

welcome.

Belle 1K offers access to reference text and images that may be similar to a digital skin image you provide for quick reference and is not a medical diagnostic tool.

The Belle 1K is not intended for individual use and is intended for professional use by healthcare providers only.

Instructions for Use
April 1, 2023

Belle 1K™

contact us.

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Available Monday - Friday (excluding national holidays)

Or you can reach us at <https://www.belle.ai/contact-us>

We are here to help!

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about Belle 1K.

- Immediately assesses geometric patterns of smartphone clinical images to provide healthcare professionals with access to similar reference text and images.
- Preserves the privacy and integrity of source images.
- Is a standalone module that can be a part of other apps via an API (application interface call or link). For instance, it is currently integrated into the bellePro™ app and may be integrated into other mobile apps or web applications.



**instructions
for use.**

intended use.

The Belle 1K allows you: dermatologists, general practitioners, nurses, physicians assistants, remote/field practitioners, first responder medical personnel, clinical investigators, and any healthcare professional, to access reference text and images that may be similar to a digital skin image you provide for quick reference.

The Belle 1K is not a diagnostic tool.

indications for use.

The Belle 1K can be used for all skin types.

The Belle 1K provides on-demand comparisons of digital photos to similar reference text and images to aide assessment of patients. The list of these referenced text and images can be found on page 31 of these Instructions for Use.

You can submit photos and see similar reference text and images based on relative size, texture and shape/geometry.

The Belle 1K can be installed and used on any compatible mobile platform referenced in the technical prerequisites of these Instructions for Use.

intended users.

The Belle 1K allows you: dermatologists, general practitioners, nurses, physicians assistants, remote/field practitioners, first responder medical personnel, clinical investigators, and any healthcare professional, to access reference text and images that may be similar to a digital skin image you provide for quick reference.

The Belle 1K is not a diagnostic tool.

You, acting as a licensed Health Care Professional, use your own medical training to make any diagnosis.

performance and benefits ●

Get on-demand comparisons of uploaded digital photos to similar reference text and images to aide assessment of patients. Submit photos and see similar reference text and images based on relative size, texture, and shape/geometry, which results in substantial time savings. The Belle 1K provides convenient and HIPAA-compliant access to image comparison and integrates with existing clinical workflows. Note that the result of similar images given should not be considered or relied upon as a diagnostic aid of any skin condition.

assumed risks.

- The device may wrongly consider a good quality image as a poor quality image. Therefore, the device may return incomplete comparisons on such image.
- The device may wrongly consider a bad quality image as good quality and return incomplete comparisons on such image.
- Even with small probability, the device might return incomplete comparisons.
- If the device server or user accounts hacked, important personal information of user data may be stolen or lost.
- If the device is not used according to the standard instruction, the image comparisons may be incomplete.
- If the skin image naming convention in the device is different from the user's skin image naming convention, the user may not understand the comparative result.
- If the internet connection is too weak, the device may take long for image comparisons or return an error.
- If the device server is down, action in progress may be lost and user may not be able to use the device.

contra-indications and cautions.

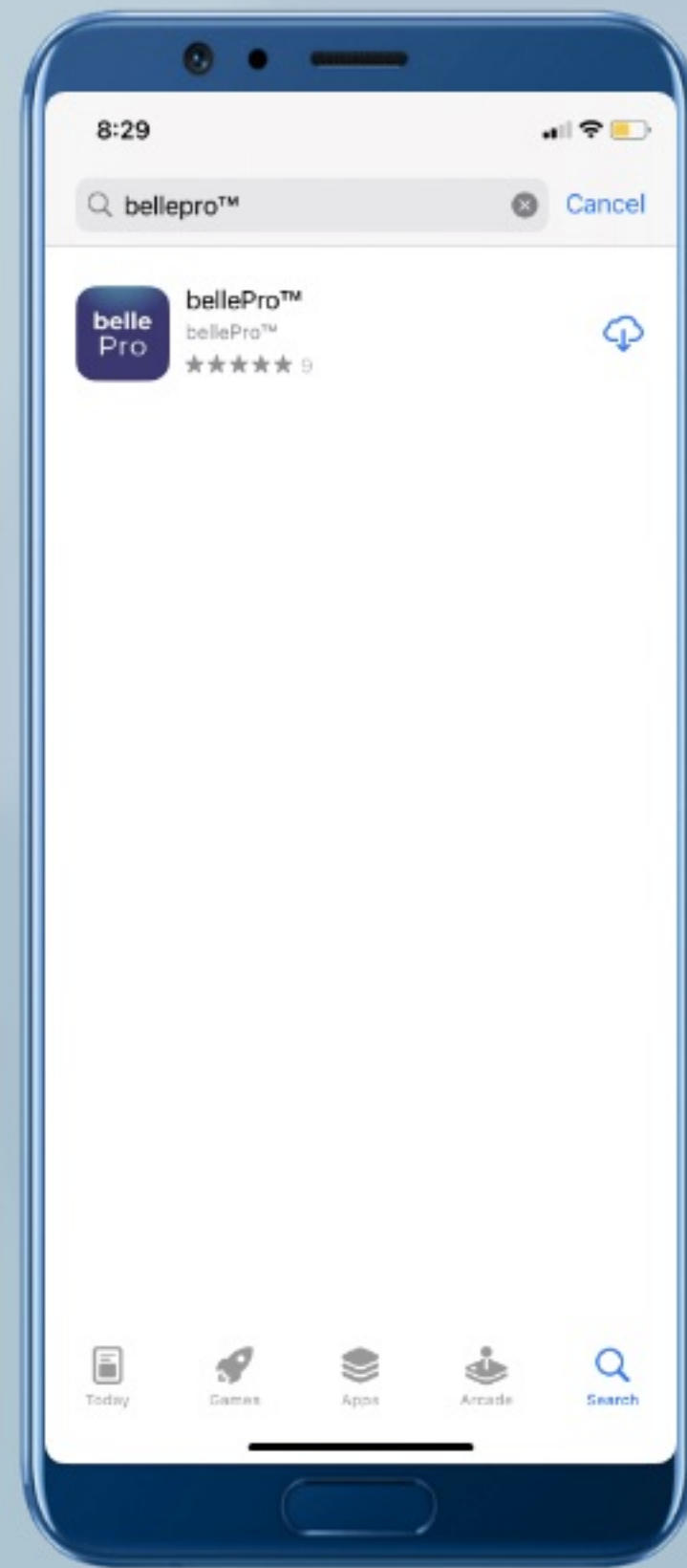
Contra-indications include:

- The Belle 1K is not intended as a diagnostic tool.
- The Belle 1K is not intended to be used for serious skin conditions, such as cancerous skin lesions.
- The Belle 1K is not intended for women who are pregnant or breast feeding, infants, or children.
- The Belle 1K is not intended for early signs of high-risk diseases.

Cautions include:

- The Belle 1K should only be used as a reference guide for the skin images accessible by this device.
- The Belle 1K is not intended as a substitute for and does not replace professional healthcare providers.
- The Belle 1K should not be used for medical decisions or as an aid to diagnosis.
- The Belle 1K does not diagnose cancerous skin lesions.

There are no side effects associated with Belle 1K.

