professional information guide

the trueTear® intranasal tear neurostimulator (trueTear® device) provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

2 indications for use

the patient should not be prescribed the device if they have any of the following (these contraindications are also provided in the patient labeling):

• a cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device in the head or neck
• a known hypersensitivity to the hydrogel device material that contacts the nasal mucosa
• chronic or recurrent nosebleeds, a bleeding disorder, or another condition that can lead to increased bleeding

3 warnings

the patient should be warned of the following (these warnings are also provided in the patient labeling):

• only apply stimulation in a manner consistent with the instructions in this document.
• do not apply stimulation in the presence of electronic monitoring equipment (eg, cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
• do not apply stimulation when in the bath or shower.
• do not apply stimulation while driving, operating machinery, or during any activity in which sneezing or watery eyes may put the user at undue risk of injury.
• do not apply the device to the neck, chest, or areas other than the nose.
• persistent use of stimulation in the presence of irritation of the target nasal tissue may cause injury.
• operation in close proximity (eg, 3 feet or less) to shortwave or microwave therapy equipment may produce instability in the output of the device.
• do not use the device in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide as there is a remote possibility (comparable to the risk of a mobile phone) it could ignite the gas.

4 precautions

the patient should also be advised of the following (these precautions are also provided in the patient labeling):

• before operating the device, the patient should consult their healthcare provider for instructions.
• if the patient feels pain, discomfort, or numbness in their nose with higher levels of stimulation or a longer duration of stimulation, they should reduce the level or a longer duration of stimulation, they should reduce the level or number of times they stimulate the nose. if symptoms persist, they must discontinue use and contact their provider.
• for proper operation and good hygiene, the disposable tip must be disposed of every 48 hours and replaced with a new tip.
• remove any studd, nose rings, or other piercings from the nose prior to using the device.
• ophthalmic prescription eye medications (eye drops, gels, or ointments) should not be used within 30 minutes before or after applying stimulation.
• nasal sprays should not be used within 30 minutes before or after applying stimulation.
• patients with suspected or diagnosed heart disease should follow precautions recommended by their providers.
• keep this device out of the reach of children.
• patients with a severe phobia of placing objects in the nose may not be able to effectively utilize this device.
• clean as directed.
• failure to replace the tip as directed will cause the device to not work properly.

5 potential complications

• nasal pain, discomfort, or burning sensation
• transient electrical discomfort
• nosebleeds
• nasal congestion
• excessive sneezing
• nasal irritation or numbness
• nasal infection, abrasion, ulceration or inflammation
• irritation or sensitivity of the target nasal tissue
• headache, light headedness
• trace blood, dot heme in nostril
• facial pain or pain around the eye, sinus pain, sore eye
• increased salivation
• sensation of teeth vibrating
• excessive nose running
• temporary aggravation of symptoms associated with nasal allergies
• allergic reaction to contact materials
• permanent nasal scarring with prolonged use

6 trueTear® device overview

the trueTear® device consists of four distinct parts:
1. A reusable base unit, which produces the electrical stimulation
2. A disposable tip that inserts into the nasal cavity and stimulates the target intranasal tissue
3. A reusable cover to protect the disposable tip
4. A charger, which recharges the battery inside the base unit

the disposable tip connects to the base unit and contains a hydrogel (similar to the material used in contact lenses) which provides the contact for conducting the stimulation current, which is produced by the base unit, to the target site on the inside of the nose. remove and replace the disposable tip every 48 hours; a separate cover can be used to protect the disposable tip between uses. with the disposable tip removed, the base unit can be inverted and placed onto the charger to recharge the base unit’s battery. the base unit should be recharged every 48 hours or when you change the tip. all images show in this guide are for referencing only.

7 charging the battery

note: only use the provided AC adapter for attaching to charger.

1. ensure the base unit is fully charged if using the device for the first time.
2. if the device has been fully charged and placed on the charger throughout the day (in between uses), it is not necessary to wait for the LED light to turn from a steady orange to green.
3. connect the charger to the wall outlet (120-240V) using the micro USB wall adapter and cable (Figure 2). caution: the AC adapter provides protection from high voltages and should only be plugged into easily accessible outlets.

