

PainChek Android User Guide

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PainChek Ltd



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 Welcome to the PainChek Android User Guide.

Here you'll find details on how to use the PainChek Android mobile application.

If you don't find the information you are looking for, email us at support@painchek.com.



2 Introduction

The PainChek Mobile Application assists healthcare workers and carers in assessing the levels of pain in non-communicative patients with cognitive impairment, especially those with dementia.

PainChek uses facial recognition technology to detect facial cues indicative of the presence of pain and then combines these with non-facial pain cues to assess a pain severity score.

This guide documents the use of the PainChek App.

2.1 Document History

Version	Date	Author	Comment
1.0	16th November 2017	Darwin Digital (Jessica)	Initial Version
1/1	29th January 2018	Scott Robertson	Update company name

2.2 Approval

Term	Description	Approval Date
Product Owner	Scott Robertson	29th January 2018

2.3 Intended Audience

This document is intended for use by any person using the PainChek Mobile app.

NB: See the "WAP User Guide" for the instructions on how to use the corresponding Web Administration Portal web site.

2.4 Referenced Documents

Document Name	Comment
WAP User Guide	The PainChek Web Administration Portal user guide

2.5 Glossary

Term	Description
Patient	For the purpose of this user guide and to avoid any ambiguity, the term patient will be applied for anyone on which the app may be used. The term patient encompasses residents and clients or anyone for whom a pain assessment is being carried out. Within an installation of the PainChek app users can select what terminology they would like to use, patient, resident or client.



Term	Description
Resident	See Patient
Client	See Patient
Admin	Admin accounts are only available for PainChek commercial licenses. Admins have access to all of the functionalities on the Mobile App.
Institution	Institutions include hospitals, aged care facilities, primary care centres (e.g. GP practices or outpatient clinics).
User	The person utilising the PainChek Mobile App to assess patients, residents or clients. User accounts are only available for PainChek commercial licenses. Users have access to all of the functionalities on the Mobile App
Commercial License	Type of license giving access to all of the functionalities on the Mobile App and the Web Admin Portal including creating users with specific roles.
Private License	Type of license giving access to all of the functionalities on the Mobile App with restricted uses of the Web Admin Portal. It excludes creating additional users.
App	An Android App that runs on a device enabling a user to perform pain assessments and other PainChek Adult functions
Web Admin Portal	A website that allows a user to perform administration functions of the PainChek system
WAP	See Web Admin Portal
Device	A supported Apple device running the PainChek app
TGA	Therapeutic Goods Administration (https://www.tga.gov.au/tga-basics)
PainChek	Means PainChek Adult
PainChek Adult	A system intended to be used to assess and monitor pain in people who cannot verbalise such as people with dementia or communication difficulties. The major components are the App and the Web Admin Portal.



Term	Description
Google Play Store	The Google online store used to download and install apps on Android devices
Manual Facial Assessment	An assessment of a patient where the user evaluates if the 9 items in the “facial domain” are present or absent
Automated Facial Assessment	Assessment of a patient where the PainChek app evaluates if the 9 items in the “facial domain” are present or absent
Domain	One of 6 areas that the PainChek app assesses for a patient – the 6 domains are being: “The Face”, “The Voice”, “The Movement”, “The Behaviour”, “The Activity”, “The Body”

2.6 Compliance Information

PainChek Adult is a certified Class I medical device, with CE Marking and TGA Australian Register of Therapeutic Goods (ARTG) inclusion

Item	Symbol	Details
Manufacturer and Australian Sponsor		PainChek Ltd Suite 401, 35 Lime Street Sydney NSW 2000, AUSTRALIA
Authorised European Representative		Priory Analysts Ltd The Pinnacle 160 Midsummer Boulevard Milton Keynes MK9 1FF United Kingdom



Item	Symbol	Details
Device Identifier	REF	PainChek Adult
Year of manufacture		2017
CE marking	CE	
Serial Number	SN	Refer to the product version number displayed on the iOS app login page



3 General Instructions for Use

The PainChek App is a mobile application that is downloaded from the Google Play Store and it is generally used in much the same way as any other app.

Devices running the PainChek app should be used, charged, maintained and disposed of according to the standard instructions provided by Google– search the Google Play web site <https://support.google.com/googleplay#topic=3364260> for the user guide relevant to your particular device.