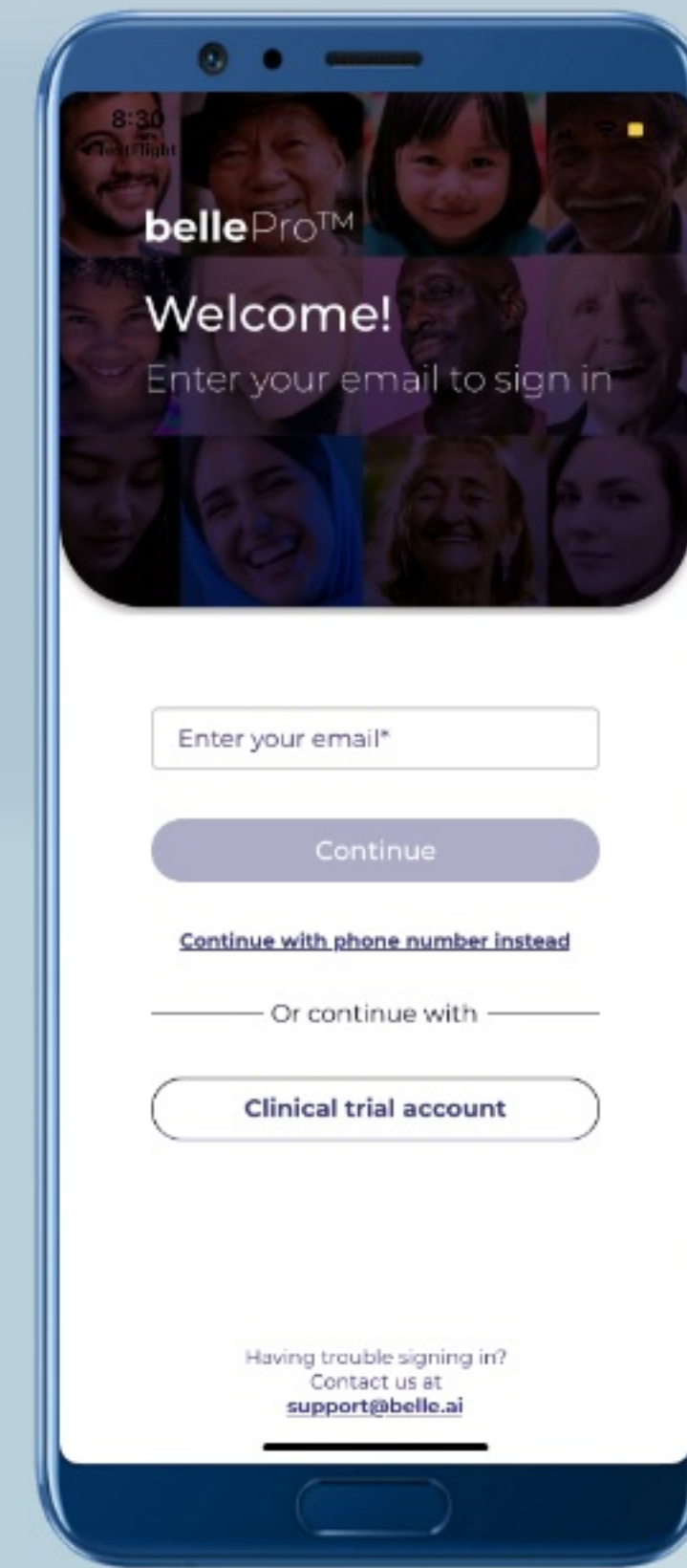


Step 1

Download the bellePro app from the Google Play or iOS App Store.

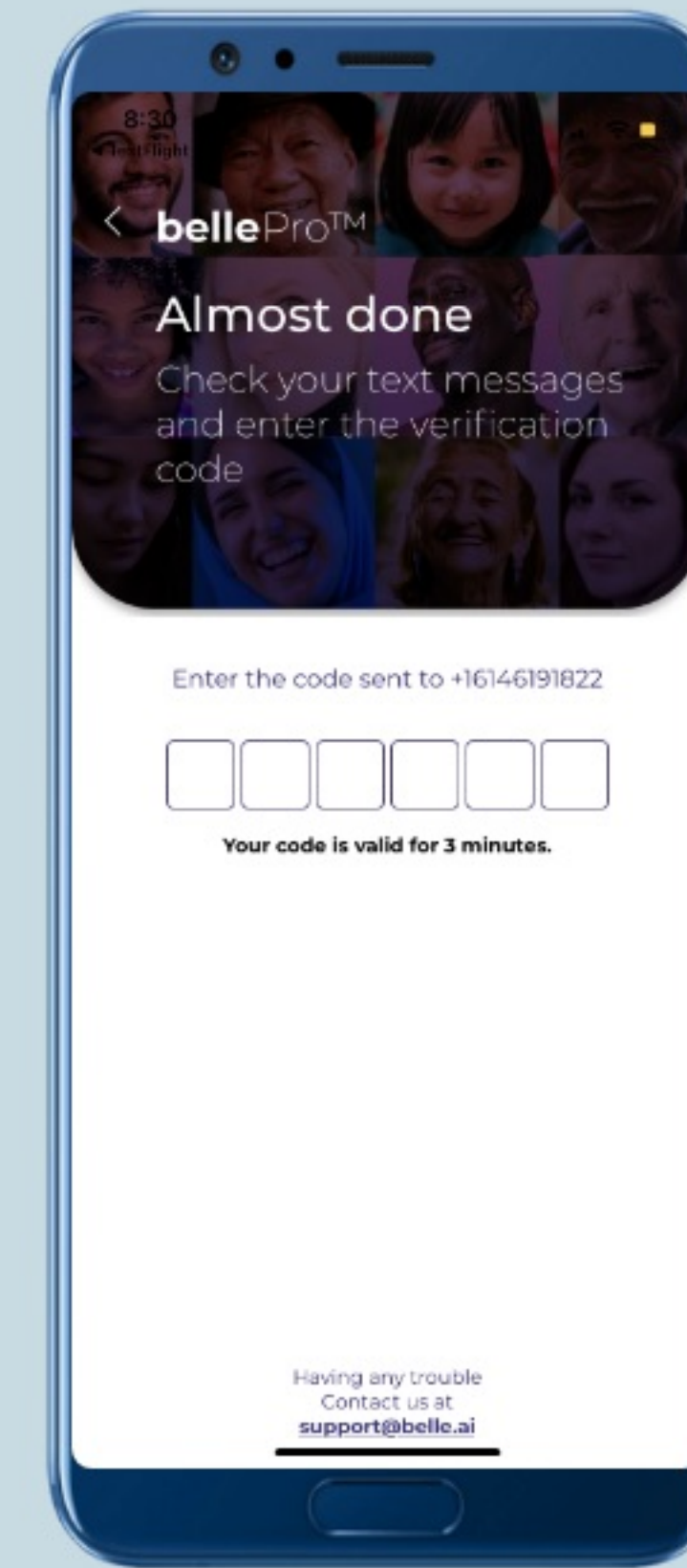


Tip: You must be connected to wifi to download and use the bellePro app



Step 2

Open the app and enter your email or mobile number to begin setting up your account, or to sign in to a previously created account.

