the item must be included if returned (e.g. headsets, transducers and couplers).

Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport.

Returned according to agreement with LORECa or others:

Date:

INFO@LORECA.COM