4. remove the disposable tip from the base unit by rocking the tip away from the buttons—the disposable tip should disconnect easily. then place the base unit onto the charger. an LED light will turn to a steady orange to indicate that the base unit is correctly charging (Figure 3).

trueTear® device components.

Figure 1. The trueTear® device components.

Figure 2. Connecting the charger.

Figure 3. Placement of base unit on the charger.

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trueTear® device components.

Figure 1. The trueTear® device components.

Figure 2. Connecting the charger.

Figure 3. Placement of base unit on the charger.
5. Remember to charge the base unit every 48 hours. The charging process should take less than 4 hours to complete. An LED light will turn green to indicate that charging is complete. The base unit may be removed or left on the charger when charging is complete (Figure 4).

6. Gradually increase and adjust stimulation level (using the +/- buttons) until you feel a gentle tingling in your nose; this feeling is an indication that you are stimulating the correct tissue location and tears will start forming.

7. There are 5 stimulation intensity levels. The base unit vibrates briefly when a + button is pressed to indicate an increase or - button is pressed to indicate decrease in stimulation level. The blue LED light will be lit to indicate the stimulation level selected (Figure 9).

8. If you do not feel any sensation at all, replace the tip with a new tip and try again.

9. If you feel uncomfortable during stimulation, remove the device from your nose.

10. The device automatically turns off after one minute of stimulation. Alternatively, the device may also be turned off by holding down the - button for 2 seconds. The device will vibrate and the LED lights will turn off to indicate that the power has been switched off.

11. If you prefer a longer stimulation time, restart the device after it turns off.

12. When finished, clean system with tissue or an alcohol wipe (see CARING FOR DEVICE) prior to attaching the cover to protect the disposable tip between uses (Figure 10).

8 ASSEMBLY INSTRUCTIONS

1. Ensure the base unit is fully charged if using the device for the first time (see CHARGING THE BATTERY).

2. Tear tip pouch at notch to open, and remove disposable tip from the pouch by grasping the base (as shown in Figure 5). Avoid touching the hydrogel.

3. Connect the disposable tip to the base unit by aligning the tab on the underside of the disposable tip with the notch on the base unit, then rotate forward until the disposable tip snaps into place, as shown in Figure 6.

4. Do NOT submerge or immerse the base unit, electrical plug, or charger in water or other liquid.

5. Place thumb near buttons of the base unit, then insert the disposable tip into the nasal cavity with the buttons pointing towards your lips and face, as shown in Figure 7 above.

6. Effective stimulation, ensure tip is inserted all the way to the top and front of the nose, as shown in Figure 8.

7. Gradually increase and adjust stimulation level (using the +/- buttons) until you feel a gentle tingling in your nose; this feeling is an indication that you are stimulating the correct tissue location and tears will start forming.

IMPORTANT: DO NOT USE A DISPOSABLE TIP FOR MORE THAN 48 HOURS. The disposable tip should be replaced every 48 hours. Failure to replace the disposable tip causes the hydrogel to dry out and may result in ineffective stimulation.

9 STIMULATION INSTRUCTIONS

The following set of instructions is provided to the patient in a separate document; however, the healthcare provider should confirm the patient’s understanding of these instructions, including the patient’s demonstration of stimulation and the tearing response, prior to prescribing the device and, if necessary, at subsequent visits:

1. With the device fully assembled, hold the + button for 5 seconds to turn on the device.

2. Press the + button to select a desired stimulation intensity level. Blue LED lights show the level selected.

3. Place thumb near buttons of the base unit, then insert the disposable tip into the nasal cavity with the buttons pointing towards your lips and face, as shown in Figure 7 above.

4. For effective stimulation, ensure tip is inserted all the way to the top and front of the nose, as shown in Figure 8.

5. Rest thumb on the + or - button. Press + or - to change levels if desired.

6. Insert tip into your nose, as far as is comfortable.

7. Tip may be repositioned along the inside surface of the nose to achieve the desired stimulation. At its maximum, the sensation should be mild.

