VX90

User Manual

8290-0000-ENG/V12_EN/2023-01-18

VISIONIX

INNOVATION TO UNLOCK YOUR POTENTIAL

Contents

I - Introduction

Product Description:

Thank you for purchasing the Visionix Auto Refractometer VX 90.

The VX 90 is an autorefractometer and a keratometer,

The VX 90 is measuring the objective refraction of the eye giving sphere, cylinder and axis, using an Infra-red ring projection on the Retina.
The keratometer measurement of radius of cornea is done in the same time with another Infra red ring, by measuring the reflection of this ring on the cornea. 4 external fixation dot allow the user to perform peripheral keratometry.
The Machine is showing the intra ocular lens potential opacity with the retro illumination mode.
The practician could also measure the pupil diameter by moving 2 cursors on the screen, the pupil diameter is then displayed on the screen.
A moving fixation target with auto fogging allows the patient to fully desaccomodate in order to get the patient refraction in the best conditions.

Intended Use : The VX 90 is an ophthalmic diagnostic device, autorefractor, keratometer, intended for

- Measuring the refraction of the eye, giving sphere, cylinder and axis
- Measuring the radius of the cornea, central and peripheral keratometry.
- Measuring the pupillary diameter
- Retro illumination for detection of the internal opacities.

Intended Users : the intended users are Opticians, Optometrists, and Ophthalmologists.

The data given by the VX 90 will be used by a qualified person as starting point to start the subjective refraction to make the final prescription. The VX 90 only is not suitable to give the data for the final prescription.

Manufacturer information:

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II - Safety

Luneau Technology Operations provides sufficient information to ensure patient safety, avoid system malfunctions, and prevent incorrect readings.

Luneau Technology Operations declines all responsibility for injury to patients or damage to equipment due to ignorance of its safety instructions or in the event that they are not followed.

The safety information appears in the form of warnings and alert messages.

Important!

- Never attempt to disassemble or reassemble the equipment. There are no user serviceable parts in the device.
- Do not modify the equipment in any way.
- Repairs and maintenance must be carried out only by qualified service personnel.
- Operators and patients should keep hands and body clear from moving parts on the device.

II.1 - Electricity

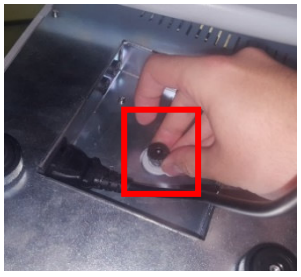
Important!

- To avoid risk of electric shock or bodily injury, do not handle the electrical plugs with wet hands.
- To avoid risk of electric shock or fire, make sure the Vx90's power cord is not damaged before plugging it into an electrical outlet.
- To avoid risk of electric shock, the power cord should be fully inserted in an outlet equipped with a protective ground connection.
- The socket must be easily accessible after the installation of the device
- When connecting external devices such as a screen or printer, ensure that the device conforms to IEC 60950-1 Information Technology Equipment - Safety.

II.2 - Transport, Storage, and Handling

Important!

- Transport the VX90 in its specially designed case.
- Block the VX90 unit with the specially designed screw, below the unit



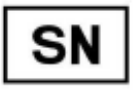
- Make sure the packing is firm and secure.
- Do not subject the VX90 to strong vibrations. Shocks or violent movements can cause malfunctions.

II.3 - Precautions During Use

Important!

- Do not place or use the VX90 in direct sunlight.
- Do not expose the VX90 to excessive dust or humidity.
- Do not place the VX90 in a hot air current (e.g. above a heater).
- Do not obstruct the ventilation vents.
- Never place the VX90 close to the following types of equipment which can perturb the reception of commands from the remote control:
  - Halogen lamp (direct or indirect)
  - Fluocompact lamp
  - Equipment emitting infrared radiation (auto-phoropter, automatic tonometer, etc.)
- Keep the screen surface clean. Protect it from dust, fingerprints, and shocks.
- When you switch off the VX90, wait at least 5 seconds before switching it on again.

II.4 - Symbols

Symbol	Descripion
	Important: consult the documents supplied with the equipment
	Type B applied parts
	The equipment must be returned to the manufacturer for scrapping (see Waste Electrical and Electronic Equipment (WEEE) Directive)
	Manufacturer
	Year of Manufacturing
	Serial Number
CE 0051	Compliance with Medical Device Directive 93/42/EC amended by Directive 2007/47/CE 0051 : identification number of Notified Body IMQ (I)
Rx only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

III - Equipment and Installation

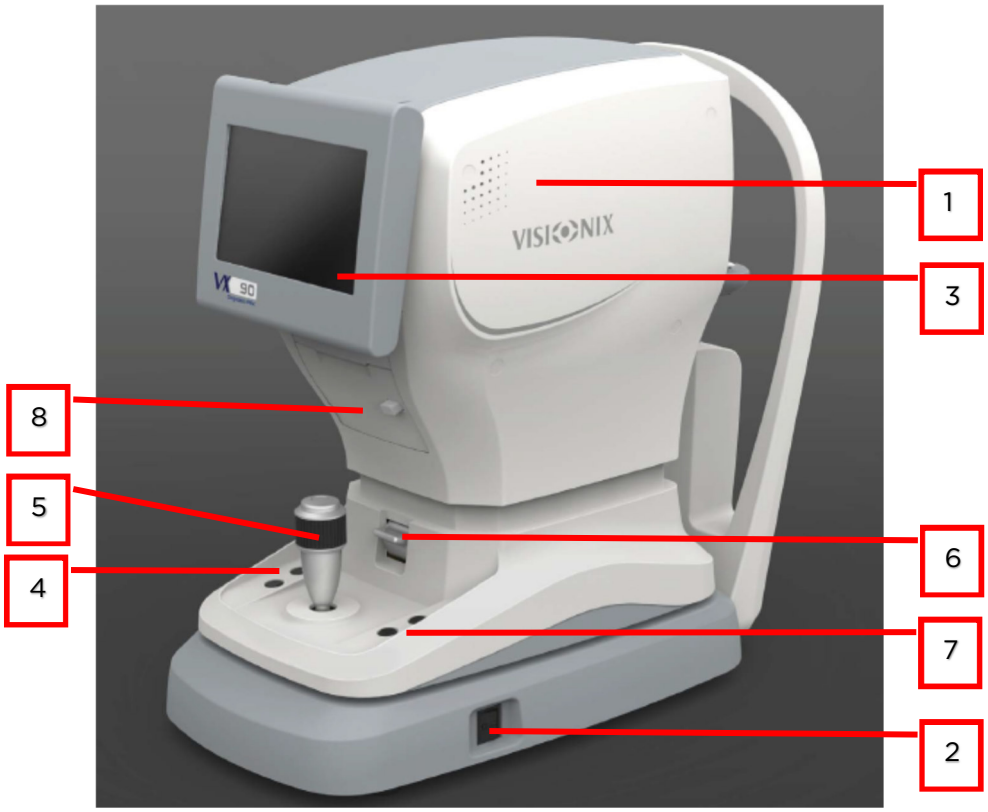
III.1 - List of Equipment Supplied

The VX90 package contains the following items:

- VX90 unit
- Socket head wrench: to unlock plug screw
- Power supply
- Dust cover
- Chin-rest paper
- Printer paper roll
- User Guide
- Model eye
- Fuse

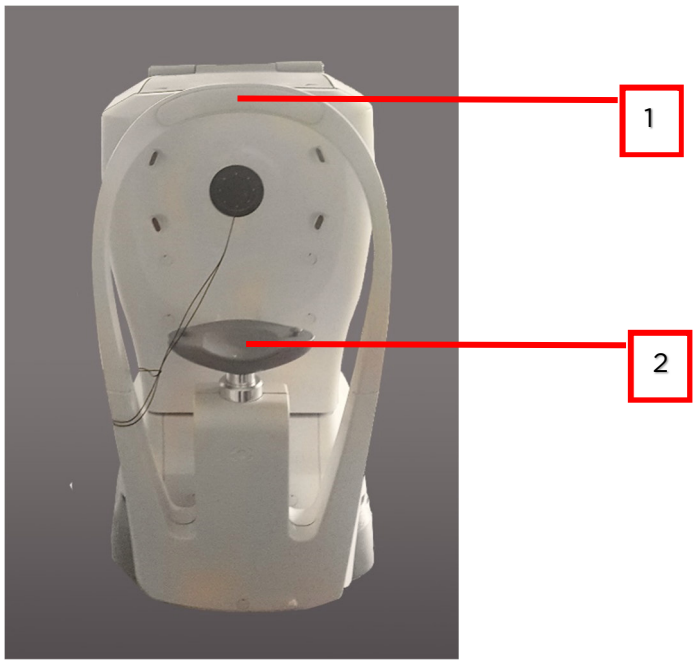
III.2 - Description of the Device

2.a) User Side



N°	Description
1	**Optical-measurement head** Contains the hardware used to perform all of the measurements during patient diagnostic exams.
2	**On/Off switch** Shuts down the machine
3	**LCD touch screen**
4	**Up and Down Chin Rest button**
5	**Joystick** to move up /down/left / right the machine
6	**Lock Switch** To lock the head
7	**Reset and Print Key** Reset print function
8	**Printer**

2.b) Patient Side



N°	Description
1	**Headrest** The patient should lean their forehead on the headrest during all diagnostic procedures.
2	**Chin rest** The patient should lean their chin on the chin rest during all diagnostic procedures.

