

Instructions for use

for the Triage App



TRIAGE

Triage Technologies, Inc.

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1. Intended purpose

Triage is a software application that uses artificial intelligence to perform user-specific analyses of skin conditions. It is designed to assist users in early detection as well as monitoring of potential skin conditions. Triage lists up to five conditions in order of likelihood and assists the user in making a decision to see a healthcare professional.

2. Intended users

Triage is intended to be used by:

- Lay users with potential skin conditions.

Children shall only use the app under supervision by parent or guardian.

3. Contraindications (when the app should not be used)

No contraindications have been identified so far.

4. Warnings and precautions

- Triage does neither provide a diagnosis nor information to take diagnostic decision and is no substitute for professional medical advice. Please see your doctor for a diagnosis. Always consult your dermatologist or another qualified healthcare professional before beginning any treatment. If you are experiencing a medical emergency, please call your emergency line.
- Please make sure the photo(s) you submit are of good quality and the information you provide is accurate, as the accuracy of the services will vary depending on the quality of this information.
- As part of the registration process, the responses the user enters through the process are important for the best results to be displayed. It is crucial that this information is accurately entered by the user.

5. System requirements

Triage supports:

- Web browsers that support HTML, JavaScript and CSS
- Cameras with at least 10 MPixels sensor resolution

6. How to use the Triage app

Please note that the Triage app is designed to be self-explanatory with prompts and instructions provided throughout the process on a step-by-step basis. The guidance to follow is additional information that is to be used at the option of the user.

6.1. How to use the Triage app

6.1.1. Create account / log in

Once landing on Triage's website, a user can create an account, sign into a previously created account or begin an analysis of one's skin condition by selecting the "Get Started" link.

After selecting the "Get Started" link, if a user has not already done so, the user must log into a previously created account or create a new account. Creating an account will require an active email address and password. This email address and password can be used for future sign in.

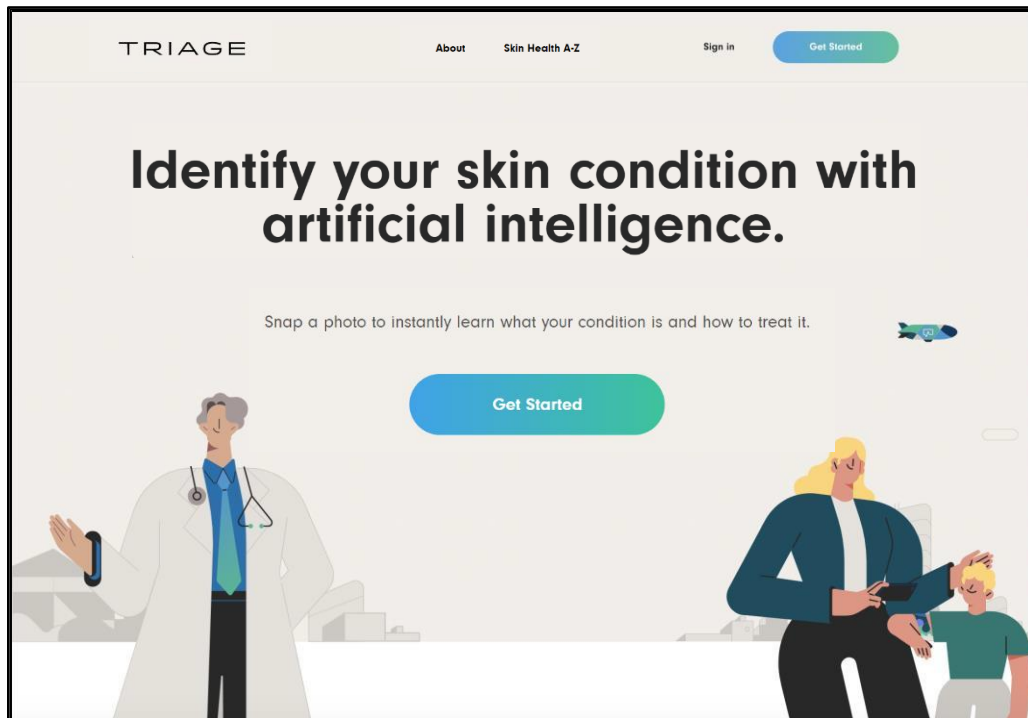


Figure 1: triage.com landing page with “Get Started” links to start using the Triage app

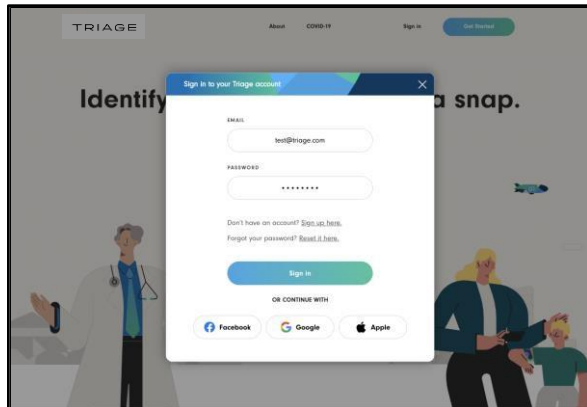


Figure 2: Signing into an existing user account

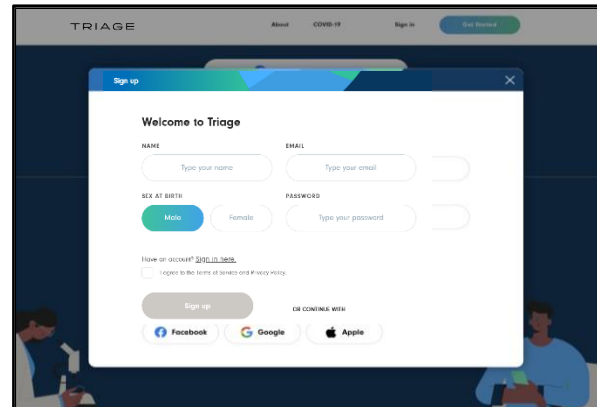


Figure 3: Creating a new user account


6.1.2. Enter basic information

Once passed the log in step, a user will be prompted to provide their sex at birth and age in years old.

TRIAGE


AboutSkin Health A-Z

TR



Tell us about yourself

This information will help us narrow down possible conditions and give you more accurate results.



Sex at birth

Male

Female

Age

30

PreviousNext

Figure 4: Basic information to be entered by the user


6.1.3. Take a photo and upload the image

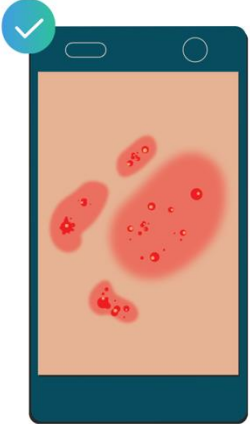
After inputting basic user information, the user will be prompted on how to best capture an image of the skin condition in question.

6.1.3.1. Instructions for taking a photo

For users using a smartphone or tablet camera:

How to take a photo





Snap a photo

- Take the photo about 4 inches away from the problem area
- Center your symptom in the photo
- Make sure there is good lighting
- Ensure your photo isn't blurry

Figure 5: Guidance for how the user should capture an image

6.1.3.2. Take a photo, upload and crop the image

The user will be prompted to take a photo and upload the image of their skin condition. Once the image is uploaded, the system will either accept the image or provide reason for why the image is not acceptable and request that a new image be uploaded. An accepted image will be displayed with brief guidance on how best to prepare the image for analysis through cropping and centering the skin condition. Once completed properly, the user can click the "Next" link at the bottom of the page to continue to the next step of the process.

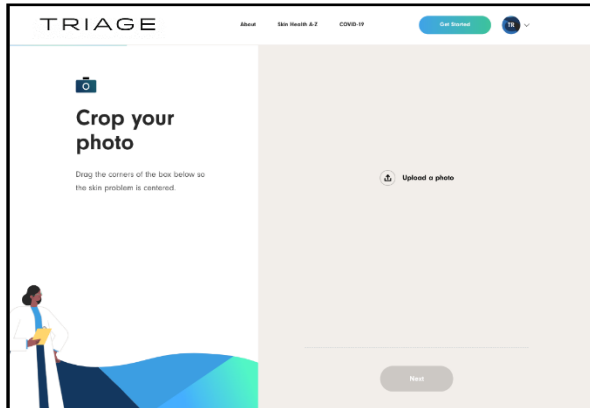


Figure 6: Prompt to upload an image

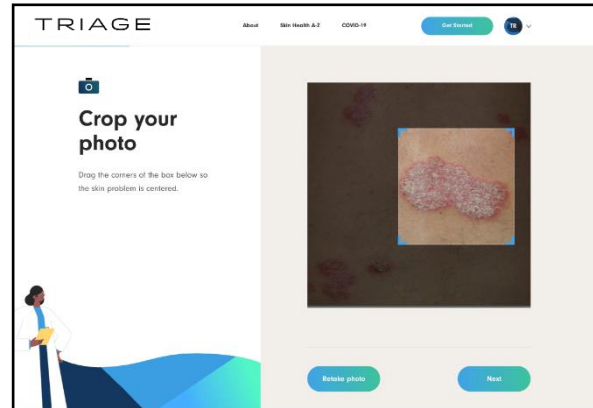


Figure 7: An accepted photo will appear with ability to crop according to guidance provided

6.1.4. Select the location of the image

The user will be prompted to provide the location of the image and the accompanying skin condition in the image on the avatar. This can be done through typing in a searchable location on the left side of the screen or by 'clicking' the applicable section on the avatar on the right side of the screen. A user can rotate the avatar 180° for either the front or back side of the avatar. Once completed, the user can 'click' the "Next" link at the bottom of the page to continue.

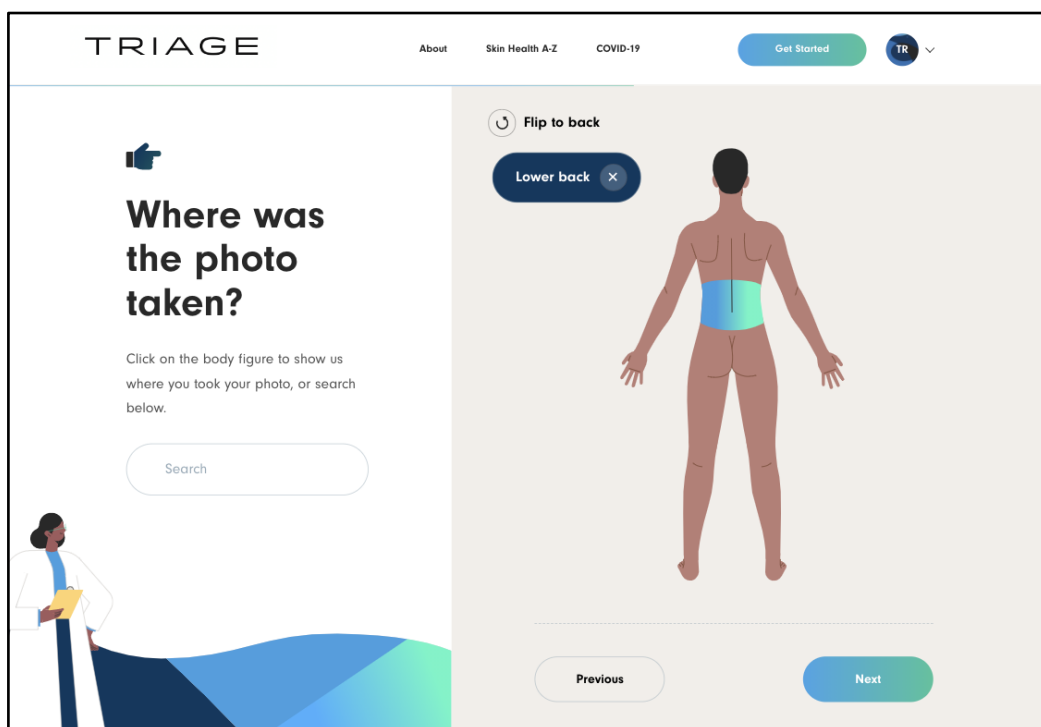


Figure 8: User is asked to provide the location of the image of the skin condition

6.1.5. Question page

The application will perform an initial assessment of the information entered to this point by the user and may follow up with questions. Should questions appear, the user will be given a choice of answers to which a response can be 'clicked' below each question. Once all responses are properly selected, the user will proceed to the results page.

Figure 9: Specific question generated based on user's information entered to this point, which, upon answering, will take the user to the results page

6.1.6. Results

6.1.6.1. Initial potential results screen

The user will now be provided with a list consisting of up to five of the most probable results. Additional information and resources about the potential skin conditions will also be displayed. The webpage extends beyond the initial screen view which the user can access by scrolling. Each result will be ranked in order of likelihood and listed on the left side of the screen. In addition, each skin condition listed on the initial screen view is 'clickable'. This is viewed in Figure 10, *which is displayed below*.

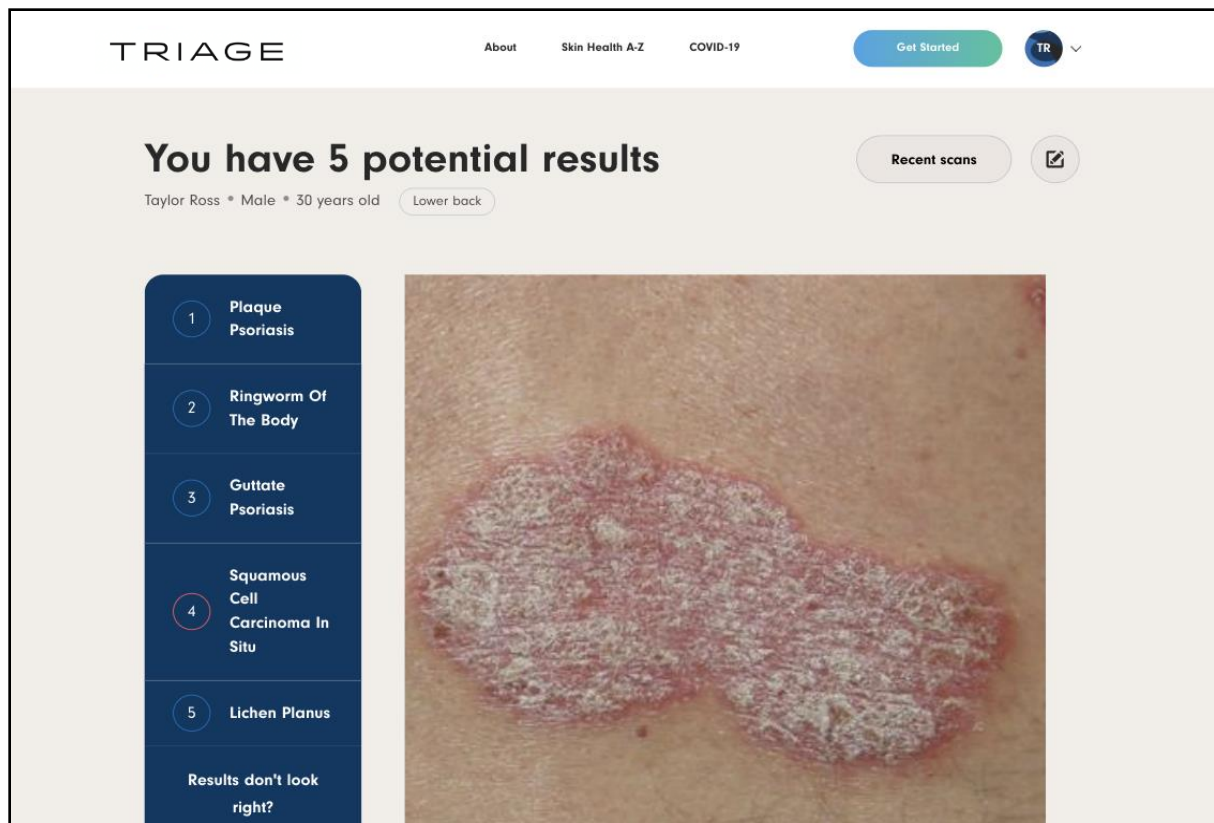


Figure 10: Initial potential results page

6.1.6.2. Additional information on potential results

When a skin condition is 'clicked' in Figure 10 above, the user will be advanced to a section on the webpage for specific information regarding the skin condition (as seen in Figure 11, below). Under most skin conditions, an additional link titled "Learn more about this condition" will advance the user to a new webpage with further detailed information and resources regarding the skin condition (*as seen in Figure 12, below*).

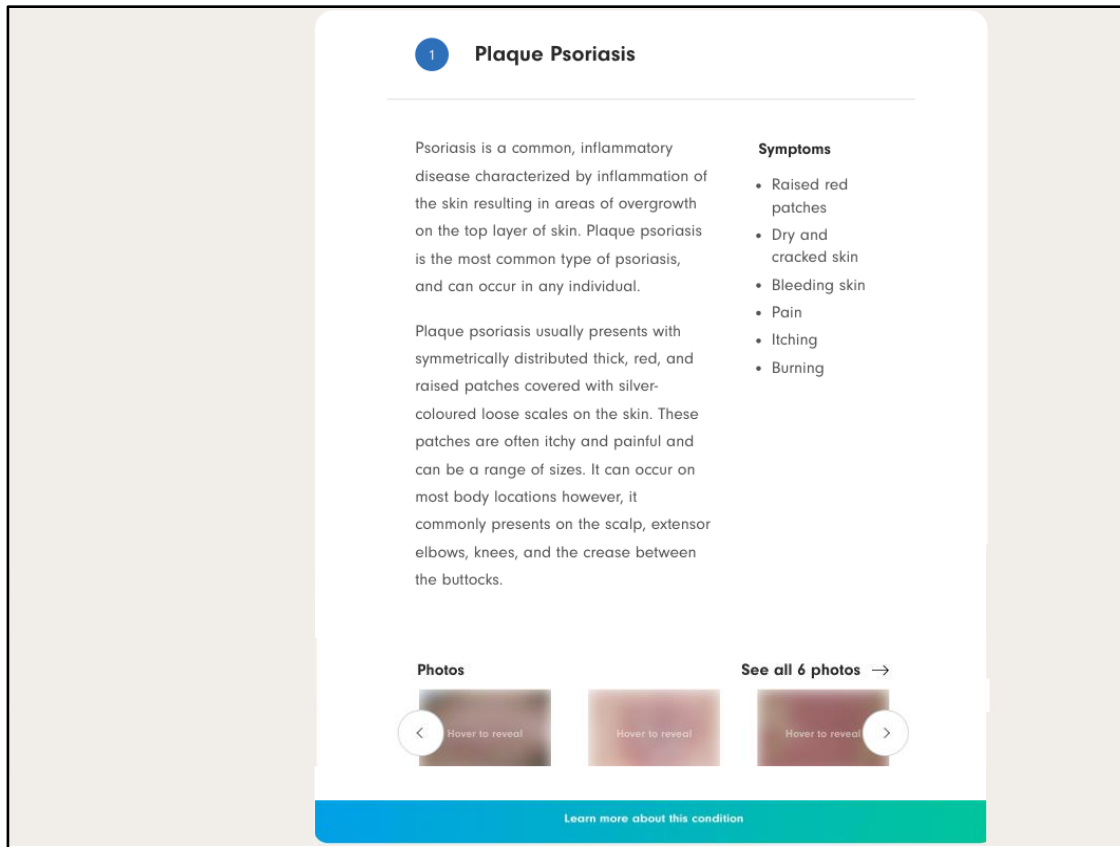


Figure 11: Skin condition information viewable when scrolling or 'clicking' the respective potential result

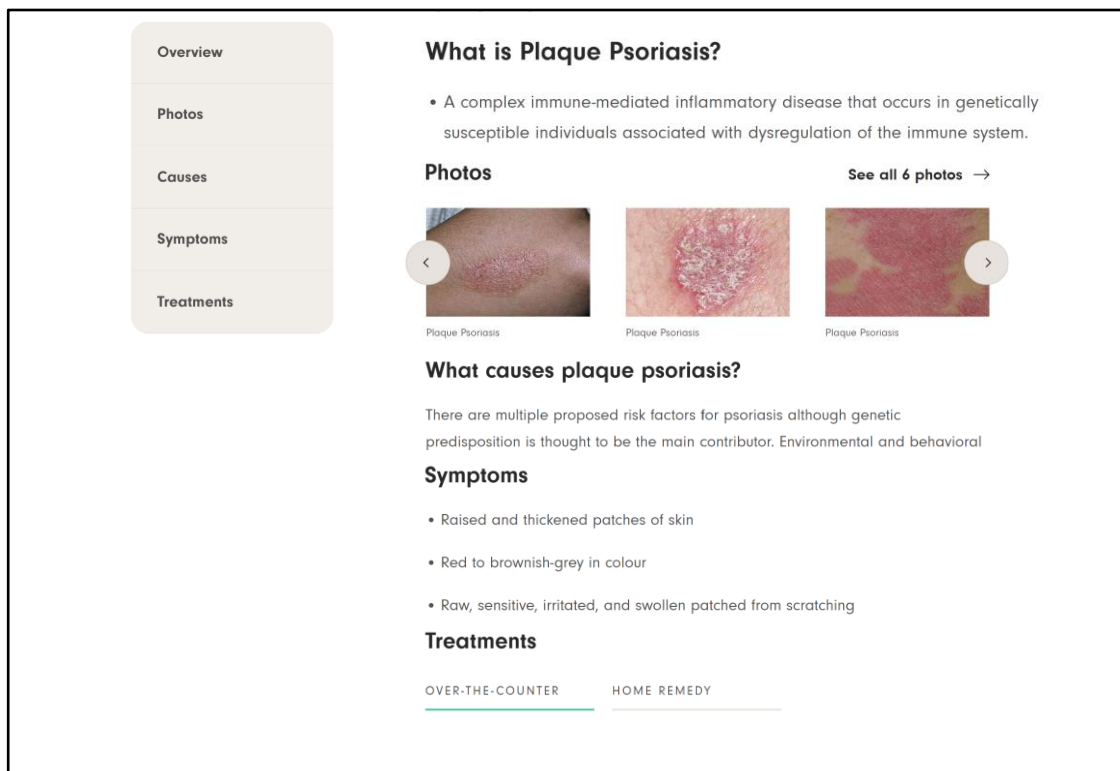


Figure 12: Additional information and resources provided on a new webpage after a user 'clicks' the "Learn more about this condition" link on the results page

Note: The information provided in this example has been intentionally shortened for brevity. Information provided to users on Triage is more detailed and in-depth than shown.

6.1.6.3. Results containing a potential high risk condition

If a result displays a potential high risk condition, the user will see a red circle outline the result number (as seen in Figure 13 / result #4, below).

This will be further highlighted when the user views the information associated with such a high risk condition. An emphasized red tag will appear next to the title of the skin condition stating "high risk condition". The user will also see that the link to additional information – "Learn more about this high risk condition" – will be emphasized in red. These high risk condition tags and markings can be seen in Figure 14, below.

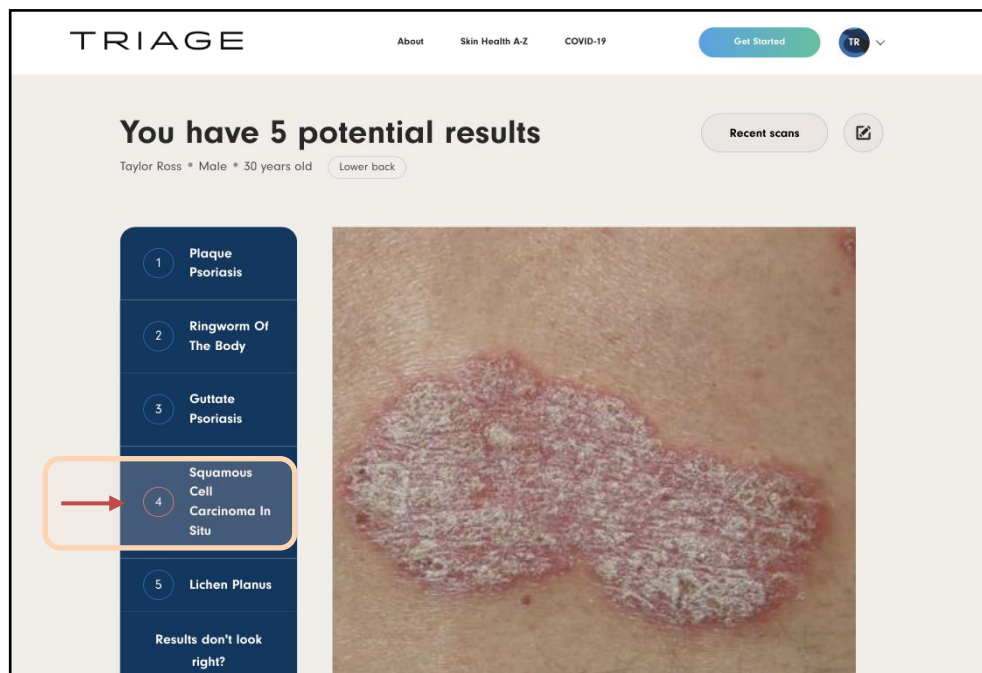


Figure 13: Initial potential results page with high risk condition marking

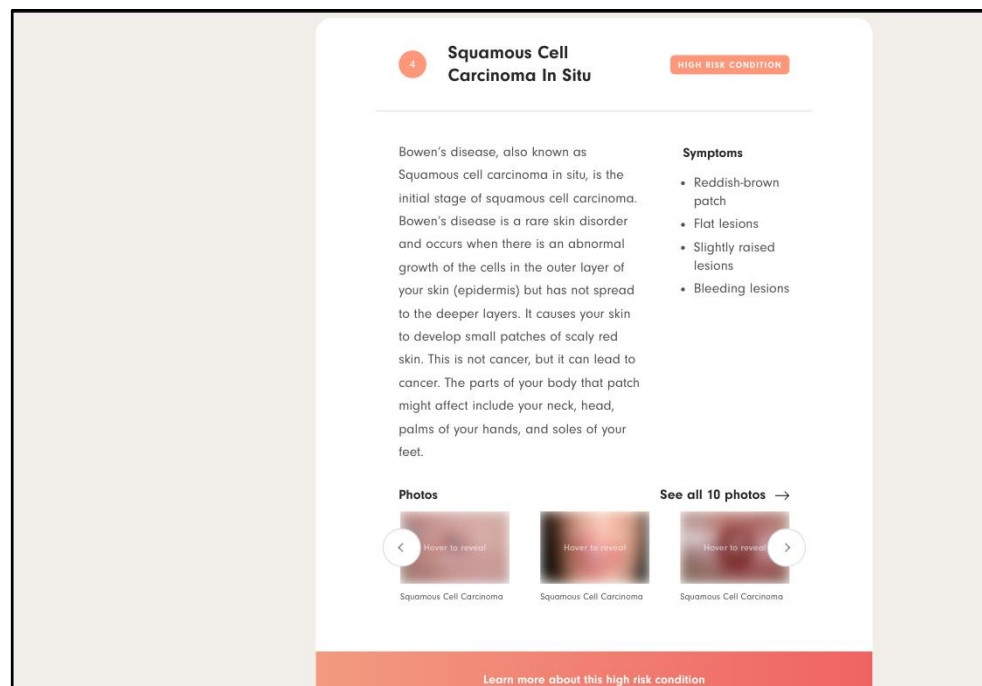


Figure 14: Unique markings for additional information on potential high risk conditions

6.1.7. Dashboard

Within the dashboard, previous fully completed skin condition analyses performed by Triage - along with accompanying potential results - will remain available for the user to view. When signed in, the user can access a dashboard through their account showing these previous scans displayed by the skin condition image uploaded. Previous complete scans can be sorted by most recent scan or by the oldest scan. By 'clicking' the "View results" link under each uploaded skin condition image within the dashboard, the user will be advanced to the previously provided potential results for the accompanying skin condition analysis page, as previously seen in Figure 10, *above*.

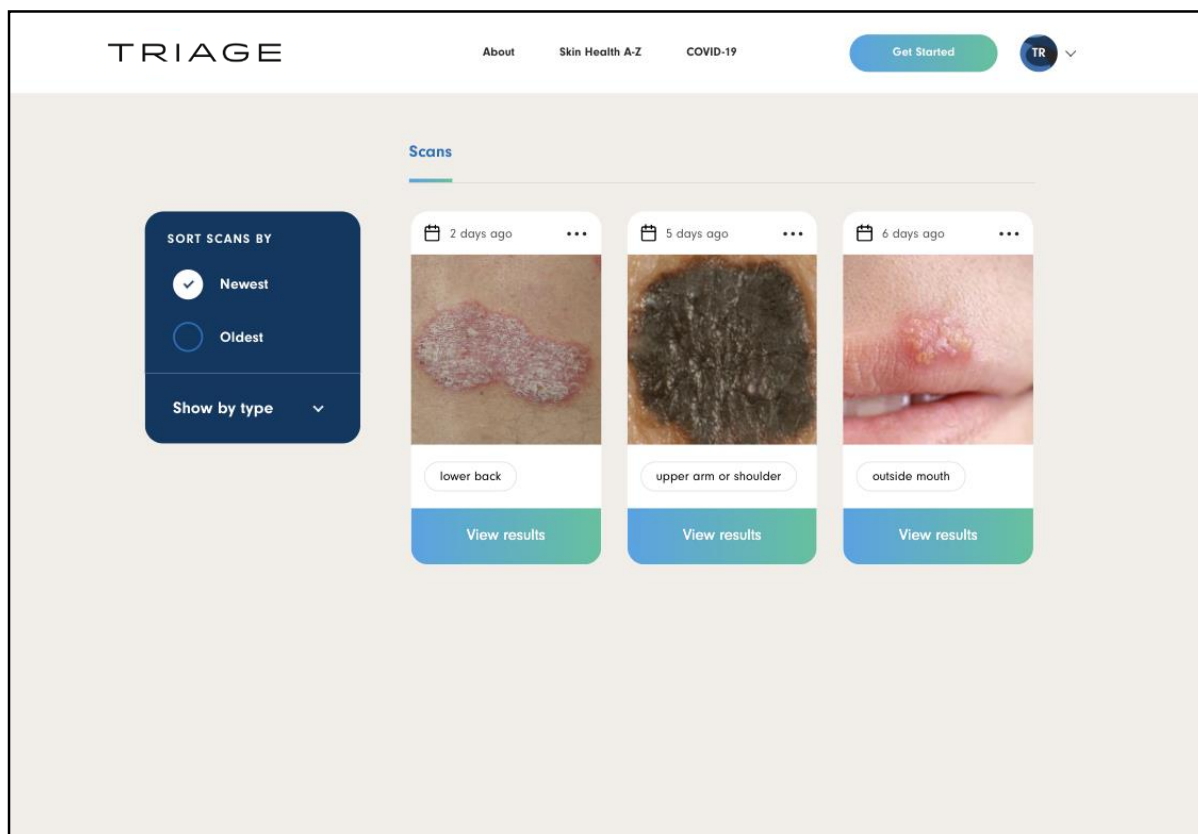


Figure 15: Previous scans fully completed on the Triage app available within a dashboard

7. Software status

For the current software version of Triage, please refer to <https://www.triage.com/version>.

8. Manufacturer

Triage Technologies, Inc.

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Email: support@triage.com

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9. European authorized representative








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10. Explanation of symbols

| Symbol | Explanation |
|---|--|
|  | Manufacturer |
|  | European Authorized Representative |
|  | Follow the instructions for use |
|  | The product is governed by REGULATION (EU) 2017/745 MDR. The CE marking symbolizes conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing |
|  | Date of manufacture |
|  | Unique Device Identifier |
|  | Medical device |

11. Troubleshooting

Refer to the Frequently Asked Questions page at <https://www.triage.com/faq> or contact support@triage.com for help with troubleshooting.

12. State of the information

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