8. If you do not feel any sensation at all, replace the tip with a new tip and try again.

9. If you feel uncomfortable during stimulation, remove the device from your nose.

10. The device automatically turns off after one minute of stimulation. Alternatively, the device may also be turned off by holding down the - button for 2 seconds. The device will vibrate and the LED lights will turn off to indicate that the power has been switched off.

11. If you prefer a longer stimulation time, restart the device after it turns off.

12. When finished, clean system with tissue or an alcohol wipe (see CARING FOR DEVICE) prior to attaching the cover to protect the disposable tip between uses (Figure 10).

10 RECOMMENDED STIMULATION SCHEDULE

The patient is to perform intranasal tear stimulation at least twice a day, as needed. For each instance, stimulation longer than 3 minutes (3 sequential cycles) is not recommended and the patient should wait for at least 60 minutes before proceeding to the next application.

The device is capable of single-day stimulation up to a limit of 30 minutes, for all stimulation levels combined. Once the daily limit has been reached, the device will turn on and then off immediately and will no longer deliver stimulation.

11 CARING FOR THE TRUETEAR® DEVICE

The following set of instructions is provided to the patient in a separate document; however, the healthcare provider should confirm the patient’s understanding of these instructions prior to prescribing the device and, if necessary, at subsequent visits:

1. Use alcohol wipes to clean the cover, disposable tip, and device between uses. Avoid damaging the hydrogel.

2. Use alcohol wipes to clean the durable parts of the device including the base, charger, and cover (including the interior of the cover). Clean the inside of the cover weekly or more often if needed to ensure proper hygiene.

3. Do NOT submerge or immerse the base unit, electrical plug, or charger in water or other liquid.

4. Handle with care. Store the True Tear® device system in a clean, cool, and dry location. Avoid exposure to direct heat and high humidity. Avoid exposure to extremes of temperature and humidity.

CAUTION: Exposure to direct heat can cause the hydrogel in the disposable tip to dry out and may result in ineffective stimulation. Avoid touching the metal contacts of the base unit or charger if either unit is exposed to high temperature extremes (eg, sitting in a hot car).

5. If you feel uncomfortable during stimulation, remove the device from your nose.

6. If you do not feel any sensation at all, replace the tip with a new tip and try again.

7. If you feel uncomfortable during stimulation, remove the device from your nose.

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9. If you prefer a longer stimulation time, restart the device after it turns off.

10. When finished, clean system with tissue or an alcohol wipe (see CARING FOR DEVICE) prior to attaching the cover to protect the disposable tip between uses (Figure 10).

11. Cover attached to base unit to protect disposable tip.
Two pivotal clinical studies have been conducted with the TrueTear® device. Both studies evaluated the TrueTear® device's safety and effectiveness in dry eye patients. Both pivotal studies (OCN-009 and OCN-010) demonstrated the device’s capability to temporarily increase tear production during stimulation.

Study OCN-010 demonstrated the device’s capability to improve dry eye symptoms as a result of stimulation. The next section summarizes both pivotal studies.

**Acute Tear Production Pivotal Clinical Trial (OCN-009)**

This pivotal trial, “A Randomized, Controlled, Double-Blind, Multicenter Trial Designed to Evaluate the Efficacy and Safety of the TrueTear® Device for Increasing Tear Production During Stimulation With the TrueTear® Device Compared to Two Control Applications in Patients With Aqueous Deficient Dry Eye,” evaluated the safety and effectiveness of the TrueTear® device at multiple time points during the study (7, 30, 90, and 180 days) for subjects with aqueous deficient (ATD) dry eye.

Potential subjects were required to meet the following main inclusion criteria at screening:
- At least 22 years of age or older
- Baseline Ocular Surface Disease Index (OSDI®) score of at least 33 with no more than three responses of “not applicable”

In conclusion, there was a clinically and statistically significantly higher degree of tear production during stimulation with the TrueTear® device than with either of the 2 control applications. Safety during the study was acceptable, and there were no relevant changes in any cardiorespiratory measures.