III.3 - Installation Procedures

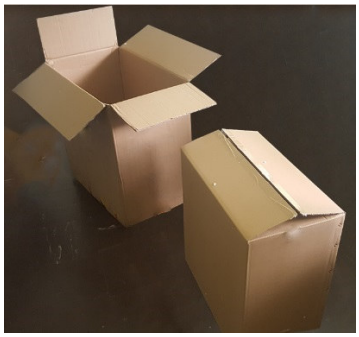
Site Requirements

The VX90 unit should be placed on a clear table or desktop close to a power outlet. The unit should not expose to direct light on the patient side. Better results will be obtained if the unit is located in a room with limited illumination.

3.a) Unpacking the Unit

To unpack the unit:

- Remove the tape around the box.
- take out the carton with care.



- Remove the Polystyrene box to uncover the VX90 unit, which is packed in a protective plastic bag.
- Take the VX90 out of the box and put it on the table.

- Lift the protective plastic bag to uncover the device.

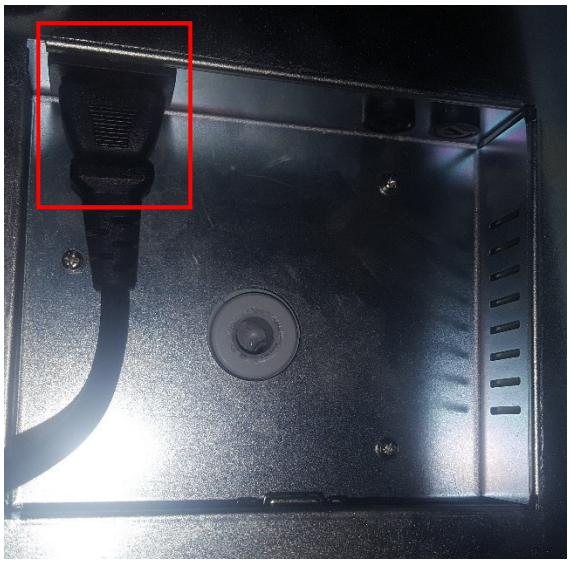
To Unlock the unit:

To unlock the head, turn this screw below the unit

3.b) Electrical Connection

To connect the unit to an electric outlet:

- Check that the power supply voltage corresponds to that required by the equipment (see the identification label on the back of the unit).
- Insert the power connector under the unit
- Connect the power plug to a wall outlet.



under the Vx90

3.c) Loading Paper into the Printer

To insert a paper roll into the printer:

- Lift the handle in the middle of the paper compartment and pull the cover down.
- If an empty paper roll is in the printer, remove it.
- Insert the new roll with the end of the paper on the top of the roll.
- Feed the paper into the slot at the top of the compartment.
- Push the paper-compartment door closed.

III.4 - Turning the Unit On and Off

To turn the unit on:

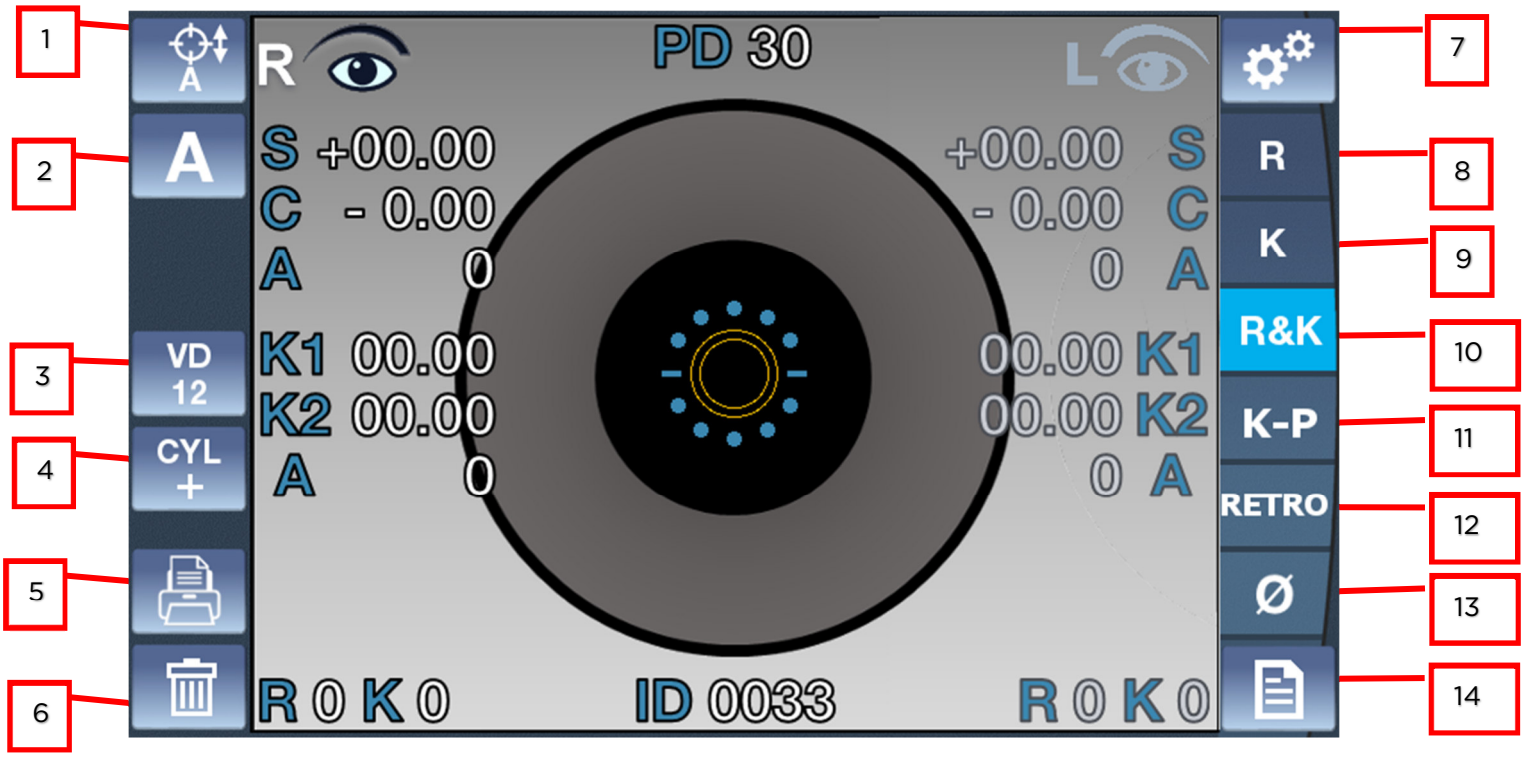
- Press the On/Off switch (#2 in the illustration).

To turn the unit off:

- On the unit, press the **On/Off** switch.