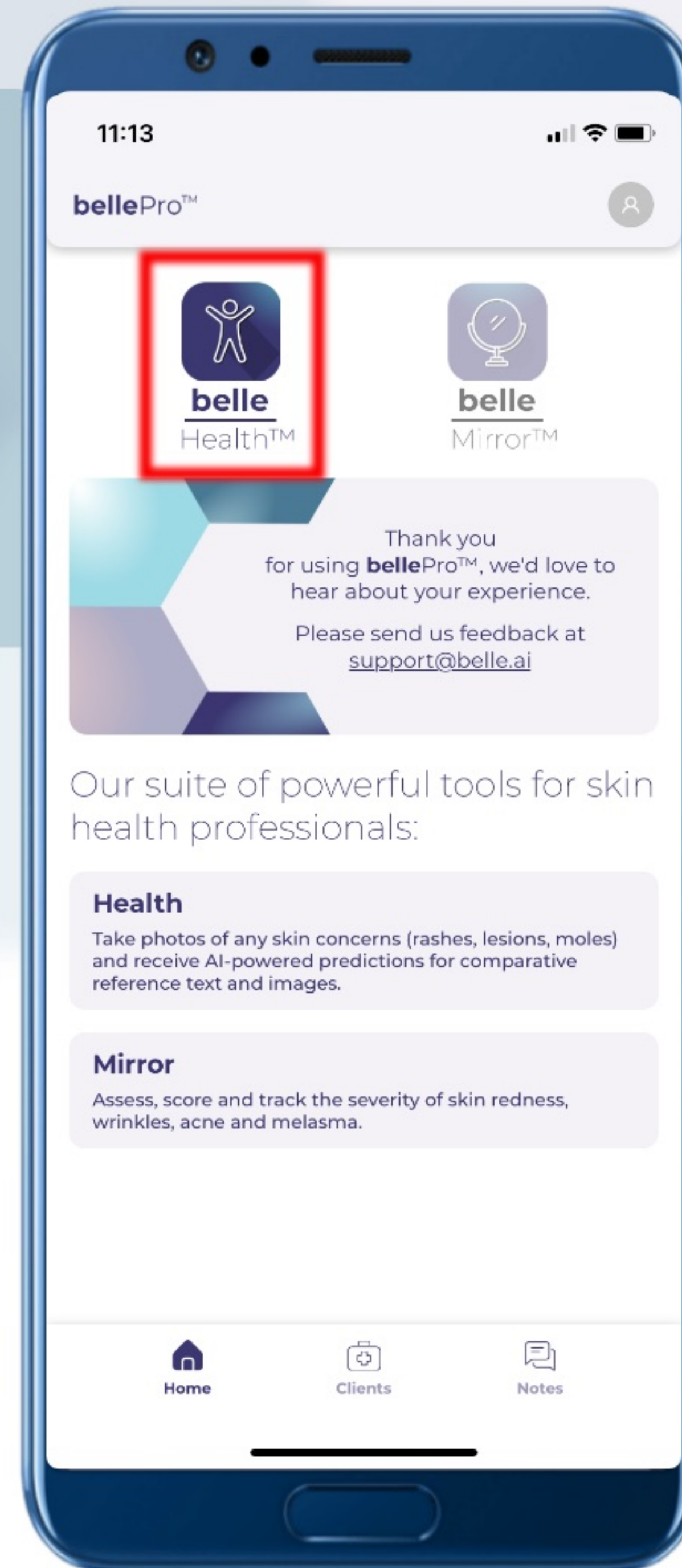


Step 3

A verification code will be sent to the email or mobile number. Type the verification code into the app to activate your bellePro account. A new verification code will be sent each time you sign into your account.

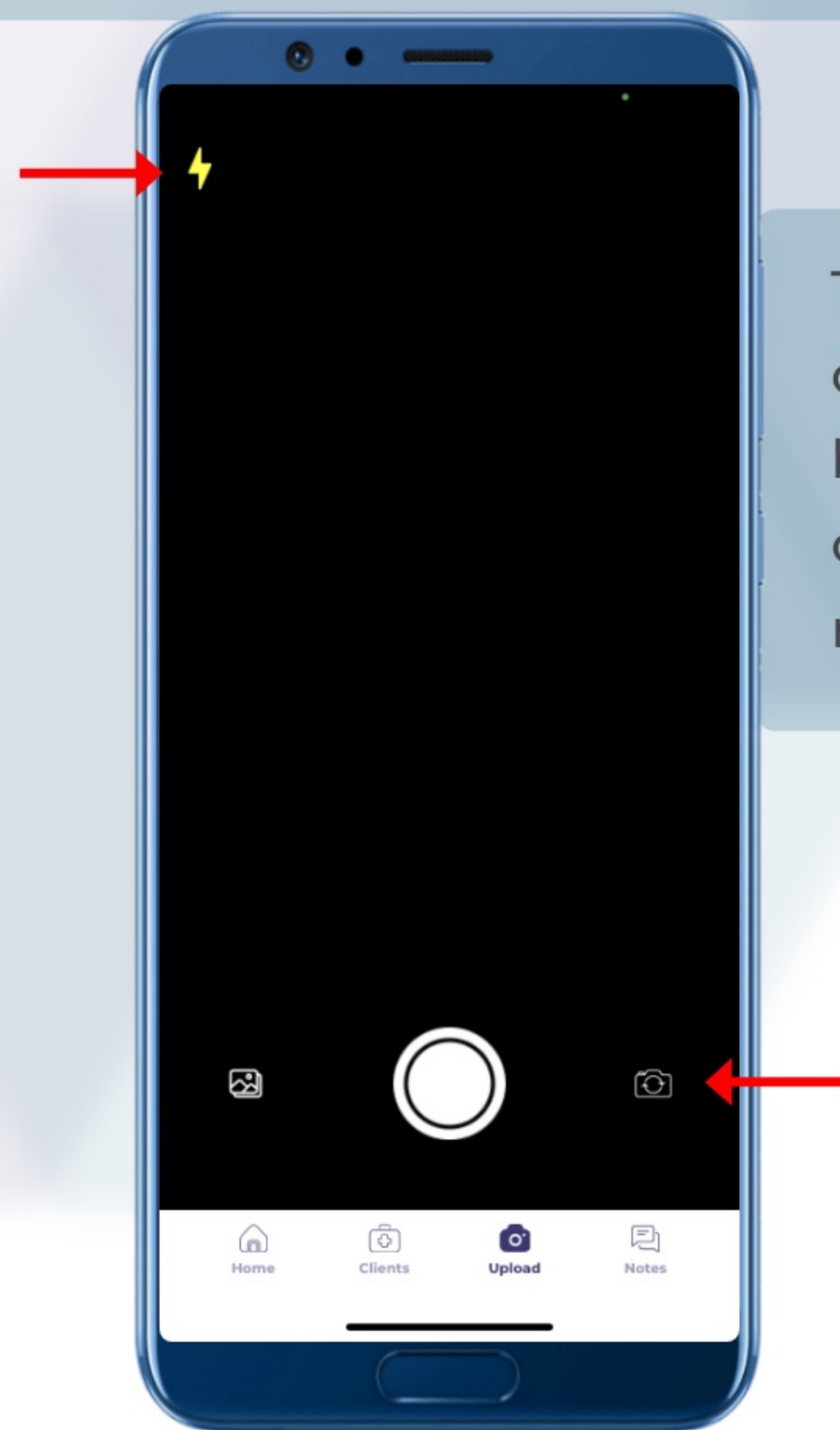
Step 4

After you are signed in, on the home screen, choose the belleHealth™ icon on the top left of the screen.



Step 5

After you select the belleHealth icon, the camera will automatically open. Position the phone and tap the white circle to capture an image.



The flash can be activated or deactivated by tapping on the lightening bolt icon. You can also switch between the phone's front facing and back facing cameras by tapping the camera icon in the bottom right corner.

Step 6

Once you snap a picture or upload an image, if you feel it is not sufficient you can retake it. You can also crop the image to focus on a particular area of interest or to reduce background space.



Tip: You will have to allow the bellePro app to use your smartphone device camera to take a photo

