ResMed

EasyCare Tx

ENGLISH

GDPR Guide for EasyCare Tx

Introduction

On 25 May 2018 the European General Data Protection Regulation (GDPR) comes into effect. The full text of the GDPR can be read here, in the language of your choice.

http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32016R0679

As a user of EasyCare Tx, you may be processing sensitive personal data about natural persons. Your organisation would have performed a readiness review for GDPR and you should always follow the policies and guidance of your organisation when processing sensitive personal data. This Guide is intended to provide clarity on how you can perform certain activity defined by GDPR when using the EasyCare Tx.

A secondary purpose of this document is to clarify privacy topics that may not be clear when operating EasyCare Tx. In an era of connected devices, it's important to note that the EasyCare Tx is a stand-alone desktop product that only connects to other EasyCare Tx tools and devices.

The EasyCare Tx can be operated as intended without processing any personal data. The section below titled 'Article 11 - Processing which does not require identification' describes how you can achieve this. You should review the operations of EasyCare Tx within your organisation to ensure your use of EasyCare Tx is compliant with your organisation's policies.

This Guide is organised by the Articles of the GDPR, selecting only the Articles that apply or require clarification. If a GDPR Article is not listed in this Guide, that Article does not apply to the use of EasyCare Tx.

By providing EasyCare Tx, ResMed is acting as an Independent Software Vendor (ISV), and is not acting as a Data Controller nor Data Processor in normal operations.

Article 4 – Definitions

Data concerning health means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.

Data Controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

Data Processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Data Controller.

GDPR is the European General Data Protection Regulation, which comes into effect on 25-May-2018. The exact official title is Regulation (EU) 2016/679 but the term 'GDPR' is widely known and understood.

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly.

Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information.

Article 9 – Processing of special categories of personal data

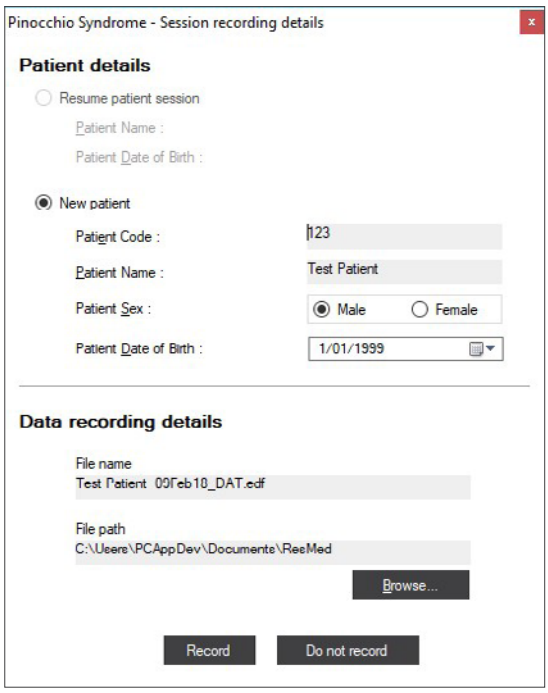
EasyCare Tx is assessed to be processing sensitive personal data concerning the health of a natural person, as declared in paragraph (1) of Article 9.

You are responsible for obtaining consent from the data subject to allow processing under paragraph (2) a) of Article 9, in order to obtain a legal basis for processing a special category of personal data.

Article 11 – Processing which does not require identification

EasyCare Tx can operate without ever processing any personal data. Personal data is only processed when you elect to save the titration data to a disk file. You can elect to use pseudonymisation tokens if you wish to manage the storage of sensitive personal data within your organisation.

When you enter patient details, you can use any pseudonymisation token determined by your organisation's policies. The pseudonymisation tokens would be entered in the Patient Code, Patient Name. EasyCare Tx will also work with any allowable Date of Birth; you do not have to enter the actual date. Note that the recipient of the report will likely need to re-identity the data subject in order to continue medical assessment.



Article 12 – Data Subject Request

If you receive a request to provide any information related to processing of a data subject, you can perform the following steps to obtain this data from EasyCare Tx.

When you elect to save the titration output to disk, the file is saved in the European Data Format (EDF) specification for the exchange and storage of multichannel biological and physical signals. The location of the EDF file is as you defined when you elected to save the Data Recording details (see screen shot above). The default location is %USERPROFILE%\Documents\ResMed.