**Six-Month Pivotal Clinical Trial (OCN-010)**

In this 2-vision study, potential subjects underwent a screening (visit 1) to determine eligibility prior to device use on the study day (visit 2). On the study day, each subject underwent 3 applications, 1 active and 2 control applications, administered in random order. These applications consisted of the following:
- **Active intranasal stimulation (active)**
- **Active extranasal (off-target) device application (control)**
- **Sham device intranasal application (control)**

The primary effectiveness endpoint was the difference between the Schirmer test score during active stimulation and during each of the 2 control applications. A crossover linear model was fit with Schirmer test result as the response variable; sequence, application, period, and the application-by-period interaction as fixed effects; and subject (sequence) as a random effect to account for correlation among observations within a participant. Pairwise comparisons between the active device and each of the controls were formed using least-squares means from the crossover model. The direct clinical benefit of temporarily increasing tear production was as a therapy for patients with dry eye disease was not assessed as part of this clinical trial.

The primary safety measure was the proportion of subjects reporting 1 or more adverse events (AEs) in addition to the proportion of subjects reporting device-related AEs. Additional safety measures included CDVA, still lamp biomicroscopy findings, nasal endoscopy, and sensitivity of occlusion (UPST) at study exit compared to baseline.

In conclusion, there was a clinically and statistically significantly higher degree of tear production during stimulation with the TrueTear® device than with either of the 2 control applications. Safety during the study was acceptable, and there were no relevant changes in any cardiorespiratory measures.

**Table 1: Subject accountability**

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>Day 0</th>
<th>Day 90</th>
<th>Day 180</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available analysis</td>
<td>97 (100%)</td>
<td>97 (100%)</td>
<td>97 (100%)</td>
</tr>
<tr>
<td>Missing</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Discontinued</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Subject choice</td>
<td>97 (100%)</td>
<td>97 (100%)</td>
<td>97 (100%)</td>
</tr>
<tr>
<td>Adverse event</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Percentages are based on the total number of subjects enrolled.

The study met its primary effectiveness endpoint and each of its secondary effectiveness endpoints. Mean acute stimulated tear production in the study eye during use of the device was significantly higher in the same eye than the mean unstimulated tear production on day 180 (P < .001, one-sided paired t test compared to unstimulated tear production during the study). Within the initial stimulus, there was a trend toward decreased effectiveness (tear production) in comparison with the time with the use of the TrueTear® device; this trend appeared to plateau toward the end of the study. The mechanism for this decrease has not been identified and was not analyzed as part of this study. The mean difference in Schirmer score (stimulated versus unstimulated) was 18.0 mm on day 0, 18.0 mm on day 7, 13.1 mm on day 30, 8.3 mm on day 90, and 9.4 mm on day 180.

**Figure 13. Schirmer test scores of study eye by device application group.**

The TrueTear® device presented an acceptable safety profile in this study, with no serious adverse events (SAEs) and no AEs that led to discontinuation from the study. Two AEs were deemed related to or possibly related to the device. These included transient lightheadedness and sinus congestion. No AEs were reported as serious or anticipated change during study.
The primary study endpoint outcomes at day 180 were stratified by age, sex, race, and baseline Schirmer score. The outcomes were statistically significant for all age strata except those subjects over age 70, which was composed of only one subject. The results were also statistically significant for both males and females, as well as white and nonwhite races.

Subjects with a baseline Schirmer score of 0 to 5 mm experienced a mean (SD) increase in stimulated Schirmer score of 8.9 (11.4) mm, and subjects with a baseline Schirmer score of 6 to 10 mm experienced a mean increase of 9.8 (10.5) mm. The results were statistically significant for both the 0- to 5-mm group and the 6- to 10-mm group.

Secondary effectiveness endpoints included the acute stimulated tear production in the study eye on days 0, 7, 30, and 90. Mean acute stimulated tear production in the study eye compared to baseline ranged from 8.1 mm (11.2) to 18.0 mm (9.6) following device application was statistically significantly better than the mean unstimulated study eye on days 0, 7, 30, and 90. Mean acute stimulated tear production in the study eye was significantly for both the 0- to 5-mm group and the 6- to 10-mm group.

Mean Difference (SD), Stimulated vs Unstimulated 8.05 (11.150) ---
95% CI for the Mean Difference (5.73, 10.38) ---
P value, paired t test < .0001 ---
P value, Wilcoxon signed rank test < .0001 ---

Abbreviations: CI: confidence interval; Min: minimum; Max: maximum; N: total number of subjects; n: number of subjects in given subgroup; SD: standard deviation.