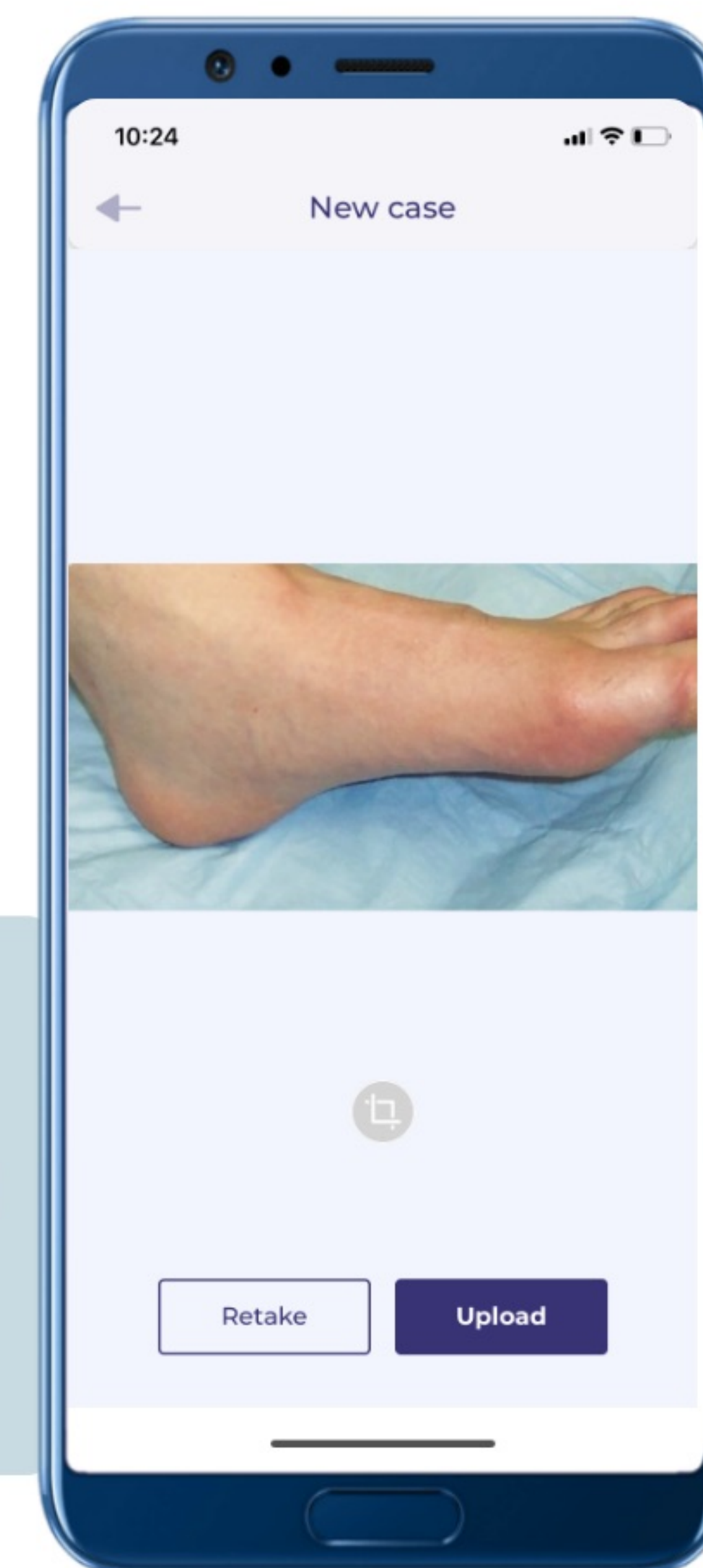


image capture best practices •

To ensure you are receiving the best results possible, try the following image capture suggestions:

- Make sure the image that you upload is relevant. This means that it should contain actual skin. For example, an image of a lion would be considered irrelevant and therefore would not be processed.
- Make sure the input image is not blurry, or too dark. The region of interest should be clearly seen on the image and not be off-center or too small.
- Crop the image if necessary in order to zoom in on the region of interest.
- You can take and check several images (uploaded one at a time) of the same skin area instead of only one.
- Once you are confident your image passes all of the above steps, then you can proceed to upload to the Belle 1K skin image reference tool.



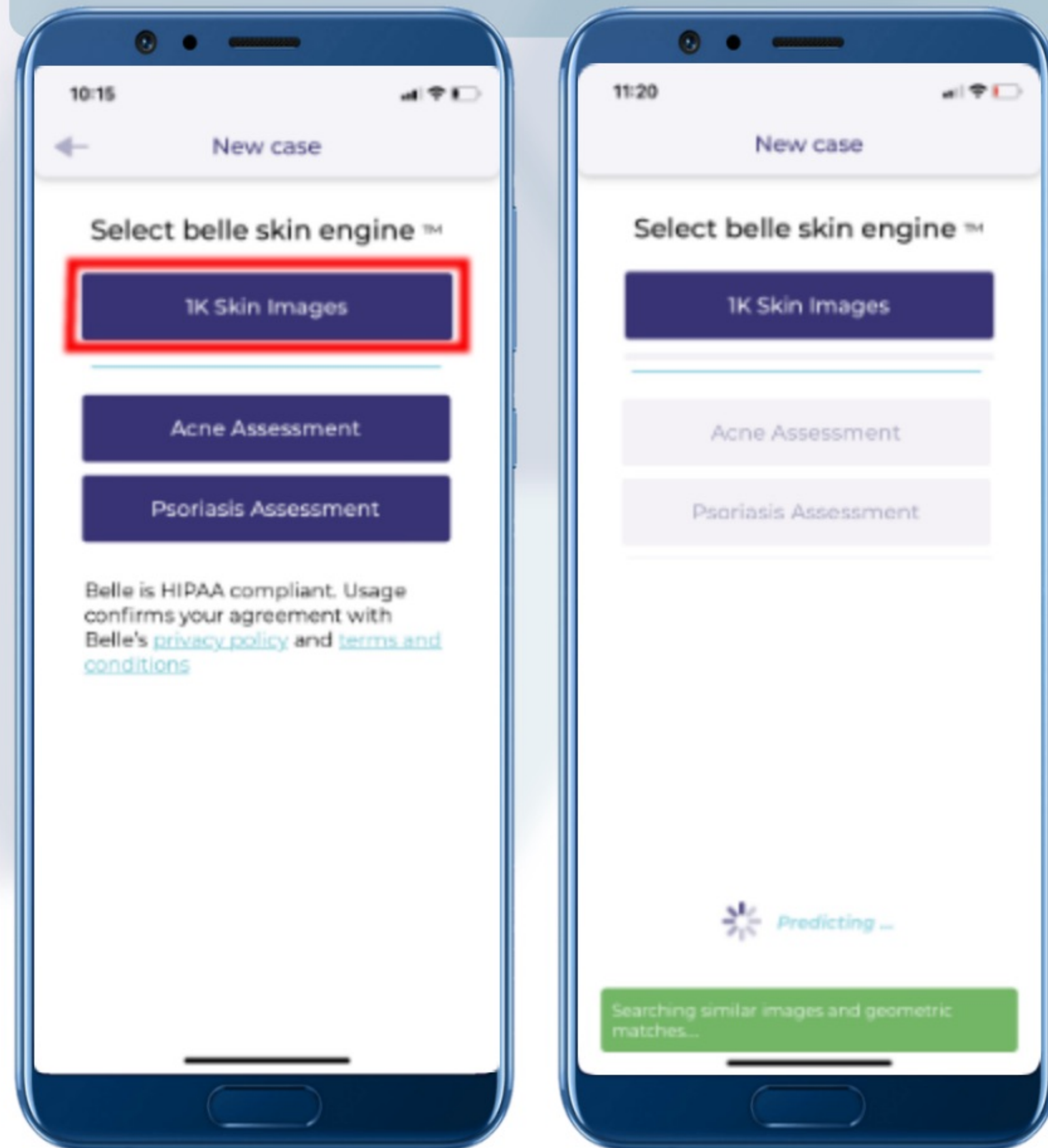
Example of an image that is too dark



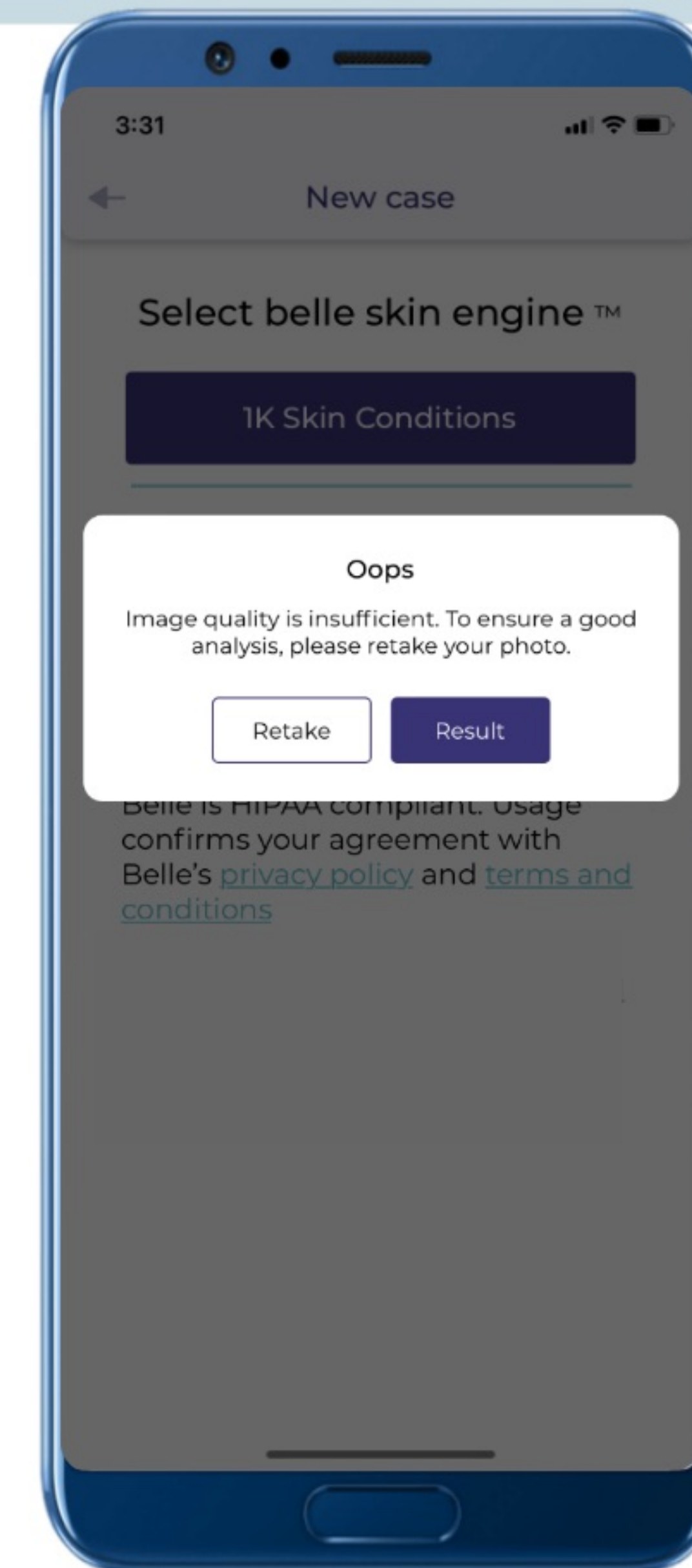
Example of an image that is too far away