You and your new Data Controller can learn more about the EDF at their website: https://www.edfplus.info/

Normal operations of EasyCare Tx does not require the use of data storage. It is up to each health care professional using EasyCare Tx to determine if the titration data should be saved, and also to determine how much personal data to enter for saving with the titration report.

The EasyCare Tx software does not provide transmissions or file transfer capabilities. The transmission of personal data must be performed by the organisation using their current processes for disclosing sensitive personal information to another Controller.

Article 14 – Information to be provided where personal data have not been obtained from the data subject

Article 14 does not apply to the use of EasyCare Tx, as no other Data Controllers are involved. EasyCare Tx does not transmit data nor collect data of any nature with another Data Controller or Data Processor. There are no automated transmissions of data from EasyCare Tx back to ResMed. EasyCare Tx is solely within the security domain of your organisation's Windows domain or desktop profiles.

EasyCare Tx collects titration data from ResMed devices based on the interaction of that device with a data subject. The ResMed device that provided the data is under the control of you, acting as the same Data Controller that obtained the personal data.

Article 17 – Right to erasure ('right to be forgotten')

If you receive a request from a data subject to have their personal data erased, you can delete the EasyCare Tx data by deleting a file using Windows file explorer. The personal data will be located in the Windows folder you selected when you saved the file. The default location is %USERPROFILE%\Documents\ResMed. Simply delete the file using Windows File Explorer commands. You will also need to delete the file from the Windows Recycle Bin; contact your IT System Administrator if you are not sure how to perform that command.

Your organisation, as the Data Controller, is responsible for assessing the legality of data retention under paragraph (3) of Article 17.

Article 20 – Right to data portability

If you receive a request to provide a structured, commonly used and machine readable format of their personal data, you can perform the following steps for any personal data processed in EasyCare Tx.

When you elect to save the titration output to disk, the file is saved in the European Data Format (EDF) specification for the exchange and storage of multichannel biological and physical signals. The location of the EDF file is as you defined when you elected to save the Data Recording details (see screen shot above). The default location is %USERPROFILE%\Documents\ResMed.

You and your new Data Controller can learn more about the EDF at their website: https://www.edfplus.info/

Normal operations of EasyCare Tx does not require the use of data storage. It is up to each health care professional using EasyCare Tx to determine if the titration data should be saved, and also to determine how much personal data to enter for saving with the titration report.

The personal data must be exported from the EasyCare Tx software, and the transmission of the personal data must be performed by your organisation using their current processes for disclosing sensitive personal information to another Controller.

Note that the Data Controller operating EasyCare Tx is responsible for determining if the rights in paragraph (1) of this article adversely affect the rights and freedoms of others, as declared under paragraph (4) of Article 20.

Article 22 – Automated individual decision-making, including profiling

The EasyCare Tx software does not perform profiling or automated decision making. The EasyCare Tx software is used for decision-making by trained medical professionals operating the EasyCare Tx.

Article 25 – Data protection by design and by default

ResMed has assessed the state of the art, cost of implementation, and the nature, scope, context and purposes of processing for this upgrade of EasyCare Tx. As a manufacturer of medical devices, ResMed has an existing robust process for cybersecurity by design in all our devices, desktop products, and cloud services. As an independent software vendor for the EasyCare Tx desktop suite, privacy by design was added to our cybersecurity by design protocols.

Specific to the EasyCare Tx, this is reflected in the ability to operate the EasyCare Tx without any personal data. This complies with the data minimisation guidance for privacy by design.

You can learn more about your organisation's obligations under GDPR by contacting the appropriate department of your organisation. You can also inspect the site of the European Commission Rules for business and organisations on data protection reform here:

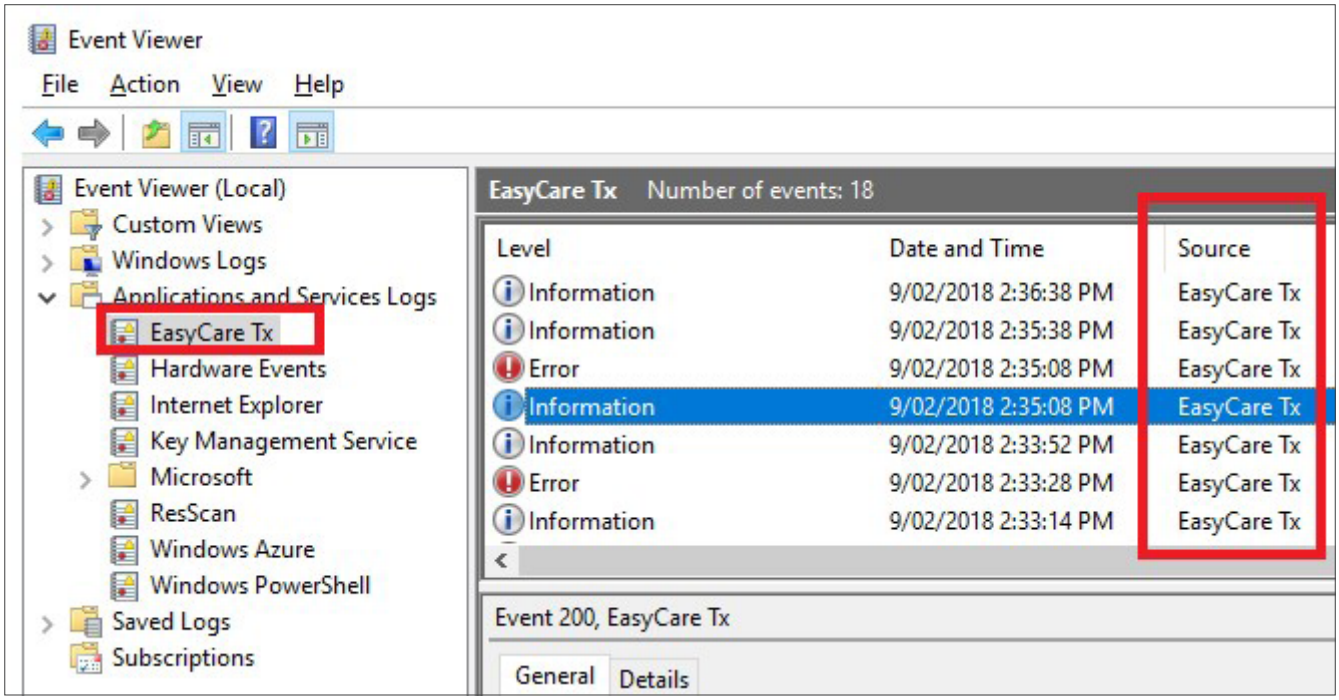
https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations_en

You can also search the site of your national Data Protection or Privacy Commission.

Article 32 – Security of processing

EasyCare Tx maintains audit records of processing activities in the Windows event logs.

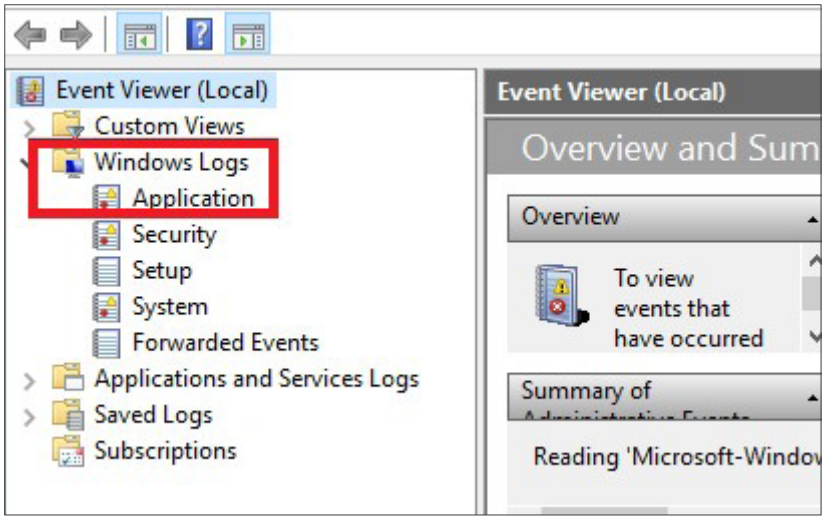
After you deploy EasyCare Tx 9.0, you should re-boot the personal computing device to apply the updates to the Windows Event log configuration. The reboot is required for Windows to create a new Event log file specific to EasyCare Tx. The EasyCare Tx log will appear under the Event folder "Applications and Service Logs".



The EasyCare Tx events be located in a Windows file located at

%WINDIR%\System32\winevt\Logs\EasyCare Tx.evtx

If you have not re-booted the personal computing device after deploying EasyCare Tx, the EasyCare Tx log entries will be the "Windows Logs\Applications" location, and you'll have to filter on Source when you select that log.



The Event Source of all entries in EasyCare Tx. The Event Data describes the specific actions performed by the User against which patient record.

Appendix A provides the details below describes the Event Data and the associated activity with that Event Data.

Your organisation has determined the risk profile for the operations of the EasyCare Tx software, based on the unique operating conditions within your organisation. Part of that risk assessment includes the use of Windows desktop encryption capabilities. There are commercial and free desktop encryption products that provide state of the art encryption services, and the EasyCare Tx system will operate as intended on encrypted disks.

If your encryption services use folder level encryption, and you have elected to save titration reports, you should check with your organisation's policies for encrypting this data.

If you use actual patient names in your use of EasyCare Tx, Windows Event Logs will also contain the patient name. The location of this folder is %WINDIR%\System32\winevt\Logs. Note that other Windows services write to Event logs at this location, so you should only encrypt this folder in consultation with your Windows IT Administrator.

User management, including password requirements, for EasyCare Tx is performed solely via Windows account management tools and services. If a Windows account can log onto a personal computing device where EasyCare Tx is deployed, that account will be able to launch EasyCare Tx.

As a best practice for data protection, the device running EasyCare Tx should implement Windows inactive desktop lockout policy. Contact your Windows IT Administrator to understand how your organisation has implemented this control.

Article 44 – General principle for transfers

The EasyCare Tx system does not transmit data of any type to ResMed or any other Controllers or Processors. Any transfer of personal data from EasyCare Tx can only be performed manually by an authorised member of the Data Controller operating EasyCare Tx.

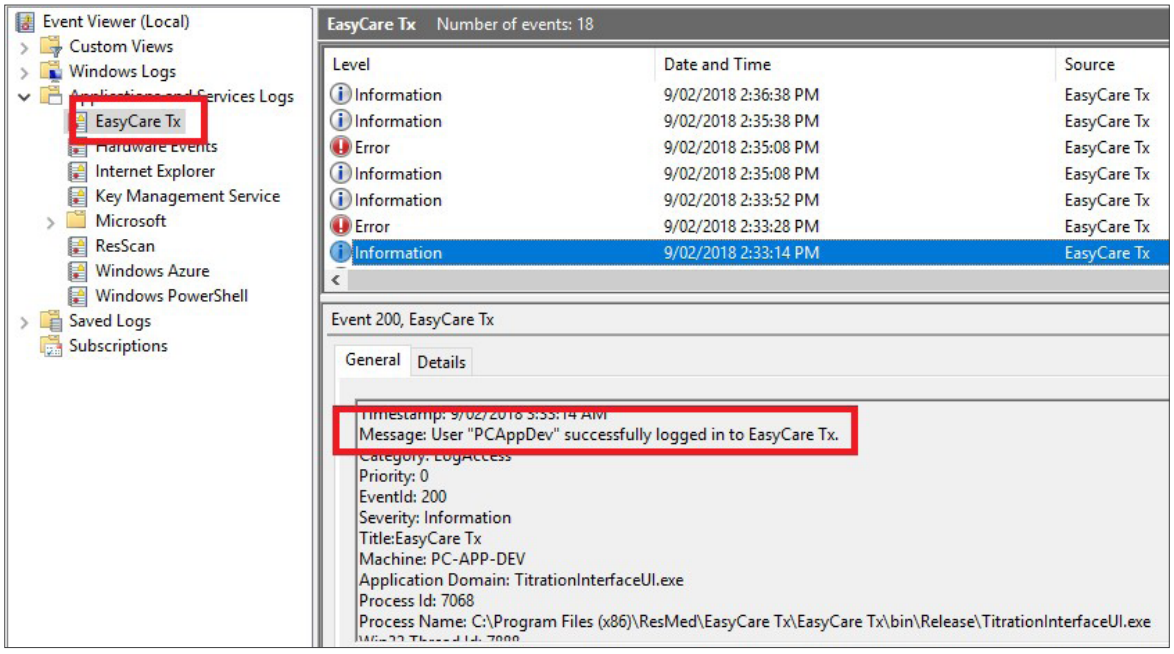
Article 87 – Processing of the national identification number

The use of a national identification number is not required for the effective operation of EasyCare Tx, and ResMed recommends that the national identification number not be used within EasyCare Tx.

