SAFIRA

Instructions for Use (en)

MEDOVATE
Developing Innovation

(English)

Definition:

The SAFIRA System (SAFIRA) consists of a sterile SAFIRA Syringe (20ml), SAFIRA Driver and a SAFIRA Operator.

The SAFIRA Syringe may be manually engaged and disengaged to the gearing of the SAFIRA Driver unit.
The battery operated SAFIRA Driver is activated by means of a cable connected SAFIRA Operator.
Flowrates are limited by design to a maximum of 0.5ml/sec.
Approved needle types and extension tubing may be attached to the connection interface at the end of the SAFIRA Syringe.
The SAFIRA System is to only be used in conjunction with the single use SAFIRA Syringe.
The SAFIRA Driver's internal battery power will perform 200 procedures.

Indications for Use:

The Medovate SAFIRA System is intended for use by trained clinicians to administer local anaesthetics below a specified pressure threshold to a target nerve bundle for regional anaesthesia.

Approved Needle Types:

Anaesthesia needles, which fall into the following ranges, have been approved for use with SAFIRA:

- The minimum sized needle gauge approved for use with this system is 22G.
- The maximum length of the needle approved for use with this system is 120mm.

Contraindications:

SAFIRA is not intended for the following uses:

- Intravascular delivery.
- Delivery of blood, blood products, lipids, fat emulsions or Total Parenteral Nutrition (TPN).
- Infusion of fluids that will enter or contact circulatory blood or cerebrospinal fluid.
- Delivery of life-supporting medications where under– or over-delivery may cause serious injury or death.
- Use with Neonates and Paediatrics.

Warnings:

1. Sterile technique should be used at all times during syringe filling, needle introduction and connection. Aseptic technique should be used for removal.
2. Medications or fluids must be administered per instructions provided by the drug manufacturer. Physician is responsible for prescribing drug based on each patient's clinical status (such as age, body weight, disease state of patient, concomitant medications, etc).
3. Make sure the medication being infused is approved for Regional Anaesthesia / PNB's (e.g. Lidocaine); follow all labelling instructions for medication use.

Warnings (continued):

4. SAFIRA is MRI unsafe.
5. Opening injection pressure varies among different tissues, being the highest when the needle tip is lodged in low compliance tissue (e.g., roots of brachial plexus, tendon) and lowest when injected in the soft connective tissues (e.g., adipose tissues, perineural space). SAFIRA limits the injection pressure to less than 20psi.
6. The SAFIRA Syringe is designed for single use in one patient and must not be re-sterilised, reconditioned or re-used. Re-use of the SAFIRA Syringe risks infection (due to accumulation of pathogens in the device that are subsequently injected) or potentially hazardous drug effects (due to residual drug compounds contaminating the intended drug and then being injected).
7. No modification of this equipment is allowed.
8. This product can expose you to chemicals including Ethylene Oxide which is known to the State of California to cause cancer and/or birth defects or other reproductive harm.
   For more information, go to www.P65Warnings.ca.gov

Precautions:

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

1. SAFIRA has no user serviceable parts. **Do not attempt to repair or alter the device.**
2. The SAFIRA Syringe component is disposable and must be discarded after use in accordance with hospital, administrative and /or local government policy.
3. Do not use the SAFIRA Syringe if the packaging is open or damaged or if the sterile barrier is compromised.
4. The SAFIRA Syringe component is single use only.
5. The SAFIRA Driver component is a limited re-use device.
6. Flow rates may vary due to fill volume, viscosity and/or drug concentration, positioning the SAFIRA Driver above or below the injection site, and temperature.
7. Start delivery within 8 hours of filling the SAFIRA Syringe. Storage of a filled SAFIRA Syringe component for more than 8 hours may result in slower flow rates.
8. SAFIRA is not made with natural rubber latex.
9. SAFIRA is only to be operated by a trained Health Care Professional.
10. The SAFIRA Syringe is not intended for measurement use.

SAFIRA System Instructions For Use

SAFIRA consists of 3 separate components. They are the **SAFIRA Syringe**; the **SAFIRA Driver**; and, the **SAFIRA Operator** (all pictured and labelled below). Please note that not all of the listed components may be available in all territories, please contact your local distributor for further details.