3.1 Intended Use

PainChek is a software system which is comprised of the following components:

- a) Mobile Application (the App)
- b) Web Admin Portal

PainChek is intended to be used to assess and monitor pain in people who cannot verbalise such as people with dementia or communication difficulties

PainChek is a point-of-care App which uses a smart-device camera to capture a short video of a person’s face, this is then analysed in real-time using facial recognition technology to detect nine muscle movements - these are indicative of the presence of pain. This data is then combined with non-facial pain cues including movements, behaviours and vocalisations and inputted into the App to allow the automatic calculation of a pain severity score. The App has a graphing function which allows monitoring the person’s pain over time.

3.2 Users

All users must thoroughly read and comprehend this user manual.

If any aspect of this user guide is unclear or you have any questions about the use or suitability of the app, seek assistance from the support team (via support@painchek.com)¹ before using the application.

3.3 Supported Devices

PainChek can only be used on supported devices running the Android mobile operating system: version 5.0 and above.

You should keep the operating system up-to-date and download the latest official patch versions from Google when they are made available to the public (version 5.0 as of November 2014).

The supported devices are:

Model	Specification
Samsung Galaxy S6	Display size: 5.1 inches, 71.5 cm ² (~70.7% screen-to-body ratio) Resolution: 1440 x 2560 pixels, 16:9 ratio (~577 ppi density) https://www.gsmarena.com/samsung_galaxy_s6-6849.php

¹ <mailto:support@painchek.com>



Model	Specification
Samsung Galaxy S7	Display size: 5.1 inches, 71.5 cm ² (~72.1% screen-to-body ratio) Resolution: 1440 x 2560 pixels, 16:9 ratio (~577 ppi density) https://www.gsmarena.com/samsung_galaxy_s7-7821.php

3.4 Operating Environment

The app is designed to be used indoors, in areas with good lighting. As the PainChek app relies on using the devices camera, good lighting (such as you would find in an office) is essential to ensure consistent results.

3.5 Internet Connectivity

The app relies on internet connectivity in order to synchronise the data collected on the app with the data stored in the PainChek cloud database. The app can use WiFi and/or mobile (cellular) data connections. Please follow the standard instructions from Android or from your organisation in order to set-up internet connectivity on your device.

You do not need to be continuously connected to the internet in order to use the app, but you do when you are:

- Downloading the App from the Google Play Store
- Setting up the app for the first time
- Logging onto a device for the first time
- Synchronising data between your device and the PainChek cloud database

3.6 Updating the PainChek App

It is recommended that the PainChek app up is kept up-to-date. If a new version is released onto the App Store, your device will notify you automatically. You should download the new version as soon as is practical.

3.7 Warnings and Cautions

3.7.1 Automated and Manual Facial Assessments

The App requires that patients be reasonably still and co-operative in order to record a video of sufficient duration to allow for an automated facial assessment.

It might not be possible to perform an automated facial assessment due to:

- The patients face not being clearly visible
- The patient moving too much
- Lighting being of poor quality
- The patient preferring that they are not recorded

In any of these circumstances, a manual assessment should instead be performed.



4 Setting up the PainChek App

4.1 Securing Your Device

PainChek stores some data on your device. This is not the main copy of the data (which is securely stored and backup on our servers) and so it doesn't matter if you device fails or is lost.

However, in order to completely secure that local data, it's necessary to encrypt your device. Fortunately, with modern versions of Android, that is very easy. On devices (running android Gingerbread 2.3 or later) this is achieved by enabling encryption (go to Settings and then Security) and check to see if your device is already encrypted. If not, enable it.

It is also recommended that you have a PIN, password, or pattern on the lock screen to further boost the security. A strong passcode (6 or more random characters/numbers) should be used..

 Encrypting your device is considered industry best practices and it is beneficial, not just for PainChek data, but for all data on your Android device

4.2 Downloading PainChek

Once your device is secured (encrypted), the Mobile App can be downloaded through the Google Play Store, users need to have a Google account to download on their phone the PainChek Mobile App.

When the PainChek Mobile App is found on the Google Play Store, users need to click on the download button and sign into their PainChek account.

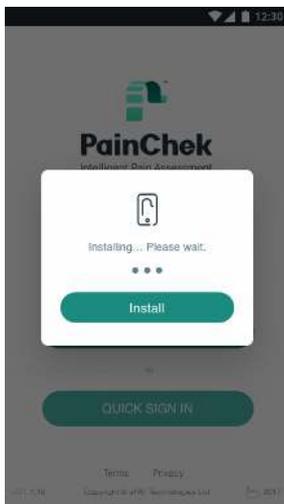
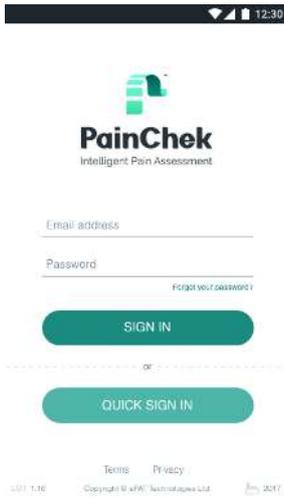
At this moment, it is checked the license number registered on the Web Admin Portal according to the users account. The system allows the downloading if the account is active. If the account is not active, the system shows an alert message. Once the Mobile App is downloaded, there are no configurations requirements. Users can directly open the Mobile Application and sign in.