Step 7

This step will allow you to choose your skin image reference engine. To access reference text and images for a skin image, you must choose 1K Skin Images.



If the system detects low image quality or does not detect skin on the picture (for example, you upload a picture of a lion) it will not provide references for the image. Instead, an error message will appear that will ask you to retake the image.



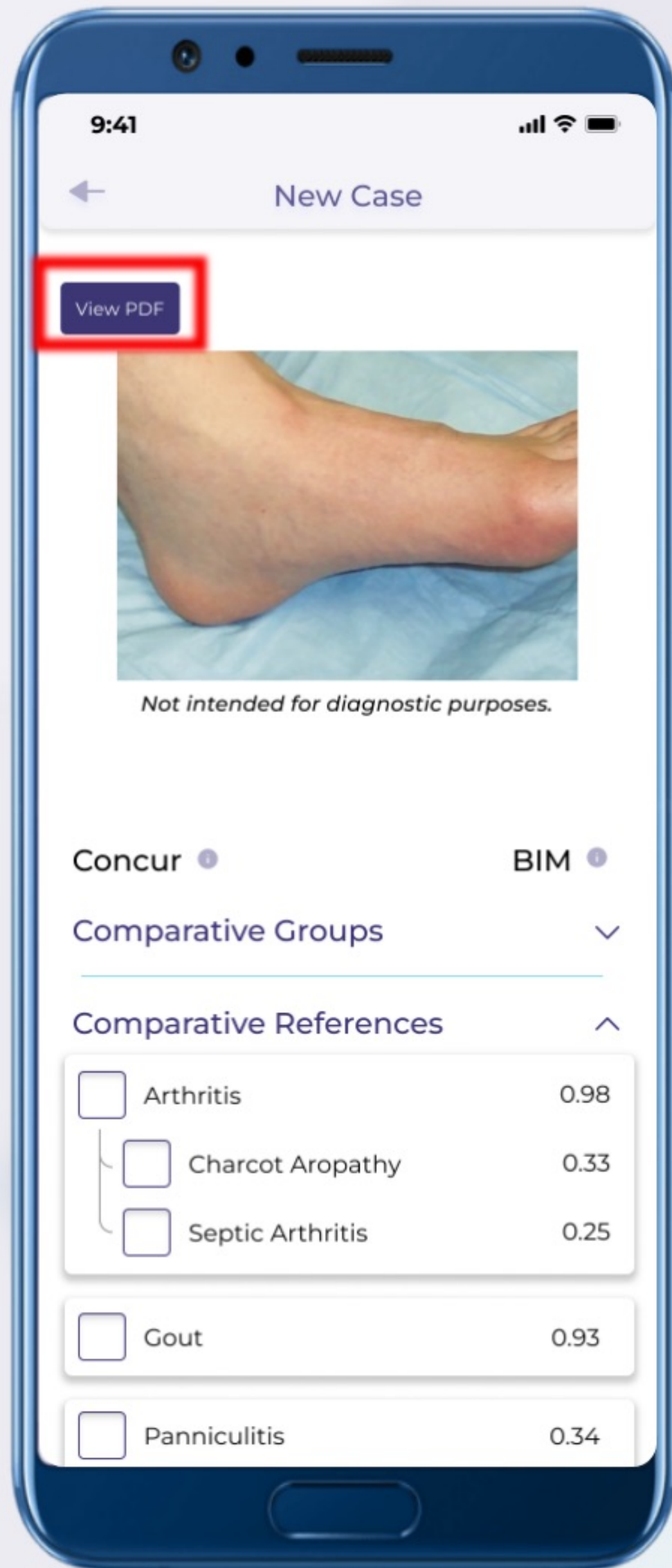
 **Tip:** The Belle Image Match™ (BIM™) score indicates how similar the image looks to a comparative reference in Belle's database



Step 8

After choosing the Belle 1K engine, the system will return comparative results for the processed image. This may take a few seconds.

The results include a scrollable list of possible comparative references and comparative reference groups. Each comparative reference is a subset of a comparative reference group. If there are additional results, you can view them by clicking the See More option below the results in each section.



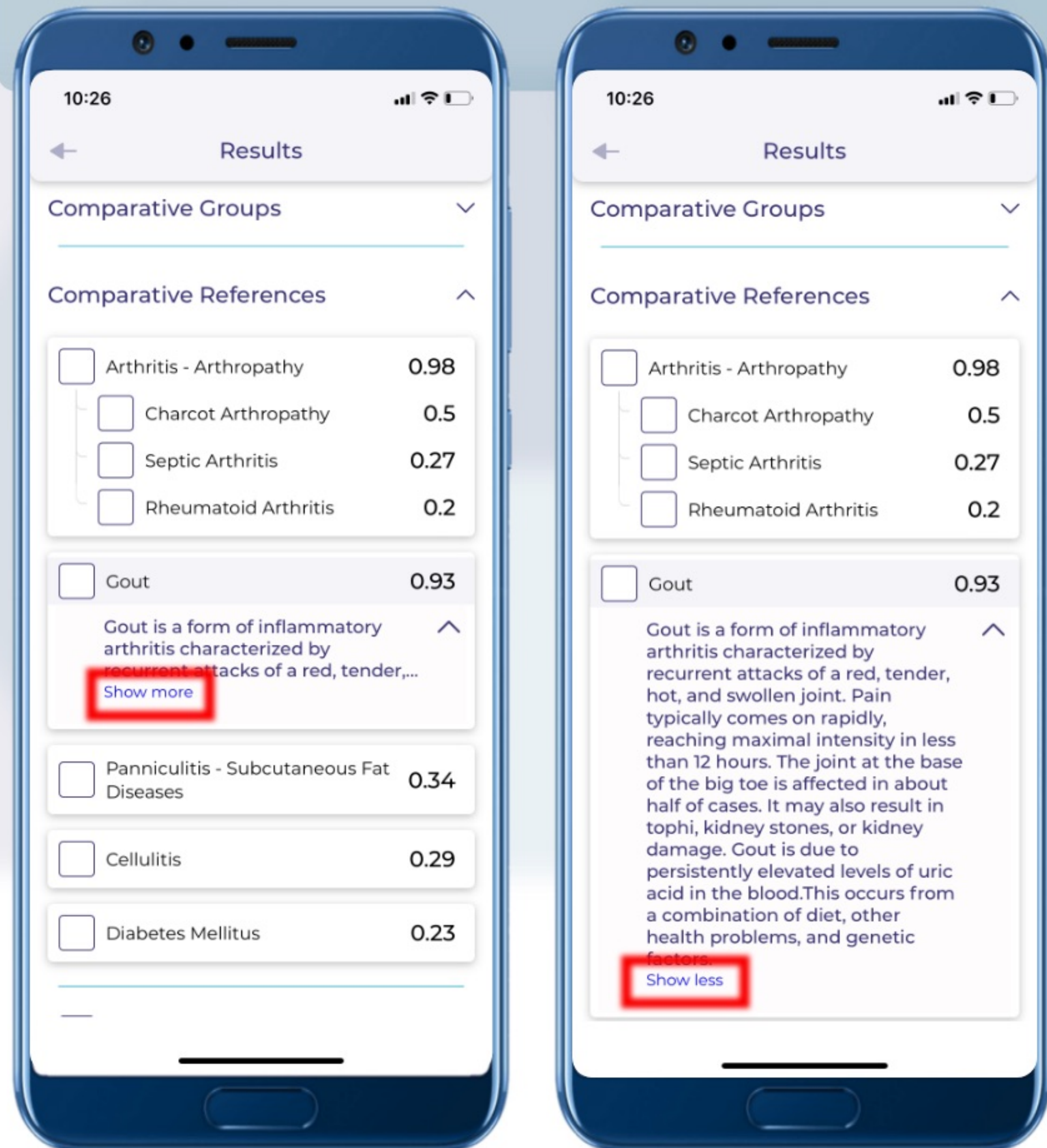
Step 9

In the top left corner of the results screen, you can tap the View PDF button to download a PDF version of the comparative results and save them to your smartphone. On the righthand side of this page, there is an example of what the PDF download might look like on your device.



