



NIKI V4

Veterinary Infusion Pump

OPERATOR'S MANUAL



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LIMITED WARRANTY ON DISTRIBUTOR SOLD PRODUCT

The NIKI V4 Infusion Pump has been carefully manufactured from the highest quality components.

Caesarea Medical Electronics Ltd. Warrants that the pump will be free from defects in material and workmanship for twelve (12) months from the date of purchase by the original purchaser.

CME's or its designated representative's obligation under this Limited Warranty shall be limited, at CME's or its designated representative's option, to repairing or replacing pumps which upon examination, are found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the term of the Warranty beyond the original term set forth above.

All repairs qualifying under this Limited Warranty must be performed by qualified, trained service personnel. In the event that any pump is found to be defective during the warranty period, the purchaser shall notify Caesarea or its designated representative of any claimed defect within thirty (30) days after such defect is discovered.

The pump claimed to be defective must then be promptly delivered to CME or its designated representative for inspection, repair or replacement.

Material returned to CME or its designated representative must be properly packaged and sent prepaid. Severe pump damage may result if CME shipping cartons and inserts are not used.

This Limited Warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped pumps, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel, or damage resulting from improper shipment to Caesarea or its designated representative.

If, after inspection, CME or its designated representative is unable to identify a problem, Caesarea or its designated representative reserve the right to invoice purchaser for such inspection.

This Limited Warranty is the sole and entire warranty pertaining to CME's products and is lieu of and excludes all other warranties of any nature whatsoever, whether express, or implied or arising by operation of law, trade. Usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purposes. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.

Managing Director

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1. Introduction

This Manual Provides direction for setup and operation of the NIKI V4 Volumetric Infusion Pump.

NIKI V4 Features

- ◆ Small, light and compact pump.
- ◆ Multi Programs:

MACRO

 Macro program Infusion Rate : 1 to 999 ml/hr.
Volume : 1 to 9999 ml.

MICRO




 Micro program. Infusion Rate: 0.1 to 99.9 ml/hr.
Volume : 0.1 to 2500 ml.
- ◆ Highly accurate fluid delivery. The “**SUPER**” linear peristaltic system assures accurate volume delivery
- ◆ Rechargeable internal battery.
- ◆ Integrated Mounting Clamp for securing the pump to an IV pole.
- ◆ A.B.S. **Anti-Bolus System**
- ◆ Silent operation.
- ◆ Ultra Sonic air detection- air bubbles greater than 50 micro liters.

About This Manual:

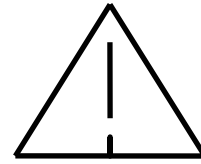
The information in this manual is presented as follows:

- 1. Introduction -**
NIKI V4 features and capabilities.
- 2. NIKI V4 Volumetric Infusion Pump Overview -**
Functional description and specifications.
- 3. Setting Up the NIKI V4 Infusion Pump -**
Instructions for unpacking and setting up the pump before operation.
- 4. Operating the NIKI V4 Infusion Pump -**
Procedures for operating .

Terms and conditions used in manual :

 NOTE	<hr/> <hr/> Operating procedure or condition that is essential to highlight. <hr/> <hr/>
 CAUTION	<hr/> <hr/> A precaution that, if not followed, could result in extensive damage to the equipment. <hr/> <hr/>
 WARNING	<hr/> <hr/> A precaution that, if not followed, can result in personal injury or loss of life. <hr/> <hr/>

Safety Precautions



WARNING


To avoid possible personal injury or loss of life, observe the following:

Note : Read and understand the entire Operation Manual before using the pump since important precautions follow throughout the text.

- Disconnect the pump from main, prior to opening the casing. Voltage present on internal components may cause severe shock or death on contact. Only trained service personnel should open pump cover.
- Before servicing pump, remove rings, watches, and other jewelry that may cause a shock / burn hazard.
- To prevent fire hazard, replace blown fuses only with fuses of same type and rating. (see fuse values on the rear Pcb close to the fuses housing) .
- The Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Watch your fingers / nails when opening the pump's door.

To avoid possible injury to patient, observe the following:

- Make sure pump is attached securely to IV pole.
- If the pump was dropped, send the pump back to be inspected by qualified service personnel.
- Before operation, verify that administration set tubing is not kinked or occluded.

 **NOTE:** The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.1 ml.




CAUTION

To avoid possible damage to the equipment, observe the following:

- Do not immerse pump in liquids.
- Clean solution spills immediately from the pump. Use a damp cloth or sponge. A cleaning disinfectant may be used. Wipe thoroughly with a dry cloth.
- Do not clean pump with chemicals such as Xylene, Toluene, Acetone, or similar solvents. These chemicals cause damage to plastic components and paint.
- Do not use pens or any other sharp object to press keys. Torn or punctured membranes expose keys to damage.

