U.S. FOOD & DRUG ADMINISTRATION

May 11, 2020

Christopher Wood
Director – Quality Assurance & Regulatory Affairs
Ascom (US) Inc.
9024 Town Center Parkway, Suite 200
Bradenton, FL 34202

Dear Mr. Wood:

This letter is in response to your[1] request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the Ascom teleCARE IP Nurse Call System (hereafter referred to as teleCARE IP Nurse Call System)[2] for use by healthcare providers and patients in healthcare environments, including temporary hospital facilities, as a powered environmental control system intended for medical purposes with additional hardware and software modifications implementing the capability for remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. During the Coronavirus Disease 2019 (COVID-19) outbreak, the remote communication and monitoring capabilities of the teleCARE IP Nurse Call System may reduce the amount of contact by healthcare providers with patients who are in isolation rooms, thereby reducing healthcare provider risk of exposure to SARS-CoV-2, the virus that causes COVID-19.[3]

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination,

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to Ascom (US), Inc.

[2] The teleCARE IP Nurse Call System is a wireless nurse call system, similar to the Telligence Nurse Call System that is currently marketed in the United States as a powered environmental control system under 21 CFR 890.3725, product code IQA. The Telligence Nurse Call System is class II, exempt from premarket notification requirements in section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (510k exempt), pursuant to 21 CFR 890.9. The new feature to monitor ventilator status would exceed the limitations of the exemption from section 510(k) premarket notification requirements, and therefore, in order to market the teleCARE IP Nurse Call System with this new feature in the United States, Ascom (US) Inc. would be required to submit a premarket notification under section 510(k) and receive FDA clearance prior to marketing.

[3] Under the circumstances of this public health emergency, it would not be feasible to require healthcare providers to limit the use of the product only to patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.

[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration*

the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[5]

The teleCARE IP Nurse Call System allows the patient to communicate with the healthcare provider through a wireless nurse call system, including when the patient needs help or is in distress. Additionally, for those patients utilizing a ventilator, the system connects the ventilator to the wireless nurse call system via the "nurse call interface" available on most ventilators. This allows ventilation issues and alarms from the ventilator to be sent to alert the healthcare provider through the nurse call system. The teleCARE IP Nurse Call System is not FDA-cleared or approved.

FDA has concluded there is a need for wireless products such as the telecare IP Nurse Call System for the totality of healthcare settings used during the COVID-19 outbreak, including temporary hospitals. There are no FDA-approved or cleared (or 510k exempt) devices for remote monitoring of ventilator status updates to alert the healthcare provider, which may reduce the exposure of healthcare providers to SARS-CoV-2. Finally, there is a history of safe use of the wired Telligence Nurse Call System in the United States and the global use of the wireless teleCARE IP Nurse Call System outside the United States.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the teleCARE IP Nurse Call System, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the teleCARE IP Nurse Call System, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the use of the teleCARE IP Nurse Call System in healthcare environments may be effective for preventing COVID-19 exposure in healthcare providers by enabling remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare

that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

provider. I have concluded that the known and potential benefits of the teleCARE IP Nurse Call System, for such use, outweigh the known and potential risks of the product; and

3. There is no adequate, approved, and available alternative to the emergency use of the teleCARE IP Nurse Call System.[6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the teleCARE IP Nurse Call System by healthcare providers and patients in healthcare environments, including temporary hospital facilities, as a powered environmental control system intended for medical purposes with additional hardware and software modifications implementing the capability for remote communication between patients and healthcare providers, and for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. During the COVID-19 outbreak, the remote communication and monitoring capabilities of the teleCARE IP Nurse Call System may reduce the amount of contact by healthcare providers with patients who are in isolation rooms, thereby reducing healthcare provider risk of exposure to SARS-CoV-2.

The Authorized teleCARE IP Nurse Call System

The teleCARE IP Nurse Call System is a system that facilitates wireless communication between healthcare providers and patients in healthcare environments, including temporary hospital environments. Patients may request assistance from healthcare providers through a pull cord or a wireless wrist- or neck-worn transceiver.

The teleCARE IP Nurse Call System also employs a wired or wireless transceiver that connects to dry contact relay closures available on most ventilators. Detection of the relay closure can prompt an alert to the healthcare provider.

The teleCARE IP Nurse Call System contains the following components in configurations specific to each installed location:

- NUUTX-HU, Wireless Universal Transceiver US (United States)
- NITX-BAB and/or NITX-AAB, Mobile Transmitter NA (North America)
- NUREP-HU, Wireless Repeater (US Band)
- NIRC3-GMN (gray) and/or NIRC3-WMN (white), teleCARE IP Room Controller 3
- NIRX-1AB, Transceiver for use with NIRC3-GMN and/or NIRC3-WMN
- NIFX-1AB, Wireless Pull Cord (used with NIRX-1AB Wireless Transceiver)
- NIFX-1BB, Wireless Bedside Module (used with NIRX-1AB Wireless Transceiver)
- NIPH1-A1A, Bedside Handset

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- NUWBM3-HU, Wireless Bedside Module with NUHS1B-H, 1 Button Handset
- FE3-NKABAE (NISM2), teleCARE IP System Manager on Elise3 Platform
- UCM (United Connectivity Manager)
- Ethernet Switch (EIS8-100T, EIS6-100T/FCS, EIS6-100T/FC
- Ascom Wi-Fi and/or DECT (Digital Enhanced Cordless Telecommunications) Handset
- NIRD-GAA or NIRD-WAA, Room Display

These components can be combined into many different configurations to fit the needs of the healthcare facility.

