



Abbott

**Field Safety Notice
For TactiSys Quartz
PN-004 400
(Part Numbers 100110641, 600075377, 600075378)**

November 2023

Dear Abbott Customer,

We are writing to notify you that the Instructions for Use (IFU) insert was not included in the packaging for TactiSys Quartz equipment (Model PN-004 400) part numbers 100110641, 600075377 and 600075378. According to our records your institution has received one or more affected unit, and below is a list of impacted serial numbers.

| Part Number: 100110641 TactiSys Quartz Global Pack | | |
|---|-------|-------|
| 31855 | 31877 | 32116 |
| 31858 | 31890 | 32474 |
| Part Number: 600075377 TactiSys v1.7.1 Global Pack | | |
| 34193 | 35306 | 36420 |
| 34519 | 35363 | 36430 |
| 35047 | 35489 | 36552 |
| 35050 | 35516 | 36580 |
| 35093 | 35517 | 35855 |
| 35110 | 35729 | 35922 |
| | | 36069 |
| Part Number: 600075378 TactiSys v1.7.1 SWAP | | |
| 33428 | 34144 | 34751 |
| 34003 | 34487 | 35436 |
| 34031 | | |

Scope of Problem and Associated Risk

The units referenced above were packaged without the IFU insert. Based on Abbott's risk analysis, it is unlikely that an adverse health consequence will occur due to exclusion of the IFU insert. The user could potentially experience a procedure delay if information necessary to connect, operate, or troubleshoot the TactiSys Quartz hardware is needed and unavailable during a procedure. There have been no reported complaints for this issue.

Actions Requested

Abbott requests that you take the following steps:


- For any affected inventory, please retain a copy of the IFU insert that has been provided in this packet for use with the equipment.
- Contact your local Abbott Representative with any questions related to this issue.

Reporting and Customer Assistance

The appropriate Regulatory Agencies have been notified of this action. Should you have questions about this issue, please contact your local Abbott Representative.

Abbott is committed to providing the highest quality products and support. Thank you for your assistance in this matter, and we sincerely apologize for any inconvenience this action may cause you.

Sincerely,



Melissa A. Owsley
 Divisional Vice President, Quality
 Abbott Electrophysiology