IV - Overview of the Software

IV.1 - Home Screen

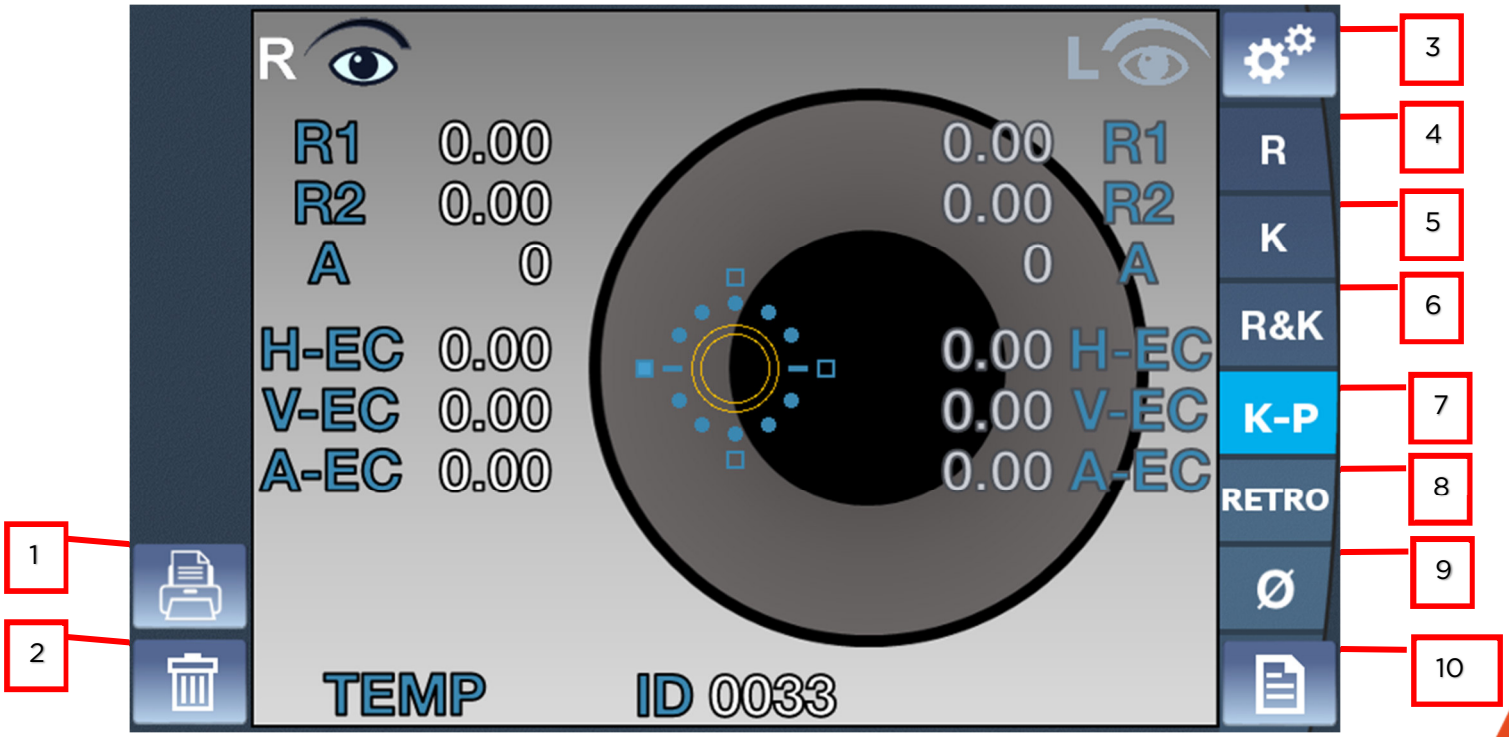


The **Home** screen is the main menu of the VX90. It gives you access to all of the functional screens of the interface.

N°	Description
1	**Alignment** To select an automatic vertical alignment or a manual vertical alignment: 
2	**Measurement** Touch to select an automatic or manual measurement 
3	**VD Value** Touch this key to switch the VD Value: 
4	**Cylinder sign** To select the cylinder sign, minus, plus or auto.
5	**Print mode** Use to print ticket or send data
6	**Clear Button** Press this button to clear the data
7	**Settings Menu** Touch this button to access the settings menu

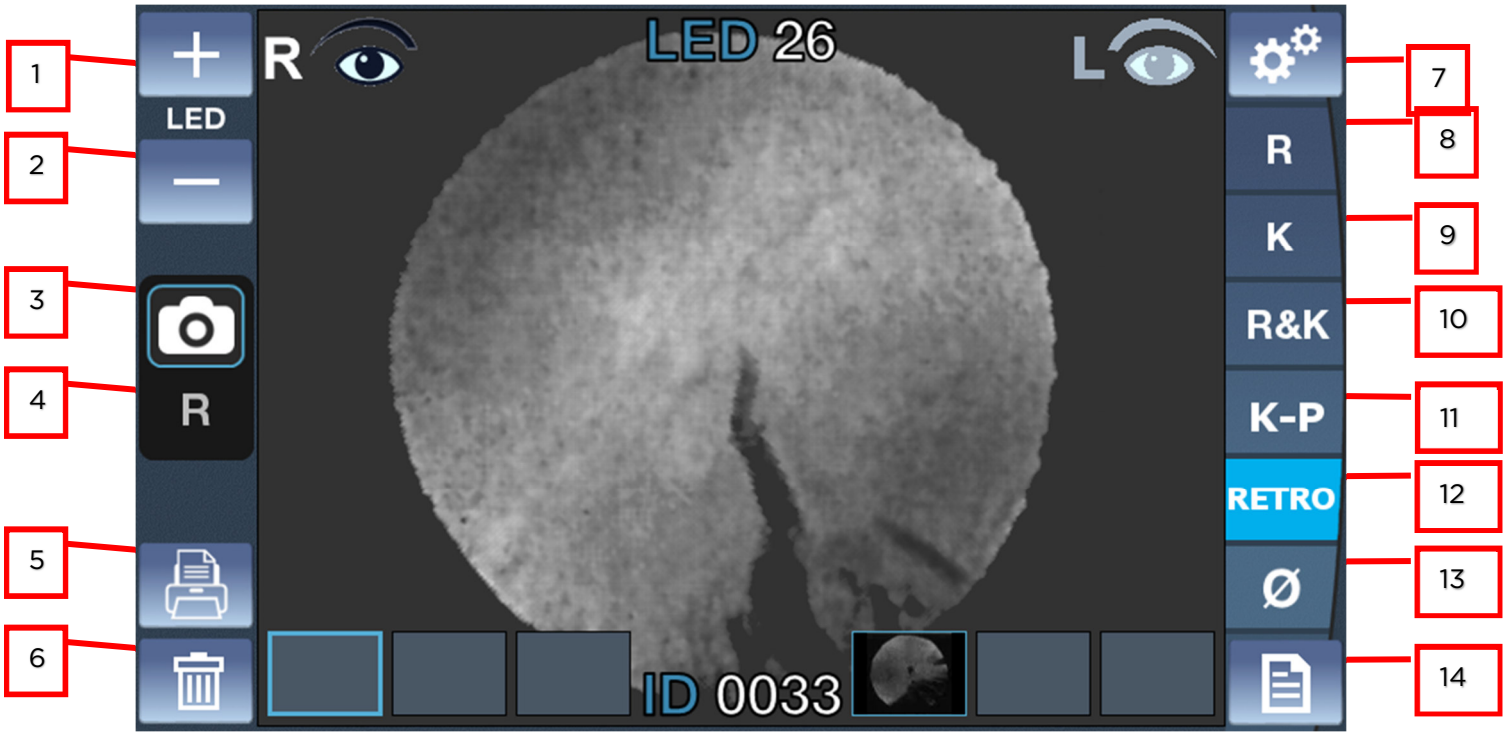
8	**Refraction Measure** Touch this button to select only refraction measurement
9	**Keratometry Measure ,** second push of the button will call the **peripheral K** mode proceed the same as the central K on the 4 different fixation targets (nasal/temporal/up/down) Third push of this button will call back central keratometry measurement
10	**Refraction Keratometry measure** Touch this button to have the refraction and keratometry value
11	**Keratometry peripheric measurement** To open the keratometry peripheric measurement screen
12	**Retro-illumination mode** To open the retro-illumination screen
13	**Corneal Radius** It is the mode to measure the corneal radius Second push on the button will call the **Retro illumination** mode, to acquire the picture of the eye with the back reflexion from the retina. Third push of the button will call back the Corneal radius measurement
14	**Data Menu** To open the menu of the data you have already measured

IV.2 - Keratometry peripheral screen



N°	Description
1	**Print mode** Use to print ticket or send data
2	**Clear Button** Press this button to clear the data
3	**Settings Menu** Touch this button to access the settings menu
4	**Refraction Measure** Touch this button to select only refraction measurement
5	**Keratometry Measure ,** second push of the button will call the **peripheral K** mode proceed the same as the central K on the 4 different fixation targets (nasal/temporal/up/down) Third push of this button will call back central keratometry measurement
6	**Refraction Keratometry measure** Touch this button to have the refraction and keratometry value
7	**Keratometry peripheric measurement** To open the keratometry peripheric measurement screen
8	**Retro-illumination mode** To open the retro-illumination screen
9	**Corneal Radius** It is the mode to measure the corneal radius Second push on the button will call the **Retro illumination** mode, to acquire the picture of the eye with the back reflexion from the retina. Third push of the button will call back the Corneal radius measurement
10	**Data Menu** To open the menu of the data you have already measured