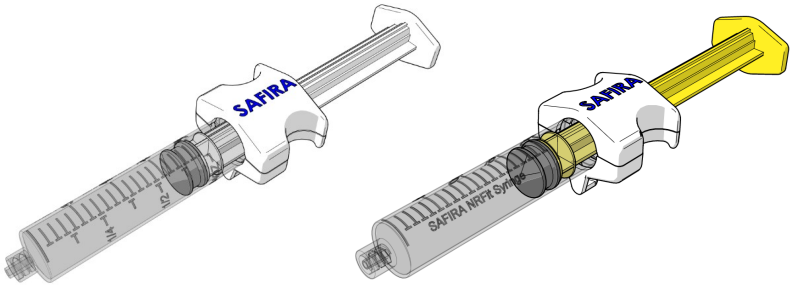


Diagram #1: SAFIRA Syringe
SAFIRA Luer Syringe (Left) and SAFIRA NRFit Syringe (Right)

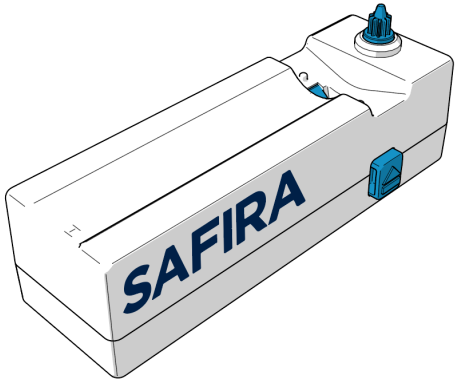


Diagram #2: SAFIRA Driver

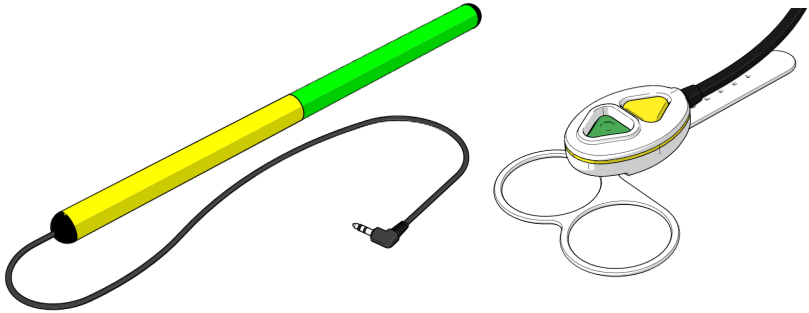


Diagram #3: SAFIRA Operators
SAFIRA Foot Pedal Operator (Left) and SAFIRA Palm Operator (Right)

SAFIRA Syringe Definition:

The SAFIRA Syringe is available in two variants defined by its barrel connection type. One variant uses a Luer connection and the other an NRFit connection. All variants of the SAFIRA Syringe are compatible with the SAFIRA Driver. The different variants are shown below:

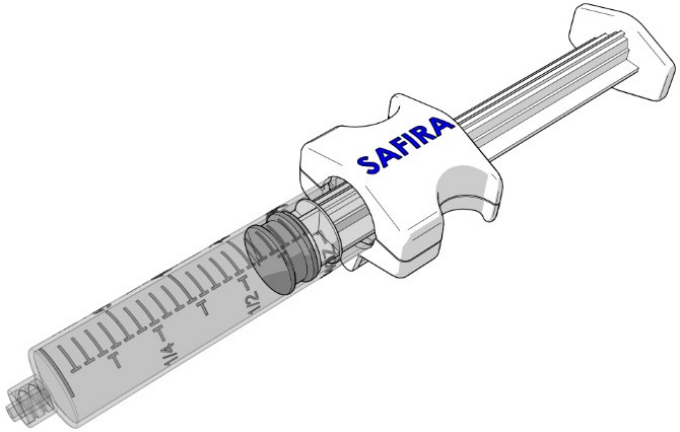


Diagram #4:
SAFIRA Syringe (Luer Connection)
White plunger

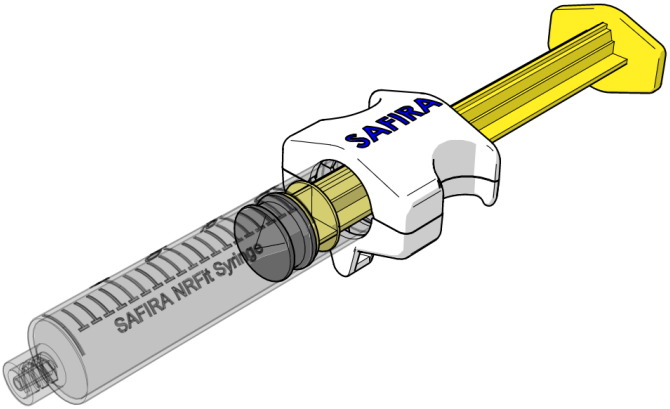


Diagram #5:
SAFIRA Syringe (NRFit Connection)
Yellow plunger

SAFIRA Operator Definition:

The SAFIRA Operator is available in two variants. The SAFIRA Foot Pedal Operator is a foot controlled operator than sits on the floor during the procedure, whilst the SAFIRA Palm Operator is a hand mounted operator that is worn under the glove of the Needle Hand. The Needle Hand is the hand that controls the Nerve Block Needle.

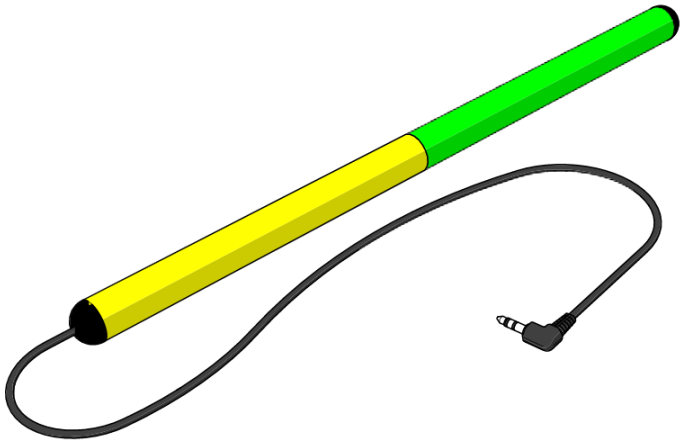


Diagram #6:
SAFIRA Foot Pedal Operator

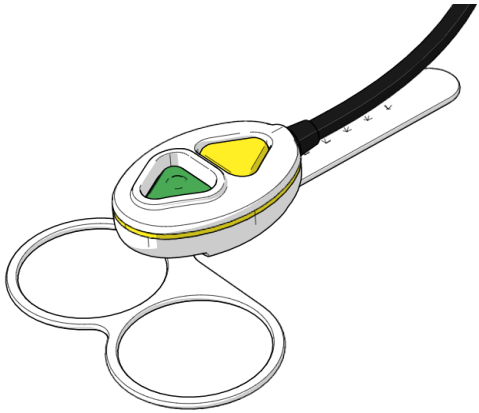


Diagram: #7:
SAFIRA Palm Operator

SAFIRA Operator Setup:

The SAFIRA Foot Pedal and Palm Operators have identical functions, but differ in their set-up.

It is recommended that the SAFIRA system should be checked for any signs of damage before use.

SAFIRA Foot Pedal Operator:

1. Attach the SAFIRA Foot Pedal Operator to the SAFIRA Driver. The SAFIRA Foot Pedal connects to the SAFIRA Driver as shown in **Diagram #8.**

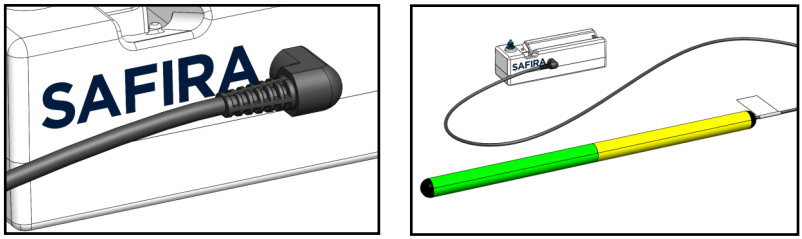


Diagram #8: SAFIRA Foot Pedal Operator plugged in

2. Place the SAFIRA Foot Pedal Operator on the floor below the surgical site in a convenient location for the Anaesthesiologist. See **Diagram #9** for reference.

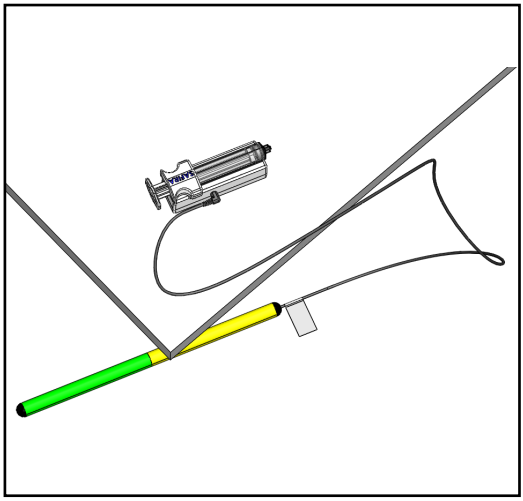


Diagram #9: SAFIRA Foot Pedal Operator placed on floor below surgical site

SAFIRA Palm Operator:

1. Mount the SAFIRA Palm Operator onto the Needle Hand. Ensure that body of the SAFIRA Palm Operator lines up with the fourth finger of the Needle Hand as shown in **Diagram #10**.

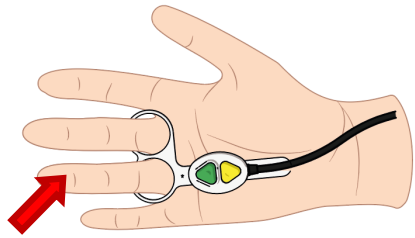


Diagram #10: Palm Operator shown in position on right hand

2. The finger grip component can be configured to fit both left and right hands. Hold the body of the Operator in one hand and pull on the finger loops of the finger grip component to separate the components. Rotate the finger grip component 180° and reinsert.

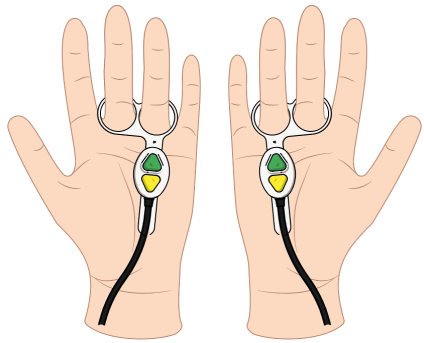


Diagram #11: Orientation for left and right hands

3. The Palm Operator body can be adjusted proximally and distally until comfortable.

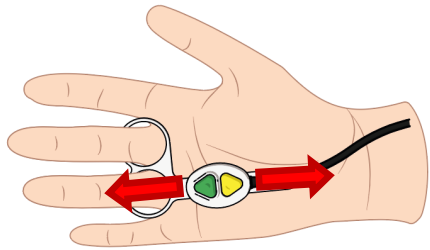


Diagram #12: Adjustment of the Palm Operator Position

4. Cover the Needle Hand with a sterile surgical glove as shown in **Diagram #13**. Check position of the Palm Operator is still in the desired position, and adjust if required.

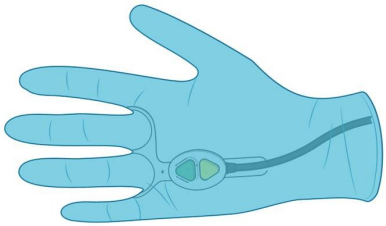


Diagram #13: Palm Operator positioned under glove

5. Attach the SAFIRA Palm Operator to the SAFIRA Driver. The SAFIRA Palm Operator connects to the SAFIRA Driver socket shown in **Diagram #14**.

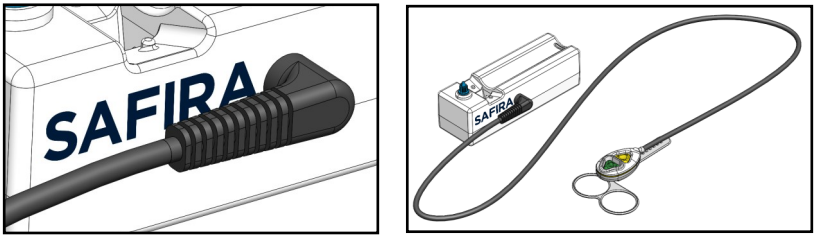


Diagram #14: SAFIRA Palm Operator connected

SAFIRA Syringe and SAFIRA Driver Setup:

1. Open the sterile package and remove SAFIRA Syringe. Use normal hospital technique to fill and prepare the syringe.

2. Connect an appropriate needle to the SAFIRA Syringe. Once secured, prime the SAFIRA Syringe, needle and tubing set to remove the air.