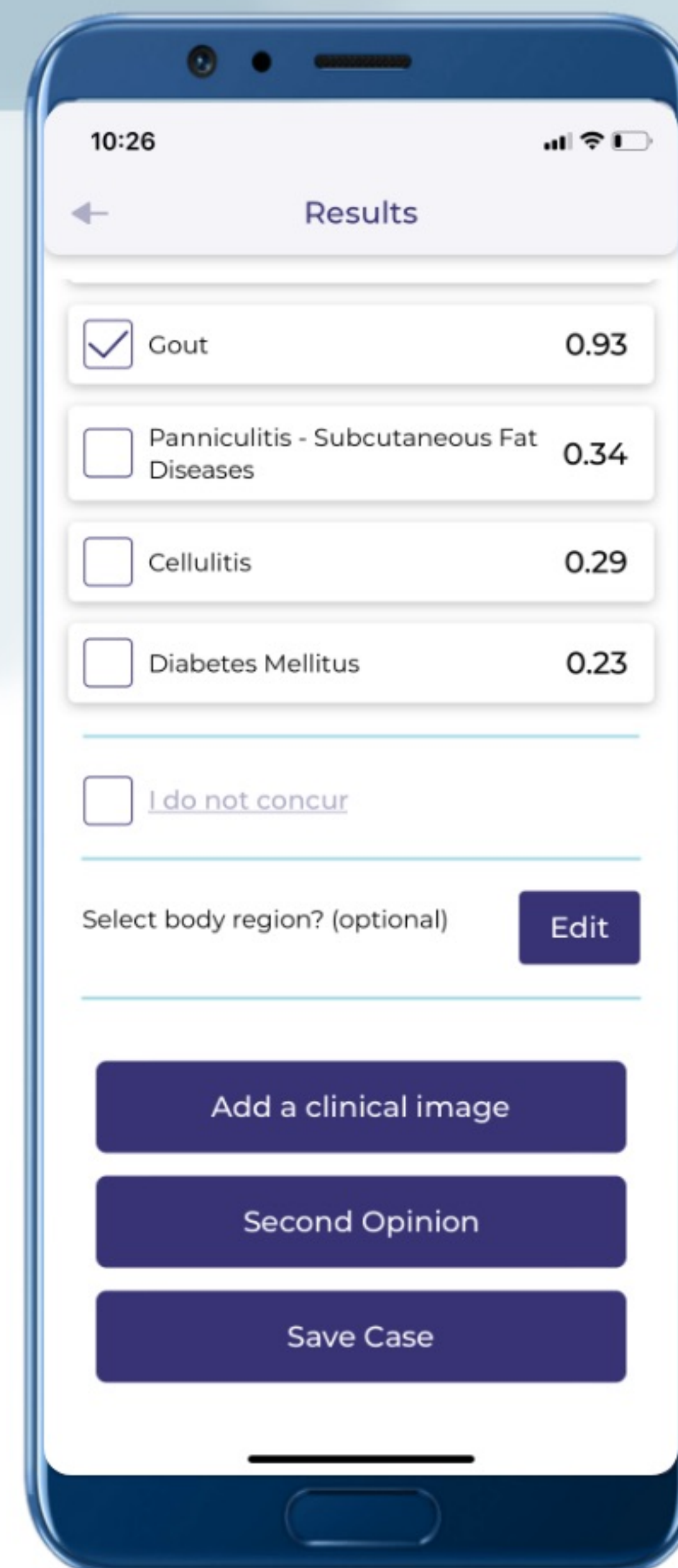
Step 10

If you tap on any result, a description of the comparative reference or group will display for more information. Click Show more to expand the view and Show less to collapse the view.



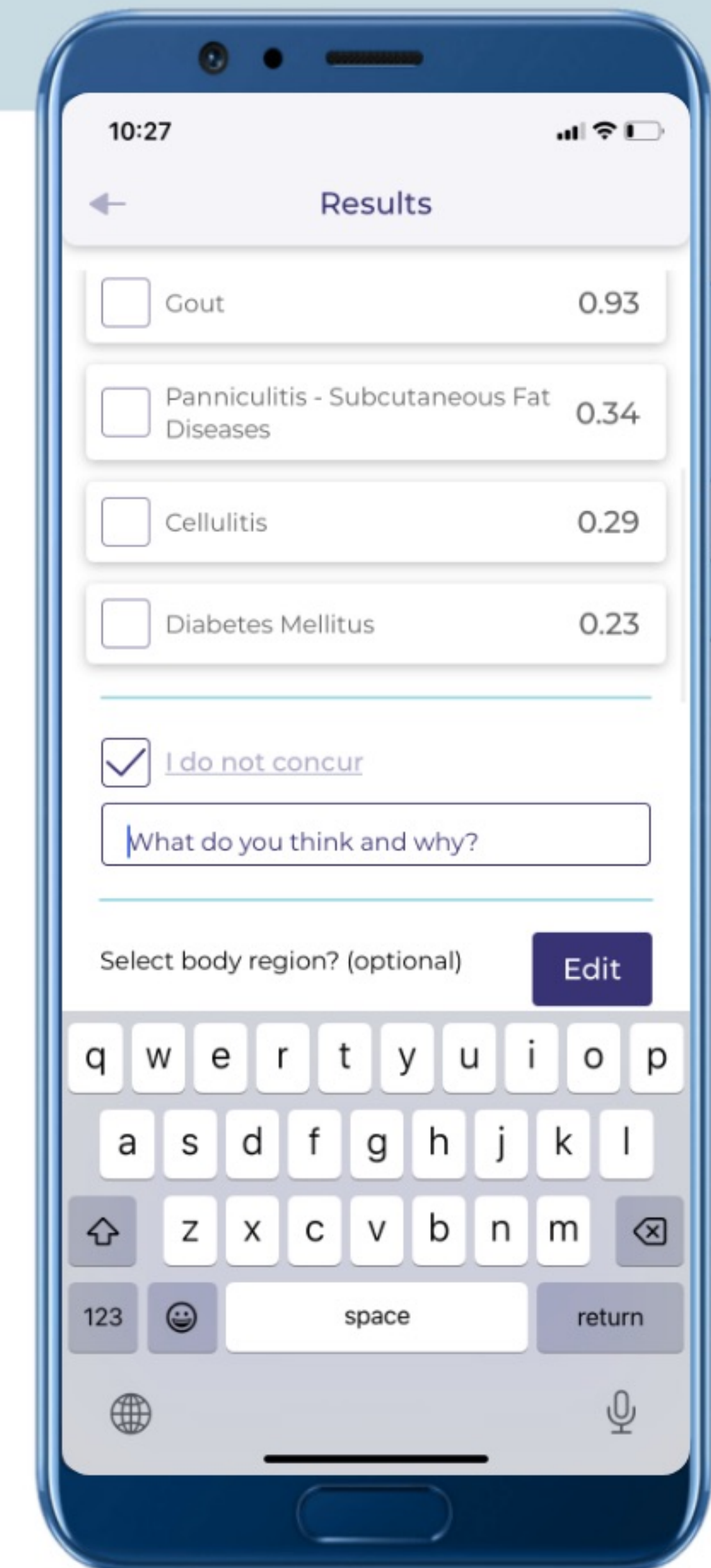
Step 11

If you agree with a reference, tap the checkbox next to the condition. This can be saved with the case and used for subsequent reference.