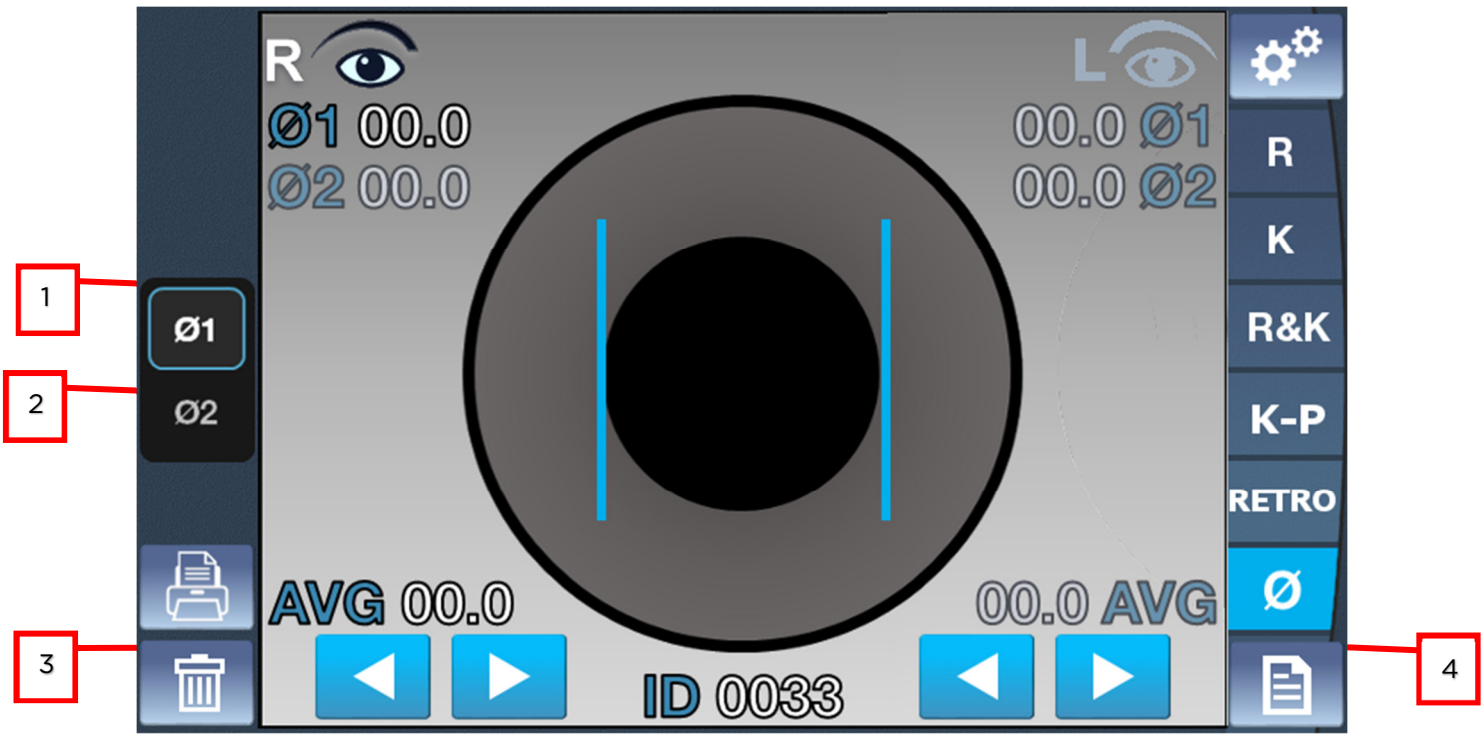
IV.3 - Retro-illumination screen



N°	Description
1	**Increase illumination button** Used to increase the illumination of the LED
2	**Decrease illumination button** Used to decrease the illumination of the LED
3	**Retro-illumination mode** Touch it to have the retro illumination mode
4	**Refraction observation in retro-illumination mode** Touch it to observe the refraction in the retro illumination mode
5	**Print mode** Use to print ticket or send data
6	**Clear Button** Press this button to clear the data
7	**Settings Menu** Touch this button to access the settings menu
8	**Refraction Measure** Touch this button to select only refraction measurement

9	**Keratometry Measure ,** second push of the button will call the **peripheral K** mode proceed the same as the central K on the 4 different fixation target (nasal/temporal/up/down) Third push of this button will call back central keratometry measurement
10	**Refraction Keratometry measure** Touch this button to have the refraction and keratometry value
11	**Keratometry peripheric measurement** To open the keratometry peripheric measurement screen
12	**Retro-illumination mode** To open the retro-illumination screen
13	**Corneal Radius** It is the mode to measure the corneal radius Second push on the button will call the **Retro illumination** mode, to acquire the picture of the eye with the back reflexion from the retina. Third push of the button will call back the Corneal radius measurement
14	**Data Menu** To open the menu of the data you have already measure

IV.4 - Corneal Measure



N°	Description
1	**Diameter 1** Touch to modify diameter 1

2	**Diameter 2** Touch to modify diameter 2
3	**Left perpendicular bar arrow** To move the le left perpendicular bar
4	**Right Perpendicular bar arrow** To move the right perpendicular bar

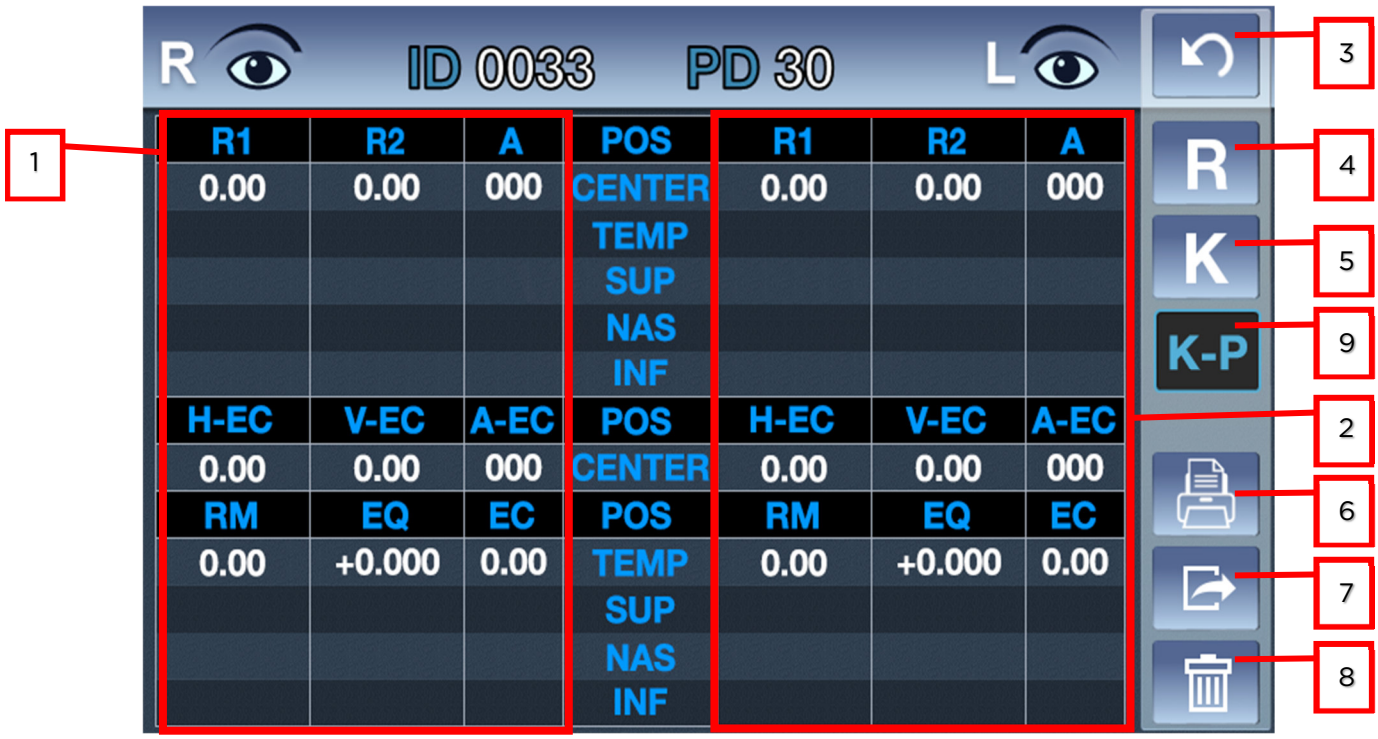
IV.5 - Data Menu

N°	Description
1	**Right Refraction measure** Display of the all measure with the average at the bottom of the column
2	**Left Refraction measure** Display of the all measure with the average at the bottom of the column
3	**Return** Touch it to return at the main screen
4	**Refraction Measure**

	To select refraction table
5	**Keratometry measure** To select the Keratometry table
6	**Print** Touch this button to print one ticket
7	**Export** Touch this button to export at an external device
8	**Delete** Touch this button to clear the data
9	**Peripheral Keratometry measure** To select the Peripheral Keratometry table
10	**Confidence Index** Give the measure reliability, 4 steps possible: - CI=0 All the measures are false - CI=3 the reliability is low - CI=6 the reliability is medium - CI=9 the reliability is High
11	**Exam ID reset** To reset it long press (about 15 seconds) on "ID".