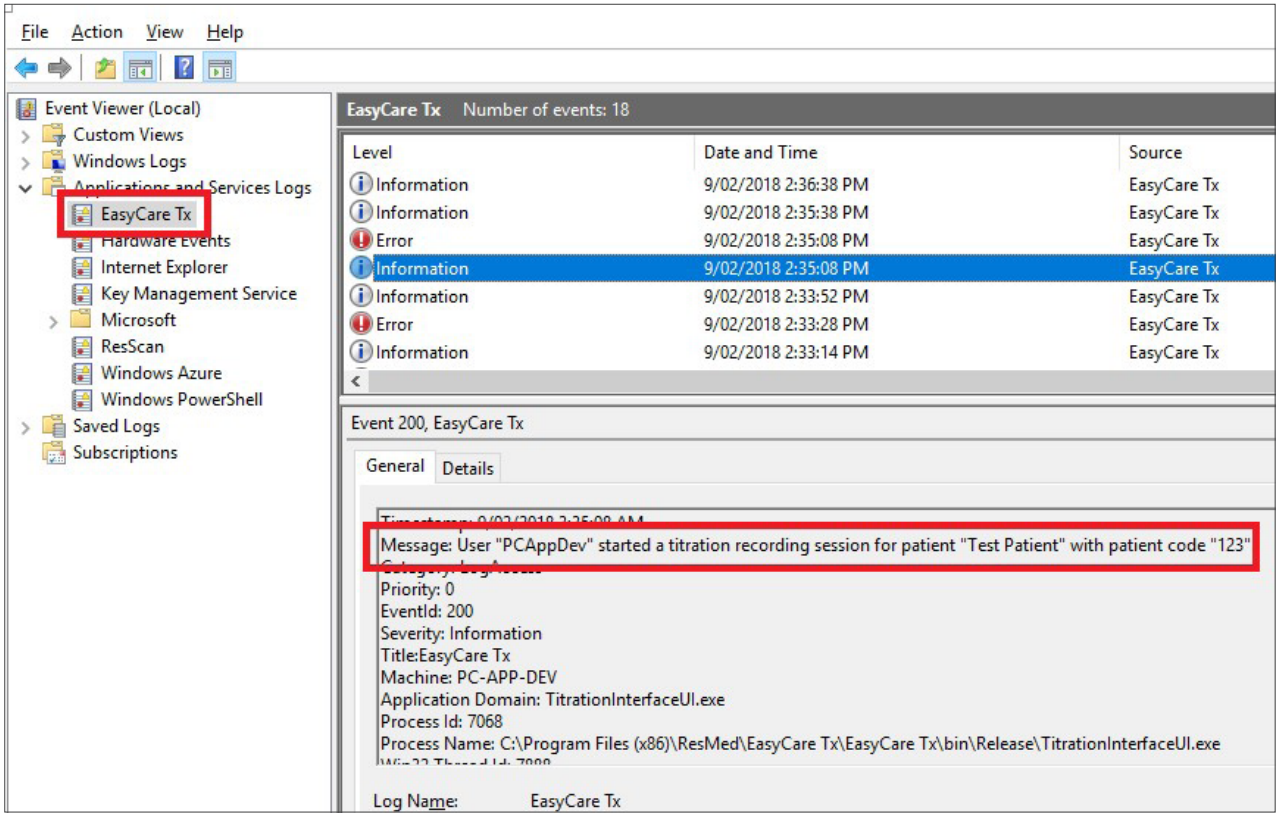
Appendix A – Examples of Windows event log entries

Below are screen shots are examples of what the entries in the Windows event logs will look like:

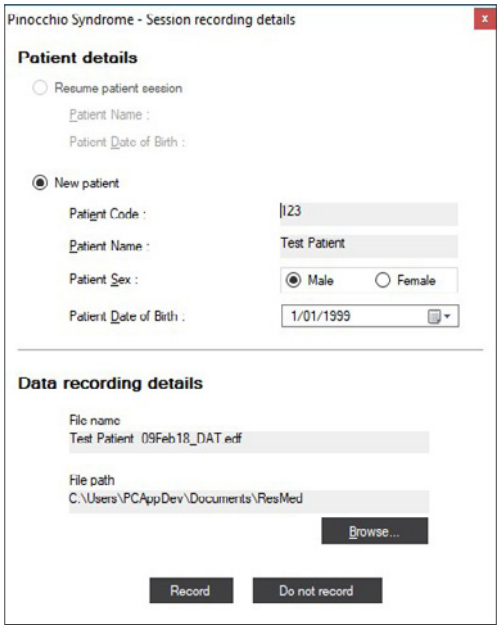
ACTION: User 'PcAppDev' successfully logged onto an EasyCare Tx system.

