Dot Medical Limited

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Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inspected but not rated
Are services safe?	Inspected but not rated
Are services effective?	Inspected but not rated
Are services well-led?	Inspected but not rated

Summary of findings

Overall summary

The location has not previously been inspected. This was a focused inspection to clarify the regulated activities that the service was delivering.

- We saw examples of when the managing director advised clinicians on the interpretation of the data from the continuous heart monitoring device.
- Staff were trained and competent for identified devices. Some were required to fit the wearable defibrillators, in hospital settings and signposted patients to appropriate support when needed.
- Evidence reviewed indicated that the service was supporting patients' treatment pathways in ways that were consistent with a service that was carrying on activities that amounted to registrable regulated activities falling within the scope of registration..

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inspected but not rated	

Summary of findings

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Summary of this inspection

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Summary of this inspection

Background to Dot Medical Limited

The organisation supplies medical equipment and fits devices to patients, for the NHS and independent hospitals. The provider registered with Care Quality Commission (CQC) in November 2020.

The organisation supplies devices for adults and children.

The provider has one location but operates across the UK nationally. This was the first inspection since registration.

It was a focused inspection to determine if the service was carrying out regulated activities within the CQC Scope of Registration. A full inspection will be carried out in due course.

How we carried out this inspection

We inspected this service using our focused inspection methodology. We carried out this short announced inspection on 29 March 2023.

The inspection included two inspectors and a CQC National Professional Advisor for medicine.

During the inspection, we visited the organisations main office and storage areas. We spoke with 6 of the organisations 10 members of staff including: the Director who was the nominated individual, staff focused on quality, and staff trained for either the heart monitoring system or the wearable defibrillator.

During our inspection, we reviewed patient data received via the organisations electronic portal, daily briefing records and a sample of staff training records.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

Inspected but not rated

Diagnostic and screening services

Safe	Inspected but not rated
Effective	Inspected but not rated
Well-led	Inspected but not rated

Is the service safe?

Inspected but not rated

The location has not previously been inspected. This was a focused inspection to clarify the regulated activities that the service was delivering.

Assessing and responding to patient risk

Staff identified and quickly acted upon patients at risk of deterioration.

The organisation supported consultant cardiologists who worked either in NHS hospitals or independent hospitals.

Patients did not self refer. Consultant cardiologists or physicians referred patients for either continuous heart monitoring or for a wearable defibrillator with details of patient symptoms, such as irregular heart rate, and other reasons for referral.

. For the continuous heart monitor data was downloaded once the prescribed time for wearing was completed. For the wearable defibrillator, data was downloaded on a daily basis from a remote monitoring station in the home of the patient.

We were told that about 300 heart monitoring devices, a month, were distributed to patients. The continuous heart monitor was posted to a patient with instructions about application including maintaining a diary for any events whilst wearing. Patients were requested to record symptoms in the diary. There was continuous monitoring by the equipment and storing of data for a prescribed time of up to 48 hours, seven days or 14 days. Staff trained in managing the device were available for technical support. If there were any clinical concerns the patient was signposted either to their own GP, their cardiologist or 999 if an emergency.

On completion of the monitoring period the device was posted back to the organisation in a pre-paid package. Staff downloaded the collected data onto the manufacturer's portal as well as inputting patient diary information. Any concerns in relation to the data were escalated to senior managers.

The downloaded data was accessed, via the portal, by the manufacturer's clinicians. The device monitored specific parts of the heart rhythm. We were told that there were occasions when the manufacturer's clinicians consulted with the organisation's managing director in the interpretation of the recorded data. During the onsite visit we reviewed an example of a consultation, on the organisation's electronic system, and were provided with further examples following the inspection. This showed that the Director had provided clinical advice in the interpretation of the data, which was in line with CQC's regulated activities.

