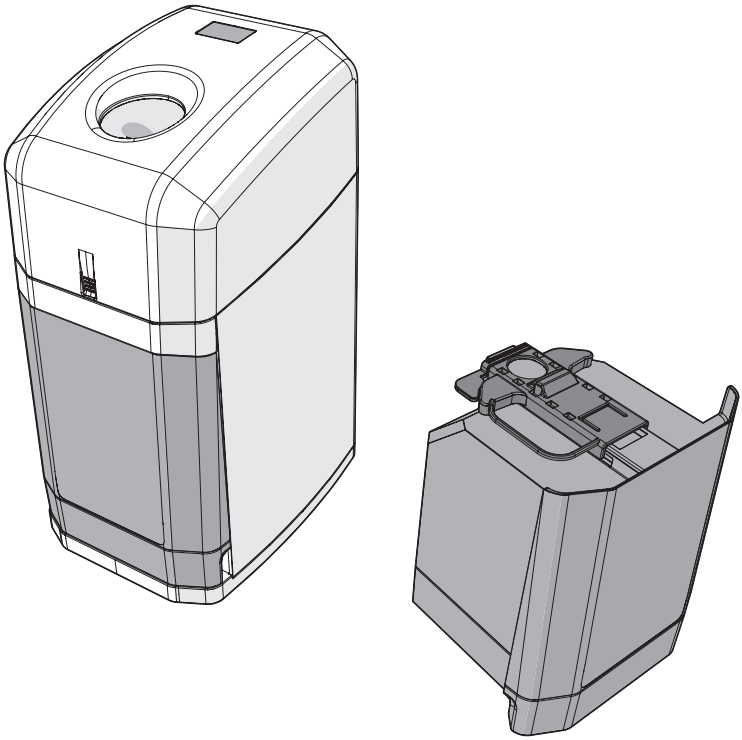
NEEDLE OFF

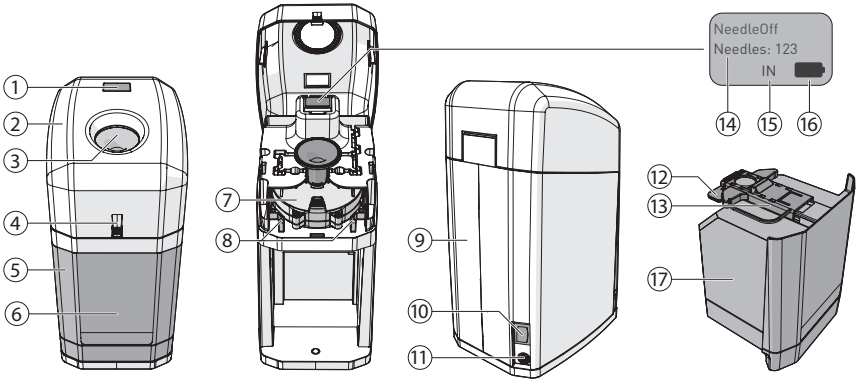


USER MANUAL

Sharpfield Company B.V. | Westplein 6 | 3016 BM Rotterdam | The Netherlands | **www.needleoff.com**

EN | Original instructions

Image A



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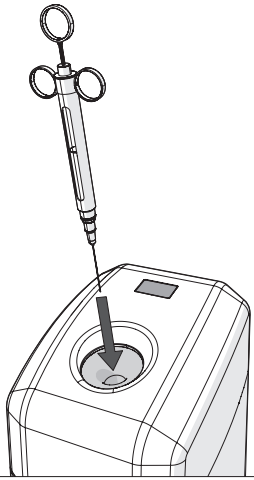

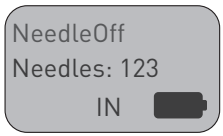

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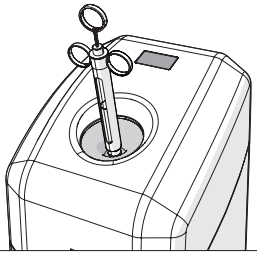

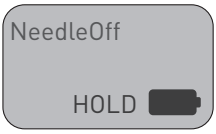

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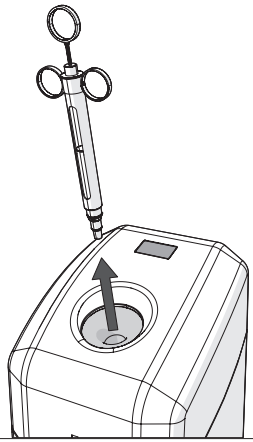

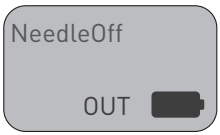

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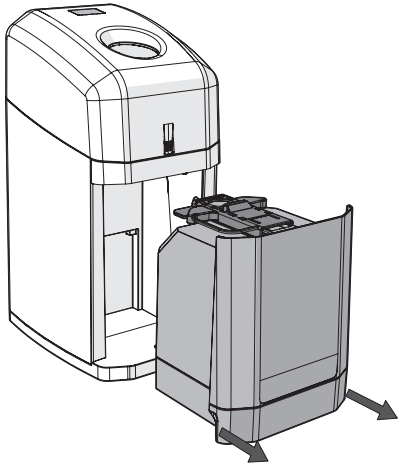

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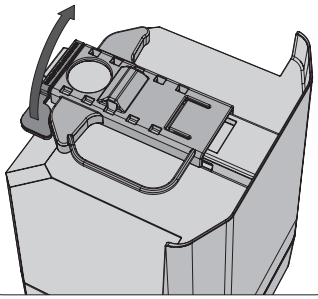

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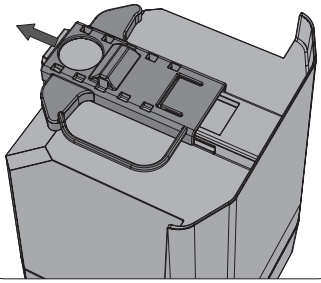


Image H

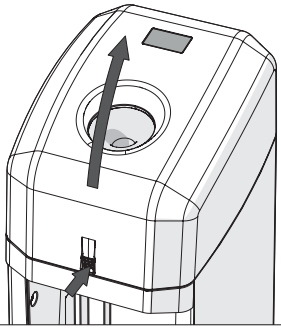
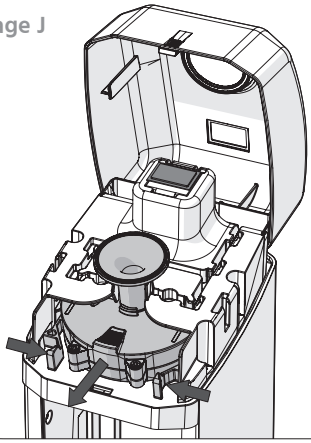


Image J



NEEDLEOFF
USER MANUAL

EN

CONTENT

INHOUDSOPGAVE

1	Introduction	7
2	Product description	9
3	Safety	12
4	Use	14
5	Maintenance	19
6	Storage	20
7	Troubleshooting	21
8	End of life	22
9	Terms of warranty	22
10	Liability	23
11	Declaration of Conformity	24

1 INTRODUCTION

Thank you for purchasing NeedleOff. This manual is written for the end user and contains instructions and descriptions to ensure safe installation, use and maintenance of the product.

Before using the product, make sure to read and fully understand the contents of this manual and always follow all safety instructions.

1.1 INTENDED USE

NeedleOff is exclusively intended as a mobile removal and storage device for straight mounted, uncapped and threaded (metric and imperial) dental needles. The product is designed for singlehanded use only. The product can only be used with the accompanied Sharptainer. Without the Sharptainer in place, the product will not function.

Please carefully read the instructions for use before using your product for the first time. Store this manual close to the product for future reference. Sharpfield Company cannot accept liability for non-compliant product use.

Warning! Incorrect use of the product may cause injuries.

1.2 UNINTENDED USE

Do not use NeedleOff for any type of needle other than a straight, threaded (metric and imperial) dental needle. It is not designed for other needles (such as Luer-Lock), needles that are mounted to the syringe under an angle (such as Citoject) or devices that don't offer unobstructed access to the needle hub (such as Quicksleeper).

Removal of incompatible needles should not be attempted and use with incompatible devices should be avoided, as it can cause severe damage to the product.

Never empty a used Sharptainer. The integrated RFID chip will always remember the number of procedures performed with the Sharptainer. The product will no longer function with a Sharptainer that has reached the maximum number of procedures.

Do not dispose of any other materials into the Sharptainer. This can fill up the Sharptainer without increasing the procedure count and lead to unsafe situations; for example when needles can no longer fit in the Sharptainer. It can also result in having to replace the Sharptainer before the procedure count limit has been reached.

Do not insert a capped needle into the entry funnel of the product.

1.3 SYMBOLS USED

1.3.1 SYMBOLS USED IN THE MANUAL

Danger! Risk of serious injury or death.

Warning! Risk of possible malfunctioning, damage or destruction of the product.

General or important information concerning the operation of the product.

1.3.2 SYMBOLS USED ON THE PRODUCT

Consult the user manual.

This product can never be treated as general household waste. It must therefore be sent to a waste collection centre for the recycling of electrical and electronic equipment.

CE mark. This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in the European Directives.

TÜV Rheinland certification logo.

UN Packaging symbol. This symbol signifies that the packaging has passed the UN packaging performance tests.

Caution! Consult accompanying documents.

Manufacturer information.

Serial number.

1.3.3 SYMBOLS USED ON THE PACKAGING

	The product packaging can be recycled.
	CE mark. This symbol is a mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in the European Directives.
	TÜV Rheinland certification logo.

2 PRODUCT DESCRIPTION

NeedleOff is a portable device with built-in battery that safely removes and stores used dental needles from syringes. NeedleOff allows you to comply with the global ban on recapping contaminated needles and significantly lowers the danger of needlestick injuries and contamination.

The removed needles are automatically dropped in a secure Sharptainer that can safely hold up to 400 needles. The number of performed removal procedures is shown on the display of the product and is stored on the RFID chip in the Sharptainer. The number of procedures will be remembered even after removing and re-inserting the Sharptainer. When a Sharptainer is full, the lid of the Sharptainer can be permanently sealed to ensure safe transportation and disposal of the contents.

2.1 PRODUCT OVERVIEW (IMAGE A)

1	Display	10	Power switch
2	Lid	11	Charging port
3	Entry funnel	12	Sharptainer lid seal
4	Lid lock	13	Sharptainer lid
5	Sharptainer with RFID chip	14	Procedure counter
6	Safety notice	15	Instructions
7	Gripper Cassette	16	Battery level indicator
8	Gripper Cassette clamps	17	Spare Sharptainer
9	Rating plate	18	DC Power supply (not shown in image)

2.2 TECHNICAL SPECIFICATIONS

Specification*	Value
Art. no.	58602 (EAN 8719326586021)
Battery type	14.8V Li-ion
Battery capacity	4,400 mAh
Power supply	⎓ DC 24V 1.0 A
Maximum continuous charge current	1A
Power consumption	24 W
Dimensions (H x L x D)	259 x 125 x 165 mm
Weight EA89	2.0 kg

*All specifications are subject to technical adaptations of the product.

2.3 ENVIRONMENTAL CONDITIONS

NeedleOff is designed to be safe at least under the following conditions:

- Indoor use;
- Altitude up to 2,000 m;
- Ambient temperatures between 5 - 40 °C;
- Max relative humidity of 80% at <31 °C, with a linear decrease to 50% at 40 °C;
- Mains supply voltage fluctuation of ± 10% of the nominal voltage;
- Transient overvoltages up to levels of overvoltage Cat II*;
- Temporary overvoltages occurring on the mains supply;
- Applicable pollution degree of the intended environment**.

* These levels of transient overvoltage are typical for equipment supplied from the building wiring

** Pollution degree 2 in most cases

2.4 CHARGER SPECIFICATIONS

This charger should only be used with the NeedleOff device. Only use this original charger to power the NeedleOff device. Do not replace any part of the charger with third party spares.

Specification	Value
Model no.	VEP36US24
Output power	36 W
Output voltage	24.0 V
Output current	1.5 A
Ripple & Noise	200 mV
Overvoltage trip	42.0 V
Efficiency	87%
Supplier	XP Power

*All specifications are subject to technical adaptations of the product.

2.5 COMPATIBLE NEEDLES

NeedleOff is compatible with all available lengths of dental needles with either metric or imperial thread, as listed in the table below.

Needle Gauge	Outer Diameter (mm)
21	0.82
21.5	0.77
22	0.72
22s	0.718
22.5	0.67
23	0.64
23s	0.642
23.5	0.59
24	0.57
24.5	0.54
25	0.51

Needle Gauge	Outer Diameter (mm)
25s	0.515
25.5	0.49
26	0.46
26s	0.474
27	0.41
28	0.36
29	0.34
30	0.31
31	0.26
32	0.23
33	0.21

3 SAFETY

Always follow the following safety instructions when using NeedleOff.