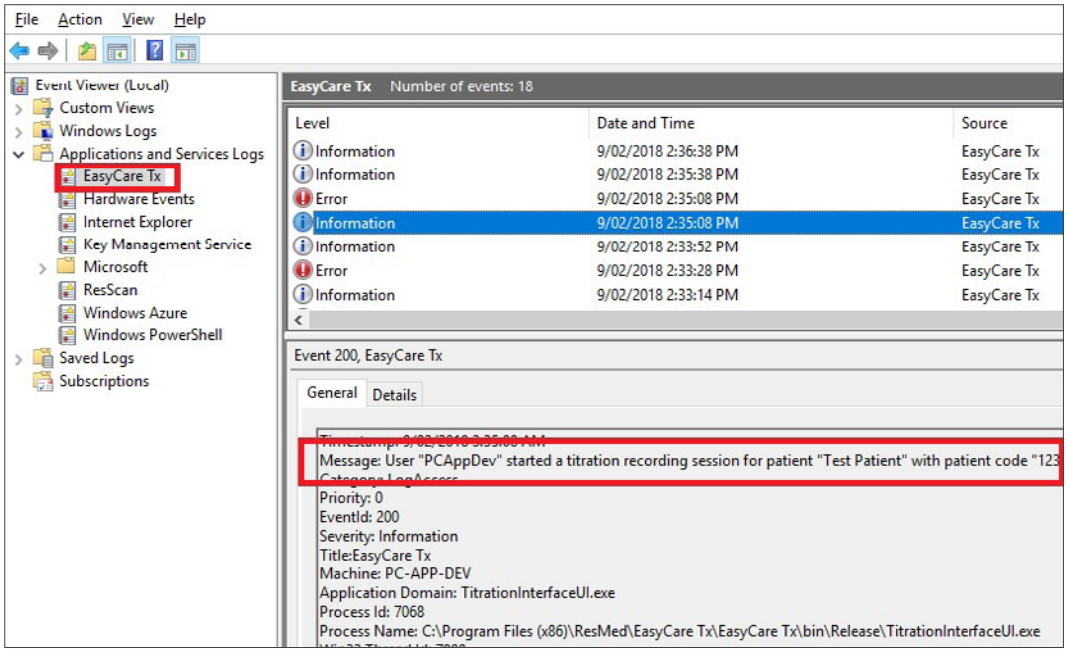


ACTION: User 'PcAppDev' created a Titration Report, and elected to add a patient name of 'TestPatient' with a code of '123'.