N°	Description
1	**Right Refraction measure** Display of the all measure with the average at the bottom of the column
2	**Left Refraction measure** Display of the all measure with the average at the bottom of the column

3	**Return** Touch it to return at the main screen
4	**Refraction Measure** To select refraction table
5	**Keratometry measure** To select the Keratometry table
6	**Print** Touch this button to print one ticket
7	**Export** Touch this button to export at an external device
8	**Delete** Touch this button to clear the data

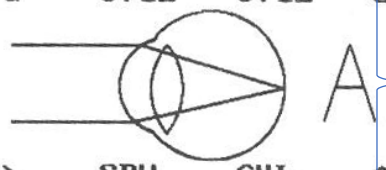


N°	Description
1	**Right Refraction measure** Display of the all K-P measurement
2	**Left Refraction measure** Display of the all K-P measurement
3	**Return** Touch it to return at the main screen
4	**Refraction Measure** To select refraction table
5	**Keratometry measure** To select the Keratometry table

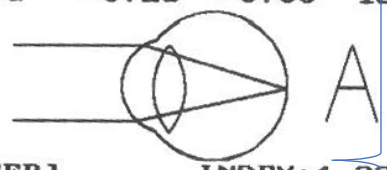
6	**Print** Touch this button to print one ticket
7	**Export** Touch this button to export at an external device
8	**Delete** Touch this button to clear the data
9	**Peripheral Keratometry measure** To select the Peripheral Keratometry table

Ticket:

```
Optique Marceau
Paris
01.45.05.05.05
--------- 8426 ----------
NAME:_____M/F
DATE:2017-04-28     17:29
[REF]             VD:15.00
                Cyl.Sign:[-]
<R>     SPH     CYL     AX
       -0.12   -0.12    54
       -0.12   -0.12    55
       -0.12   -0.00   180
     ---------------------
AVG    -0.12   -0.12    55
```



```
<L>     SPH     CYL     AX
       -0.25   -0.00   180
       -0.25   -0.00   180
       -0.25   -0.00   180
     ---------------------
AVG    -0.25   -0.00   180
```



```
[KER]           INDEX:1.335
<R>      R1      R2      AX
        7.94    7.94   180
        7.94    7.94   180
        7.94    7.94   180
      ---------------------
          mm      D      AX
R1      7.94   42.37   180
R2      7.94   42.37    90
      ---------------------
AVG     7.94   42.37
CYL            -0.00   180
<L>      R1      R2      AX
        7.98    7.85    89
        7.97    7.85    89
        7.97    7.85    89
      ---------------------
          mm      D      AX
R1      7.97   42.12    89
R2      7.85   42.75   179
      ---------------------
AVG     7.91   42.50
CYL            -0.62    89
PD= 72mm

                      VX90
Visionix
```

Head: include header (can be modify in the settings), patient ID, Name, Gender, Date, Hour

Refraction: Include all the value measured on each eyes, the average of each eyes, and diagram of each eyes.

Keratometry: Include all measurement on each eyes and average.

Value of the PD and have the ticket footer, which can be modify in the settings

V - Performing a Measurement

You can initiate a new measurement procedure by opening the Measure screen. The **Measure** screen appears at the start up of the machine

Once the **Measure** screen is opened, you can prepare the patient and select the test options, as explained under Preparing to Run a Diagnostic

V.1 - Preparing to Run a Measurement

After you open the Measure screen, there are different operations you should do before you start running the diagnostic:

- Clean the headrest.
- Place a new sheet of protective paper over the chin rest, or clean the chin rest.
- Instruct the patient to sit down, place their chin on the chin rest, and lean their forehead on the headrest.
- If you need to fine-tune the position of the chin rest, select the **Chin Rest** up and down arrows as necessary to move the chin rest up or down.
- If you need to adjust the position of the unit's head, use the Joystick to adjust the position of the head, up/down / left and right
- Instruct the patient to look at the target (balloon). You should see their eye in the image of the lens view in the **Measure** screen.
- Align the patient's pupil with the center of the target (see Centering the Patient's Eye).

Once you have done all of these things, the measurement start automatically if you are set in automatic mode or manually by pushing the joystick button if you are set in manual mode.

V.2 - Managing the Measurement Procedure

The diagnostic procedure is managed in the Measure screen. In this screen, you can select the measurement you want to perform, position the unit head and chin rest so that the patient's eye is centered in the lens, modify default test settings, start the measurement procedure, and monitor its progress.

Centering the Patient's Eye

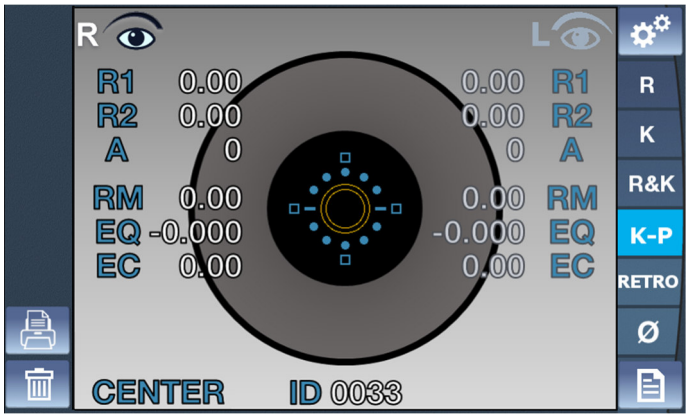
In the Measure screen, you can see what the lens is aimed at in the lens view. If the pupil is visible, move the joystick until the pupil is centered and focused. If the patient's pupil is not visible at all in the lens view, adjust the position of the unit's head by moving the joystick to the center of the lens view,

V.3 - Managing Keratometry Peripheral Measurement

It is the mode to measure the curvature of part around cornea. Based upon the center of cornea, measure the curvature of part around cornea from the positions of up/down and left/right direction. It is to indicate the relative eccentricity while comparing the curvature of part around cornea with the curvature of corneal center.

1. Keep pushing K-P button on the right side of the screen.
2. Measurement of Corneal Center

The initial measurement position is the corneal center, and it is indicated as CENTER on the Bottom left of screen. The curvature measured in the corneal center is the same with the one measured in KER mode.

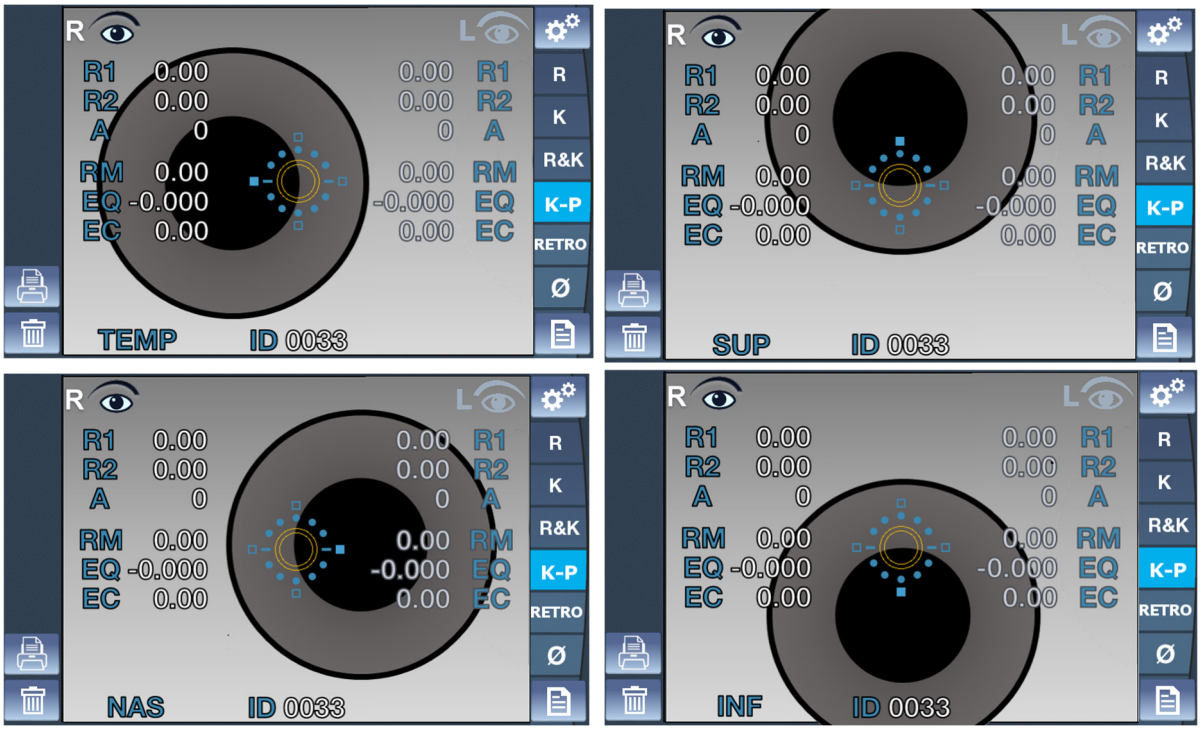


3. Measurement of part around cornea

The direction of part around cornea which is measure at present is to be indicated at the bottom left of measurement mode indication. Four boxes are to be indicated in INF, SUP, NAS, TEMP side of Mire ring. Each box indicates the proceeding state of measurement on part around cornea. If there is the measured result
around part of cornea where the box is located, the inside of box is to be full with color: In case of no result, the box is to be indicated as an empty box. The relevant box indicated at the part around cornea which is measured now is to flicker.
Direction of part around cornea:
- Superior (SUP): Upside from corneal center
- Inferior (INF): Downside from corneal center
- Temple (TEM): To the temple of examinee from corneal center
- Nasal (NAS): To the nose of examinee from corneal center

