



Update of Dialog® User manual for USA and Canada

During the FCC and ISED approval process of Dialog®, ACB has suggested some changes to the submitted version of Dialog® user manual. Novo Nordisk confirms that these changes will be implemented before releasing Dialog® device in the market. These changes are summarized in this document.

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Requirement: US version of Dialog IFU should include FCC part 15.21, 15.105, and 15.19 statement.

The table below contains a summary of what is the requirement and how NN proposes to implement these requirements. These statement will be included in the US version of IFU.

FCC 15.21-Information to user.	
<div><div>§ 15.21 Information to user.</div><div>The users manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.</div><div>[54 FR 17714, Apr. 25, 1989, as amended at 68 FR 68545, Dec. 9, 2003]</div></div>	
Current NN implementation:	<div><div><div><div>Caring for your Dialog®</div><div><div><div>• Where do I keep my Dialog®?</div><div><div><div><div><div>2° C</div><div>36° F</div></div><div><div>40° C</div><div>104° F</div></div></div><div>Storage: When Dialog® is not attached to your FlexTouch® pen, store Dialog® at temperatures above 36° F (2° C) and below 104° F (40° C).</div></div><div><div><div>5° C</div><div>41° F</div></div><div><div>40° C</div><div>104° F</div></div></div><div>During use: Dialog® is intended to be used at home or in a normal public environment at these conditions: Temperature: 41° F (5° C) to 104° F (40° C) Humidity: 15% RH to 90% RH Atmospheric pressure: 700 hPa to 1060 hPa</div></div></div><div><div><div>When Dialog® is attached to your FlexTouch® pen, follow the instructions for maximum in-use temperature that came with your FlexTouch® pen.</div><div><div>• How do I take care of my Dialog®?</div><div><div>Do not try to repair your Dialog® or pull it apart. This will break it.</div><div><div><div>☂</div><div>Keep your Dialog® away from dust, dirt, and liquid.</div></div><div><div><div>⚠</div><div>Do not attach Dialog® to a FlexTouch® pen with a visibly scratched, damaged, or dirty dose button. Otherwise, Dialog® may not be able to identify the drug brand name and strength in your FlexTouch® pen correctly.</div></div><div><div><div>⚠</div><div>Do not modify Dialog® in any way. Do not try to insert any foreign objects or fingers in your Dialog®. If you do, Dialog® may not work as intended.</div></div><div>Do not use your Dialog® if it is visibly damaged. If you think your Dialog® is not working the right way, call 1-833-4-DIALOQ.</div></div></div></div></div></div></div></div></div></div></div></div>
NN proposal: The yellow highlighted part in the above current NN implementation will be replaced by the text below.	<div><div>Do not make any changes to Dialog® in any way. Changes or modifications not expressly approved by Novo Nordisk could void the user's authority to operate the Dialog®. Do not try to insert any foreign objects or fingers in your Dialog®. If you do, Dialog® may not work as intended.</div></div>

FCC 15.105- Information to the user.

§ 15.105 Information to the user.

- (a) For a Class A digital device or peripheral, the instructions furnished the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

Note:

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

- (b) For a Class B digital device or peripheral, the instructions furnished the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Current NN implementation:

Electromagnetic compatibility
Dialog® lives up to the emissions and immunity requirements from IEC 60601-1-2:2014 for Home Healthcare Environments. See details on tests in technical description at www.mydialog.com

Dialog® complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Before you use Dialog® on an airplane, ask the cabin attendants for instructions for using a Bluetooth connection on the flight. You can also ask the airline you fly with for instructions.

Wireless technology
Frequency Band: 2.4-2.4835 GHz
Technology: Bluetooth low energy
Modulation type: Gaussian Frequency Shift Keying (GFSK)
Output power: 0 dBm

Dialog® and FlexTouch® are registered trademarks of Novo Nordisk. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc.

Dialog® is classified as a device receiver category 3: noncritical communication.

Dialog® collects data to enable improvements in device performance. The data can only be reviewed during device maintenance.

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For information about Dialog® contact:
1-833-4-DIALOG
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
Attention: Customer Care

Manufactured by:
www.novonordisk.com
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsvaerd, Denmark
Issued: 2020-XX-XX

NN proposal: Use exact text from the clause 15.105 as below. The yellow highlighted part in the above current NN implementation will be replaced by the text below.

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

FCC 15.19 Labelling requirement

§ 15.19 Labeling requirements.