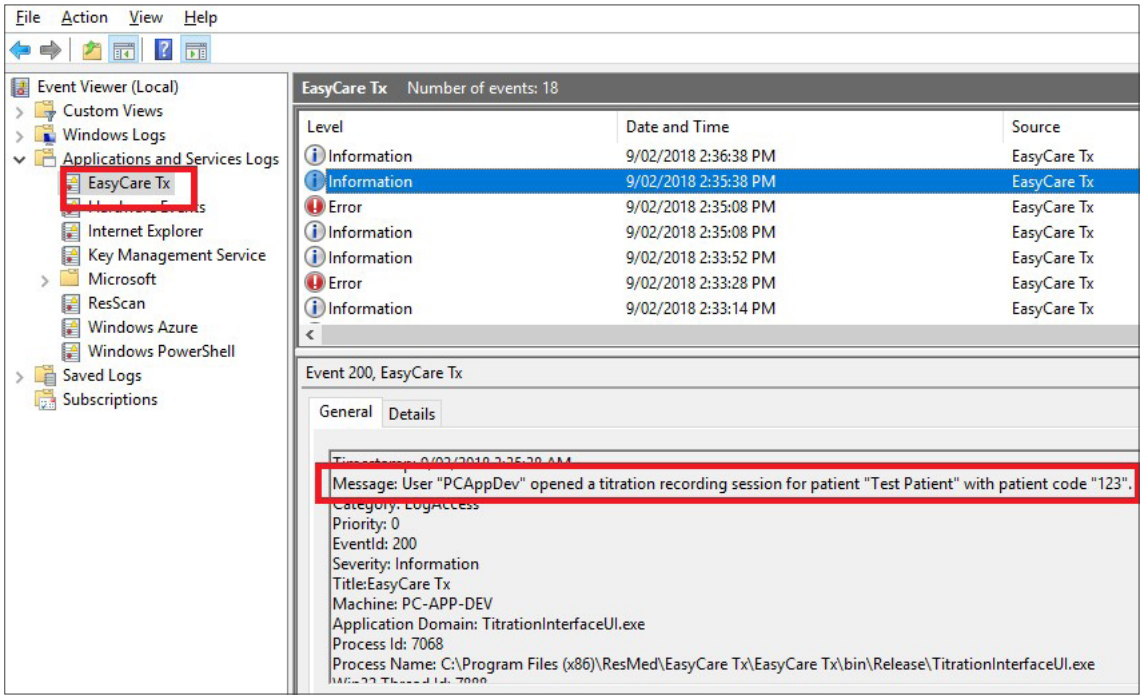


ACTION: A titration reading for a patient was recorded and saved.

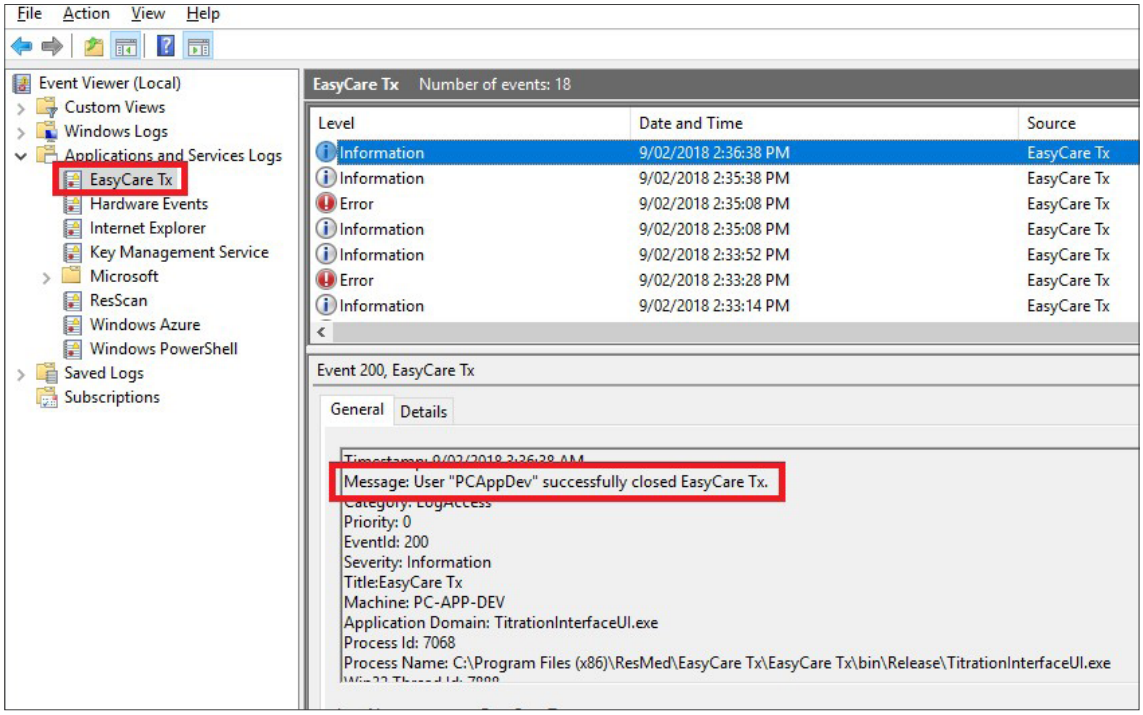




ACTION: A titration reading for a patient was opened.



ACTION: User 'PcAppDev' closed EasyCare Tx.



References

The full text of the GDPR legislation, in a language and format of your choice:

http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32016R0679

MANUFACTURER **ResMed Pty Ltd**
1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

See ResMed.com for other ResMed locations worldwide. Microsoft and Windows are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries. For patent and other intellectual property information, see www.resmed.com/ip. © 2018 ResMed Pty Ltd258264/1 2018-02