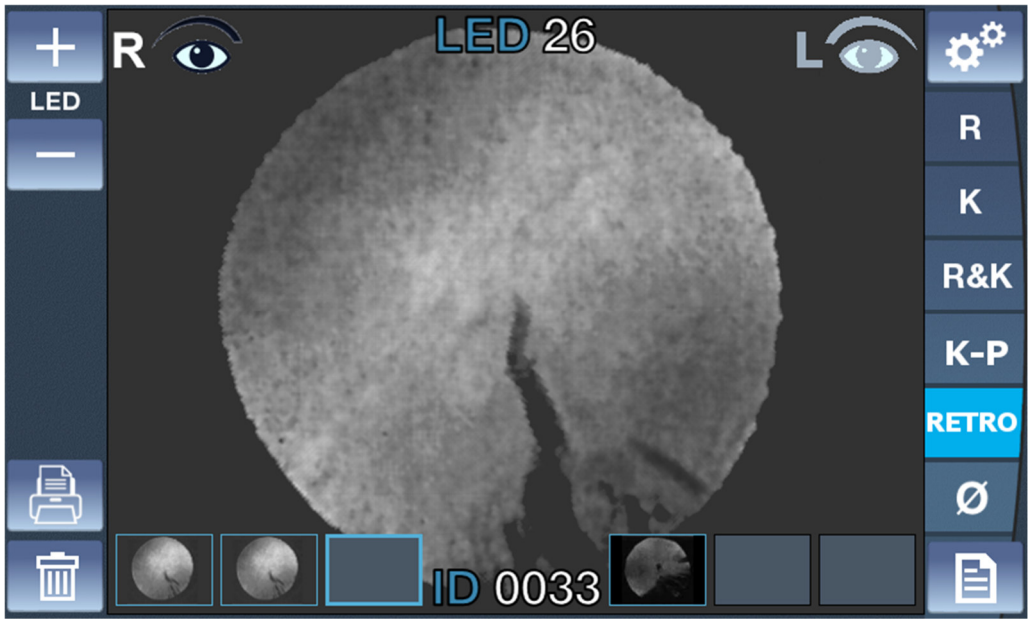
4. Sequence to measure the part around cornea

Measure it following the sequence of TEM -> SUP -> NAS -> INF In case that the measurement in the direction of part around cornea becomes difficult, the direction lamp (guidance LED light) is to radiate in order to draw the examinee's sight around Mire ring actually. After the examiner shall ask the examinee to look at the light of direction lamp, then he or she can perform the measurement by adjusting the focus of Mire ring.



V.4 - Managing the Retro-Illumination Image.

1. It is to examine the crystalline lens of patient who has the severe symptom of cataract or undergoes it examine the degree of opacity of crystalline lens with the shape of light reflected from retina while changing intensity of light shed on the eye.



1. Adjustment of brightness of the LED
   - Adjust the brightness of the LED clicking on button + and button -.
2. Observation of retro illumination image
   - Place the VX90 in front of the eye (right or left).
   - Use the joystick to center and focus properly.
   - In order to protect the patient's eyes, avoid examining the eyes over 30 seconds.
3. Acquisition of the image
   - Click on the joystick to save an image.
     It will be saved in the selected box of the current eye. As the live mode of the camera continues after each acquisition, it is possible to take several images consecutively.
   - If more than 3 images are acquired for a same eye, the 1st one will be erased and will be replaced by the 2nd one (and the 3rd one becomes the 2nd one, and the new one becomes the 3rd one).
4. Review an image
   - Click on the wanted image.
   - To come back on live camera, click on the joystick or click on an empty box image of retro illumination.
5. Delete an image
   - Click on the wanted image.
   - Click on clear button.
     If there is an image after the deleted one, the images will be translated to avoid empty box image.

VI - Configuring the Unit

VI.1 - Accessing the Configuration Settings

To open the Settings Menu:

- Select the **Settings Menu** button.

VI.2 - Overview of the Configuration Screen

The **Configuration** screen gives you access to the VX90's settings and system maintenance functions.

2.a) Main Screen and Refraction Settings

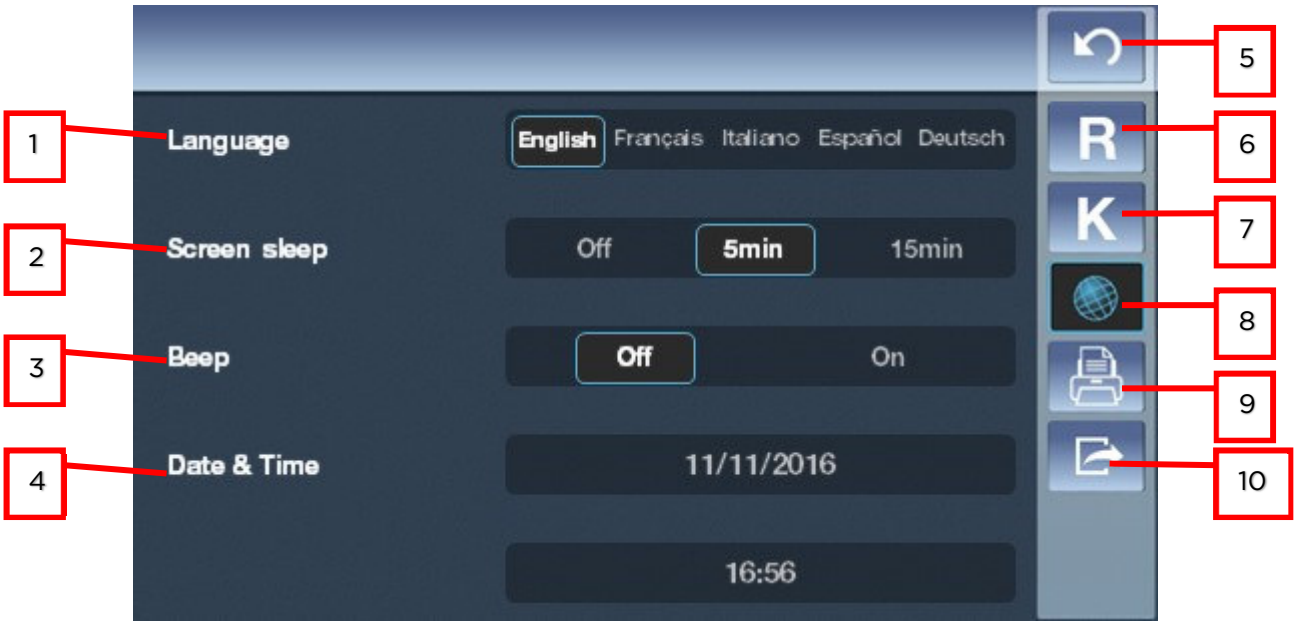
N°	Description
1	**Step** To choose the step of the measurement, two choice possible 0.12 Diopter or 0.25 Diopter
2	**Vertex Distance** Touch this button to modify the step of the VD, four choices possible (0, 12, 13.75, 15)
3	**Cylinder Notation** To choose the sign of the cylinder, plus, minus or automatic
4	**# Measures** To choose the numbers of measure in one diagnostic (for each eye and for each value)
5	**Fogging** To choose, if the Fogging is doing at the first measure or all measure when you have selected # Measures > 0
6	**Return** To return at the main screen
7	**Refraction settings** To set the taking of the refraction measurement
8	**Keratometry Settings** To set the taking of the Keratometry measurement

9	**Device Settings** To change the settings of the device
10	**Print Settings** To set the printing
11	**Export Settings** To set all information to export data to an external device