Commercial licenses can install the Mobile App on unlimited number of devices as they have unlimited users accounts. Users created for that license can access the Mobile App with their accounts. Private licenses can install the Mobile App on five devices but can only access through one account as this license can only have one user account registered in the Web Admin Portal. Every device that has installed the Mobile App, it will be shown on the Web Admin Portal.

4.3 Setting up your PainChek account

To set up your account successfully, your device needs to be connected to the Internet. Type in your email and password to sign in. If you make a mistake and enter an incorrect email address or password, you will be asked to re-enter this information. For security reasons, your PainChek account will be blocked after ten successive incorrect entries of your username and password. If your account has been locked, please contact the PainChek support team.

Once you have entered your email and password correctly, you will be logged in. PainChek will then download your personal settings, company information (only applies to professional license holders), your data and those of the license holder onto the app from the PainChek Web Administration Portal[1].



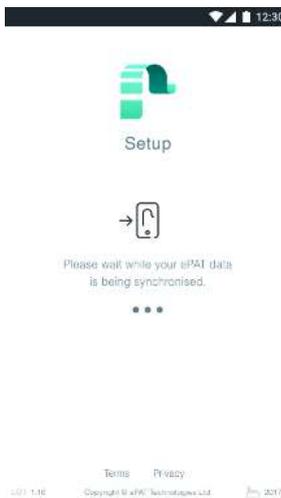
4.4 Defining target audience

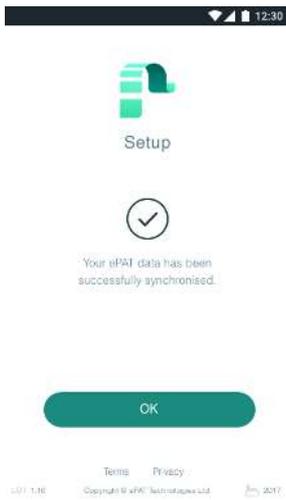
When you log into your PainChek mobile application for the first time you have a choice as to how you would like to refer to the people you look after in your PainChek installation. This is dependent on your place of practice and preference. You can select between a) Patients b) Residents or c) Clients. You need to choose one of the options and click 'Continue'. PainChek will then synchronise this information.



4.5 Data Synchronisation

When the application is connected to the Internet, it will synchronise new or updated data. You can manually synchronise your data by swiping up on the PainChek dashboard. You will receive a confirmation message once the synchronisation has been completed. Patient, application, and user information will be synchronised on all mobile devices belonging to the license key.





[1] The PainChek Web Administration Portal is a secure website that allows users to manage patient data, their PainChek licence, institutions (for professional licences), users, installations and edit your PainChek profile settings.



5 Login

5.1 Quick login

After your first login you have the option of signing in using the quick login function. This functionality can be activated in the profile settings. If you have switched on the quick login function, you will be able to identify yourself by selecting an icon displaying your profile picture and name. You will be prompted to enter your four-digit PIN along with the icon to log into the PainChek application.

1. Activate quick login from your profile settings



2. When you open the app, select the **account** you want to log in with

**For Private licenses, there will be only one account registered. This screenshot shows the home page of a device under a commercial license. This type of license can have unlimited accounts created.*



3. Enter **PIN**



5.2 Resetting your password

If you have forgotten your password, you can reset it on the sign in page by tapping **Forgot your password?** under Password.

Then enter the email address you use to sign in to the email field. Once you hit 'Confirm' a reset password link will be sent to your inbox. The link will redirect you to a web page on the PainChek Web Administration Portal where you can reset your password by entering your new password twice.

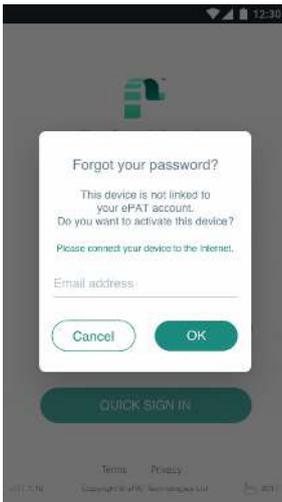
The password must be at least eight alpha-numeric characters and cannot be the same as your previous password. Once this process has been completed, you will receive a confirmation email in your inbox notifying you that your password has been changed.