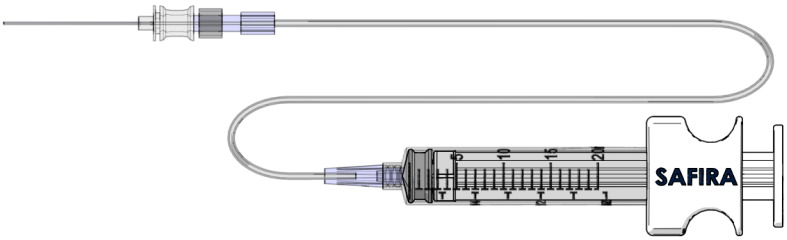


Diagram #15: Needle connected to SAFIRA Syringe

3. To attach the SAFIRA Syringe to the SAFIRA Driver; **remove protective foam cap from the SAFIRA Driver gear prior to connecting (see below).** Align SAFIRA Syringe with SAFIRA Driver as shown in **Diagram #16**. Once aligned, gently press the SAFIRA Syringe in the SAFIRA Driver. It will be seated correctly when you hear it "click" into place.

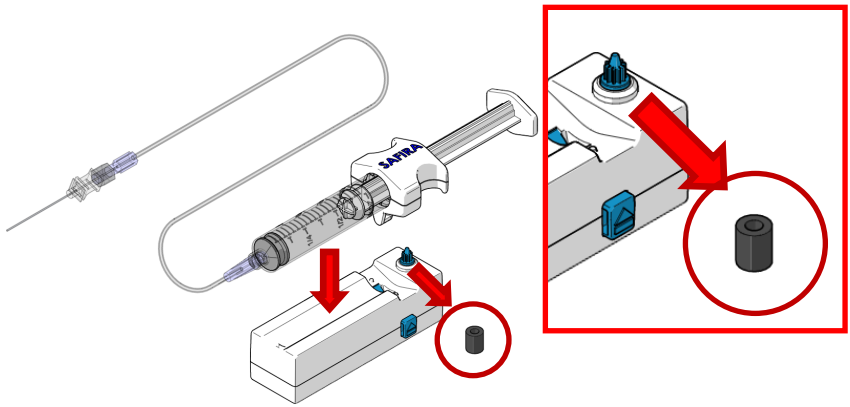


Diagram #16: SAFIRA Driver ready for connecting the SAFIRA Syringe

Check Operator Functionality:

4. Press the infuse function (green section / button, furthest from the cable as shown in **Diagram #17**) of the SAFIRA Operator to check that the tubing is correctly primed and SAFIRA System is operating as expected.

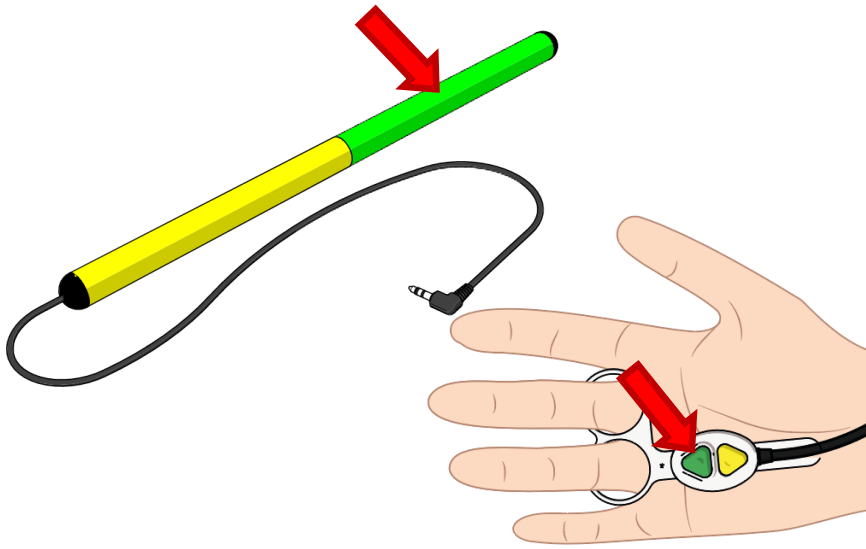
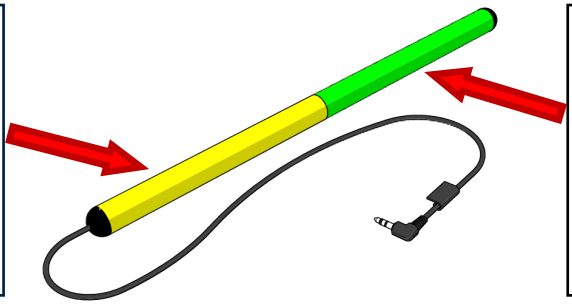


Diagram #17: Press green button / section to test function

SAFIRA Operator Functions:

5. The SAFIRA Foot Pedal Operator has two colours: **Green** = Infusion; and, **Yellow** = Aspiration as shown in **Diagram #18.**

The **"aspiration function"** is accessed by stepping on the **yellow** half of the SAFIRA Foot Pedal Operator, the end **closest to the cable**.

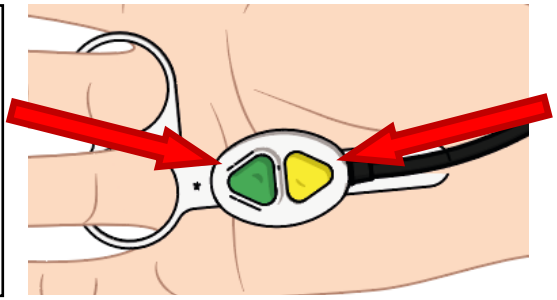


The **"infusion function"** is accessed by stepping on the **green** half of the SAFIRA Foot Pedal Operator, **furthest from the cable**.

Diagram #18: SAFIRA Foot Pedal Operator showing Infusion and Aspiration functions

6. The SAFIRA Palm Operator has two coloured button: **Green** = Infusion; and, **Yellow** = Aspiration as shown in **Diagram #19.**

The **"infusion function"** is accessed by pressing the **green** button on the SAFIRA Palm Operator, **furthest from the cable**.

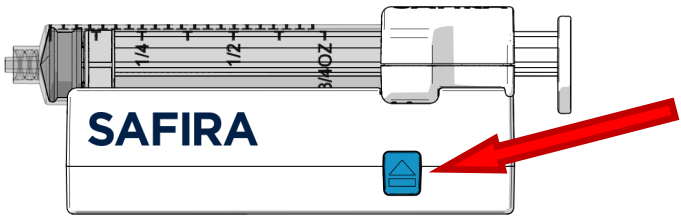


The **"aspiration function"** is accessed by pressing the **yellow** button on the SAFIRA Palm Operator, **closest to the cable**.

Diagram #19: SAFIRA Palm Operator showing Infusion and Aspiration functions

Removal:

7. In order to remove the SAFIRA Syringe from the SAFIRA Driver, press the square teal button on the side of the SAFIRA Driver as shown in **Diagram #20**. The SAFIRA Syringe will immediately release from the SAFIRA Driver.



Press square teal release button to remove SAFIRA Syringe

Diagram #20: Press square release button to remove Syringe

SAFIRA Driver Indicator Lights:

8. On the top edge of the SAFIRA Driver (refer to **Diagram #21**) colour indicator lights are displayed representing various functions in action or functions that require additional action. The indicators are as follows:

LED Colour	State	Meaning	Operator Response
Red	**Flashing** (Infusion has stopped)	**Warning:** *Immediate response* by operator is required	**Operator:** Infusion has stopped; 1. Verify needle patency and/or reposition needle to allow low pressure infusion 2. Reset SAFIRA (see steps #10 and #11 for details)
Red	**Steady** (End of Driver Life)	**Warning:** *Immediate response* by operator is required.	**Operator:** Immediately disconnect the syringe and either replace Driver or continue the procedure manually.
Green	**Steady** (Infusion Function Active)	**Normal:** System operating as designed indicating infusion activity	**Operator:** Continue infusion activity until medical result is achieved.
Yellow	**Steady** (Aspiration Function Active)	**Caution:** Aspiration occurring - system operating as intended	**Operator:** Follow Standard Precautions during use of aspiration function
No Active Light	N/A	**Normal:** System is ready for infusion or aspiration	**Operator:** N/A

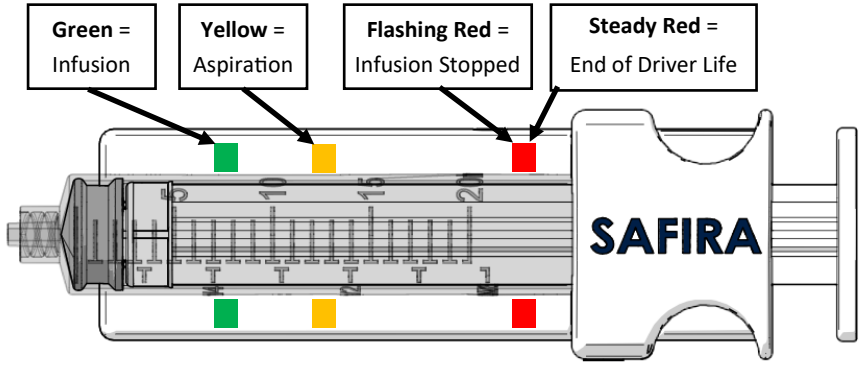


Diagram #21: Top edge of driver, illustrated with all indicators.

9. Begin the procedure following standard hospital guidelines. Throughout the injection SAFIRA is designed to limit the infusion pressure up to a maximum of 20 psi.

10. Should an infusion stoppage be encountered during the procedure, it may indicate an intraneural injection or a blockage in the fluid path. Verify needle patency and/or reposition needle to allow low pressure infusion and then **reset the Flashing Red Light / Infusion Stopped** on the SAFIRA Driver.

11. To **reset the Flashing Red Light / Infusion Stopped** on the SAFIRA Driver, follow either of the two (2) steps indicated below:

    a. **Aspirate** (Yellow area/button closest to the cable of the SAFIRA Operator) until red lights go out: or
    b. **Release SAFIRA Syringe** (see **Diagram #20**) and re-click into place

    Now the procedure can be continued.

12. When the procedure is complete, follow standard hospital protocol for the following:

    a. Dispose of the SAFIRA Syringe using acceptable standard practice for biohazard waste
    b. The SAFIRA Driver and SAFIRA Operator components should be stored according to hospital practice for reuse

End of Driver Life Indicator:

13. Once the End of Driver Life indicator on the SAFIRA Driver (steady red lights) comes on, the component should be disposed of in accordance with hospital procedure. Do not start a procedure if the end of life indicator is already on from the beginning. If the End of Driver Life indicator lights up during a procedure, immediately disconnect the syringe and either replace the Driver or complete the procedure manually.

Disposal:

For SAFIRA components, follow standard hospital protocol for disposal.

1. **SAFIRA Syringe:** Use acceptable practice for biohazard waste.

2. **SAFIRA Driver:** Should not be disposed of as unsorted municipal waste. Dispose of unit in line with local guidelines.

3. **SAFIRA Operator:** Should not be disposed of as unsorted municipal waste. Dispose of unit in line with local guidelines.

Reuse:

1. **SAFIRA Syringe:** The SAFIRA Syringe component **is not reusable** and must be discarded using standard biohazard disposal procedures.

2. **SAFIRA Driver:** The SAFIRA Driver component **is reusable** and should be wiped with gauze soaked in at least 70% isopropyl alcohol, Clinell Universal, or Clinell Clorox wipes.

3. **SAFIRA Operators**: Both SAFIRA Operators **are reusable** and should be wiped with gauze soaked in at least 70% isopropyl alcohol, Clinell Universal, or Clinell Clorox wipes.

The SAFIRA system should be inspected for cleanliness before use. Failure to follow hospital guidelines may result in patient cross contamination.

How Supplied:

The SAFIRA Syringe component is provided sterile; the contents are sterile unless the package is opened, damaged or the expiry date has been exceeded.

Use Environment:

SAFIRA is designed for use by a physician, in either a hospital or surgical centre environment. The device is not intended to be used outside of stated environments.

Environmental Operating Conditions, Transport and Storage Between Uses

Temperature Range (Product Use):	50F (10C) to 104F (40C)
Temperature Range (Shipping & Handling):	14F (-10C) to 104F (40C)
Humidity Range:	10% to 95%, noncondensing
Atmospheric Pressure:	500 to 1060 Millibars

Device Type:

SAFIRA is a Type BF device.

SAFIRA components are not conductive and can be immediately released from the patient. The needle and tubing (which is not supplied by Medovate) attached to SAFIRA is the component in physical contact with the patient and can be immediately released from the patient.

Mode of Operation:

Transient.

Power Supply:

Two (2) AAA 1.5V alkaline batteries power the SAFIRA Driver component.

Troubleshooting:

1. See **Diagram #21** on Page 12 describing actions required should either flashing red light or steady red light appear.
2. ***If unit stops working during the middle of a procedure, simply press the teal button on the side of the SAFIRA Driver component and release the SAFIRA Syringe. You may complete the procedure using the SAFIRA Syringe in the traditional manual mode.***
3. Should the SAFIRA Driver component fail to operate either before or during a procedure, please return to Medovate for replacement. ***The device should not be taken apart or repaired by anyone other than authorised Medovate personnel.***
4. Should a serious incident occur during the use of or as a result of the SAFIRA System, please contact Medovate.
5. See the Medovate website for details of a local Medovate representative.

End of Section

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Important Technical Information:

Electromagnetic Compatibility (EMC):

SAFIRA was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

This product needs precautions regarding EMC and needs to be installed into service according to the EMC information provided. This unit can be affected by portable and mobile RF communication equipment.

1. Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. They may result in incorrect operation of the unit.

2. SAFIRA should not be used at the same time as Electrocautery or Diathermy equipment. This may result in incorrect operation of the unit.

3. **CAUTION:** SAFIRA should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this unit should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emission:

Guidance and Manufacture's Declaration: Electromagnetic Emission		
SAFIRA is intended for use in the electromagnetic environment specified below. The customer and/or user of SAFIRA should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment: Guidance**
RF Emissions **CISPR 11**	**Group 1**	SAFIRA 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**	**Group A**	SAFIRA is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Guidance and Manufacture's Declaration: Electromagnetic Immunity			
SAFIRA is intended for use in the electromagnetic environment specified below. The customer and/or user of SAFIRA should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±2, 4, 8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (50Hz/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Immunity (continued):

Guidance and Manufacture's Declaration: Electromagnetic Immunity			
SAFIRA is intended for use in the electromagnetic environment specified below. The customer and/or user of SAFIRA should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: Guidance**
Radiated RF IEC 61000-4-3	3V/m (1kHz 80%) 80MHz – 6.0GHz	3V/m	Portable and mobile RF communication equipment should be no closer to any part of SAFIRA, including cables, than the recommended separation distance of 300mm. Field strength 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: The guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic Immunity (continued):

[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 and TV 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 SAFIRA is used exceeds the applicable RF compliance level above, SAFIRA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating SAFIRA.

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

End of Section

Guide to SAFIRA References:

900016	(Component Level—stands for the SAFIRA Luer Syringe component)
900058	(Component Level—stands for the SAFIRA NRFit Syringe component)
900029	(Component Level—stands for the SAFIRA Driver component)
900044	(Component Level—stands for the SAFIRA Foot Pedal Operator Component)
900059	(Component Level—stands for the SAFIRA Palm Operator Component)

End of Section

Guide to Symbols:

#	Symbol	Symbol Meaning
1		Component reference number
2		Lot number or batch code
3		Serial number
4		Do not use if package is damaged
5		Single use only
6		Use by date
7		Date of manufacture
8		Manufacturer
9		Caution: US Federal Law restricts this device to sale by or on the order of a physician
10		Consult Instructions for Use (IFU) (Recommended)
11		Consult Operating Instructions or IFU (Mandatory)
12		Caution
13		Product sterilised using ethylene oxide

Guide to Symbols (Continued)

#	Symbol	Symbol Meaning
14		Type BF: Provides protection against electrical shock
15		Electromagnetic emissions
16		Temperature limitation
17		Do not re-sterilise
18		MRI Unsafe
19		WEEE compliant
20		RoHS compliant
21		CE Mark
22		Luer Syringe
23		NRFit Syringe
24		Authorised Representative

End of Section

Warranty Statement:

The product and each component of its system (hereinafter “the product”) have been designed, manufactured, tested and packaged with all reasonable care. However, Medovate has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. In this respect, the warnings in the product publication/instructions for use are expressly to be considered as an integral part of this disclaimer and provide more detailed information. For this reason, Medovate disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation, or any expressed or implied warranty. Medovate is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. This does not apply in the case of intention or in the case of gross negligence of legal representatives or executive staff of Medovate. In commercial transactions relating to merchants, the liability is limited to the compensation of typical damages; compensation for any untypical or incidental damage is excluded. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable in the respective country. If any clause of the disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects Medovate's legitimate interest in limiting liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind Medovate to any warranty or liability regarding this product.

SAFIRA...SAFer Injection for Regional Anaesthesia

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