2. NIKI V4 Volumetric Infusion Pump Overview

Specifications

Pumping Mechanism:	Linear peristaltic movement
Flow Rate:	Micro - 0.1 to 99.9ml/hr in 0.1ml increments Macro - 1 to 999ml/hr in 1ml increments
Total Infusible Volume:	Micro - 0.1 to 2,500ml. Macro - 1 to 9,999ml.
Total Time Setting	99:59 hours
Accuracy:	± 5%.
KVO rate:	0.1 to 5 ml/hr.
Air Sensor:	Ultrasonic
Maximum Pressure:	0.7 bar or 10 psi Adjustable (high, normal, low)
Power Supply:	100-240 V, 50/60 Hz. 10w 0.3A max.
Battery:	Nickel-Cadmium 7.2V, 0.9Ah.
Battery Operation at 125 ml/hr:	16 hours
Battery Charging:	Automatic when connected to an AC power source (12 hours)
Alarms:	Bad System Low & End Battery Push Run Air Fill Set Bad set High Pressure (HI PrES) (down occlusion) Door Open End of Program (FIN) Loc
Dimensions:	138 x 138 x 72mm. 5.4" x 5.4" x 2.8" (l x w x h).
Symbol 	Attention (Consult accompanying documents)
Classification	Type CF Equipment (Degree of protection against electrical shock)
IPX4 CLASS 1	Protected against splashing water (Degree of protection against liquid ingress)

Housing:	ABS (with fire retarded)
Memory Retention	All calibration and set information will be retained in the pump memory for a minimum of 10 years.
Electrical Safety	Comply with EN-60601-1 (medical electrical equipment safety), IEC60601-2-24 (Infusion pumps and controllers).
Standards	Manufactured in accordance to ISO 9001:2000 and ISO 13485:2003 CE marked (In accordance with the Medical Devices Directive 93/42/EEC)
Weight	1100 gr. 2.5 pounds

Specifications – Technical Description

The following details outline the safety checks designed into the NIKI V4 infusion pump, to minimize the possibility of under / over infusions.

Anti-Bolus Function

The anti-bolus function is designed to reduce the bolus that may occur upon the release of an occlusion following a downstream occlusion alarm. Upon the detection of a downstream occlusion, indicated by a “PRES” alarm, the pump returns the IV set line pressure to neutral within 15 seconds. Reverse operation of the pumping mechanism and measurement of the IV set line pressure through the in-line pressure detection system achieve this neutral line pressure. This feature can prevent the inadvertent fluid bolus to the patient that can occur upon the release of an occlusion, which may be caused by a downstream clamp.

Battery Management System

To manage the recommended charge and discharge cycle for the internal Nickel Cadmium batteries, an automatic battery management system is provided with the NIKI V4 infusion system. This battery management system is designed to reduce the amount of preventative maintenance required for the pump and prolong the life of the internal Nickel Cadmium batteries. This system automatically activates a discharge and charge cycle of the batteries after 1500 hours of pump operation. The activation and operation of the cycle is indicated to the user by the presence of the “b” message on the front panel display. The system will only be activated when the pump is connected to main supply. During this process, the pump should remain connected to a mains power source. If it is desired to perform this process manually, the battery management system can be de-activated through the configuration mode. If de-activated, the pump will not automatically initiate a discharge and charge cycle after 1500 hours of operation. If this system is deactivated, insure that a proper preventative maintenance schedule is followed including a manual battery discharge and charge cycle to prolong the life of the internal batteries.

Air-in-Line Accumulation

To improve the detection of air in the IV administration set, the NIKI V4 infusion pump utilizes an air-in-line accumulation detection system in addition to the standard single bubble detection. This feature monitors the volume of air that passes through the IV administration set by accumulating the volume of individual bubbles over a moving 0.5-milliliter window. The limit is configurable. Although an individual bubble may not exceed the pre-programmed threshold, the additive volume of bubbles in a 0.5-milliliter volume may exceed that limit and initiate an air-in-line alarm. This accumulation feature is particularly useful with infusions for patients that are highly sensitive to air or when infusing products that create significant volumes of small air bubbles.

Specifications – Trumpet and Flow Rate Curves

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations cause short – term fluctuations in rate accuracy.

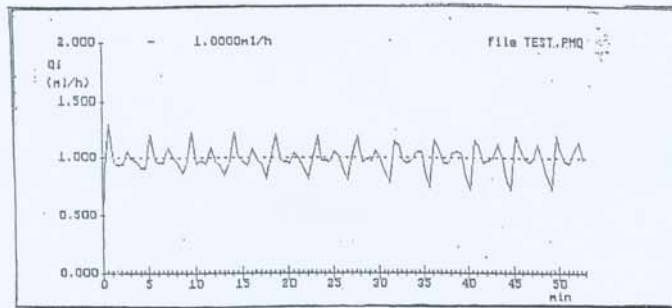
The following curves show typical performance of the system in two ways:

1. The accuracy of fluid delivery over various time periods is measured (trumpet curves).
2. The delay in onset of fluid flow when infusion commences (start up curves).

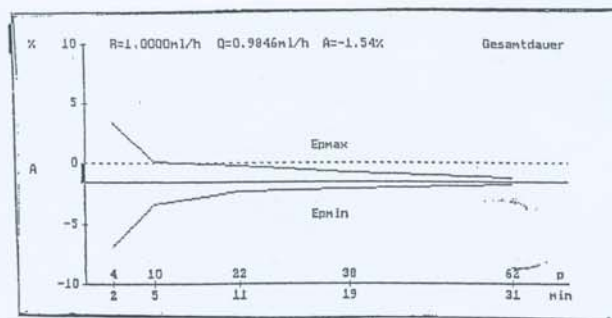
Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or “observation windows”, not continuous data versus operating time. Over long observation windows, short-term fluctuation has little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effects as represented by the “mouth” of the trumpet.

Knowledge of system accuracy over various observation windows may be interesting when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on the half-life of the drug being infused and the degree of inter vascular integration; the clinical effect cannot be determined from the trumpet curves alone.

The start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Test performed according to IEC 601-2-24 standard.

