




<b>CEFALY</b> Rue Louis Plescia, 34 4102 Seraing Belgium	<u>Form</u> <b><u>Product Sheet: Labeling Item</u></b>	<b>FO-119</b> Version 05	
		Ed.: LMD	On: 08/30/2021 <i>RMD</i>
		App.: SC	On: 08/30/2021 <i>[Signature]</i>
Recording: In the Product file			

Product File: 34205 V03	Date: 22 July 2024
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Validation					
Regulatory: <i>[Signature]</i>	Medical: <i>Max Johnson</i>	Production: <i>[Signature]</i>	Design: <i>[Signature]</i>	Marketing: <i>Jennifer Trainor McDerrott</i>	Quality: <i>Stephen Chan</i>
Date: 07/25/2024	Date: 07/29/2024	Date: 07/29/2024	Date: 07/29/2024	Date: 07/25/2024	Date: 07/23/2024

<u>Codification</u>	34205 Manual CEFAY Connected EN USA OTC
<u>Description</u>	English manual for the CEFALY Connected for the OTC distribution of USA and Canada
<u>Technical Description</u>	<ul style="list-style-type: none"> <li>• Color printed</li> <li>• Double Sided Printed</li> </ul>
<u>Qualified Subcontractors</u>	<ul style="list-style-type: none"> <li>• BOI or BOI appointed supplier</li> </ul>
<u>Implementation</u>	<ul style="list-style-type: none"> <li>• Released on website at launch of Connected/Enhanced+ Device</li> </ul>
<u>Comments / Specificities</u>	This version of CEFALY Connected does NOT include RFID

**History of the Product Sheet**

<u>Version</u>	<u>Change Log:</u>
01	Initial
02	<p>Per FDA direction, change indications of use on pg 2, 10, and 12 to:</p> <ul style="list-style-type: none"> <li>• <del>The a</del>Acute treatment of migraine with or without aura in patients 18 years of age or older.</li> <li>• <del>The p</del>Preventative treatment of migraine in patients 18 years of age or older.</li> </ul> <p>Page 22 – complete the missing text:</p> <ul style="list-style-type: none"> <li>• To minimize the risk of unexpected electric shock, avoid using CEFALY Connected at <b>the same time as other active electronic medical devices.</b></li> <li>• <b>Do not touch the metal pin on the top of charging dock.</b></li> </ul>
03	<p>Response to FDA Request on Subject Reports 3010760764-2024-00002, 3010188009-2024-00002</p> <ul style="list-style-type: none"> <li>• Under “Operating and Storage Conditions” (2 sections): Use <b>and charge</b> CEFALY Connected</li> <li>• Add charging tips for medical devices based on <a href="#">FDA guidances published May 2024</a>: <ul style="list-style-type: none"> <li>o Only use an adaptor that meets the requirements specified in the user manual and a CEFALY-provided USB cable and charging dock for charging the CEFALY device.</li> <li>o Please refer to the Adaptor requirement below. If you do not have a suitable adaptor, please contact Customer Service for assistance (Email: info@cefaly.us Phone: 1.844.475.7100)</li> <li>o The USB adaptor shall be a class II power supply that is IEC 60601-1 Ed 3.1 2012 certified, with two means of operator protection, input 110V~240 V, 50/60 Hz, max 0.2A and the output is 5 V direct current, 1 A. The USB adaptor shall have the below marking: <div style="text-align: center; margin: 10px 0;"> <p><b>Input: 100-240 V ~ 50/60 Hz 0.2 A</b>     </p> <p><b>Output: 5 V  1A</b></p> </div> </li> <li>o Do not use third-party charging accessories, including accessories made by a different manufacturer or meant for a different device, such as your phone or tablet.</li> <li>o Inspect your CEFALY device and charging accessories for signs of damage, including melting and warping where the charger plugs into the device. If you see signs of damage, stop charging the device and contact CEFALY.</li> <li>o Charge your CEFALY device where you can clearly see it, away from anything that can easily catch fire. Do not charge your CEFALY device on or near a soft surface like a couch, pillow, curtains, or other materials, where it can overheat more easily.</li> <li>o Charge your CEFALY device during the day when you are awake. Do not charge your CEFALY device overnight when you might miss early signs of the device overheating.</li> <li>o Unplug the adaptor when your CEFALY device shows a solid green LED, that indicates the device is fully charged. Do not leave your CEFALY device plugged into the charger after it is fully charged.</li> <li>o Protect your CEFALY device from extreme temperatures. Do not leave your CEFALY</li> </ul> </li> </ul>

device in direct sunlight, or in your car on an especially hot or cold day. Only charge your CEFALY device indoors with temperature between 50° F and 95° F (10° C and 35° C).

- o Adaptors that meet the specifications in the user manual and accessories provided by CEFALY limit the power provided to safely charge the battery, but other accessories may allow much higher power, increasing the risk of overheating, spark, or fire, which may lead to minor injuries or serious burns.
- o If the device remains unused for an extended period, please check the battery level regularly, approximately every month. If the battery level is low, indicated by a solid yellow glow on the LED indicator, please fully recharge the device until the solid green LED is shown. Keeping the battery at an appropriate charge level helps maintain its health and longevity.

#### Other Updates (unrelated to MDR)

- Belgian Office Changed Location in 4 locations in manual:  
Boulevard Patience et Beaujonc 3, bte 28  
4000 Liège  
BELGIUM
- Change the CTA for the CEFALY Coach on the 2<sup>nd</sup> page: Need help getting started? Visit our website or call us at the number below to schedule a [bold] free CEFALY Coach Session [unbold] for personal one-on-one assistance! To view this user manual in Espanol [add symbol above the n as seen now], please visit [cefaly.com/start](http://cefaly.com/start).
- Add and Update the CeCe Section for the updated Cece version (per K234029) – add new screenshots, new directions, new troubleshooting app section, and new Cybersecurity section.
- Should you press and hold the device button again, the intensity will increase again.
- Update the “Keep Dry” symbol: <https://www.iso.org/obp/ui/#iso:grs:7000:0626>
- Add a “Batch Code” symbol, title, and description: <https://www.iso.org/obp/ui/#iso:grs:7000:2492> | To identify the manufacturer's batch or lot code.

**SIGNATURE CERTIFICATE**



**REFERENCE NUMBER**

B5B53ECF-FF34-449F-AD1B-890100A2658F

**TRANSACTION DETAILS**

**Reference Number**  
B5B53ECF-FF34-449F-AD1B-890100A2658F

**Transaction Type**  
Signature Request

**Sent At**  
07/23/2024 13:13 EDT

**Executed At**  
08/13/2024 10:33 EDT

**Identity Method**  
email

**Distribution Method**  
email

**Signed Checksum**  
afa5fe243420c54ef80da7b06eec44d0fb1c52d483a532cf8cc8ca8dd8745b27

**Signer Sequencing**  
Enabled

**Document Passcode**  
Disabled

**DOCUMENT DETAILS**

**Document Name**  
34205 V03 Connected EN US OTC User Manual

**Filename**  
34205\_V03\_Connected\_EN\_US\_OTC\_User\_Manual.docx

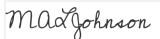

**Pages**  
3 pages





**Content Type**  
application/vnd.openxmlformats-officedocument.wordprocessingml.document

**File Size**  
220 KB

**Original Checksum**  
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**SIGNERS**

SIGNER	E-SIGNATURE	EVENTS
<p><b>Name</b> Michael Johnson</p> <p><b>Email</b> m.johnson@cefaly.com</p> <p><b>Signer Sequence</b> 5</p> <p><b>Components</b> 2</p>	<p><b>Status</b> signed</p> <p><b>Multi-factor Digital Fingerprint Checksum</b> 8f3b7cd4dd86985d1f6bd6f813a6f761e8c60c9cfc27411f97784369b792fc45</p> <p><b>IP Address</b> 71.211.144.53</p> <p><b>Device</b> Microsoft Edge via Windows</p> <p><b>Typed Signature</b> </p> <p><b>Signature Reference ID</b> B631E4E9</p>	<p><b>Viewed At</b> 08/13/2024 10:33 EDT</p> <p><b>Identity Authenticated At</b> 08/13/2024 10:33 EDT</p> <p><b>Signed At</b> 08/13/2024 10:33 EDT</p>
<p><b>Name</b> Mickaël Jean</p> <p><b>Email</b> m.jean@cefaly.com</p> <p><b>Signer Sequence</b> 4</p> <p><b>Components</b> 2</p>	<p><b>Status</b> signed</p> <p><b>Multi-factor Digital Fingerprint Checksum</b> 0f78b0f572550abe94e888bc82dbc29b1048249c2b8186b5eb976244829a13ab</p> <p><b>IP Address</b> 154.52.44.180</p> <p><b>Device</b> Chrome via Windows</p> <p><b>Drawn Signature</b> </p> <p><b>Signature Reference ID</b> 9B41E153</p> <p><b>Signature Biometric Count</b> 3</p>	<p><b>Viewed At</b> 07/29/2024 06:19 EDT</p> <p><b>Identity Authenticated At</b> 07/29/2024 06:19 EDT</p> <p><b>Signed At</b> 07/29/2024 06:19 EDT</p>