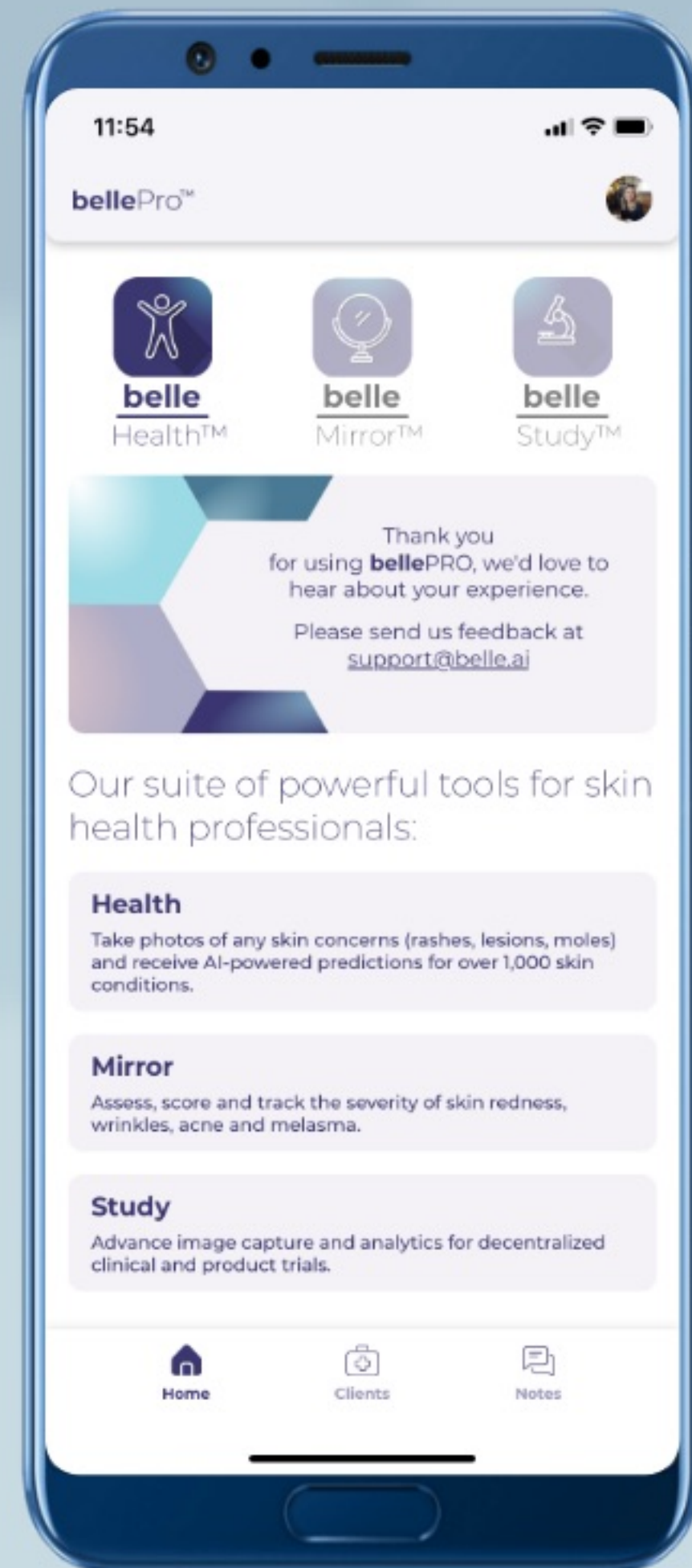
Step 12

If you do not agree with any of the references, you can tap the I do not concur checkbox and consider explaining your reasoning.



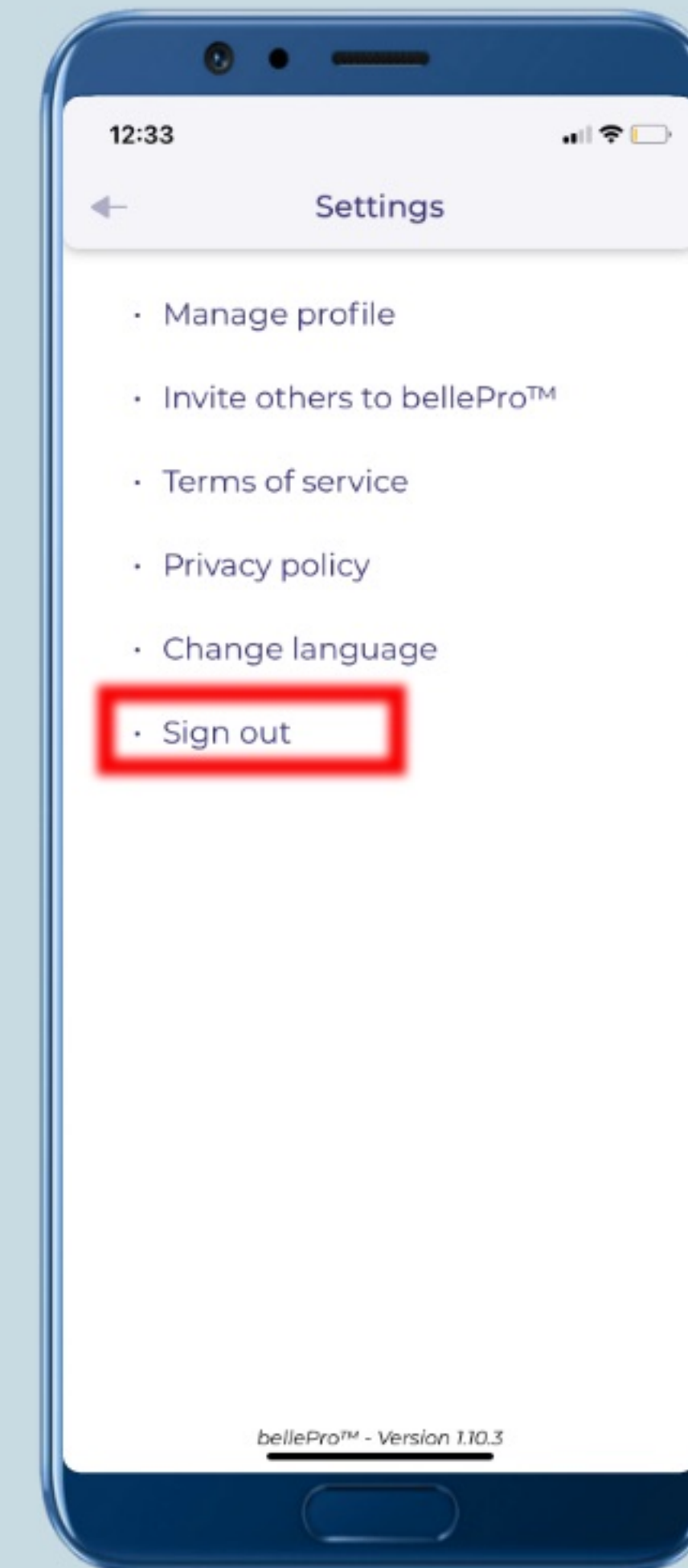
Step 13

To stop using the Belle 1K, you can close the application. If you would like to log out of the application, then return to the home screen. Next, click on the profile icon.



Step 14

On the profile screen, select the Sign out button. This will completely log you out of bellePro. In order to use Belle 1K again, you must log back in using your email or mobile number.





**operating
instructions.**



troubleshooting and FAQs.

common messages, including errors.

Message Display

“Forgive my delay ... I am so sorry.
Please try again! Thank you.”

Situation Meaning

There may be a network problem that causes the device to process the image slowly or not at all. The device may freeze or fail to process the image for an extended amount of time.

Actions to be Taken

Consider connecting to a better network, or restart the app. If the issue persists, contact our support email.

“Network Error”.

There may be a problem with your internet that is causing the device to process the image slowly or not at all.

Consider connecting to a better network, or restart the app. If the issue persists, contact our support email.

“Image quality is insufficient. To ensure a good analysis, please retake your photo.”