If you did not request this change and you suspect that your account has been compromised, please contact the PainChek support team. The PainChek mobile application must be connected to the Internet for the first login after changing your password.

1. Tap **Forgot your password ?** in the login page



2. Enter **email address** and press OK



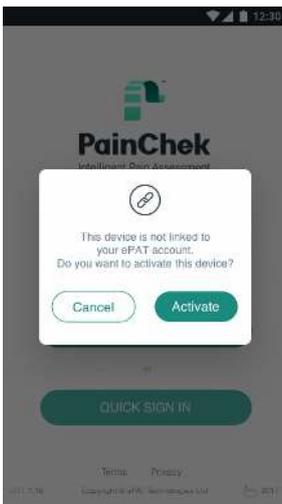
5.3 Devices linked to your PainChek account

Private PainChek license holders can install the PainChek app on up to three devices whereas professional license holders can install the app on an unlimited number of devices.

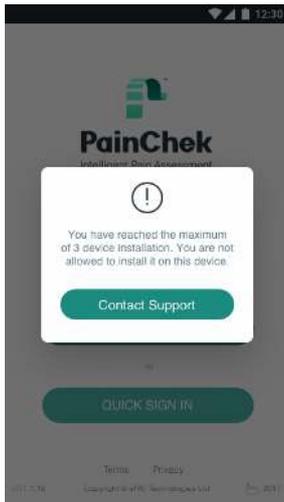
If you have downloaded PainChek on a device that is not yet linked to your PainChek account, you will be prompted to confirm that you want to activate the new device. If you are a private license holders and have reached the limit of three devices you can no longer install the application on new devices unless you deactivate the installation on other devices.

You can manage your installations on the PainChek Web Administration Portal.

1. **Activate** device



2. Device **blocked**





6 Personal Settings

6.1 Profile settings

You can update your personal information in the profile settings. The profile settings can be accessed by clicking on your profile picture at the top of the screen on the PainChek dashboard. You can update your Name, Phone Number, Institution and Job Title. If you want to add a profile picture to your user account or change the picture you can also do this in the profile settings by clicking on the edit button that appears next to your profile picture when you click on it. You can also activate the quick login function in your profile settings by entering a four-digit PIN.

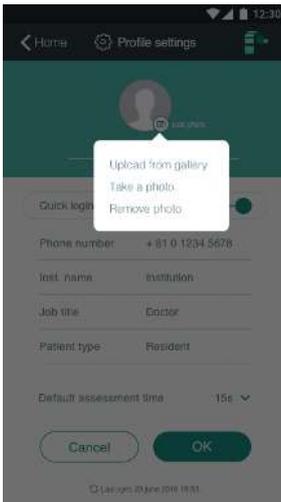
1. Click your **name** or picture in the top left corner. You can also go to **Profile Settings**



2. In this section, you can edit your personal details and change your profile picture by tapping **Edit photo**



3. Take a **new picture** with your camera phone, or browse to the photo you want to use



6.2 PainChek Dashboard

After you have successfully logged into PainChek, you will be able to see your dashboard. The dashboard gives you an overview of the people you are currently caring for, recently conducted pain assessments and quick links to various sections of PainChek such as Therapies, Medications, Patients, Add New Patient, My Patients and Recent Patients.

1. The **dashboard**





7 Patient Settings

The PainChek mobile application allows you to view and manage patients.

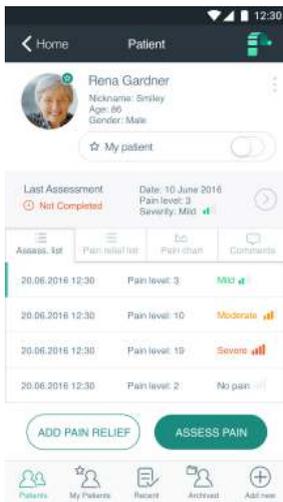
You can:

- View the profile of a patient
- See which patients have recent been updated
- Edit a patient
- Archive a patient
- Create a personalised patient list
- Search for patients

7.1 Patient Profile

If you click on a patient profile, you will be able to see an overview of a person's personal information such as Full Name, Nickname, Age and Gender. You can access information about past pain assessments, administered pain relief, as well as a pain chart that displays the pain level of the person over time and comments. You can start a pain assessment from the patient profile screen and log the type of pain relief administered to a person. You can also edit existing profile information or archive a profile.