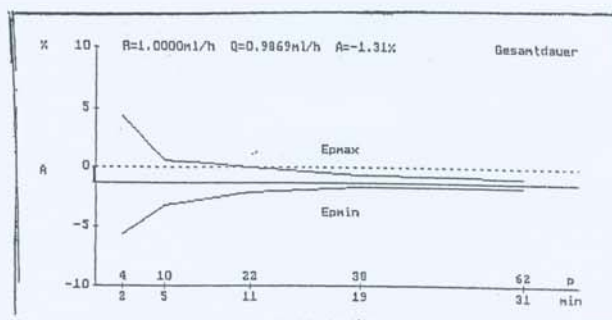


Start-up Graph at 1.0 ml/h (Initial Period)



Observation Window (min.)

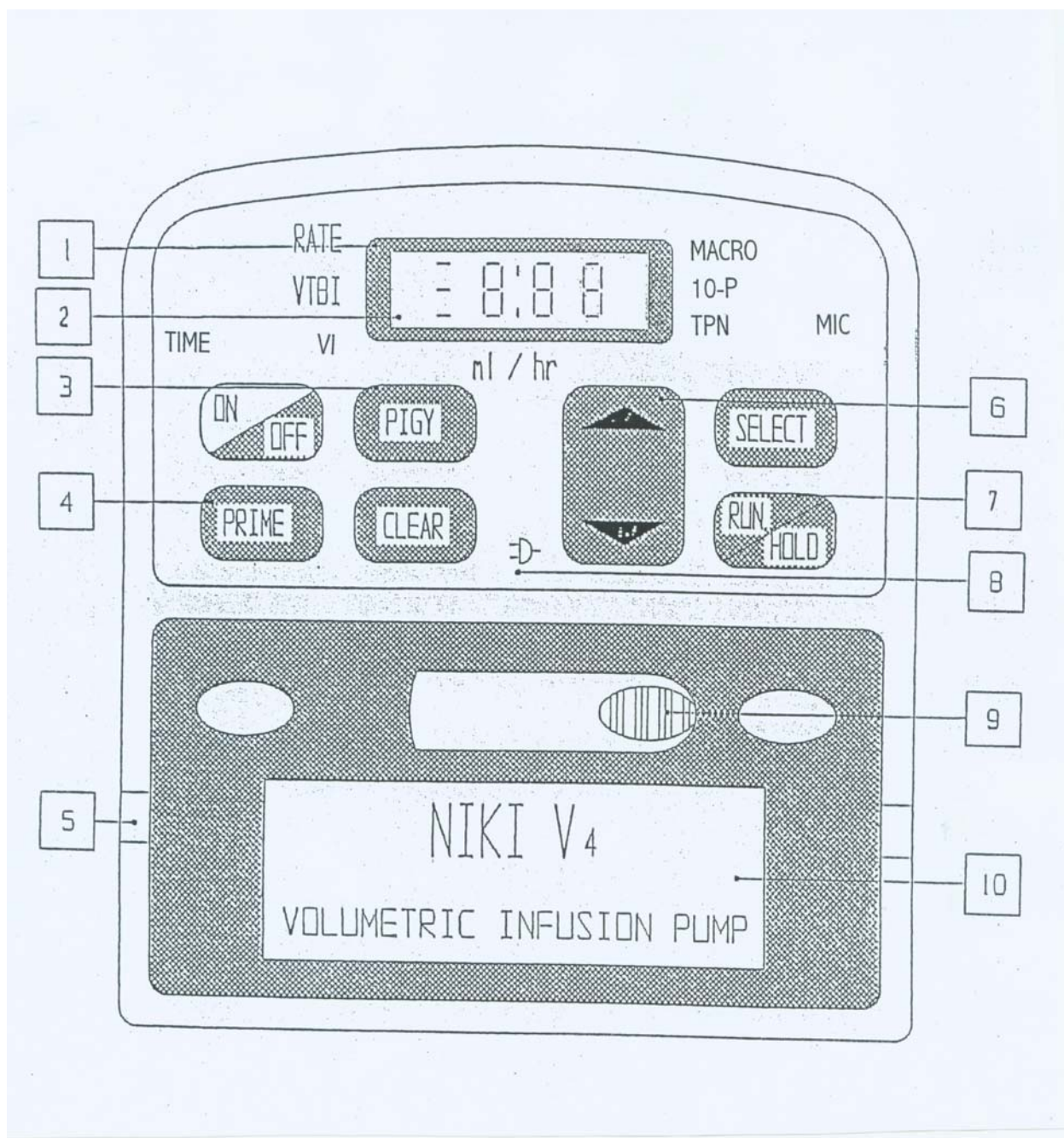
Trumpet Graph at 1.0 ml/h (Initial Period)
Overall Mean Error = -0.1% Max Rate Error = 8%

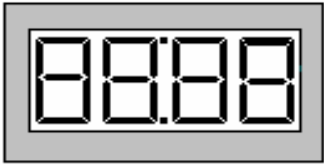








Observation Window (min.)

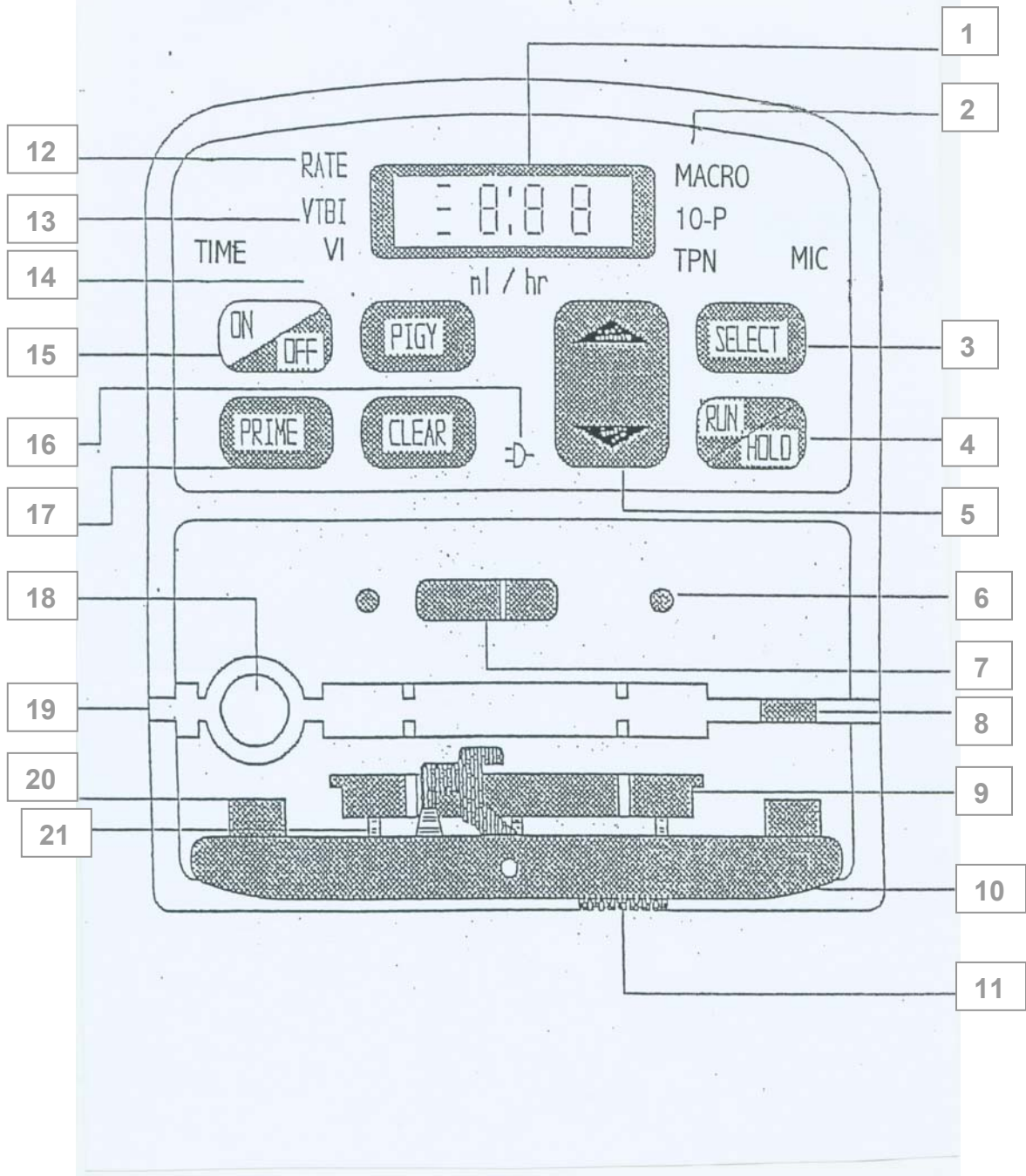
Trumpet Graph at 1.0 ml/h (After 24 Hours)
Overall Mean Error = -1.1% Max Rate Error = 5%

