

# Selecting an Iontophoresis Device: A Source of Consternation

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## Background

- Primary hyperhidrosis can significantly impair quality of life.

- Iontophoresis is a safe and effective treatment that is often underutilized; this may be due to lack of provider and patient familiarity with these devices.

- The goals of this project were to identify, evaluate, and summarize iontophoresis devices advertised on the Internet for the treatment of hyperhidrosis.

## Methods

- Search engines = Google Shopping (first 100 results) and Amazon (all 63 results generated)

- Search date = 09/24/2023

- Search terms = "iontophoresis hyperhidrosis"

- Inclusion criteria = listed by the manufacturer as intended for hyperhidrosis

- Exclusion criteria = non-machine delivery systems (e.g. patches), devices not listed as intended for hyperhidrosis, and machines not distributed to the United States

Device Name/Manufacturer	Cost	Treatment Area	Current type (direct/pulsed)	Current strength (mA)	FDA status on website	FDA Decision
Divonic Wireless Hand/Foot Device	\$253	Hands/Foot	Pulsed	Information not found	Approved	Substantially equivalent
IontoDri iD-100 Iontophoresis Machine/IontoDri	\$269	Hands/Foot	Direct	Maximum 30	No	Not in database
Electro Antiperspirant Forte	\$699	Hands/Foot/Axilla	Information not found	Information not found	Approved	Substantially equivalent
Dermady Hand and Feet	\$958	Hands/Foot	Pulsed	1 - 25	Approved	Substantially equivalent
Dermady Total	\$998	Hands/Foot/Axilla	Pulsed	1 - 25	Approved	Substantially equivalent
Dermady Underarms	\$918	Axilla	Pulsed	1 - 8	Approved	Substantially equivalent
Electro Antiperspirant Elite/HERITECH DEVELOPMENT	\$977	Hands/Foot/Axilla	Pulsed	Information not found	Approved	Substantially equivalent
Idromed SPS	\$75 pounds <sup>†</sup>	Hands/Foot/Axilla	Pulsed	Maximum 25	Approved	Not in database
Hidrex PSP 1000	689 Euro <sup>‡</sup>	Information not found	Pulsed and Direct	Information not found	Website not found	Substantially equivalent <sup>¶</sup>
Saatio(Saatioma) <sup>††</sup>	\$700-1000	Hands/Foot/Axilla	Pulsed and Direct	Maximum 30	Approved	Substantially equivalent <sup>¶¶</sup>
Divonic Wireless Anmpil Device <sup>†††</sup>	\$237	Axilla	Pulsed	Information not found	Approved	Substantially equivalent

<sup>†</sup>Identified from textbooks

<sup>‡</sup>Idromed and Hidrex PSP are manufactured internationally but may be shipped to the United States.

<sup>††</sup> Saatio requires a prescription to purchase.

<sup>†††</sup> Precision device to Dermady

<sup>¶¶</sup> Marketed as "The Friction" in the US and distributed by RA Fischer

**Table 1.** Summary of Iontophoresis Devices Advertised on the Internet for Treating Hyperhidrosis

## Results

- 9 devices met inclusion criteria

- 2 additional devices were identified/included from textbooks widely used in dermatology residency curriculum<sup>1, 2</sup>

- 7 devices utilized pulsed current only

- 1 device utilized direct current only

- 2 devices had the option to utilize either type of current

- 9/11 devices were listed by the FDA as having a "substantially equivalent" predecessor

## Limitations

- Methodology may not have captured all currently available iontophoresis devices

- The 2 manufacturers not listed in the FDA database were not able to be contacted, and FDA clearance statuses were not verified by representatives

## Conclusion

- As Class II Medical devices, iontophoresis devices only require a prescription and Premarket Notification 510(k). The latter indicates a device has been deemed substantially equivalent to one legally in commercial distribution. This is in contrast to Class III devices which require Premarket Approval and supportive clinical data. Hence, while a manufacturer may market an iontophoresis device as FDA approved, the device did not need to be clinically tested in order to be FDA registered/cleared.<sup>3</sup>

- The FDA updates its database weekly. Devices not listed in database have not received FDA clearance.

- Providers should assist patients with choosing device parameters, such as current type, most suitable for treatment goal. While direct current (DC) provides constant delivery of electrical charge and is thus more potent, DC is associated with more side effects, including skin irritation.<sup>4</sup> In contrast, pulsed current delivers current with periodic interruptions, which decreases charge buildup and may reduce skin irritation.<sup>5</sup>

- Patients should work with providers in selecting a FDA cleared iontophoresis device to ensure an effective and safe treatment regimen.

## References

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