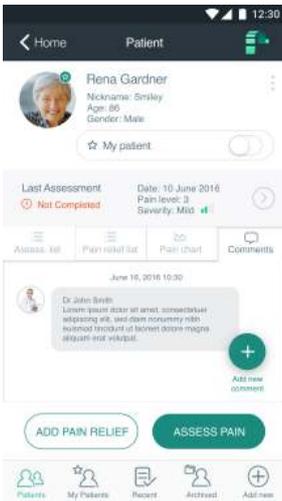
1. Patient **profile**



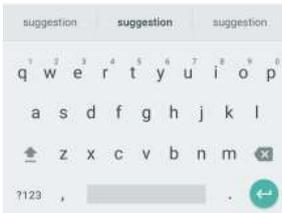
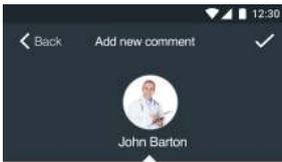
2. The **pain chart** shows the pain level and the severity score of a patient in a timeline



3. Add comments about your patient, resident or client by tapping on **Add new comment** button



4. Enter your comment in the text form

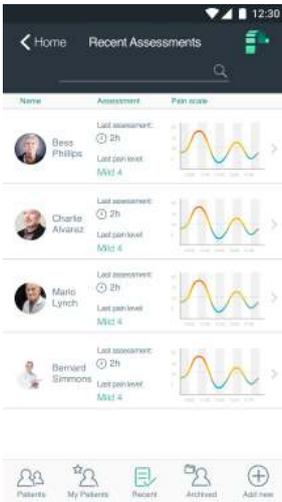


7.2 Recent Patients

People who have recently had their pain assessed are displayed.

It displays their name, how much time has passed since the last pain assessment and their last pain level. A graph shows the evolvement of pain levels over time.

1. Recent patients





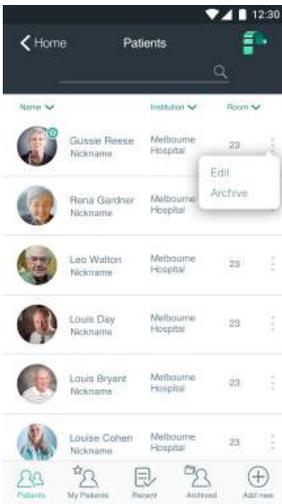
7.3 Editing a Patient

After creating a new patient, you can edit the person’s profile details and photo.

1. Go to **My Patients** (Residents or Clients) from your Dashboard



2. Select **Patients** (Residents or Clients) in the bottom left corner
3. Press the **options** button next to the person’s name you want to edit
4. Select **Edit**



5. **Modify** now the personal details or photo of your patient, resident or client



6. Press **OK**



7.4 Adding a Patient

Add a new patient by clicking on 'Add New Patient' on the PainChek dashboard. You will be asked to set up a new patient profile. You can add a photo to make identification easier as well as personal information such as First Name, Last Name, Nickname and Date of Birth. Complementary information such as Institution Name, Room and Bed Numbers can also be added and saved.

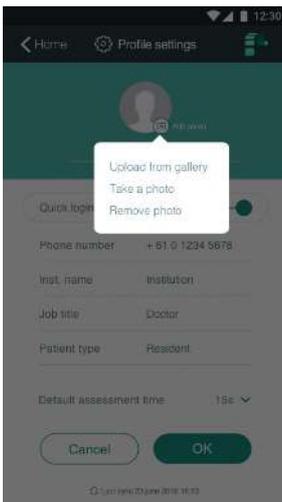
1. Tap **Add new Patient** (Client or Resident) button on your Dashboard



2. To add a photo tap **Add photo** on the profile circle above the form



3. Choose one of the options available: **Take Picture** with your camera phone, or **Upload from gallery**. If you choose the second option browse to the photo you want to use and select it. The photo will appear on the profile



4. **Fill in** all fields in the form (First Name, Last name, Nickname, Gender, Date of birth (dd/mm/yyyy) and Residence (home or institution))



5. Press **OK**. You can now find the new profile saved on **My Patients** (Residents or Clients) section on your Dashboard

6. If you do not want to create the profile, click on **CANCEL** instead of OK. You will lose all the information previously entered



7.5 Archiving a Patient

 You need Admin permissions to use this functionality

If you have admin permissions, you have the option to archive an existing patient. Recently archived patients can be accessed by clicking on 'Archived Patients' on the PainChek dashboard.

You can access a list of the last 20 patients that were archived (along with their Name, Institutions, Room Number and Gender) or search for a particular patient by entering their names in the search field at the top of the screen.

By clicking on an archived patient profile you have the possibility to restore the profile and add it again to your active patient list.