Front Panel – Control and Indicators



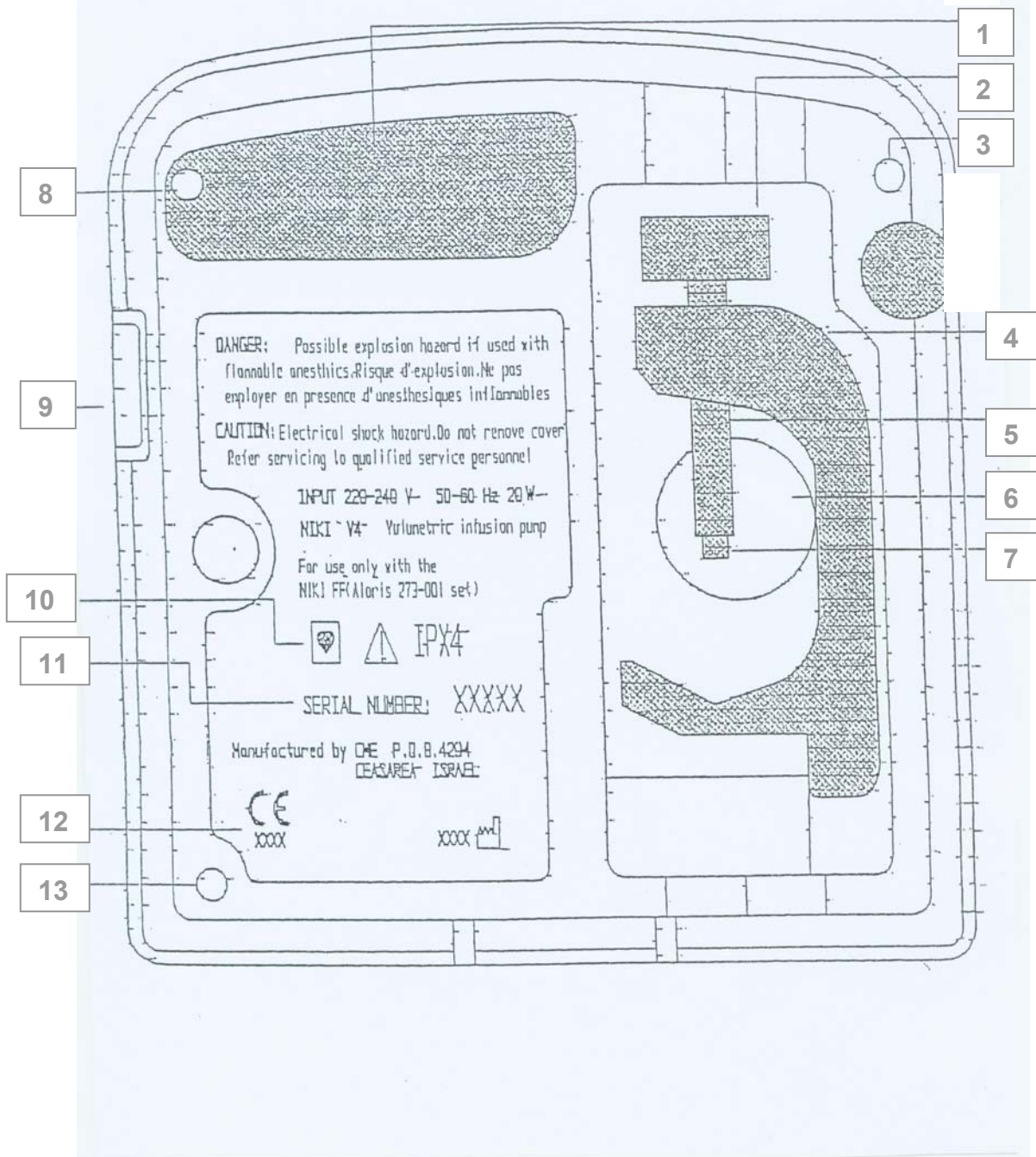
No.	Description	Function
1.	Display 	<ul style="list-style-type: none"> Displays selected infusion rate, total time, volume to be infused, and volume infused. Whenever the pump is operated on battery, the display will blink on and off.
2.	Cursor 	<ul style="list-style-type: none"> The cursors indicate that the set program is running.
3	Piggy key 	<ul style="list-style-type: none"> Sets a PIGY program <ul style="list-style-type: none"> - Single Pigy program - Auto Pigy program
4.	Prime key 	<ul style="list-style-type: none"> Automatically primes the administration set Unprimed set- priming volume 16 ml. Partially primed set- priming volume 5 ml.
5.	Tubing Guide	<ul style="list-style-type: none"> Guide the administration set.
6.	Arrow keys 	<ul style="list-style-type: none"> Increases / Decreases the infusion RATE, TIME limit, and VTBI. Continue to press the arrow key to increase the setting steps and speed.
7.	RUN / HOLD Key 	<ul style="list-style-type: none"> Starts or stops pump operation and delivery. Hold may be used to silence an alarm condition and pause priming.
8.	Charging Indicator 	<ul style="list-style-type: none"> Lights when pump operates on AC power and battery is being charged.
9.	Door Latch	<ul style="list-style-type: none"> Opens and closes the pump door.
10.	Door Label	<ul style="list-style-type: none"> NIKI V4 VOLUMETRIC INFUSION PUMP

Front Panel – with Door Open



No.	Description	Function
1.	Display	LED display
2.	MACRO	The pump is operating in the Macro program.
3.	SELECT key	Used to scroll between rate, time, volume to be infused, and total volume infused.
4.	RUN / HOLD key	Start/hold the program
5.	Arrow key	Setting the desired values for rate, time and vtbi.
6.	Pumping block mounting screw	Connect the pumping block to the front housing.
7.	Latch holder	Holds the door closed when latch is positioned Horizontally.
8.	Pressure sensor	<ul style="list-style-type: none"> • Detects downstream tubing restriction and occlusion. • The alarm level can be adjusted to suit the needs of the hospital department.
9.	Press plate	Connected to the door by 3 springs.
10.	Pump door	Covers the press plate.
11.	Recessed latch	Push to open door.
12.	RATE	The rate message indicates that the figure shown on the display is the current rate.
13.	VTBI	The volume to be infused.
14.	VI (Volume Infused)	The accumulated infused volume, from the time the CLEAR key was last pressed.
15.	ON/OFF key	Switches the pump on and off.
16.	Charge indicator	Lights when pump is connected to main.
17.	PRIME key	Pressing the prime key, at the data setting stage, after door open or air alarm, will remove air from administration set.
18.	Air sensor	Ultrasonic air detector, mounted on the front housing.
19.	Tubing Guide	Guide the Administration set
20.	Air sensor	Mounted on the door.
21.	Door springs	Located between the door and press plate.

Rear Panel



	Description	Function
1.	Pump handle	Pump carrying handle
2.	Pole clamp handle	Fixing the pump to an IV pole
3.	Pump mounting screw	Used to assemble/disassemble the housing
4.	Pole clamp	Mounts the pump on the IV pole
5.	Pole clamp screw	Turn clockwise to secure the pump to the IV pole
6.	Buzzer	Sounds an acoustic alarm
7,	Pole screw adapter	A plastic tip to assure connection to the IV pole
8.	Pump mounting screw	Same as 3
9.	Electrical cord connector	Attachment for AC power cord 100-240v 50/60 Hz
10.	CF protection	Pump safety classification
11.	Serial number	Display's the serial number of the pump
12.	CE marking	Admission to market the NIKI V4 pump in Europe
13.	Pump mounting screw	Same as 3

Priming Function


Priming Function is used:

1. Before starting a program.
2. After **air in line** alarm. Disconnect IV tubing from patient, press “PRIME” key to push air bubbles through.