Inspected but not rated

Diagnostic and screening services

If a serious event in the heart rhythm was identified in the data, the organisation contacted the patient's cardiology department, and confirmed receipt, to ensure they were aware. In the absence of the managing director, another member of staff was delegated to liaise with the manufacturer. We were told there were about one to five of these incidents each week.

We were told that between 12 and 20 of the wearable external defibrillators were fitted a month. The defibrillator monitored the heart rhythm and sensed an abnormality in the rhythm. The technology provided a physical and a loud verbal notification to a patient if it identified a shock was needed. The patient was able to override, if conscious, by pressing a cancelling button. The verbal notification also instructed other people to stand back. It then fired a cream to moisten the electrodes prior to a shock being deployed. Once a shock was fired there was a further verbal notification to call an ambulance. The patient and significant relatives were trained to use the device including that it was there to save their life in the event of an emergency.

Staff members, for the organisation, were trained to apply and set up the wearable defibrillator in hospital settings nationwide as prescribed by the consultant cardiologist. The vests were requested as a temporary alternative to an internal device such as if the internal device became infected and required removing. This meant the patient could still be monitored until any infection resolved. They were often worn for about three months. Patients instructions included not to remove if a shock was fired. In this case the organisation's staff were contacted and would instruct the hospital how to take the defibrillator off. If a serious event occurred, the vest could take a trace of the heart rhythm. This data was recoded on the portal that was accessed by the manufacturer and the organisation. The organisation contacted the hospital to let them know the patient had received any treatment required.

Daily briefing calls were held between the organisation and the manufacturer. Any serious events were discussed and recorded at these meetings to ensure cardiologists had been informed. The briefings discussed events with other devices including the wearable defibrillator.

Is the service effective?

Inspected but not rated

The location has not previously been inspected. This was a focused inspection to clarify the regulated activities that the service was delivering.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held meetings with them to provide support and development.

Senior managers gave all new staff a full induction tailored to their role before they started work.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Senior managers made sure staff received any specialist training for their role.

Copies of staff records were retained for each member including records of induction, job description, previous qualifications obtained, curriculum vitae, any courses completed both internally and externally, and any appraisals completed. We reviewed training records for the two staff who supported patients with the wearable defibrillator and all relevant training had been completed.

Inspected but not rated

Diagnostic and screening services

The organisation maintained a matrix of staff training competencies for the devices for oversight of completed courses.

Senior managers supported staff to develop through yearly, constructive appraisals of their work.

Senior managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge.

Staff had the opportunity to discuss training needs with their manager and were supported to develop their skills and knowledge.

Is the service well-led?

Inspected but not rated

The location has not previously been inspected. This was a focused inspection to clarify the regulated activities that the service was delivering.

Management of risk, issues and performance

Leaders used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions. They had plans to cope with unexpected events. Staff contributed to decision-making.

The organisation provided medical devices, on behalf of manufacturers that were outside of the UK, to patients receiving either NHS secondary care and treatment with a consultant cardiologist or physician or at an independent hospital.

The organisation supplied the devices to patients and downloaded data on to their electronic portal that was accessed by the manufacturer's clinicians. For the continuous heart monitoring there were times when the manufacturer would seek advice from the managing director to interpret the results.

The organisation had processes in place that included the Event Handling Procedure and the Complaints process that were available for staff.

For any serious incidents that occurred whilst the devices were in situ, the organisation discussed them at daily briefing sessions and ensured the hospital cardiologists were aware. This acted as an additional safety net.

We were provided with copies of the organisation's daily briefing meetings. These indicated when an event had occurred for any device supplied and what steps had been taken.

Patients were provided with contact details of the organisation in case of any concerns. The organisation recorded the content of the calls. We were provided with examples; these tended to be technical issues. Any clinical concerns would be signposted to either the GP, cardiologist or emergency services as appropriate.

The organisation provided two examples of contracts with NHS organisations which outlined the key responsibilities of the NHS and the organisation so accountability was clear and understood by both parties.