APPENDIX A: SUMMARY OF LABELING AND SUPPLEMENTAL INFORMATION RELATED TO ELECTRONICS SYSTEM EMISSIONS

ELECTROMAGNETIC EMISSIONS

- Hospital Electronics Systems Instructions for Use
    - If two electronic units are proximate to each other and are used at the same time, pressure measurements may be affected due to interference between the two systems. In such isolated cases, it is recommended that operation of each electronics unit occur at separate times.
    - The use of accessories, transducers and cables, other than those specified and sold by the manufacturer of the system as replacement parts for internal components, may result in electromagnetic interference or decreased electromagnetic compatibility of the system. The use of other attachable parts other than the parts provided may result in inaccurate readings, damage to the system, or injury to the user.

Abbott is providing the following additional information for CardioMEMS™ Patient Electronic Systems (Models CM1000, CM1100) and CardioMEMS™ Hospital Systems (Model CM3000) to replace references to compliance with CISPR 11 and FCC Part 18 standards:

- The emissions characteristics of this equipment might not offer adequate protection to radio-frequency communication services when taking readings. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Abbott has performed device testing and evaluations to demonstrate continued safety of device emissions. Higher emissions do not impact the ability of the device to accurately read sensor data.

Note: Instructions For Use are available to physicians on the Abbott CardioMEMS™ HF System website under Manuals & Technical Resources. CardioMEMS HF System Manuals & Technical Resources | Abbott (https://www.cardiovascular.abbott/int/en/home.html)