(a) In addition to the requirements in [part 2](#) of this chapter, a device subject to certification, or Supplier's Declaration of Conformity shall be labeled as follows:

(1) Receivers associated with the [operation](#) of a licensed radio service, e.g., FM broadcast under [part 73](#) of this chapter, land mobile [operation](#) under [part 90](#) of this chapter, etc., shall bear the following statement in a conspicuous location on the device:

This device complies with part 15 of the FCC Rules. [Operation](#) is subject to the condition that this device does not cause [harmful interference](#).

(2) A stand-alone [cable input selector switch](#), shall bear the following statement in a conspicuous location on the device:

This device complies with part 15 of the FCC Rules for use with cable television service.

(3) All other devices shall bear the following statement in a conspicuous location on the device:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

(4) Where a device is constructed in two or more sections connected by wires and marketed together, the statement specified under [paragraph \(a\)](#) of this section is required to be affixed only to the main control unit.

(5) When the device is so small or for such use that it is impracticable to label it with the statement specified under [paragraph \(a\)](#) of this section in a font that is four-point or larger, and the device does not have a display that can show electronic labeling, then the information required by this paragraph shall be placed in the user manual and must also either be placed on the device packaging or on a removable label attached to the device.

(b)-(c) [Reserved]

(d) Consumer electronics TV receiving devices, including TV receivers, videocassette recorders, and similar devices, that incorporate features intended to be used with cable television service, but do not fully comply with the technical standards for cable ready equipment set forth in [§ 15.118](#), shall not be marketed with terminology that describes the device as "cable ready" or "cable compatible," or that otherwise conveys the impression that the device is fully compatible with cable service. Factual statements about the various features of a device that are intended for use with cable service or the quality of such features are acceptable so long as such statements do not imply that the device is fully compatible with cable service. Statements relating to product features are generally acceptable where they are limited to one or more specific features of a device, rather than the device as a whole. This requirement applies to consumer TV receivers, videocassette recorders and similar devices manufactured or imported for sale in this country on or after October 31, 1994.

[54 FR 17714, Apr. 25, 1989, as amended at 59 FR 25341, May 16, 1994; 61 FR 18509, Apr. 26, 1996; 61 FR 31048, June 19, 1996; 62 FR 41881, Aug. 4, 1997; 63 FR 36602, July 7, 1998; 65 FR 64391, Oct. 27, 2000; 68 FR 66733, Nov. 28, 2003; 68 FR 68545, Dec. 9, 2003; 82 FR 50830, Nov. 2, 2017]

Current NN implementation:

<p>ng water</p> <p>d ME</p> <p>99% of crement</p>	<p>Electromagnetic compatibility</p> <p>Dialog® lives up to the emissions and immunity requirements from IEC 60601-1-2:2014 for Home Healthcare Environments. See details on tests in technical description at www.mydialog.com</p> <p>Dialog® complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p> <p>Before you use Dialog® on an airplane, ask the cabin attendants for instructions for using a Bluetooth connection on the flight. You can also ask the airline you fly with for instructions.</p> <p>Wireless technology</p> <p>Frequency Band: 2.4-2.4835 GHz Technology: Bluetooth low energy Modulation type: Gaussian Frequency Shift Keying (GFSK) Output power: 0 dBm</p>	<p>Dialog® and FlexTouch® are registered trademarks of Novo Nordisk. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc.</p> <p>Dialog® is classified as a device receiver category 3: noncritical communication.</p> <p>Dialog® collects data to enable improvements in device performance. The data can only be reviewed during device maintenance.</p> <p>© 2020 Novo Nordisk</p> <p>For information about Dialog® contact: 1-833-4-DIALOG Novo Nordisk Inc. 800 Souders Mill Road Plainboro, NJ 08536 Attention: Customer Care</p> <p>Manufactured by: www.novonordisk.com Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd, Denmark Issued: 2020-XX-XX</p>
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NN Proposal: Since only point number 3 of 15.19 is applicable to Dialogq, no changes proposed as current implementation is sufficient.

Requirement for Canada

For Canadian version of IFU we need to make sure that following requirements are met. Moreover, the statement below should be both in English and French.

8.4 User manual notice

In addition to containing other required statements specified elsewhere in this standard or in the applicable RSS, user manuals for licence-exempt radio apparatus shall contain the following text, **or an equivalent notice**, that shall be displayed in a conspicuous location, either in the user manual or on the device, or both:

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- 1. This device may not cause interference.*
- 2. This device must accept any interference, including interference that may cause undesired operation of the device.*