Equally, you can click on an existing active patient profile and archive the person. You will be asked why you want to archive a person and can choose between a) Discharged b) Transferred c) Deceased or d) Other.

1. Tap **My Patients** (Residents or Clients) button on your Dashboard



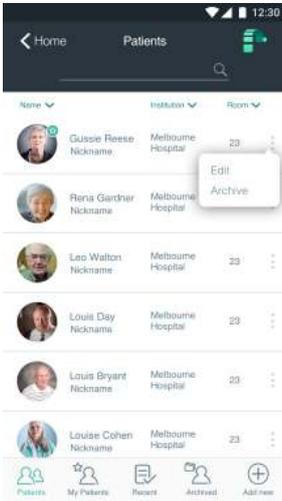
2. Select **Patients** (residents or clients) in the bottom left corner



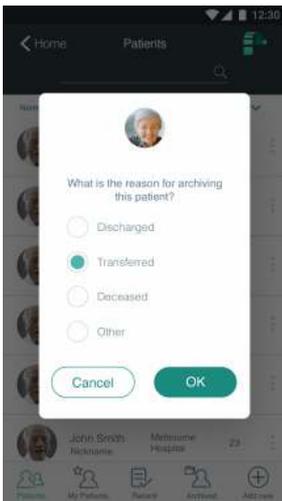


3. Press the **options** button next to the person's name

4. Select **Archive**



5. **Choose the reason** for archiving: discharged, transferred, deceased or other



6. Press **OK** or **Cancel** if you decide not to archive

7. Go to **Archived** and browse Patients (residents or clients) that are not active anymore

8. To restore a patient tap again the options button on a patient's profile and select **Restore**



9. **Confirm** you want to restore by pressing **Restore** or **Cancel** if you decide not to restore



7.6 Creating a Personalised Patient List

PainChek patient's data from a license number is synchronised with all devices belonging to the same institution or organisation.

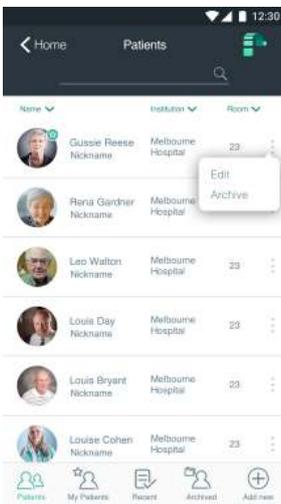
This means that you can see not only the patients you have assessed but other patients from your colleagues too. Every new patient added is saved in the “Patients” section which is a general list.

However, you can create a personal list that filters your patients. This information is shown in “My patients” section. To create a personal list follow the steps below.

1. Tap **My Patients** (Residents or Clients) button on your Dashboard.



2. Select **Patients** (residents or clients) in the bottom left corner.



3. **Select** the profile you want to include in your personal list by pressing on the person's name, institution or room

4. Activate **My Patient** (resident or client) button





5. Check your new list on **My Patients** (residents or clients)



7.7 Searching for a Patient

To find easily patients use the search bar available in the app.

1. Go to **My Patients** (Residents or Clients) on your Dashboard



2. Click directly in the **search text box** and type the first name or last name of the person you want to find



3. If the patient, resident or client exists, the person's profile will appear on the list



8 Pain Assessments

The PainChek mobile application allows you to view and manage patient assessments.

You can:

- Conduct a pain assessment
- Conduct a manual facial assessment
- Adjusting the time for an automated facial assessment
- Reviewing an assessment

8.1 Conducting a Pain Assessment

To assess the pain level, the application does not need to be connected to the Internet to function correctly. However, it is recommended to stay connected whenever possible to ensure all data is quickly synchronised and updates are installed in a timely manner.

It is recommended to use the PainChek app in a well-lit indoor environment that allows accurate observation of the person whose pain level you want to assess and accurately enter visual and audible pain cue data.

When you and the patient are ready, start pain assessment by clicking on the 'Assess Pain' button on the respective patient profile. You need to complete the steps described below to successfully conduct a pain assessment.