Priming Function Operation:

1. Switch On the pump using **ON/OFF** key.
After a short self test the pump will display ON followed by the last rate setting.

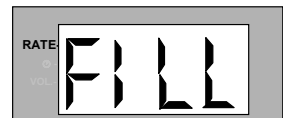


-  **WARNING:** Make sure the IV set is not connected to patient.

2. Press **Prime**.



3. The display will show FILL.





4. Once the priming is completed, the display will change from FILL to the last rate setting.



5. Press the RUN/HOLD key to start operation.




-
-  **NOTE:** The pump will prime 5 ml instead of 16 ml in case the set is partially primed.
-

-
-  **NOTE:** The priming program is performed at a rate of 1000 ml/h. During priming the air in line alarm is disabled.
-


3. Setting up the NIKI V4 Volumetric Infusion Pump


Site Requirements

The pump power cord should be connected to a grounded AC outlet furnishing.

 **WARNING** Any adjustments, maintenance, or repair of the uncovered pump under voltage, should be avoided. If necessary, these repairs should be carried out by skilled technicians who are aware of the hazards involved.

The pump should be operated within a temperature range of 15°C (50°F) to 45°C (115°F).

 **WARNING** Do not operate pump near equipment that emits high-energy radio frequencies, such as electro-surgical cauterizing equipment, and cellular telephones. False alarm signals may occur.

 **NOTE:** Read and understand the entire Operation Manual before using the pump since important precautions follow throughout the text.

Unpacking

1. Carefully remove the pump from the box
2. Make sure no items were damaged during shipment
3. Make sure you have the following items:
 - NIKI V4 Volumetric Infusion Pump
 - Operator's Manual

If any items are missing or damaged, contact your NIKI V4 dealer.

Before Operating the Pump

1. Mount the pump on an IV pole.
2. Connect a standard power cord to a grounded AC outlet.
3. Insert administration set into the pump's tubing guide.

4. Operating the NIKI V4 Volumetric Infusion Pump Startup Test

Before attaching the NIKI V4 to a patient, run a startup test to verify that all indicators and alarms work properly.

When an alarm is activated the following will occur:

1. An alarm message appears on the display.
2. An audible alarm sound.
3. The infusion is stopped.


Pump Operation Test:

1. Connect the pump to AC power. Verify that the CHARGE indicator is on.
2. Insert an administration set into the pump.
3. Switch on the pump by using the ON/OFF key. The pump will display **ON** and perform a self-test. Verify that a long beep sound is heard and that all the leds and messages on the display are on for 2 sec. (CHARGE indicator stays on constantly).



4. Prime the set using the PRIME key.



-  **WARNING:** Make sure the IV set is not connected to patient.

5. During priming the display will show " FILL "



6. Verify that a "PUSH RUN" alarm appears on display after one minute.



7. Press the RUN/HOLD key to silence the alarm.



Air in Line Alarm Test:

1. Press on the door's latch to open pump's door. Insert administration set in the pump's tubing guide.

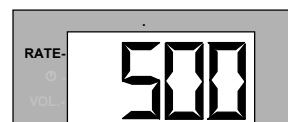


press here

2. Close the door. Press on the door recessions until a click is heard.



3. Set the infusion rate to 500ml/hr. Use the arrows key.



4. Press the RUN/HOLD key to start operation. Turn the drip chamber, up side down, to allow 5 mm of air to enter into the administration set.



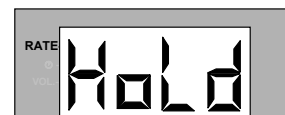
5. AIR alarm will activate as soon as the air bubble enter the set segment located behind the pumping door.



7. Press the RUN/HOLD key to turn the alarm off.



8. HOLD appears on the display.



Door Open Alarm Test:

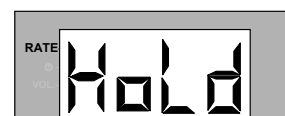
1. Insert primed administration set into the pump.

2. Press the RUN/HOLD key to start operation.



4. Close the door.

5. HOLD appears on the display.



High Pressure (Occlusion) Alarm Test:

1. Occlude the administration set. Press the RUN/HOLD key to start operation at a rate of 200 ml/hr.



2. After 10 seconds HI PRESSURE alarm will activate.
(at a rate of 60 ml/hr the high pressure alarm will occur after 60 sec. at a rate of 1 ml/hr after 13 min.)



3. Press RUN/HOLD key to silence the alarm.
4. HOLD appears on the display.



NOTE The pressure threshold can be changed to suit the ward need, (see Changing the current default "Pressure" Limit to another on page 26).

Charge Indicator Test:

1. Disconnect the power cord from the AC power outlet.
2. Verify that the CHARGE indicator is off. After one second, the display starts flashing constantly to indicate that the pump is operating on battery power.
3. Connect the power cord to the AC power outlet. Verify that the CHARGE indicator is on, and the display has stopped flashing.



Tailoring the Pump to the Hospital Needs

Changing the current default Program to another:

1. Press **SELECT** key continuously.



2. Switch on the pump using the ON/OFF key.



3. Release the **SELECT** key once **SLCT** shows on display




4. Using the SELECT key, scroll through the different programs and choose the desired program from the following choices:

MICRO

MACRO

5. Press the RUN/HOLD key, in order to store the parameter in the pump's memory.



 **NOTE** The selected program will remain in the pump's memory until changed again.

The programs

The NIKI V4 volumetric infusion pump features 2 different programs.