SIGNER	E-SIGNATURE	EVENTS
<b>Name</b> Siobhan Roubinet <b>Email</b> s.roubinet@cefaly.com <b>Signer Sequence</b> 3 <b>Components</b> 2	<b>Status</b> signed <b>Multi-factor Digital Fingerprint Checksum</b> 7b8a8b20cdea80ca84a155c2df352ea5f3507f9b8fa5c00f4defc74f8cf07096 <b>IP Address</b> 213.211.128.145 <b>Device</b> Chrome via Mac <b>Drawn Signature</b>  <b>Signature Reference ID</b> F411DA02 <b>Signature Biometric Count</b> 2	<b>Viewed At</b> 07/29/2024 03:48 EDT <b>Identity Authenticated At</b> 07/29/2024 03:48 EDT <b>Signed At</b> 07/29/2024 03:48 EDT
<b>Name</b> Jennifer Trainor-McDermott <b>Email</b> j.trainor@cefaly.com <b>Signer Sequence</b> 2 <b>Components</b> 2	<b>Status</b> signed <b>Multi-factor Digital Fingerprint Checksum</b> cd55ed5021bada8949b1e1b4e16fbf827c3373a1a93d4b209356b35fe2a5b59b <b>IP Address</b> 131.226.37.36 <b>Device</b> Chrome via Mac <b>Typed Signature</b>  <b>Signature Reference ID</b> 1DE4B2D4	<b>Viewed At</b> 07/25/2024 10:36 EDT <b>Identity Authenticated At</b> 07/25/2024 10:37 EDT <b>Signed At</b> 07/25/2024 10:37 EDT
<b>Name</b> Drew Pannone <b>Email</b> a.pannone@cefaly.com <b>Signer Sequence</b> 1 <b>Components</b> 2	<b>Status</b> signed <b>Multi-factor Digital Fingerprint Checksum</b> c19005cb1c65334a8203b311343c9689b9672d8438d7c276bd1dfd16aff53292 <b>IP Address</b> 73.149.129.232 <b>Device</b> Microsoft Edge via Windows <b>Drawn Signature</b>  <b>Signature Reference ID</b> 9326ECBF <b>Signature Biometric Count</b> 2	<b>Viewed At</b> 07/25/2024 10:27 EDT <b>Identity Authenticated At</b> 07/25/2024 10:27 EDT <b>Signed At</b> 07/25/2024 10:27 EDT
<b>Name</b> Stephen Chan <b>Email</b> s.chan@cefaly.com <b>Signer Sequence</b> 0 <b>Components</b> 2	<b>Status</b> signed <b>Multi-factor Digital Fingerprint Checksum</b> f25a4ed37046d305f88731629cdddec77595e7ae32208b36c79ad03bda71d6c6c <b>IP Address</b> 216.232.183.116 <b>Device</b> Chrome via Windows <b>Typed Signature</b>  <b>Signature Reference ID</b> 34E2E019	<b>Viewed At</b> 07/23/2024 16:00 EDT <b>Identity Authenticated At</b> 07/23/2024 16:00 EDT <b>Signed At</b> 07/23/2024 16:00 EDT

## AUDITS

TIMESTAMP	AUDIT
07/23/2024 13:13 EDT	Lilliana Delmonico (l.delmonico@cefaly.com) created document '34205_V03_Connected_EN_US_OTC_User_Manual.docx' on Chrome via Mac from 68.194.153.22.
07/23/2024 13:13 EDT	Stephen Chan (s.chan@cefaly.com) was emailed a link to sign.
07/23/2024 16:00 EDT	Stephen Chan (s.chan@cefaly.com) viewed the document on Chrome via Windows from 216.232.183.116.
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<b>TIMESTAMP</b>	<b>AUDIT</b>
07/23/2024 16:00 EDT	Drew Pannone (a.pannone@cefaly.com) was emailed a link to sign.
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07/25/2024 10:37 EDT	Jennifer Trainor-McDermott (j.trainor@cefaly.com) signed the document on Chrome via Mac from 131.226.37.36.
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07/29/2024 03:48 EDT	Siobhan Roubinet (s.roubinet@cefaly.com) signed the document on Chrome via Mac from 213.211.128.145.
07/29/2024 03:48 EDT	Mickaël Jean (m.jean@cefaly.com) was emailed a link to sign.
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07/29/2024 06:19 EDT	Michael Johnson (m.johnson@cefaly.com) was emailed a link to sign.
07/31/2024 19:02 EDT	Michael Johnson (m.johnson@cefaly.com) was emailed a reminder.
08/07/2024 19:03 EDT	Michael Johnson (m.johnson@cefaly.com) was emailed a reminder.
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