3.1 USE

Danger! Working with contaminated needles comes with risks. The user should always be aware of the dangers, take safety precautions and use personal protection measures (e.g. gloves, mask, protective glasses) to avoid contamination.

Danger! Never open the product housing yourself. There's risk of serious injury or death. Opening the housing will void your warranty.

Danger! After the needle has been removed, do not reuse the syringe. This eliminates the risk of cross-contamination. Make sure the syringe is cleaned in accordance with the applicable hygiene protocol for contaminated medical instruments before the next use.

Danger! Dental needles contain approved anesthetics for human use and are contaminated with biological substances when used. When using NeedleOff to detach the contaminated needle, both substances are considered to be transferred to the device, hence contaminating the device. Make sure NeedleOff is cleaned in accordance with the Maintenance procedures before the next use, or replace the Gripper Cassette.

Warning! Incorrect use of the product may cause injuries.

Warning! This product is intended for indoor use by medical professionals only.

Warning! Although it is possible to remove a slightly bent needle from a syringe using the product, it results in an increased risk of obstruction of the entry funnel. The procedure to clear the entry funnel is potentially unsafe and increases the risk of needlestick.

Warning! Never stick your finger in the entry funnel. If there is a needle stuck in the funnel, you may get needlestick.

Warning! Never use your free hand to hold NeedleOff in place during a removal procedure to avoid needlestick.

Warning! Do not apply any downward force while inserting or holding the syringe.

Warning! Do not let go of the syringe while the removal procedure is in progress.

Warning! Do not pull out the syringe while the removal procedure is in progress.

Warning! Trying to remove the syringe while it is being held by the Gripper Cassette will severely damage the product.

Warning! Never manually open the Sharptainer lid.

Warning! Do not insert foreign objects into the entry funnel. The sensors may be triggered when activating the mechanism, which could result in injury and severe damage to the product.

Always place the product on a flat, stable surface before use.

Always keep the product upright to avoid needles from falling out of the entry funnel or blocking the Gripper Cassette.

In case the needle is not properly removed from the syringe (e.g. if you don't hold the syringe during the procedure), the syringe will remain stuck in the entry funnel. Do not try to forcefully remove the syringe. After 5 seconds, the syringe with needle will be released and can be removed with care. You can repeat the removal procedure. Keep in mind that the needle can already be partially loosened during the first removal procedure.

After removal from the product, the Sharptainer is automatically closed but not yet sealed.

If the display shows "**No Sharptainer**", the Sharptainer has not been inserted properly or is not in place. Remove the Sharptainer and carefully try again until the displays shows "**IN**".

Every procedure performed by NeedleOff will be registered by the display procedure counter, even if the procedure fails to remove the needle (e.g. if you don't hold the syringe during the procedure).

This charger should only be used with the NeedleOff device. Only use this original charger to power the NeedleOff device. Do not replace any part of the charger with third party spares.

3.2 MAINTENANCE, STORAGE & DISPOSAL

Danger! Dental needles contain approved anesthetics for human use and are contaminated with biological substances when used. When using NeedleOff to detach the contaminated needle, both substances are considered to be transferred to the device, hence contaminating the device. Make sure NeedleOff is cleaned in accordance with the Maintenance procedures before the next use, or replace the Gripper Cassette.

Warning! Always turn off and unplug NeedleOff before performing any maintenance or removing the Sharptainer or Gripper Cassette. Removing the Gripper Cassette before turning off the product could trigger a sensor causing NeedleOff to start a removal procedure.

Warning! Do not immerse the product, power cord, charger or any of its other parts or consumables in water or any other liquid. Do not place the product or any of its parts/consumables in a dishwasher.

Warning! Always follow the local rules and regulations regarding the disposal of contaminated sharps.

Warning! Always store the product in a dry place at room temperature. Avoid placing the product in direct sunlight for extended periods of time.

If the product is not used for a longer period of time, it is advised to charge the device regularly to ensure it can be used whenever necessary.

4 USE

4.1 CHARGE THE BATTERY

The battery of the product is only partially charged out-of-the-box. Before the first use, make sure to fully charge the battery. To charge the battery:

1. Plug the DC power supply into the charging port ⑪ of the product.
2. Plug the other side of the DC power supply into a working power outlet.

The display ① will show a mains icon ⑯ to indicate that the product is plugged in. While the battery is charging, the battery icon around the mains icon is empty. The battery icon is filled when the battery is fully charged.

When the product is running on battery power, the display shows a full battery icon to indicate the full charge. Battery power will decrease with every procedure. The battery level indicator uses two icons to show the power decrease (half full & empty). The battery half full indicator blinks once the battery power level drops below 20%.

Mains power		Battery power		
Charging	Battery full	Battery full	Battery half full	Battery empty

When the battery has insufficient power to safely remove a needle, the battery level indicator will show as empty. The product will no longer be able to start a new removal procedure. Regardless of this safety feature, it's advised to be extra cautious whenever the battery half full indicator blinks, as the risk of incomplete removal increases. Please recharge the device as soon as possible.

It is possible to use the product while continuously plugged into the mains. This way, low battery issues will be prevented.

4.2 POWER ON

Turn on the device by switching the power switch ⑩ to the '**I**' position. If a Sharptainer in place, the Display shows "**IN**" to indicate the product is ready for inserting a needle. When no Sharptainer has been placed or is not correctly inserted, the display shows "**No Sharptainer**".

4.3 INSERT A USED SYRINGE WITH NEEDLE (IMAGE B + C)

Danger! Working with contaminated needles comes with risks. The user should always be aware of the dangers, take safety precautions and use personal protection measures (e.g. gloves, mask, protective glasses) to avoid contamination.

NeedleOff is designed to be operated using just a single hand to insert the syringe without the need to hold the product itself with your free hand.

Warning! Never use your free hand to hold NeedleOff in place during a removal procedure to avoid needlestick.

1. Place the product on a stable surface (e.g. your worktop) in the treatment room. This way the needle can be removed right after the final injection. This prevents unnecessary risk of contamination by handing over or moving with the contaminated needle.

Always place the product on a flat, stable surface before use.

2. Firmly hold the syringe so that it cannot turn in or slip from your hand.
3. Carefully insert the uncapped needle into the entry funnel and firmly hold the base of the syringe to prevent it from spinning during the procedure. See image B.

The removal procedure starts automatically and the display shows "**HOLD**" to indicate the procedure is in progress. See image C.

Warning! Do not apply any downward force while inserting or holding the syringe.

Warning! Do not let go of the syringe while the removal procedure is in progress.

Warning! Do not pull out the syringe while the removal procedure is in progress.

4.4 REMOVE A USED SYRINGE WITHOUT NEEDLE (IMAGE D)

When the procedure is finished, the display shows "**OUT**" to indicate it is safe to remove the syringe. The Gripper Cassette will firmly hold the needle.

1. Carefully remove the syringe from the entry funnel in a calm and fluent motion. Visually confirm if the needle has been successfully removed from the syringe.

Once the sensor registers that the syringe has been removed, the needle will be released into the Sharptainer. The procedure counter ⑮ will increase by 1 and the display shows "IN" to indicate the product is ready for a new procedure.

Danger! After the needle has been removed, do not reuse the syringe. This eliminates the risk of cross-contamination. Make sure the syringe is cleaned in accordance with the applicable hygiene protocol for contaminated medical instruments before the next use.

Warning! Trying to remove the syringe while it is being held by the Gripper Cassette will severely damage the product.

In case the needle is not properly removed from the syringe (e.g. if you don't hold the syringe during the procedure), the syringe will remain stuck in the entry funnel. Do not try to forcefully remove the syringe. After 5 seconds, the syringe with needle will be released and can be removed with care. You can repeat the removal procedure. Keep in mind that the needle can already be partially loosened during the first removal procedure.

Every procedure performed by NeedleOff will be registered by the display procedure counter, even if the procedure fails to remove the needle (e.g. what can happen if you don't hold the syringe during the procedure).

4.5 REPLACE THE SHARPTAINER (IMAGE E)

When the Sharptainer reaches 250 procedures, the procedure counter ⑮ will blink to indicate it is no longer guaranteed to have a safe removal of needles due to blockage by previously removed needles.

After 400 performed procedures, the display shows "**FULL**" and NeedleOff stops functioning until the Sharptainer is replaced by a new Sharptainer. To remove the Sharptainer:

Warning! Always turn off and unplug NeedleOff before performing any maintenance or removing the Sharptainer.

1. Visually ensure that there is no needle stuck in the entry funnel.

Warning! Never stick your finger in the entry funnel. If there is a needle stuck in the funnel, you may get needlestick.

2. Hold the base of the Sharptainer by the indentations on the side.
3. Gently pull the Sharptainer forwards.

When the Sharptainer is removed from the product, the Sharptainer lid ⑬ will automatically close off the opening. The display will show "**No Sharptainer**".

Warning! Never manually open the Sharptainer lid.

After removal from the product, the Sharptainer is automatically closed but not yet sealed.

4. Insert a new Sharptainer or a Sharptainer that has not yet reached 400 procedures. The Sharptainer lid will automatically open when inserted into the product.

When the Sharptainer is inserted correctly, the display will show "**IN**" and the procedure counter will show the amount of procedures performed with the new Sharptainer.

If the display shows "**No Sharptainer**", the Sharptainer has not been inserted properly or is not in place. Remove the Sharptainer and carefully try again until the displays shows "**IN**".

4.6 SEAL THE SHARPTAINER (IMAGE F + G)

The Sharptainer can be permanently sealed for secure transportation and disposal. To seal a Sharptainer:

1. Tear off the Sharptainer lid sealing strip ⑫
2. Push the lid forward until you hear a clicking sound.

The Sharptainer is now sealed and cannot be opened anymore, nor be used in NeedleOff. It is now safe to transport and dispose of the Sharptainer.

Warning! Always follow the local rules and regulations regarding the disposal of contaminated sharps.

4.7 REPLACE THE GRIPPER CASSETTE (IMAGE H + J)

The Gripper Cassette is subject to wear and should be replaced periodically. To replace the Gripper Cassette:

Warning! Always turn off and unplug NeedleOff before performing any maintenance or removing the Gripper Cassette. Removing the Gripper Cassette before turning off the product could trigger a sensor causing NeedleOff to start a removal procedure.

1. Visually confirm that there is no needle stuck in the entry funnel.

Warning! Never stick your finger in the entry funnel. If there is a needle stuck in the funnel, you may get needlestick.

2. Press the lid lock ④ to unlock the lid ② and carefully tilt the lid backwards.
3. Gently squeeze the cassette clamps ⑧ together and pull the cassette out of the product.
4. Push in a new cassette until you hear it clicking into place.
5. Close the lid until you hear it clicking into place.
6. Turn the device back on.

5 MAINTENANCE

5.1 PERIODIC MAINTENANCE

NeedleOff doesn't require a lot of maintenance. However, regular and thorough cleaning of the product is advised.

For cleaning purposes, the Gripper Cassette can be easily removed from the product (see §4.7 – "Replace the Gripper Cassette" for instructions). Make sure you have at least one spare Gripper Cassette readily available. This ensures uninterrupted operation in case a Gripper Cassette requires cleaning after use.

Clean the Gripper Cassette with alcohol, a cloth and a small brush. The entry funnel can be removed from the cassette for easy cleaning.

Clean the product housing with a moist cloth or alcohol wipes.

Danger! Dental needles contain approved anesthetics for human use and are contaminated with biological substances when used. When using NeedleOff to detach the contaminated needle, both substances are considered to be transferred to the device, hence contaminating the device. Make sure NeedleOff is cleaned in accordance with the Maintenance procedures before the next use, or replace the Gripper Cassette.

Warning! Always turn off and unplug NeedleOff before performing any maintenance or removing the Sharptainer or Gripper Cassette. Removing the Gripper Cassette before turning off the product could trigger a sensor causing NeedleOff to start a removal procedure.

Warning! Do not immerse the product, power cord, charger or any of its other parts or consumables in water or any other liquid. Do not place the product or any of its parts/consumables in a dishwasher.

For safety reasons, the battery can only be accessed by a qualified repairman. To replace the battery, please contact Sharpfield Company.

Danger! Never open the product housing yourself. There's risk of serious injury or death. Opening the housing will void your warranty.

5.2 CONSUMABLES

Consumables can be ordered from your certified NeedleOff supplier or online on the NeedleOff website. The available consumables for NeedleOff are listed in the table below.

Consumable	Article number.
Sharptainer (4 pack)	58601 (EAN 8719326586014)
Gripper Cassette	58603 (EAN 8719326586038)

Warning! Use only original NeedleOff consumables in this product. Using any other consumables voids the warranty.

6 STORAGE

Turn the device off before storing it:

- Switch the power switch ⑩ to the '**0**' position to turn off the device.

Warning! Always store the product in a dry place at room temperature. Avoid placing the product in direct sunlight for extended periods of time.

If the product is not used for a longer period of time, it is advised to charge the device regularly to ensure it can be used whenever necessary.