The above described teleCARE IP Nurse Call System is authorized to be accompanied with the following information pertaining to the emergency use of the product, consistent with the use outlined in the Scope of Authorization of this letter (Section II)), which are authorized to be made available to healthcare providers and healthcare facilities:

- Fact Sheet for Healthcare Personnel: Ascom teleCARE IP Nurse Call System
- Fact Sheet for Patients: Ascom teleCARE IP Nurse Call System
- teleCARE IP Call Module User Manual
- Installation Guide teleCARE IP Nurse Call System

User manuals for the associated components, as applicable:

- Installation Guide: Elise3
- User Manual teleCARE Handset NIPH2 + NIPH3
- User Manual teleCARE - Fixed Transceiver (NIFX-1AB and NIFX-1BB)
- User manual teleCARE - Mobile Transceiver (NITX-AAB and NITX-BAB)
- User manual teleCARE - Wireless Bed Modules (NUWBM3-HU)
- Telligence User Guide - Handset User Instructions (NUHS1B and NUHS3B)

The above described product, when accompanied with the User Manual(s) (identified above) and the Fact Sheets (collectively referred to as “authorized labeling”) is authorized to be distributed under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the teleCARE IP Nurse Call System, when used as described in the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized teleCARE IP Nurse Call System may be effective for preventing COVID-19 exposure in healthcare providers, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized teleCARE IP Nurse Call System, when used as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the teleCARE IP Nurse Call System must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the teleCARE IP Nurse Call System described above is authorized for use in healthcare environments for remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider, during the COVID-19 outbreak. The remote communication and monitoring capabilities of the teleCARE IP Nurse Call System may reduce the amount of contact by healthcare providers with patients who are in isolation rooms, thereby reducing healthcare provider risk of exposure to SARS-CoV-2, the virus that causes COVID-19.

III. Waiver of Certain Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the teleCARE IP Nurse Call System, that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Ascom (US) Inc., as Sponsor of Authorized Product

A. Ascom (US) Inc. must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Ascom (US) Inc. will make the teleCARE IP Nurse Call System available with authorized labeling. Ascom (US) Inc. may request changes to the authorized labeling. Such changes require review and concurrence from OHT2/OPEQ/CDRH.

C. Ascom (US) Inc. may request changes to the Scope of Authorization (Section II in this letter) of the authorized teleCARE IP Nurse Call System. Such requests will be made by

Ascom (US) Inc., in consultation with and require concurrence of OHT2/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

D. Ascom (US) Inc. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.

E. Ascom (US) Inc. will have process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803.

F. Ascom (US) Inc. will notify FDA of any authorized distributor(s)[7] of the teleCARE IP Nurse Call System, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Ascom (US) Inc., and any Authorized Distributor(s)

G. Ascom (US) Inc., and authorized distributors will distribute the authorized teleCARE IP Nurse Call System with the authorized labeling only to healthcare facilities with healthcare providers who are adequately equipped, trained, and capable of using the teleCARE IP Nurse Call System according to the criteria set forth by Ascom (US) Inc. This includes, but is not limited to, Ascom (US) Inc. and authorized distributors providing assistance to healthcare facilities to ensure compatibility and assist with configuration of the teleCARE IP Nurse Call System, as the components of the system can be combined into many different configurations to fit the needs of the healthcare facility.

H. Ascom (US) Inc., and authorized distributors will make authorized labeling available on their websites.

I. Authorized distributors will make Ascom (US) Inc. aware of any adverse events of which they become aware.

J. Through a process of inventory control, Ascom (US) Inc. and authorized distributors will maintain records of the healthcare facilities to which they distribute the teleCARE IP Nurse Call System and the number of each product they distribute.

K. Ascom (US) Inc. and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

L. Ascom (US) Inc. and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be

[7] "Authorized Distributor(s)" are identified by Ascom (US) Inc. in an EUA submission as an entity allowed to distribute the device.

made available to FDA for inspection upon request.

Healthcare Facilities

M. Healthcare facilities using the authorized teleCARE IP Nurse Call System must make available to healthcare providers and patients the accompanying Healthcare Provider Fact Sheet and Patient Fact Sheet, respectively.

N. Healthcare facilities using the teleCARE IP Nurse Call System must make Ascom (US) Inc. aware of any adverse events.

O. Healthcare facilities will ensure healthcare providers using the teleCARE IP Nurse Call System are adequately equipped, trained, capable, and will maintain records of product usage.

Conditions Related to Printed Materials, Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional materials relating to the use of the authorized teleCARE IP Nurse Call System shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Q. No descriptive printed matter, including advertising or promotional materials relating to the use of the authorized teleCARE IP Nurse Call System may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

R. All descriptive printed matter, including advertising and promotional materials relating to the use of the authorized teleCARE IP Nurse Call System shall clearly and conspicuously state that:

- The teleCARE IP Nurse Call System has neither been cleared or approved for remote communication between patients and healthcare providers, and for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider;

- The teleCARE IP Nurse Call System has been authorized for the above emergency use by FDA under an EUA;

- The teleCARE IP Nurse Call System has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures