

LATITUDE NXT Patient Management System for monitoring cardiac devices at home

Medtech innovation briefing

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Summary

The LATITUDE NXT Patient Management System is a remote monitoring system for people with a compatible Boston Scientific implanted cardiac device. The system collects patient and device information and transfers it to a secure central database for review by a clinical team to evaluate both the patient and the device as an alternative to some outpatient visits. The relevant clinical evidence is limited; no prospective studies were identified that compared remote monitoring using LATITUDE NXT with standard in-clinic monitoring. In 1 small non-randomised prospective study LATITUDE NXT showed a low number of false negatives and false positives for detecting adverse patient and device events when compared with other home monitoring systems. In 1 retrospective observational study, remote monitoring using LATITUDE NXT was associated with a statistically significant reduction in all-cause mortality and hospital re-admissions compared with no remote monitoring. In another retrospective observational study, the use of LATITUDE NXT was

associated with a statistically significant increase in long-term post-implantation survival compared with in-clinic monitoring. The main component of the system, the LATITUDE Communicator, typically costs up to £500 (excluding VAT) per patient. The LATITUDE NXT Heart Failure Management System, which includes the Communicator, weighing scales and a blood pressure monitor, typically costs up to £1,200 (excluding VAT).

NICE has also published a medtech innovation briefing on the [CareLink remote monitoring system \(Medtronic\) for compatible implanted cardiac devices](#).

Product summary and likely place in therapy	Effectiveness and safety
<ul style="list-style-type: none">• The LATITUDE NXT Patient Management System monitors a person's compatible implanted cardiac device remotely.• Information collected from the device is transferred securely to a central database where it can be reviewed by their clinician. The system can also send alerts to the clinician if it detects a clinical event or a problem with the device.• LATITUDE NXT is an alternative to face-to-face follow-up, with the aim of reducing the number of hospital visits and earlier detection of adverse events.	<ul style="list-style-type: none">• The relevant evidence is limited to 1 non-randomised, prospective study (n=211), which compared 4 different monitoring systems, and 2 retrospective observational analyses (n=37,742 and 194,006) from the Boston Scientific ALTITUDE registry.• No prospective studies were found that compared remote monitoring using LATITUDE NXT with standard in-clinic monitoring.• In the study comparing 4 different remote monitoring systems, all of the systems effectively detected major events. More frequent transmission of data was associated with a higher probability of detecting events early. LATITUDE NXT showed a low number of false negatives and false positives for detecting events when compared with other home monitoring devices and gave 97% event notification.• In 1 retrospective observational study, remote patient monitoring was associated with a statistically significant reduction in all-cause mortality and hospital re-admissions compared with no remote monitoring.

	<ul style="list-style-type: none"> • In 1 retrospective observational study, remote patient monitoring was associated with a statistically significant increase in long-term post-implantation survival compared with in-clinic monitoring.
<p>Technical and patient factors</p> <ul style="list-style-type: none"> • The LATITUDE NXT Patient Management System consists of a LATITUDE Communicator, the Boston Scientific secure central database and the associated server software. The Communicator automatically collects patient and device information from compatible Boston Scientific implantable cardiac devices. This information is transferred securely to the database at intervals determined by the clinician. The system does not provide continuous real-time monitoring. • The information is transferred via a standard telephone landline, mobile line (using a built-in 2G modem in later Communicator models or a separate 3G dongle) or through a wired Ethernet connection. • Authorised members of a clinic may access the data through the LATITUDE NXT website or through an iPhone app. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • The LATITUDE Communicator for use in the patient's home typically costs up to £500 (excluding VAT). • The LATITUDE NXT Heart Failure Management System, which includes the Communicator, and additional weighing scales and a blood pressure monitor, typically costs up to £1,200 per patient (excluding VAT). • Boston Scientific provides all additional services to set up a hospital with the system at no charge, including product delivery, installation, training, education and software upgrades. • In 1 abstract, annual cost savings of \$323 (about £223) per patient were estimated in a simulated cohort using remote monitoring with the LATITUDE NXT system in the US. The reduction in costs was related to a decrease in hospital admissions, and partially offset by an increase in physician visits and telephone counselling.

Introduction

More than 2 million people experience cardiac arrhythmia each year in the UK. Atrial fibrillation, supraventricular tachycardia, bradycardia, heart block and ventricular fibrillation are the main types of arrhythmia ([NHS Choices 2015](#)). Ventricular arrhythmias caused about 75–80% of the 70,000 sudden cardiac deaths in England and Wales in 2010 (NICE technology appraisal on [implantable cardioverter defibrillators and cardiac resynchronisation therapy](#)). In addition, around 900,000 people in the UK have heart failure, commonly caused by coronary artery disease and previous heart attack (NICE guideline on [chronic heart failure in adults](#)). Both arrhythmia and heart failure can significantly affect a person's quality of life as well as putting them at risk of sudden cardiac death.

The first-line treatment for arrhythmia and heart failure focuses on pharmacological therapy but when this is no longer effective or can no longer be used, one of the following implantable cardiac devices may be used:

- Pacemaker: monitors the heart's rhythm and sends small electrical pulses to restore normal rhythm if needed.
- Implantable cardioverter defibrillator: like a pacemaker, but can send larger electrical shocks for more serious heart rhythm problems that pacemakers cannot correct.
- Cardiac resynchronisation with pacing device: improves the heart's pumping efficiency.
- Cardiac resynchronisation therapy with a defibrillator device: combines cardiac resynchronisation with pacing and implantable cardioverter defibrillator.
- Implantable loop recorder: records the heart's rhythm to provide information to help guide clinical decision-making.

People with implantable electronic cardiovascular devices need regular monitoring of their condition and to ensure that the device is working correctly, to check battery life and to optimise the device where applicable. Monitoring is usually done in a hospital outpatient setting at defined regular intervals. Home monitoring technology offers another option, so that clinicians can monitor the person's device remotely. This could reduce the frequency of hospital visits, and may also help with faster identification of abnormalities.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The LATITUDE NXT Patient Management System (including the LATITUDE Communicator and the Communicator accessory and literature kit) is a class III device. Boston Scientific was first awarded a CE mark in March 2012. The most recent renewal was in June 2015.

Boston Scientific was awarded a class IIa CE mark for the LATITUDE NXT server software in May 2012.

Description

The LATITUDE NXT Patient Management System is designed to communicate remotely with a compatible Boston Scientific implanted cardiac device and transfer information to a central database where it can be accessed by authorised clinicians. The main component of the system is the LATITUDE Communicator, an in-home monitoring device for patients that periodically collects information on the function of the device and the heart function of the person. The device information is collected from a number of diagnostic tests. These include sensing, which assesses the ability of the device to detect intrinsic cardiac activity; impedance, which measures lead integrity; and threshold, which measures the amount of electrical energy needed to stimulate the heart muscle. The physiological information stored on the device is based on criteria set by the clinician and is specific to the individual patient. Information is transferred to a secure server through either a telephone line or mobile line (using a built-in 2G modem in later Communicator models or a separate 3G dongle) or through a wired Ethernet connection. The ability to transmit data using wireless broadband networks is being introduced. The Communicator measures 20.3×11.4×6.9 cm and weighs 0.38 kg. It is designed to be set up at home by the patient or a carer, and needs to be connected to a power supply and potentially a telephone socket. It should be placed at the patient's bedside or, if this is not practicable, where they spend a

lot of time each day.

The clinician decides when the data should be collected and transmitted. This can be done manually for specified dates, or automatically at predetermined intervals that may be as often as every day. The clinician sets the schedules and configuration through the LATITUDE NXT website and the Communicator updates when it next connects to the server. The system also supports non-scheduled patient-initiated interrogations, which collect the same information as the scheduled collections. This feature needs to be enabled by the clinic, and allows patients to initiate up to a maximum of 5 interrogations per week by pressing the designated button on the Communicator. Use of this feature increases the total number of interrogations, and may decrease the lifetime of the device battery. The Communicator can also send body weight and blood pressure information collected from the compatible wireless weighing scales and blood pressure cuffs supplied by Boston Scientific, as part of the LATITUDE NXT Heart Failure Management System. This feature is intended to alert clinicians to other changes in a patient's clinical status, such as increases in their body weight, which might indicate the early stages of heart failure decompensation

The server is a centralised computer database managed by Boston Scientific that receives, stores, and manages the data from the implanted device and the optional blood pressure monitor and weighing scales, alongside patient details. The system collects sensitive personal data. Patients must consent to data collection and sharing before they are registered on the system. Individual patient data may be accessed only by authorised users via the LATITUDE NXT website or the mobile app for iPhone. Access via the mobile app is read-only and allows the clinician to review patient and device information and generate reports. The website allows clinicians to access pacemaker device and patient health information. The system also issues alerts when it detects adverse clinical events or problems with the device function. The conditions that prompt an alert include clinical issues such as arrhythmia, and technical or mechanical problems with the device such as low battery life and impaired lead performance. The clinician needs to log on to the LATITUDE NXT website in order to receive alerts, which may appear as often as daily. Secondary notification of alerts may be through email or text message, although these depend on external systems. Implanted device issues that could potentially leave the patient without therapy trigger an automatic alert. Less serious alerts for other events can be configured by the clinician for individual patients. Designated Boston Scientific personnel, covered by a confidentiality agreement, also have access to patient data which is used for technical, research and clinical reporting purposes.

LATITUDE NXT can be used only with compatible Boston Scientific devices, which include: the Advantio, Ingenio, Vitalio, Essentio, Proponent, and Accolade pacemakers; the Invive, Inliven, Valitude and Visionist cardiac resynchronisation therapy-pacemakers; the Incepta, Energen, Punctua, Autogen and Inogen defibrillators; and Emblem subcutaneous implantable cardioverter defibrillators. Not all Boston Scientific devices are compatible with the system. Devices from other manufacturers are not compatible with the system. LATITUDE customer support has a telephone helpline and provides technical and general maintenance support to customers using the LATITUDE NXT system.

Setting and intended use

The LATITUDE NXT Patient Management System is intended for use in the person's home for remote monitoring of compatible Boston Scientific implanted cardiac devices. The Communicator can be used in another location (such as a hotel room when on holiday) providing it can be plugged into an electricity supply and the Communicator is able to connect to the LATITUDE NXT server through the configured method. The LATITUDE NXT system collects and sends data from a person's implanted Boston Scientific cardiac device to the secure central database for clinicians to access. The LATITUDE NXT system is intended to reduce the frequency of routine hospital device clinic appointments. The system also issues alerts to give an early warning of a clinical event or device issue.

Current NHS options

Current NHS options for the post-implantation monitoring of implantable cardiac devices include outpatient device clinic evaluations, remote management and remote monitoring.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the LATITUDE NXT Patient Management System:

- CareLink Network (Medtronic)
- Merlin@home (St Jude Medical)
- BIOTRONIK Home Monitoring (Biotronik).

NICE has produced a medtech innovation briefing on the [CareLink Network](#).

Costs and use of the technology

The LATITUDE Communicator typically costs up to £500 per patient. This is a one-off payment and provides continuing unlimited remote monitoring for as long as needed. The full LATITUDE NXT Heart Failure Management System typically costs up to £1,200 and includes the Communicator, weighing scales and a blood pressure monitor. These prices will vary depending on the specific hospital procurement arrangements. Boston Scientific provides all additional services to set up a hospital with the system at no charge, including product delivery, installation, training, education and software upgrades. All maintenance for the life of the system is also provided by LATITUDE customer services at no extra charge. The Communicator is configured to communicate with a single implanted device. Once a Communicator has been used by a patient, it cannot be reconfigured or used by a different patient. The weighing scales and blood pressure monitor are also designed for use by a single patient, and cannot be reconfigured for a different patient.

Likely place in therapy

The LATITUDE NXT Patient Management System would be used to manage and monitor a person's implanted Boston Scientific cardiac device remotely. It is intended to reduce routine outpatient appointments with a cardiologist or cardiac physiologist. The person's clinician would review data from the device using the secure database. If the data suggest a problem or if an alert is sent to the person's clinician, an outpatient appointment would be scheduled if needed.

Specialist commentator comments

One specialist commentator noted that the Communicator is easy to set up and to use, the hardware is robust and reliable, and patients report a great deal of reassurance when using the system. Another specialist commentator noted that there are a number of small switches on the Communicator that need to be correctly positioned in order for the information to be transmitted on a telephone landline, and that patients who are not technically minded or have limited dexterity may need help to set up the Communicator.

One specialist commentator noted differences in the functionality of the LATITUDE system compared with other remote monitoring systems currently available. They stated that the LATITUDE system is the only one that gives alerts for 'accelerated arrhythmias', which the technical staff find useful. However, unlike some other systems it does not have a heart

failure impedance-based assessment for pulmonary oedema, which clinicians have also reported to be useful. The commentator added that the system does have a heart-rate variability algorithm which may give data on a patient's daily performance and clinical status, but that hard data and guidance for its usage is not available as yet for the 'real world' setting.

One specialist commentator noted that the system incorporates much of the benefits of remote monitoring – easy follow-up for patients without the need to travel into the implanting centre, and the generation of alerts which are automatically generated by the system when potential clinical, technical or mechanical problems are identified.

One specialist commentator noted that the retrieval of alerts and episodes can be laborious because the system may identify a single prolonged episode of arrhythmia as several different events, each of which needs to be selected, opened and printed individually.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Implanted cardiac devices can be used by people of any age, but are more commonly used in people over 60 years old. Age is a protected characteristic under the Equality Act 2010.

Patient and carer perspective

The Arrhythmia Alliance, a not-for-profit coalition of charities, patient groups, patients, carers, medical groups and allied professionals, was asked to provide comments on the LATITUDE NXT Patient Management System.

The organisation stated that patients and users welcome and embrace remote monitoring systems. Having the monitor at home, or when travelling on business or holidays (subject to an internet connection), reduces anxiety and gives users the reassurance to enable them to live a normal life. They commented that users feel safe in the knowledge that data are backed-up daily and can be accessed by their clinician at any time. If users or their carers have any concerns they can call the clinic and data can be downloaded for the nurse or technician to review immediately. This provides them with the reassurance that if any problems are detected, they will be given a hospital appointment or the hospital will call them in urgently.

The Arrhythmia Alliance believes that home and remote monitoring is good for the patient and healthcare providers, reducing costs, hospital-acquired infections, waiting times in clinics for new and urgent cases and providing increasing confidence for the patient and carer. Monitoring also reduces anxiety and stress for those with or caring for someone with a potentially life-threatening condition and in receipt of life-saving devices.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed that no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Three relevant studies are summarised in this briefing. No studies that prospectively evaluated the clinical effects of LATITUDE NXT compared with standard in-clinic monitoring were identified.

The study by de Ruvo (2016), summarised in [table 1](#) and [table 2](#), was a prospective non-randomised cohort study that compared 4 different remote monitoring systems to

investigate how the frequency of remote monitoring data transmissions affected the early detection of clinical and device-related events. Patients with implantable cardiac devices (n=211) were monitored for 1 year using LATITUDE NXT (Boston Scientific; n=49), BIOTRONIK Home Monitoring (Biotronik; n=61), CareLink (Medtronic; n=65) and Merlin (St Jude Medical; n=36) systems. The BIOTRONIK system is designed for continuous daily monitoring and sent data daily; all the other systems are designed for periodic monitoring (up to daily, subject to configuration) and for the purposes of the study were configured to send data every 3 months. Event-free rates averaged 55% across the year and were similar for all systems (p=0.23). Daily data transmissions were independently associated with an increased probability of detecting an event compared with quarterly transmissions. The chance of detecting an event was reduced by 20% (p=0.036) for a 1-month increase in the interval between data transmission.

A retrospective observational study, summarised in [table 3](#) and [table 4](#), used patient data from the Boston Scientific ALTITUDE registry to investigate the association between the use of remote patient monitoring of implantable cardioverter defibrillators and all-cause mortality and hospital re-admission following first-time implantation (Akar et al. 2015). The study linked the patient data to the American College of Cardiology National Cardiovascular Data Registry of Implantable Cardiac Devices to adjust for differences in clinical and non-clinical factors in patients who used and did not use remote monitoring. The study used a multivariate time-dependant Cox model, and observed that patients who used remote monitoring had a significantly lower risk of death (hazard ratio 0.67, 95% confidence interval 0.64 to 0.71, p<0.0001) and hospital re-admission (hazard ratio 0.82, 95% confidence interval 0.80 to 0.84, p<0.0001) compared with those who did not.

An earlier retrospective observational study, summarised in [table 5](#) and [table 6](#), used the ALTITUDE database to compare survival in 69,556 patients monitored remotely and 124,450 patients monitored in-clinic (Saxon et al. 2010). This study showed statistically significant improvements in survival for patients having remote monitoring using both implantable cardiac devices (hazard ratio 0.56) and cardiac resynchronisation therapy defibrillators (hazard ratio 0.45, p<0.0001) compared with in-clinic monitoring. The study was unable to account for any possible clinical characteristics that may have influenced the decision to use remote monitoring, limiting the interpretation of the observed results.

Recent and ongoing studies

No current or in-development trials on the effectiveness of the LATITUDE NXT Patient Management System for heart failure or atrial fibrillation patients with implanted cardiac

devices were identified.

Costs and resource consequences

LATITUDE NXT could reduce the number of follow-up attendances at cardiac device clinics and their associated costs. There is the potential for cost savings from more timely identification and treatment of clinical events. The system is currently used by at least 21 NHS trusts.

The economic evidence identified consisted of 1 abstract that addressed how using the LATITUDE NXT system affected the costs of treatment (Stern et al. 2013). This analysis was an individual patient event-based simulation based on a multicentre prospective single-arm observational study that enrolled 889 patients each with a cardiac resynchronisation therapy defibrillator. The patients were monitored using the LATITUDE NXT system to assess the type and frequency of alert notifications, time from alert notification to medical intervention, type of medical intervention, and patient compliance with weight and blood pressure monitoring (RAPID-RF trial; Boehmer et al. 2014). A subset of 128 patients who had at least 1 alert for weight change, atrial tachycardia or cardiac device shock with a subsequent intervention was modelled. A control group was created by cloning each trial patient and simulating their response in the absence of remote monitoring to the conditions that triggered each alert in the trial. The model suggested that remote monitoring reduced the total cost per patient by \$323 (around £223) over the year of the trial. Savings were mainly related to a reduction in the cost of hospital admissions, and partially offset by an increase in physician visits and telephone counselling. Costs were based on a US healthcare payer perspective and the modelled population included only those patients whose remote monitoring system had triggered an alert. As such, the reported outcomes may not be applicable to the NHS, or representative of the general population using the LATITUDE NXT system.

The following 2016/17 National Tariff Payment System costs for NHS cardiology outpatient attendances have been provided for information:

- first attendance, single professional: £166
- first attendance, multi-professional: £230
- follow-up attendance, single professional: £96
- follow-up attendance, multi-professional: £148

Current reimbursement across the NHS for remote follow-up varies according to local arrangements.

Strengths and limitations of the evidence

No studies were identified that evaluated the clinical effects of the LATITUDE NXT Patient Management System compared with standard in-clinic monitoring.

The de Ruvo (2016) study was not UK-based, and was a non-randomised prospective cohort study with a small sample size. It was done at a single site, had short follow-up, and may be subject to sampling bias from the variation in monitoring frequency between the devices. In addition, the study included information about event classification but no clear delineation between clinical and technical events. It is possible that many events fell into several categories and may have been double-counted.

The studies by Akar et al. (2015) and Saxon et al. (2010) were observational, retrospective, non-randomised post-market analyses of the Boston Scientific ALTITUDE database, not prospectively defined clinical trials. Although adjustments were made for a number of measured clinical factors in Akar et al. (2015), it is possible other unmeasured factors could introduce bias. The only data on the cost consequences of using the system were presented in abstract format. It is therefore not possible to fully assess the quality of the evidence.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- [Chronic heart failure in adults: management](#) (2010) NICE guideline 108. Currently being updated
- [Atrial fibrillation: management](#) (2014) NICE guideline 180. Date for review: September 2016
- [Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure](#) (2014) NICE technology appraisal guidance 314. Date for review: May 2017

- [Transient loss of consciousness \('blackouts'\) in over 16s \(2014\) NICE guideline CG109.](#) Date for review: October 2019
- [Dual chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block \(2005\) NICE technology appraisal guidance 88.](#) Date for review: to be confirmed; partially updated in NICE technology appraisal guidance 324
- [Dual chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block \(2014\) NICE technology appraisal guidance 324.](#) Date for review: November 2017

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Table 6: Summary of results of Saxon et al. (2010)

Table 1 Overview of the de Ruvo et al. (2016) study

Study component	Description
Objectives/ hypotheses	To estimate and compare the event-free rate at 1 year following ICD implantation using 4 different remote monitoring systems and to investigate the effects of the frequency of data transmissions on the early detection of clinical and device-related events.
Study design	Prospective, single centre, non-randomised cohort study with 1 year follow-up.
Setting	Policlinico Casilino Hospital, Rome, Italy. Patients were enrolled between January 2009 and January 2011. One year post-implant follow-up.
Inclusion/ exclusion criteria	Included patients had a standard indication for implantable cardiac devices, with or without cardiac synchronisation therapy. No exclusion criteria were noted.

Primary outcomes	The primary endpoint was time to investigator's first evaluation of a true-positive clinical or device-related event during the first year after implant, whichever was first observed during a remote follow-up (whether or not it was triggered by an automatic alert) or during an in-person visit. Episodes were classified as false-positive if they did not trigger medical intervention other than device reprogramming. The number of RM transmissions, alerts, and the mean intervals between consecutive RM transmissions were also registered and compared.
Statistical methods	Sample distributions of continuous variables were tested for normality with the Shapiro-Wilk test. Categorical variables were reported as percentages. Comparisons among RM groups were performed with the Kruskal-Wallis rank test for continuous variables using Bonferroni's correction for pair-wise multiple comparisons. Chi-squared test was used for comparison of baseline categorical variables. Event-free rates were estimated with the product-limit method and Kaplan–Meier plots generated: comparisons among groups were performed with the log-rank test. Areas under Kaplan–Meier curves were calculated using the restricted mean method. To investigate the association between event-free rate and frequency of RM transmissions, uni- and multivariate Cox proportional hazard models were used.
Patients included	211 patients (mean age 69 years; 75% male) with implanted cardiac devices were included in the analysis (49 with Boston LATITUDE, 65 with Medtronic CareLink, 61 with BIOTRONIK, and 36 with St Jude Merlin).
Results	<p>In total, 95 patients (45%) experienced at least 1 clinical or device-related event.</p> <ul style="list-style-type: none"> • LATITUDE: 21 patients^a (43%) • CareLink: 28 patients (43%) • BIOTRONIK: 31 patients (51%) • Merlin: 15 patients (42%)
Conclusions	Although the rates of remotely detected events were similar in all systems, the time to first event evaluation was about 56 days longer in patients with quarterly compared to daily transmissions.

Abbreviations: RM, remote monitoring.

^a Incorrectly reported as 12 people in the study.

Table 2 Summary of results from the de Ruvo et al. (2015) study

	LATITUDE	CareLink	BIOTRONIK	Merlin	Analysis
Efficacy	n=49	n=65	n=61	n=36	-
Primary outcome: Clinical or device-related event-free rate at 1 year following implant.	37/ 49 (76%)	37/ 65 (57%)	30/ 61 (49%)	25/ 36 (69%)	Log-rank test p=0.23
Selected secondary outcomes:					
Cumulative rate of actionable events	45%	22%	37%	16%	Log-rank test p=0.005
False positive alerts	4	11	1	0	-
False negative alerts	1	0	7	2	-
Median maximum interval between transmissions (IQR) in days	70 (63–96)	93 (82–126)	9 (3–25)	86 (58–93)	The max expected duration of unmonitored periods was significantly shorter in the BIOTRONIK system (p<0.0001)

Abbreviations: IQR, interquartile range.

Table 3 Overview of the Akar et al. (2015) study

Study component	Description
Objectives/ hypotheses	To examine the association between the use of remote patient monitoring of implantable cardioverter defibrillators and all-cause mortality and hospital admissions among patients undergoing initial implant.
Study design	Retrospective observational cohort study. Patients were divided into 2 groups; those who had at least 1 remote transmission in the first year following implantation, and those with no remote transmissions.
Setting	A data set was constructed from Boston Scientific ALTITUDE Registry and the American College of Cardiology National Cardiovascular Data Registry ICD Registry between January 2006 and March 2010. Patients were followed up for 3 years.
Inclusion/ exclusion criteria	<p>Patients were eligible for inclusion if they had a remote patient monitoring compatible device and had first-time device implantation between January 2006 and March 2010.</p> <p>Patients were excluded if they had missing data linking fields, used devices from manufacturers other than Boston Scientific, used a non-wireless device, underwent implantation at an institute that did not participate in the ALTITUDE database, had a pacemaker or implanted cardiac device previously, died during their initial hospital stay, were under 21 or over 89 years old, had a history of cardiac transplant or an epicardial lead, were in a hospital not reporting all of its implants to the ICD registry, or had unknown vital status.</p>
Primary outcomes	All-cause mortality and re-admission to hospital during the 3-year follow-up.
Statistical methods	A multi-variate time-dependant Cox model was used to examine the association between remote monitoring and survival up to 3 years after implantation.

Patients included	After employing the exclusion criteria to the ICD registry and linking to the ALTITUDE data set, 37,742 patients were included in the cohort for mortality. For analysis of hospital admissions, this cohort was further restricted to 15,258 by including only those patients at least 65 years old enrolled in Medicare fee-for-service.
Results	<p>Patients who used remote monitoring had statistically significantly lower risk of mortality compared with patients who did not (HR 0.67, 95% CI 0.64 to 0.71, $p < 0.0001$).</p> <p>Patients who used remote monitoring had statistically significantly lower risk of hospital admission compared with patients who did not (HR 0.82, 95% CI 0.80 to 0.84, $p < 0.0001$).</p>
Conclusions	Among patients undergoing initial ICD implantation, remote monitoring is associated with a statistically significantly lower risk of adverse outcomes.
Abbreviations: CI, confidence interval; HR, hazard ratio; ICD, implantable cardiac device.	

Table 4 Summary of results from the Akar et al. (2015) study

	Remote Monitoring	No remote monitoring	Analysis
Cohort for mortality analysis	n=20,852	n=16,890	-
Cohort for hospital admission analysis	n=9,150	n=6,104	-

Primary outcome: All-cause mortality at 1 and 3 years	Not reported	Not reported	Median follow-up was 822 days (IQR: 623 to 1126). Overall cohort mortality: 1 year, 9.4%. 3 year, 20.9%. Remote monitoring was associated with a lower risk of mortality HR : 0.67, 95% CI: 0.64 to 0.71, p<0.0001
Primary outcome: Hospital re-admission	Not reported	Not reported	The 3 year all-cause hospital re-admission rate was 63.9%with a median follow-up of 922 days (IQR: 662 to 1195). Remote monitoring was associated with a lower risk of hospital re-admission HR: 0.82, 95% CI: 0.80 to 0.84, p<0.0001.
Abbreviations: CI, confidence interval; IQR, interquartile range; HR, hazard ratio; n, number of patients.			

Table 5 Overview of the Saxon et al. (2010) study

Study component	Description
Objectives/ hypotheses	To assess the influence of remote monitoring on long-term mortality following the implantation of ICD and CRT-D devices.
Study design	Retrospective non-randomised observational cohort study comparing patients with an ICD or CRT-D followed remotely or in-clinic.
Setting	Data in the Boston scientific ALTITUDE database from 2,096 participating clinics in the USA. Patients were followed up for 5 years.

Inclusion/exclusion criteria	<p>Patients were included following the implantation of an ICD or CRT-D at a participating centre.</p> <p>The decision to place a patient in the remote follow-up group was made by the implanting physician at the time of device implantation or at the post-implantation clinic visit.</p> <p>No exclusion criteria were noted.</p>
Primary outcomes	One- and 5-year survival rates following device implantation.
Statistical methods	<p>Kaplan–Meier curves and multivariate Cox proportional hazard models adjusting for baseline covariates of age, gender, implantation year, and device type were used to calculate cumulative mortality and to assess the relationship between mortality risk and the following:</p> <ul style="list-style-type: none"> • network participation • transmission of additional physiological (weight, blood pressure) or symptom data via the network • the occurrence of shock therapy.
Patients included	A total of 194,006 patients were included in the survival analysis; 69,556 were followed on the network, and 124,450 were followed in clinic only (116,222 ICD and CRT-D devices and 8228 CRT-only devices).
Results	Compared with in-clinic monitoring, patients having remote monitoring using both ICDs and CRT-Ds showed statistically significant survival improvements (hazard ratio 0.56 and 0.45 respectively, $p < 0.0001$).
Conclusions	Observed survival rates compared favourably with those reported in clinical trials. Remote follow-up of device data is associated with excellent survival.
Abbreviations: CRT-D, cardiac resynchronisation therapy defibrillators; ICD, implantable cardioverter defibrillators.	

Table 6 Summary of results from the Saxon et al. (2010) study

	Remote monitoring	In-clinic monitoring	Analysis
Efficacy	n=69,556	n=124,450	-
Primary outcome: Comparative survival at 5 years following implant.	Not reported	Not reported	10,272 matched patients implanted with ICD and CRT-D devices on and off the remote follow up network. ICD: HR 0.558, 95% CI 0.467 to 0.867 p<0.0001. CRT-D: HR 0.454, 95% CI 0.388 to 0.532 p<0.0001.
Abbreviations: CI, confidence interval; HR, hazard ratio; n, number of patients.			

Search strategy and evidence selection

Search strategy

Medline (including In Process) search

1. latitude.ti,ab.
2. boston scien*.ti,ab.
3. patient management system\$.ti,ab.
4. follow-up monitoring.ti,ab.
5. telemedicine/
6. remote monitoring system\$.ti,ab.
7. 3 or 4 or 5 or 6
8. 1 and 7
9. 1 and 2
10. 1 and 3
11. ambulatory monitoring/
12. 1 and 11

13. 8 or 9 or 10 or 12.

Embase search

1. latitude.ti,ab.
2. boston scien*.ti,ab.
3. patient management system\$.ti,ab.
4. follow-up monitoring.ti,ab.
5. telemedicine/
6. remote monitoring system\$.ti,ab.
7. 3 or 4 or 5 or 6
8. 1 and 7
9. 1 and 2
10. 1 and 3
11. ambulatory monitoring/
12. 1 and 11
13. 8 or 9 or 10 or 12.

Medline and Embase: in total 83 citations. After removal of duplicates: 80 citations.

Cochrane Library search: as above. Five reviews were found but none included because they did not concern the LATITUDE device. Three citations were identified; all were duplicates of citations in other searches.

Given that the original search limited to LATITUDE and Boston Scientific did not yield useful citations, the search was repeated without these terms in PubMed which also allowed access to the most recently added citations in progress.

Evidence selection

Citations which used the LATITUDE remote monitoring system were considered for inclusion. Only papers in the English language concerning humans were considered.

Original search specifying LATITUDE: 57 studies were considered, but did not provide useful information on relevant patient outcomes. Studies generally reported prospectively collected but retrospectively analysed data in the ALTITUDE register retrieved via the LATITUDE remote monitoring system. No studies were included.

38 references were further reviewed, retrieving full texts to see whether they met the inclusion criteria. The more general revised search considered 38 studies of which 2 included some patients having LATITUDE (de Ruvo et al. (2016) and Lorenzoni et al. (2014).

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by the Birmingham and Brunel Consortium. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Declarations of interest

No relevant interests declared.

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