7 TROUBLESHOOTING

"**No Sharptainer**" is displayed.	No Sharptainer has been placed in the product or the Sharptainer is not properly placed.	• Follow the steps from the §4.5 - "Replace the Sharptainer".
"**RFID error**" is displayed.	The Sharptainer has no contact with the product.	• Turn the product off and on again. 1. Remove the Sharptainer. 2. Turn off the product for 5 seconds. 3. Re-insert the Sharptainer. 4. Turn the product back on.
There is a needle stuck in the entry funnel.	The Sharptainer is most likely filled with too many needles and the previously removed needles prevent the needle from entering the Sharptainer.	1. Turn off the product. 2. Carefully remove the Gripper Cassette (see §4.7 - "Replace the Gripper Cassette"). 3. Carefully remove the needle using tweezers and place it in the Sharptainer. 4. Replace the Sharptainer to ensure the safe use of the product (see §4.5 - "Replace the Sharptainer" and §4.6 - "Seal the Sharptainer").
The procedure does not start when I insert a syringe.	The product is turned off.	• Turn on the device by switching the power switch ⑤ to the 'I' position.
	The Sharptainer is not placed (correctly).	• Follow the steps from §4.5 - "Replace the Sharptainer".
	The battery is low.	• Follow the steps from §4.1 - "Charge the battery".
	The syringe is not inserted deep enough into the entry funnel.	• Insert the syringe until it rests on the threshold of the funnel. ⚠ **Warning!** Do not use any downward force to push in the syringe.
The tip of the syringe is also removed and stuck in the entry funnel.		• Turn off the product and carefully remove the syringe tip from the entry funnel using tweezers. • Mount the syringe tip tightly on the syringe and repeat the removal procedure.

8 END OF LIFE

When disposing of NeedleOff, please make sure to comply with all local guidelines and legal obligations for small toxic waste, as the product contains a built-in battery.

The symbol on the packaging indicates that this product can never be treated as general household waste. It must therefore be sent to a waste collection centre for the recycling of electrical and electronic equipment.

By taking your product to a proper collection centre and disposing of your product correctly at the end of their life, you are helping to preserve our natural resources and are preventing harmful consequences for the environment and public health.

9 TERMS OF WARRANTY

- The responsibility of Sharpfield Company B.V. is limited to repairing or replacing a product or its parts; we shall not acknowledge claims for any other kind of damage or costs.
- Overdue or poor maintenance will void the warranty.
- If there are doubts about the maintenance activities or if the product fails to work correctly, always contact the supplier.
- The warranty does not apply if a defect is the result of incorrect or negligent use, or maintenance that was conducted differently from the instructions given in this manual.
- The warranty is void in the event of repairs or modifications to the product by third parties.
- Defects due to damage or accidents caused by external factors are excluded from the warranty.
- In compliance with the obligations of this warranty, replaced parts become the property of Sharpfield Company B.V.
- The provisions regarding the warranty and liability are part of the terms and conditions of Sharpfield Holding B.V. and associated entities and group corporations including Sharpfield Company B.V., which can be sent to you on request and are available for download on the product website. In the event of a conflict between this manual and the terms and conditions, the terms and conditions shall prevail.

10 LIABILITY

- Sharpfield Company B.V. excludes all liability, except for direct damage resulting from an intentional act or willful recklessness on the part of Sharpfield Company B.V.
- Our liability shall never exceed the total amount of the product value in question.
- Except for the applicable legal regulations of public order and good faith, Sharpfield Company B.V. is not liable to pay for any damage of any sort whatsoever to the counterparty or to third parties, directly or indirectly, including lost profits, damage to movable or immovable property or personal injury.
- Sharpfield Company is in no way liable for damages arising or resulting from the use of the product, or the unsuitability thereof for the purpose for which the other party has decided to purchase the product.

11 DECLARATION OF CONFORMITY

We,

Sharpfield Company B.V.
Westplein 6
3016 BM Rotterdam
The Netherlands

declare under our sole responsibility that the product;

- Machine type: NeedleOff

complies with all relevant provisions of the Directives;

- 2014/30/EU: EMC directive
- 2014/35/EU: Low-Voltage Directive
- 2014/53/EU: Radio Equipment Directive (RED)

The undersigned is authorised to compile the technical file.

Rotterdam, the Netherlands
09-09-2019

M.D. Rooker
CEO

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