1. Tap **My Patients** (Residents or Clients) button on your Dashboard



If the person does not appear on the list, check the full list by tapping **Patients** (residents or clients) in the bottom left corner

2. **Select** the profile you want to assess from the list by pressing on the person's name, institution or room

3. Tap **Assess Pain** button



5. The first pain cue will appear on the screen **The Face**, few seconds later your camera phone is activated



6. **Focus** your patient's (resident or client) face with your camera phone. The screen will become in color where the focus is accurate. Use the blue square on the screen as a guide to center your patient's face on the screen





Press on **Start analysis**. The default time is set to 3 seconds

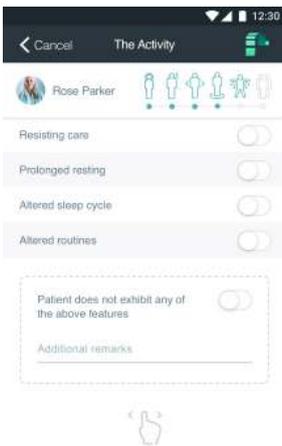
8. When the assessment is done, you will find a list with the pain cues **The Face** identified by the system. You will now see the results of your analysis. Please verify if every element was checked by the system and include any other pain cue you have identified



9. **The Voice:** You will need to check ten statements regarding any vocalisations made by the person. You also have the option to type in additional remarks at the bottom or add an **audio recording** of the person's voice by pressing the **REC** button



12. The Activity: You will need to answer five questions regarding the activity of the person whose pain level you want to assess. You can also type in additional remarks



13. The Body: You will need to answer seven questions regarding the person whose pain level you want to assess. You can also type in additional remarks



You can move back and forth between the different screens by swiping left or right.

14. When you finish The Body pain cues press on **SUBMIT ASSESSMENT**. The pain assessment will output a total score

At the end of the pain assessment you will be able to see separate scores for Face, Voice, Movement, Behaviour, Activity and Body as well as the total aggregated pain score and its intensity level (absent, mild, moderate, severe). This level is assigned according to the scale below:

1-6 = No pain

7-11 = Mild

12-15 = Moderate

> 16 = Severe



The total score is calculated by the addition of inputs in each domain. In the example above, John Smith has a total score of 14.

Once the pain assessment has been completed you can save the data. Unfinished assessments will be discarded after 15 minutes if the assessment is not saved.



15. If you want to verify a specific pain cue’s score press on the pain cue. Press **SAVE** to end the pain assessment or stop the assessment process by pressing on **CANCEL**.

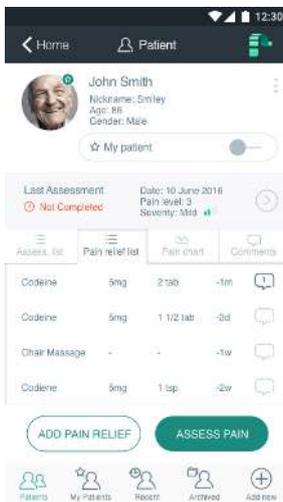
The information is not lost but the process is not completed. You can come back later to **SAVE** the results

16. Delete assessment under **CANCEL** and **SAVE** buttons. If you choose this option, you will lose all the information. This option is available if you have not saved the pain assessment. After saving it, deletion is not possible

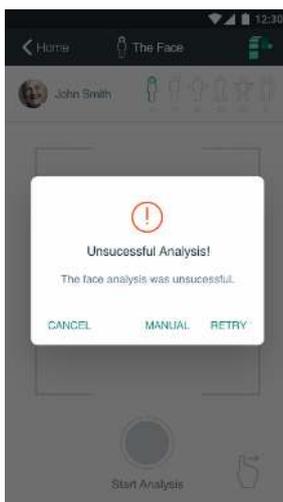
8.2 Completing a Manual Facial Assessment

If the automatic facial assessment fails when conducting a Pain assessment, a manual function is available to complete the pain cue “The Face”.

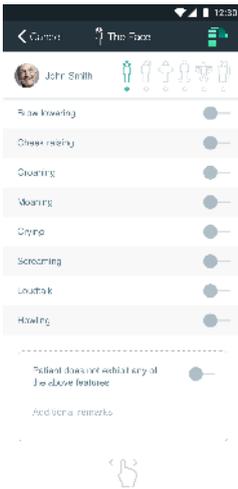
1. Tap **Assess Pain** button



2. When the error message appears, select **Manual**



3. The pain cue **The Face** will appear on the screen. You will need to check eight statements regarding the face of the person whose pain level you want to assess



4. Continue with the other pain cues as described in previous sections

8.3 Configuring Pain Assessment Time

The default assessment time is set to 3 seconds, if you want to extend the time follow the steps below.

1. In the screen before commencing an assessment, touch the **timer icon** in the upper right corner



2. Choose a **setting** between 3 and 90 seconds

3. Press **Done**

8.4 Reviewing a Pain Assessment

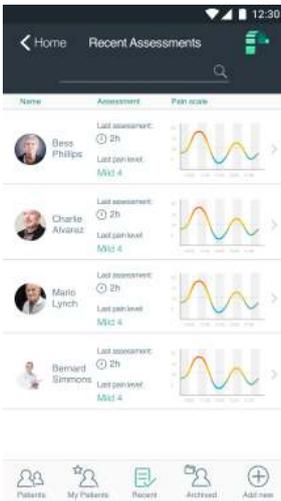
In order to review a pain assessment, go to your patient, resident or client's profile. Please note that Pain assessments of a patient, resident or client can only be edit if they are not completed. Once you save a pain assessment, this will be stored permanently.