Following are the specifications for each program:

MACRO program.

Rate: 1 to 999ml/hr
Total volume to be infused: 1 to 9999ml.

MACRO

MICRO program.

Rate: 0.1 to 99.9 ml/hr in 0.1ml increments.
Total volume to be infused: 0.1 to 2500 ml.

MICRO

Changing the current default “Pressure” Limit to another:

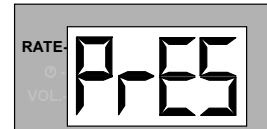
1. Press SELECT key continuously.



2. Switch on the pump by using the ON/OFF key.



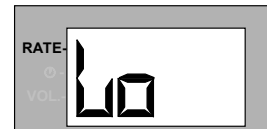
3. Press the RUN/HOLD key, PRES shows on display for one second, thereafter the current pressure will appear.



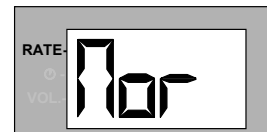
4. By pressing the SELECT key scroll through, and choose the desired limit.

 **NOTE** The following pressure parameters can be set:

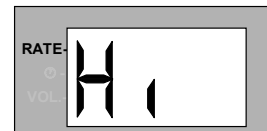
Low = 0.3 bar. (5 psi)




Normal = 0.5 bar. (7 psi)




High = 0.7 bar. (10 psi)



 **NOTE** The selected pressure setting will remain in the pump's memory until changed again.

5. Press the RUN/HOLD key, in order to store the parameter in the pump's memory.

 **NOTE** The pump has an antibolus system, which prevent a bolus delivery to the patient, once a downstream occlusion is released.

Basic Operation

1. Place the IV pole and the pump near the patient.
2. Connect the pump to an AC power outlet.
3. Verify that the administration set is set up correctly.
4. Switch on the pump using the ON/OFF key.
ON will appear on the display followed by the last rate setting.
5. The preset program will appear on the right side of the display.
6. Press the ARROW keys to set the requested infusion rate.



- ☞ **NOTE** Press the arrow up key to **increase** the units. The arrow down **decreases** the units.

Press continuously the ARROW keys to set the infusion rate quickly.

7. Prime the set if necessary, use the **PRIME** key.

- ☞ **WARNING:** Make sure the IV set is not connected to patient.



8. To set the TIME and VTBI :

- Press the SELECT key , then use the arrow keys to set the TIME limit.
- On the left side of the display, the word **RATE** will change to **TIME**.



The pump will automatically calculate the Total Volume.

- Press SELECT key again, to set the VTBI (optional)
- The pump will automatically calculate the Total Infusion Time.



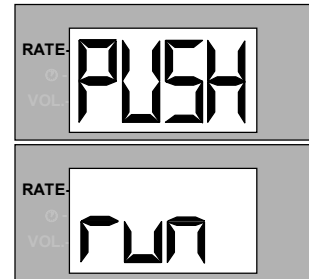
-
-
- ☞ **NOTE:**
- A “9999” can be changed to a “0” by pressing the up arrow keys.
 - Setting either the TIME or VTBI functions, avoids an Empty Fluid Container problems.
-
-

9. Press the RUN/HOLD key to begin infusion.



-
-
- ☞ **NOTE:** If the RUN/HOLD key is not pressed within one minute, a “PUSH RUN” alarm appears on display.

Press RUN/HOLD key to stop the alarm.
The display will show HOLD.



10. Verify that the infusion is proceeding normally before leaving the pump unattended.

-
-
- ☞ **NOTE:**
- To change any parameter during operation, first press the RUN/HOLD key, HOLD appears on display. Use the Select key to scroll throughout the various settings.



Set the desired rate, time or VTBI, press

- RUN/HOLD key to start operation.

The pump’s memory retains all parameters even if it was turned off.

“TIME REMAIN” Display - During Operation

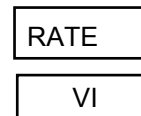
1. Pressing the SELECT key during operation causes the displayed “RATE” to change for 5 seconds to “**Time Remains** hr: min”



- ☞ **NOTE:**
- “Time Remain ” is stored even if the pump was switched OFF.
 - “Time Remain ” Will automatically adjust if Total Volume is changed during operation.
 - If TIME function is OFF, in technician mode, the TIME function will not be available.
 - “Time Remain.” Will not display if total time is more than 100 hours.
-

“VOLUME INFUSED” Display.

1. Pressing the SELECT key during operation causes the displayed rate to change for 5 seconds to the accumulated volume **infused**.



“VTBI” Display

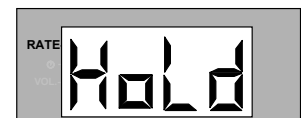
1. Pressing the SELECT key **twice** during operation causes the displayed rate to change for 5 seconds to **left** “VTBI”



- ☞ **NOTE:**
- The VTBI and INFUSED volume will automatically reset to zero, once it reaches 9999 ml.
 - The volume INFUSED , can be zeroed only using the CLEAR key.
 - When a program was completed the VTBI will reset to the original setting
-

Changing Infusion Rate During Operation

1. Press the RUN/HOLD key to hold the operation of the pump, HOLD will appear on display.



- ☞ **NOTE:** Use the Select key to display current data : Rate, Time left, VTBI, Infused volume.
-



2. Set the desired infusion rate using the arrow keys. Pressing continuously will increase the speed and steps of changes.

3. Press the RUN/HOLD key to renew operation.



The “Locking” Option

The NIKI V4 has a unique option, which enables the user to lock out the setting keys, so that entered parameters, or set programs cannot be changed once they are set, especially during operation.

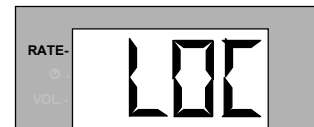
In the case of the P-10 program, once locking the set programs, it will remain in the pumps memory for the next use, even if the pump is switched off.

Locking and unlocking:

The NIKI lock out function disable all but the select key, while the pump is operating. To lock out a program:

At any time during operation simultaneously press the arrow up and arrow down. The display will show “Loc” accompanied with a short beep.

To de-activate or exit lock-out function, simultaneously press the arrow up and arrow down, the display will show Loc Off.

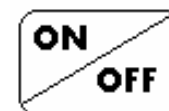


NOTE This option can only be activated while the pump is in operational state.

Changing the fluid container

Important: Use aseptic technique according to hospital protocol

1. Ensure that pump is not infusing by placing pump in HOLD mode or turning pump OFF.



2. Remove bag spike on IV set from empty / used container. Discard empty / used container according to hospital protocol.

3. Prepare new container per hospital protocol and insert spike into new container.

4. Squeeze drip chamber to fill approximately half full with fluid.

5. Restart infusion.

Battery Operation

The NIKI V4 can operate on battery power, enabling operation when the patient is being moved or during electrical power failure. When the pump runs on battery power, the CHARGE indicator is off and the display flashes.

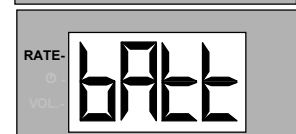
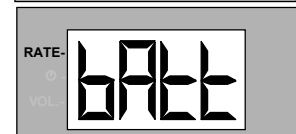
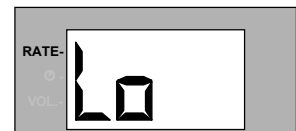
At full charge, the battery provides 16 hours of operation at an infusion rate of 125ml/hr.

When the pump is not in use, plug the pump's power cord to an AC wall outlet (If possible) to retain battery charge. If the pump is out of service for a long period, discharge (to prevent the NI-CAD memory effect) and recharge the battery periodically (at least once a month - this will insure long battery life) .

Important: Upon receipt, or following long periods of storage, it is necessary to wait 5 minutes after the pump been connected to the power supply before operating on AC power.

There are two battery alarm conditions:

- Approximately 15 minutes before the battery runs out, a beep sounds every 15 seconds and a signal LOW BATTERY message appears on the display.
- If the battery runs out, END BATTERY appears on the display. The pump stops operating.



Caution: Leaving the battery in a discharged state for a long period of time may damage the battery.

Whenever possible, operate the pump on AC power. This preserves battery power supply for when it is needed.

Replace the battery once every 4 years.


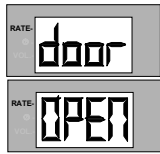

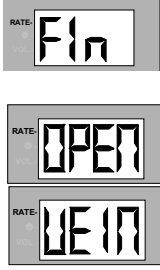
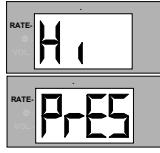
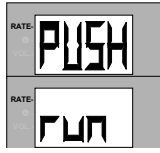
Alarms:














When the pump detects a malfunction, an alarm is activated. The “Troubleshooting Table” describes the pump’s alarm conditions.

When an alarm is activated the following will occur:

- An alarm message appears on the display.
- An audible alarm sounds.
- The infusion stops.

Troubleshooting

Alarm	Description	Result	Possible Cause	Remedy
	Air in line.	Infusion is stopped.	Air is present in administration set.	Disconnect administration set from patient. Release air bubble from administration set using prime key.
	Door is open.	Infusion is stopped.	The door of the pump was not closed prior to operation, or was accidentally opened	Close pump door and restart operation.
	The pump is priming the administration set			Set infusion Parameters and press RUN/HOLD to re-start infusion.
	Pump completed pre-set total volume (changes to KVO mode- Keep Vein Open).			<ul style="list-style-type: none"> • Press RUN/HOLD to restart infusion. • Switch off the pump to terminate infusion.
	Down stream occlusion causing high pressure on pressure sensor.	Infusion is stopped.	<ul style="list-style-type: none"> • Administration set is kinked. • Intravenous catheter position is not correctly in vein 	<ul style="list-style-type: none"> • Replace or straighten administration set. • Assure proper placement of IV catheter
	1 Minute in STOP position RUN/HOLD key was not pressed.			<ul style="list-style-type: none"> • Press RUN/HOLD to continue infusion • Switch off to terminate Infusion.

Alarm	Description	Result	Possible Cause	Remedy
 	Message displayed in the TPN programs, that the parameters entered are incorrect and cannot be calculated by the pump.			Re-enter higher volume parameter, and begin program.
 	Message displayed showing \pm 15 minutes left of battery operation.		Internal battery voltage less than 5.7V.	Reconnect pump to AC power. Recharge battery.
 	Displays when battery runs out.	Infusion is stopped.	Battery is depleted.	Reconnect pump to AC power. Recharge battery.
 	Mechanical or electrical problem.	Infusion is stopped.		Switch the pump off and CALL FOR SERVICE.
 	The pump has detected an Unprimed set.		•Unprimed set	Prime the set
 	The pump has detected a unsuitable set.		Using non-calibrated wrong set	Change to the set the pump was calibrated to.
	Pump is in lock-mode.			Press simultaneously the two arrows.