The safety profile of the TrueTear® device was acceptable in this study, with no device-related AEs, and only mild device-related AEs that were largely nasal in nature (Table 4). All device-related AEs (mostly mild discomfort or epistaxis) were evident to the patients and therefore self-limiting (with the exception of one case of ached skin around the nostrils that resolved with over-the-counter Neosporin®) since patients could remove the device and discontinue stimulation at any time. The incidence of device-related AEs decreased over the course of the study, with the highest number (22, 61%) occurring in the first month, followed by 6 (17%) mild AEs that occurred between days 31 and 90, and 8 (22%) mild AEs occurring in the final 3 months of the study. These 36 device-related mild AEs occurred in 97 subjects with 27,338 cumulative stimulations.

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The TrueTear® device has been tested for immunity to electrostatic discharge, radio frequency interference with nearby electrical equipment.

### EMISSIONS

#### Guideline and Manufacturer’s Declaration – Emissions

**Medical Equipment and Medical Systems**

The TrueTear® device contains a fully certified Bluetooth® transceiver module. This device complies with Part 15 of the FCC Rules. Operation of the Bluetooth transceiver is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received.

#### Specification

**Description**

- Bluetooth 4.1

- **ISM Frequency Band**: 2.4 – 2.48 GHz

- **Channels**: 0-39

- **Transmit Power**: +7.5 dBm

- **Modulation Method**: GFSK

- **Max Data Rate**: 1 Mbps

#### Immunity Test

<table>
<thead>
<tr>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD IEC 60100-4-2</td>
<td>±8kV Contact ±15kV Air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%</td>
</tr>
<tr>
<td>EFT IEC 60100-4-4</td>
<td>±3kV Mains ±1kV I/Os</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
<tr>
<td>Surge IEC 60100-4-5</td>
<td>±1kV Differential ±3kV Common</td>
<td>Mains power quality should be that of a typical commercial or hospital environment</td>
</tr>
</tbody>
</table>

#### RF Emissions

- **CISPR 11**
  - **Group 1**
  - **Class B**

- **EN 61000-3-2**
  - **Class A**

- **EN 61000-3-3**
  - **Complies**

### ELECTROMAGNETIC COMPATIBILITY

#### Guidance and Manufacturer’s Declaration – Immunity

**Medical Equipment and Medical Systems**

The TrueTear® device is intended for use in the electromagnetic environment specified below. The customer or user of the TrueTear® device should ensure that it is used in such an environment.

#### Emissions Test

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>The TrueTear® device 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.</td>
</tr>
<tr>
<td>RF Emissions</td>
<td>The TrueTear® device is suitable for use in all establishments, including domestic establishments and those connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
</tbody>
</table>

### ELECTRICAL SPECIFICATIONS

#### Table 6: Impedance summary, OCUIN-010 study

<table>
<thead>
<tr>
<th>Level</th>
<th>Peak Current (mA)</th>
<th>Maximum Impedance for Full Peak Current (kΩ)</th>
<th>% of Impedance Measurements Less Than Maximum for Each Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.7</td>
<td>16.6</td>
<td>100.0% (462/462)</td>
</tr>
<tr>
<td>2</td>
<td>1.5</td>
<td>2.5</td>
<td>65.3% (292/448)</td>
</tr>
<tr>
<td>3</td>
<td>3.5</td>
<td>5.2</td>
<td>85.7% (297/345)</td>
</tr>
<tr>
<td>4</td>
<td>3.7</td>
<td>3.5</td>
<td>78.4% (198/254)</td>
</tr>
<tr>
<td>5</td>
<td>5.0</td>
<td>2.6</td>
<td>56.6% (209/368)</td>
</tr>
<tr>
<td>6</td>
<td>13.1</td>
<td>3.1</td>
<td>61.5% (1,016,038/1,167,177)</td>
</tr>
</tbody>
</table>

The mean number of device applications per subject over the study period was 286 (SD: 154 applications, range: 12-685). The majority of application time was at Level 2 (= 37%), Level 3 (= 37%), and Level 4 (= 19%), with less application time at Level 1 (= 3%) and Level 5 (= 5%).

In conclusion, a clinically and statistically significant increase in tear production during stimulation events.

The device was applied for an average of 1.7±1.5 times per day with an average daily application time of 130±159 seconds/day (2.16±2.66 minutes/day). Subjects applied the device a total of 27,338 times during the study, and the total device application time for the study was 34,726 minutes. The mean number of device applications per subject over the study period was 286 (SD: 154 applications, range: 12-685). The mean duration of the TrueTear® device use per subject was 21,932 seconds or 365.5 minutes (SD: 18,582 seconds, range: 1,745-128,659).

The mean number of device applications per subject over the study period was 286 (SD: 154 applications, range: 12-685). The mean duration of the TrueTear® device use per subject was 21,932 seconds or 365.5 minutes (SD: 18,582 seconds, range: 1,745-128,659). The number of device applications varied significantly among the 37 subjects. The mean number of device applications per subject over the study period was 286 (SD: 154 applications, range: 12-685). The mean duration of the TrueTear® device use per subject was 21,932 seconds or 365.5 minutes (SD: 18,582 seconds, range: 1,745-128,659). The number of device applications varied significantly among the 37 subjects.

In conclusion, a clinically and statistically significant increase in tear production during stimulation events.
15  EXPECTED SERVICE LIFE
Base unit, charger: 3 years from date of original purchase.
Tip assemblies: expiration date provided on product labeling.

16  DISPOSAL & REPLACEMENT
The base unit, charger, and AC adapter should be returned to the local distributor for recycling and disposal in accordance with any applicable local, state, and national regulations for disposal of electronic equipment.
Tip assemblies may be discarded with regular trash. The patient is instructed to contact their doctor if any portion of the system is not operating properly or if they need additional supplies.

17  Bluetooth®
This device includes Bluetooth® Smart wireless technology. This feature allows patients to download their TrueTear® device data so they can view and track their usage on their smartphone via the TrueTear® mobile app. The Bluetooth® feature does not have to be on for patients to use the TrueTear® device. For more information on using Bluetooth® and the TrueTear® mobile app, please visit www.truetear.com/app.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Allergan is under license. Other trademarks and trade names are those of respective owners.

18  FCC COMPLIANCE
This device contains FCC ID: T9JRN4020. 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.
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:
• Reseat 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.

19  ENVIRONMENTAL OPERATING CONDITIONS
Ambient temperature range: 5°C to 40°C
Relative humidity range: 20% to 90%

20  SYMBOLS & MARKINGS

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Guidance and Manufacturer’s Declaration – Immunity to RF wireless communications equipment ME Equipment and ME Systems

The TrueTear® device is intended for use in the electromagnetic environment specified below. The customer or user of the TrueTear® device should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Test</th>
<th>Band²</th>
<th>Service¹</th>
<th>Modulation³</th>
<th>Maximum Power</th>
<th>Distance</th>
<th>Immunity Test Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380 - 390</td>
<td>TETRA 400</td>
<td>Pulse modulation²</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430 - 470</td>
<td>GMRS 460, FRS 460</td>
<td>FM ± 5 kHz deviation 1 kHz sine</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>710 - 745</td>
<td>704 - 747</td>
<td>LTE Band 13, 17</td>
<td>Pulse modulation²</td>
<td>2</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>810 - 860</td>
<td>800 - 960</td>
<td>GSM 800/900, TETRA 800, DECT 820, CDMA 850, LTE Band 5</td>
<td>Pulse modulation²</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>1720 - 1845</td>
<td>1700 - 1900</td>
<td>GSM 1800; CDMA 1900; GSM 1000; DECT; LTE Band 1, 3, 4, 25, UMTS</td>
<td>Pulse modulation²</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>2450</td>
<td>2400 - 2570</td>
<td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation²</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>6240 - 6500</td>
<td>5100 - 5785</td>
<td>WLAN</td>
<td>Pulse modulation²</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
</tbody>
</table>

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

¹ For some services, only the uplink frequencies are included.
² The carrier shall be modulated using a 50% duty cycle square wave signal.
³ As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.