2.b) Keratometry Settings

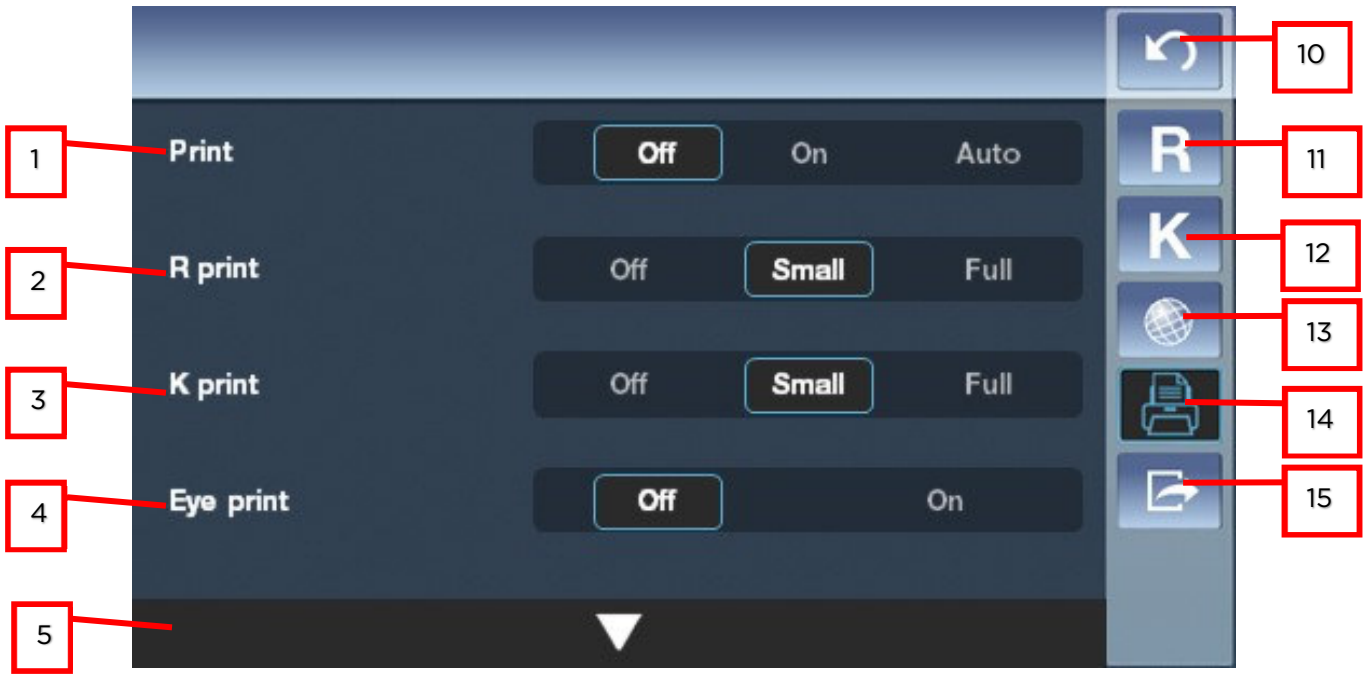
N°	Description
1	**Unit** To choose if you want the keratometry in Diopter or in Millimeters
2	**Step** To modify the step of the measure (0.12 Diopter Or 0.25 Diopter)
3	**Index** To choose the step of measurement (1.332, 1.336, 1.3375)
4	**# Measures** To choose the numbers of measure in one diagnostic (for each eye and for each value)
5	**Return** To return at the main screen
6	**Refraction settings** To set the taking of the refraction measurement
7	**Keratometry Settings** To set the taking of the Keratometry measurement
8	**Device Settings** To change the settings of the device
9	**Print Settings** To set the printing
10	**Export Settings** To set all information to export data to an external device

2.c) Device Settings



N°	Description
1	**Language** Touch the language you want to select
2	**Screen Sleep** You can select the time before Screen sleeping
3	**Beep** To choose if you want sound signal when you touch the screen
4	**Date and time** To select the date and the time of the device
5	**Return** To return at the main screen
6	**Refraction settings** To set the taking of the refraction measurement
7	**Keratometry Settings** To set the taking of the Keratometry measurement
8	**Device Settings** To change the settings of the device
9	**Print Settings** To set the printing
10	**Export Settings** To set all information to export data to an external device

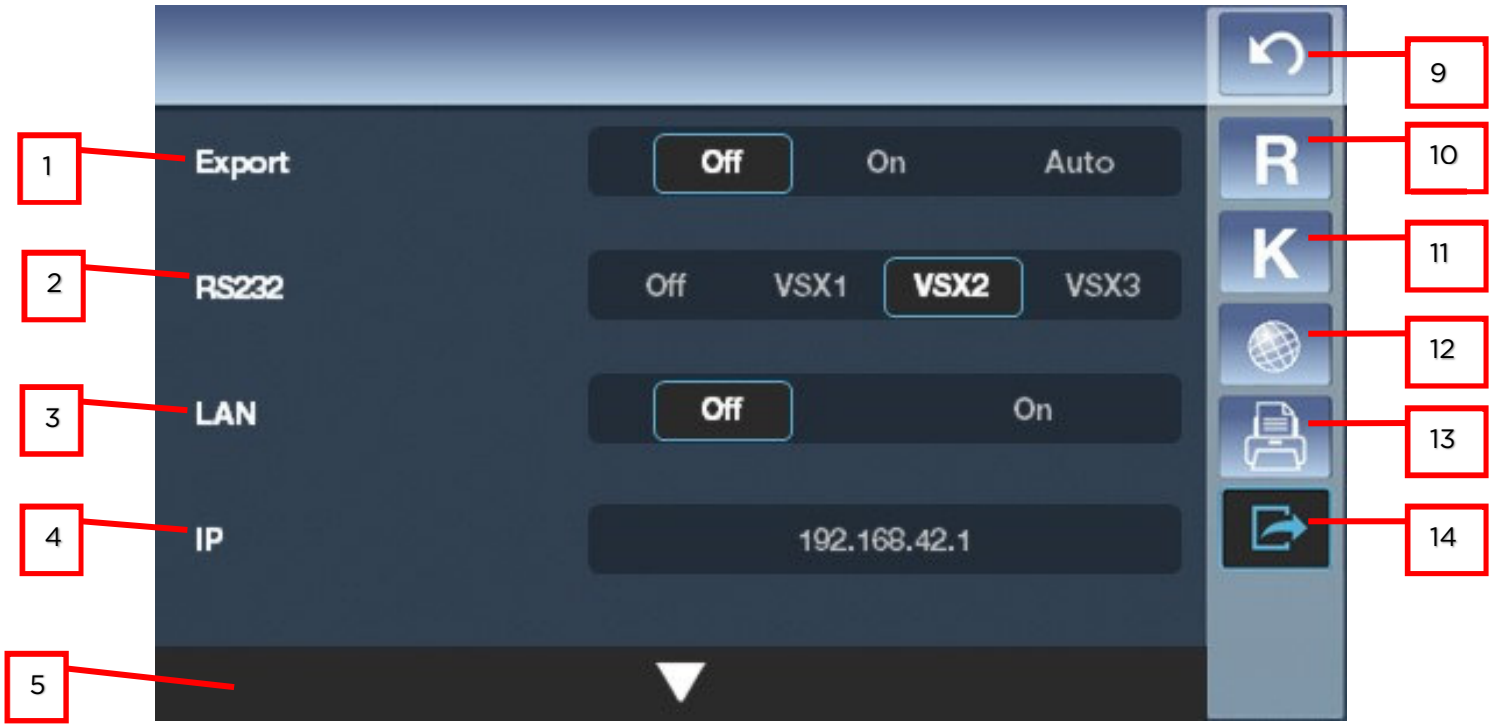
2.d) Print Settings

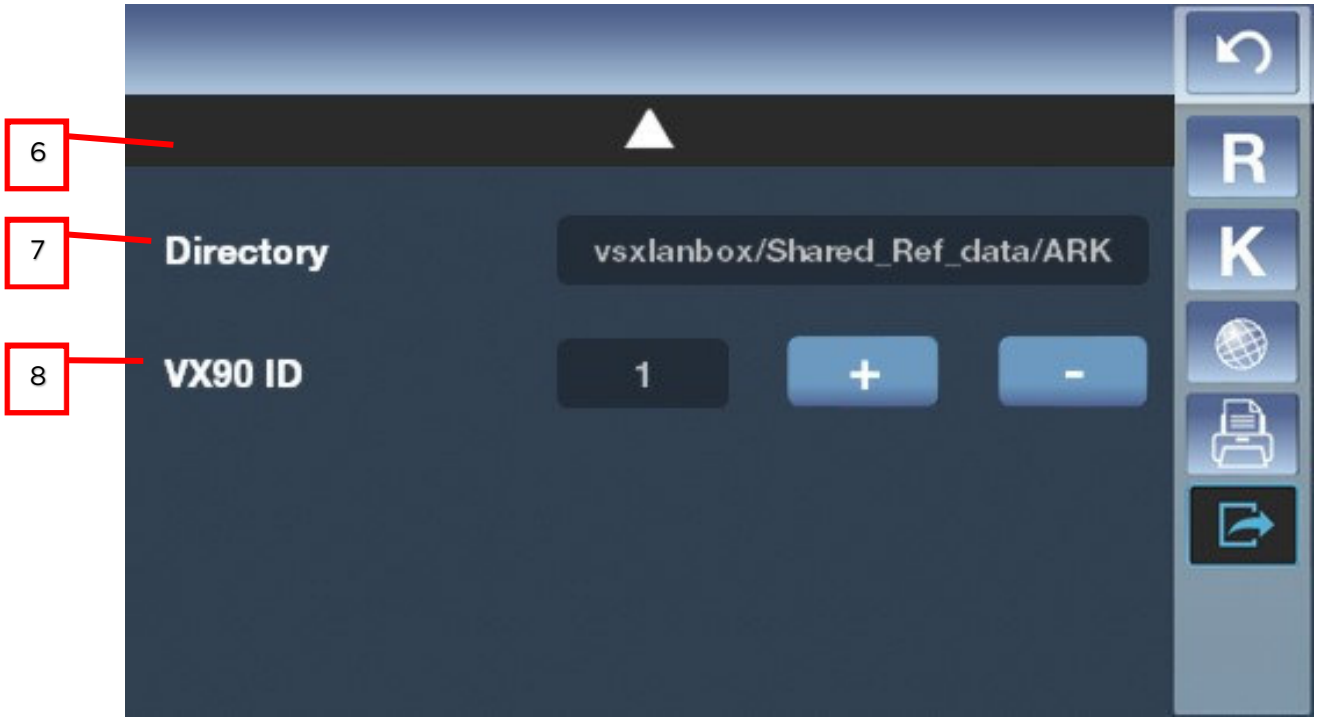


N°	Description
1	**Print** To enable or disable the printing of one ticket, or set as automatic
2	**R Print** To enable or disable the refraction part print in the ticket and choose the type
3	**K Print** To enable or disable the Keratometry part print in the ticket and choose the type
4	**Eye Print** To enable or disable the diagram of the eye on the ticket
5	**Access to the second page**

	Touch this button to access to the second page
6	**Access to the first page** Touch this button to return at the first page
7	**PD Print** To enable or disable the pint of the PD
8	**Ticket Header** To choose what you want to write on your own head ticket
9	**Ticket Footer** To choose what you want to write on your own foot ticket
10	**Return** To return at the main screen
11	**Refraction settings** To set the taking of the refraction measurement
12	**Keratometry Settings** To set the taking of the Keratometry measurement
13	**Device Settings** To change the settings of the device
14	**Print Settings** To set the printing
15	**Export Settings** To set all information to export data to an external device

2.e) Export Settings





N°	Description
1	**Export** To enable or disable the export data
2	**RS 232** to select the protocol of the communication
3	**LAN** To enable the Wi-Fi connection or disable it
4	**VX90 ID** Touch “+” “-“ to modify the Id of the VX90
5	**Access to the second page** Touch this button to access to the second page
6	**Access to the first page** Touch this button to access to the first page
7	**WiFi** To select the name of the Wifi you want to connect
8	**Password** To select the password of the wifi you want to connect
11	**Return** To return at the main screen
12	**Refraction settings** To set the taking of the refraction measurement
13	**Keratometry Settings** To set the taking of the Keratometry measurement
14	**Device Settings** To change the settings of the device
15	**Print Settings** To set the printing
16	**Export Settings** To set all information to export data to an external device

VII - What Should I Do If...?

You may encounter some of the following common problems while working with the VX90. If you do, try following the suggested solutions listed below. If the problem persists and the suggested solution does not remedy it, contact a qualified service representative or your local distributor.

Problem	Possible Causes	Suggested Solutions
Images are not properly centered	- External lights or windows near the unit - Large patches of light near the unit	- Ensure that there no bright lights or windows near the unit or the patient. - Ensure that there are no large irregular patches of light on the patient or on the unit.
Measured pupil size is different from the expected or actual pupil size	- External lights or windows near the unit - Large patches of light near the unit	- Ensure that there no bright lights or windows near the unit or the patient. - Ensure that there are no large irregular patches of light on the patient or on the unit.
Black screen	- unit is in stand by mode - unit is switched off - Fuses are blowed	- Push on any button to exit the stand by mode - Check the main power switch is on pos 1 - Check the fuses on the main power socket
Tickets do not print	- Paper jam - Out of paper	- Open the print paper door and release the paper. - Replace the paper roll.

VIII - Maintenance

This chapter explains how to clean the VX90 unit and how to perform routine maintenance tasks.

VIII.1 - Cleaning the Unit

Important!

Before cleaning the unit, turn it off and unplug it from the electric outlet.

To clean the plastic surface of the VX90, dampen a cloth with a commercial, non-abrasive cleaner and gently wipe the top, bottom, and front surfaces.

CAUTION: Do not spray or pour any liquid directly on the device.

CAUTION: Do not use caustic or abrasive cleaners.

Chin Rest

Cleaning of the chin rest with a soft cloth and alcohol is strongly recommended after each patient. Chin rest paper coverings are supplied with the device. Use the paper to cover the chin rest after each patient use.

Headrest

Regular cleaning of the forehead rest with a soft cloth and alcohol is strongly recommended. The forehead rest is the only part of the machine that comes into contact with the patient.

VIII.2 - Replacing the Printer Paper

The printer is mounted on the right side of the VX90 unit. If the paper roll is used up, the **Printer** LED indicator blinks.

To insert a paper roll into the printer:

- Lift the handle in the middle of the paper compartment and pull the cover down.
- If an empty paper roll is in the printer, remove it.
- Insert the new roll with the end of the paper at the top of the roll.
- Feed the paper into the slot at the top of the compartment.
- Push the paper-compartment door closed.

VIII.3 - Replacing Fusible

Specification : F1AL250V fuse

Position:

VIII.4 - Model eye measurement

The model eye should be measured and the accuracy checked at regular intervals.
To set up the model eye, insert the guide groove of the model eye to the chinrest tissue pin.

Set the display step of spherical/cylindrical to 0.12D and perform measurement.

2. Position the model eye

Take down the chin rest paper, alignment the holes of the model eye base and chin rest pad and then insert the chin rest tissue fixed pins.

3. Measuring position adjustment and focus

When the model eye is positioned, move the joystick back and forth to focus until there are eight luminous points appear.
Carefully move the joystick up and down, left and right, until there is a red centering mark appearing.

4. Measuring

As mentioned above, adjust the position of model eye and focus, then press the measure button.

If the measurement result is not within the tolerances given on the model eye, call your dealer.

IX - Appendices

IX.1 - Technical Specifications

Device Specifications

Target Fixation	Auto fog system
Measurement data display	7" TFT color LCD with touch screen (800x480)
Measurement data recording	Built in thermal printer
External output terminal	RS232/WIFI
Power source/power consumption	100V-240V AC, 50/60 Hz, 50VA
Fuses	F1AL250V
Size (L×W×H)	500x288x480 mm
Weight	14Kg
Travel	Back and forth: 40 mm sides: 90 mm Up & Down : 30 mm
Chinrest travel	+/- 30 mm

Operating conditions

Temperature	+10°C to +35°C
Hygrometry	30% to 90%
Air pressure	800 hPA- 1060 hPA

Storage conditions

Temperature	-10°C to + 55°C
Hygrometry	10% to 95%
Air pressure	700 hPA- 1060 hPA

Transport conditions

Temperature	-40°C to + 70°C
Hygrometry	10% to 95%
Air pressure	500 hPA- 1060 hPA

Measurement specifications

Power Range	-20 D to +20 D (step 0.12D/0.25D)
Astigmatism range	0 to 10D (step 0.12D/0.25D)
Axis range	0° to 180°
Axis step	1°
Pupil diameter measured	2 mm minimum (step 0.1 mm)
Retro illumination	IR light
PD Measurement	85 mm measuring range max, 1 mm display unit

Keratometry Specifications

Corneal radius range	5 mm to 10 mm step (0.01 mm)
Corneal refractory power	33D to 67D (n=1.3375) (step 0.12D/0.25D)
Corneal astigmatic power	0 to 12 D (step 0.12D)
Axis range	0° to 180°
Axis step	1°
Measurement diameter	2 mm to 12 mm
Peripheral K	4 external fixation target (nasal/temporal/superior/inferior)

IX.2 - Conformity to Directives and Standards

The VX90 complies with the Medical Device Directive 93/42/EC, as amended by Directive 2007/47/CE and is in Class Im (rationale: rule 12 active devices intended for diagnosis). CE0051 and with the RED Directive 2014/53/EU.

Lifetime of the product: 7 years

1rst CE marking: 2019-06

2.a) Electromagnetic Emissions

The VX90 is intended for use in the electromagnetic environment specified below. The customer or the user of the VX90 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The VX90 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	The VX90 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 purpose.
Harmonic emissions CEI 61000-3-2	Class A	
Voltage fluctuations / flicker emissions CEI 61000-3-3	Complies	

2.b) Electromagnetic Immunity

The VX90 is intended for use in the electromagnetic environment specified below. The customer or the user of the VX90 should assure that it is used in such an environment.

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±(2,4,6) kV contact ±(2,4,8) kV air	Complies	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	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 0.5 sec	Complies	Mains power quality should that of a typical commercial or hospital environment. If the user of the VX90 requires continued operation during power mains interruptions, it is recommended that the VX90 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 hertz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	Test level IEC 60601	Compliance level	Electromagnetic environment – guidance
Conduced RF CEI 61000-4-6 Radiated RF CEI 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2,5 GHz	3 V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the VX90, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,17\sqrt{P}$ $d=1,17\sqrt{P}$ 80 MHz to 800 MHz $d=2,33\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer and d is the recommended separation distance in meters (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 solutions. Electromagnetic propagation is affected by absorption and reflection form 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 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 the VX90 is used exceeds the applicable RF compliance level above, the VX90 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VX90.

[b] Over the frequency range 150 kHz à 80 MHz, field strengths should be less than 3 V/m.

2.c) Waste Electrical and Electronic Equipment (WEEE) Directive

This symbol indicates that the equipment incorporates electronic assemblies and other components that are subject to the Waste Electrical and Electronic Equipment Directive which advise that such electronic and electrical devices should not be scrapped as ordinary domestic waste.
To avoid environmental risks or other dangers caused by irresponsible scrapping, this product and all its accessories must be disposed of separately in accordance with the practices indicated in the WEEE Directive for EU member countries and in local regulations for other countries. For further information on disposal of this product, please contact your local dealer or the manufacturer.

2.d) Manufacturer

LUNEAU TECHNOLOGY OPERATIONS
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France

IX.3 - Contacts Information

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