1. From your dashboard select the person on **My Patients** (Residents or Clients) or **Recent Patients** section



2. Click on **Recent assessment >**. If there is not any assessment saved you need to create a new one



3. Tap the pain cue you wish to review. For example: The face



9 Pain Relief and Therapies

The PainChek mobile application allows you to view and manage the Pain Relief and the Therapies applied to patients.

You can:

- Record Pain Relief
- Record Therapies
- Create new Pain Relief types
- Create new Therapy types

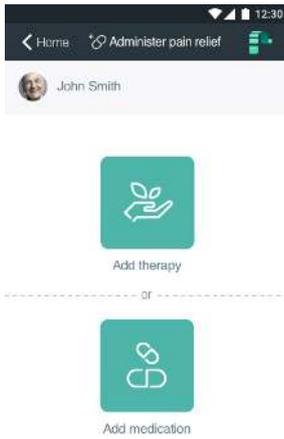
9.1 Recording Pain Relief

Once a pain assessment has been completed you may decide to administer pain relief to a person. Any pain relief you administer should be recorded in the PainChek application. To record the administration of pain relief, select the '+ Pain Relief' button from the corresponding patient profile. You can either select the appropriate pain relief you aim to administer from your medication list within the PainChek app or add the Name, Dose and Date and Time manually. In addition, you can also choose from your therapies list what type of pain relief therapy you decide to administer.

1. Tap **Add pain relief** from the patient's profile



2. Add a **therapy or a medication**



3. Add it **manually**

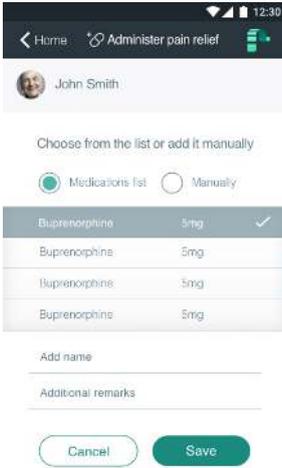


4. Enter **details**





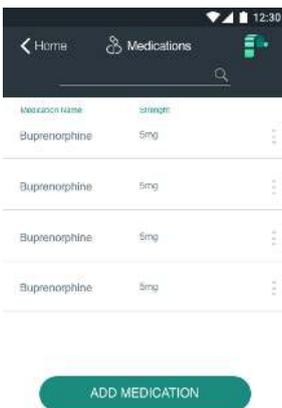
5. Or add it from an existing list



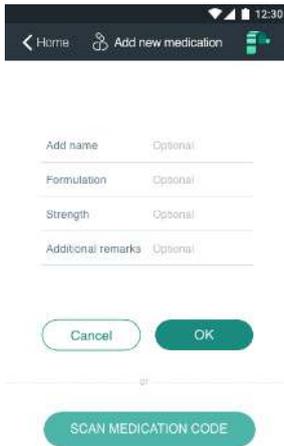
9.2 Adding New Medication

To facilitate the recording of administered pain relief, you can create a list of medications that you administer on a regular basis. To add a new medication, click on ‘medications’ on the dashboard. At the bottom of your medication list you can click the ‘Add Medication’ button. You can either add information about the medication manually by typing in the Name, Formulation, Strength and Additional Remarks relating to the medication or select an existing one from the list. You can decide to either save or discard the information and go back to entering the data manually. Once you have saved a medication, it will appear in your medications list along with the information when it was last administered.

1. Add medication



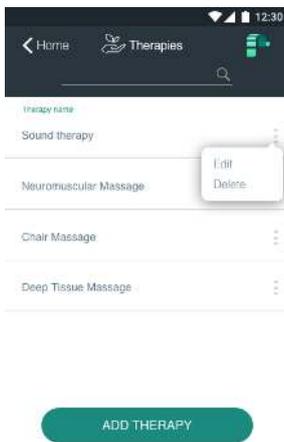
2. Enter details



9.3 Add New Therapies

To facilitate the recording of therapies, you can create a list of therapies that you use on a regular basis. To add a new therapy, click on therapies on the dashboard. At the bottom of your therapies list you can click the 'Add Therapy' button. To add a new therapy, you can type in the Name and a Description of the treatment manually. Once you have saved a therapy, it will appear in your therapies list.

1. Add therapy



2. Enter details