The image that was uploaded is not high enough quality to be processed by the device, or is irrelevant (not an image of skin).

Make sure the image is of skin. Try retaking the photo with better lighting or focusing the camera. More than 75% of the image should not be taken up by the background.

“Consult with a Specialist”.

The device cannot match the image with a skin condition recognized in the database.

Further analysis by a healthcare professional is suggested.

compatible devices.

	Android Device Minimum Specifications		iOS Device Minimum Specifications
Android OS Version	5.1 or later	iOS Version iPad iOS Version	10.0 or later 10.0 or later
Size	28.10 MB or greater	Size	35.2 MB or greater
Example Devices	Samsung Galaxy S4 or later model	Example Devices	iPhone 5 or later model iPad Mini or later model

warranties disclaimer.

BelleTorus Corporation and Belle Europe SAS provide the Belle 1K software “as is” and “with all faults”. We do not guarantee that the content will be accurate, available, free from any errors, or fit for any particular purpose. The comparative results are for reference purposes only and not for medical diagnoses. We make no representations or warranties of any kind concerning the use, safety, suitability, viruses, inaccuracies, or consequences from your use of the Belle 1K. There are inherent risks and dangers in the use of any software, and you are solely responsible for determining whether this device is suitable for your particular purposes. You are also solely responsible for your own diagnoses, the protection of your equipment, and the storage of your data. Neither BelleTorus Corporation nor Belle Europe SAS will be liable for any damages you or any other person may suffer in connection with your use of the Belle 1K or the results generated, modification, or distribution of the Belle 1K software device. By accessing and using the Services, you acknowledge this Terms of Service. https://www.belle.ai/assets/documents/terms_of_service.pdf

privacy policy.

PRIVACY POLICY

Last Revised on 1 April 2023

Welcome to the Privacy Policy (“Privacy Policy”) provided by BelleTorus Corporation (“Belle”). This Privacy Policy describes how we collect, use, and disclose information about you related to your use of and access to sites, content, applications, services, tools, and features, provided by Belle, (collectively, the “Services”). For purposes of this Privacy Policy, “you” and “your” means you as the user of the Services. This Privacy Policy applies only to the information collected in connection with the Services. Please read this Privacy Policy carefully to understand our policies and practices regarding your information. If you do not agree with our policies and practices, your choice is not to use our Services. By accessing and using the Services, you acknowledge this Privacy Policy.

https://www.belle.ai/assets/documents/privacy_policy.pdf

reference text and images.

Acanthosis Nigricans
Acne
Acneiform Eruption
Acquired Perforating Dermatitis
Acrodermatitis Continua of Hallopeau
Acropustulosis of Infancy
Actinic Cheilitis-Stomatitis
Actinic Keratosis
Actinomycosis
Albinism
Alopecia Areata
Amyloidosis
Anagen & Telogen Problems
Androgenetic Alopecia
Anetoderma (Macular Atrophy)
Angiofibroma
Angiokeratoma
Angiokeratoma of Fordyce
Angiolymphoid Hyperplasia with Eosinophilia
Angioma (Hemangioma)
Angular Cheilitis
Anthrax
Apthous Ulcer
Aplasia Cutis Congenita
Aquagenic Keratoderma (Aquagenic Wrinkling)
Arbovirus
Arsenic Kertatosis - Arsenic Poisoning

Arterial (Ischemic) Ulcer
Arthritis
Ashy Dermatitis (Erythema Dyschromicum Perstans)
Atopic Dermatitis
Atrophie Blanche
Atrophoderma
Balanitis
Bartonella Infection
Beau's Lines
Becker's Nevus
Behçet Disease
Benign Follicular Lesions
Bites & Stings
Black Hairy Tongue Syndrome
Blue Nevus
Bowen Disease
Bowenoid Papulosis
Bullous Pemphigoid
Café-Au-Lait Macules
Calcinosis Cutis
Candidiasis
Capillaritis & Schamberg Disease
Capillary Malformation & Port Wine Stain
Chancre (Primary Syphilis)
Chancroid
Cheilitis
Cholinergic Urticaria
Chondrodermatitis Nodularis Helicis
Chromoblastomycosis
Chronic Actinic Dermatitis
Clear Cell Acanthoma
Clubbing Nails
Cold Injury (Frostbite & Chilblain)
Cold Urticaria
Condyloma Accumulata

Confluent & Reticulated Papillomatosis
Congenital Dyskeratosis
Congenital Nevus
Connective Tissue Nevus (Collagenoma)
Contact Dermatitis
Corn & Callus
Crusted Scabies
Cryptococcosis
Cutaneous Crohn Disease
Cutaneous Horn
Cutis Laxa
Cutis Marmorata
Cylindroma & Spiradenoma
Cysts
Dermatitis Herpetiformis
Dermatofibroma
Dermatographism
Dermoid Cyst
Diabetes Mellitus
Discoid Eczema (Nummular Dermatitis)
Discoid Lupus Erythematosus
Dissecting Cellulitis (Dissecting Folliculitis) of the Scalp
Dowling-Degos Dark Dot Disease
Drug Reaction
Drug-Induced Photosensitivity
Ectodermal Dysplasia
Eczema Dermatitis
Ehlers-Danlos Syndrome
Elastosis Perforans Serpiginosa
Enterovirus
Eosinophilic Pustular Folliculitis
Ephelides-Freckles
Epidermal Inclusion Cyst
Epidermal Nevus
Epidermodysplasia Verruciformis

reference text and images.

Epstein-Barr Virus & Hairy Leukoplakia
Erysipeloid
Erythema Ab Igne
Erythema Infectiosum
Erythema Multiforme
Erythema Nodosum
Erythema Toxicum Neonatorum
Erythrasma
Erythrokeratoderma
Factitial Dermatitis
Fibrokeratoma
Fibroma Molle (Skin Tags)
Figurate (Annular) Erythema
Fixed Drug Eruption
Focal Dermal Hypoplasia (Goltz Syndrome)
Focal or Punctate Keratoderma
Follicular Dyskeratosis (Darier Disease)
Follicular Mucinosis (Alopecia Mucinosa)
Folliculitis
Folliculitis Decalvans (Tufted Folliculitis)
Folliculitis Keloidalis
Fordyce Spots
Fox-Fordyce Apocrine Duct Occlusion
Frontal Fibrosing Alopecia
Furuncles - Carbuncles
Ganglion (Synovial Cyst)
Geographic Tongue
Gianotti-Crosti Syndrome

Glomus Tumor
Gonococcal Infection
Gout - Tophus
Granuloma Annulare
Granuloma Faciale
Granuloma Inguinale (Donovanosis)
Green Nail Syndrome
Grover's Disease
Habit Tic (Onychotillomania)
Hailey-Hailey Disease
Half & Half Nails (Lindsay's Nails)
Halo Nevus
Hand-Foot-Mouth Disease
Heller Median Nail Dystrophy
Herpes Simplex Virus
Herpetic Whitlow
Hidradenitis Suppurativa
Hidrosystoma
Hidrosis Problems
Hot Tub Rash - Pseudomonas
HPV Warts
Hypertrichosis & Hirsutism
Hypothyroidism & Myxedema
Ichthyosis
Idiopathic Guttate Hypomelanosis
Impetigo
Incontinentia Pigmenti
Infantile (Capillary) Hemangioma
Ingrown or Plicatured Nail
Juvenile Plantar Dermatitis
Keloids
Keratoderma
Keratolysis Exfoliativa (Peeling Skin Syndrome)
Keratosis Pilaris
Kerion-Fungal Abscess

Knuckle Pads
Koilonychia & Platonychia
Kwashiorkor & Marasmus
Larva Migrans & Other Creeping Dermatitis
Leiomyoma Cutis
Leishmaniasis
Leukoplakia
Lice
Lichen Nitidus
Lichen Planus
Lichen Sclerosus
Lichen Simplex Chronicus
Lichen Striatus
Lichenoid Drug Eruption
Lichenoid Keratosis
Linear IgA Bullous Disease
Lipodystrophy & Lipoatrophy
Lipoid Proteinosis
Lipoma
Livedo Reticularis
Lyme Disease
Lymphatic Malformation (Lymphangioma)
Lymphedema
Lymphogranuloma Venereum
Majocchi Granuloma
Mastocytosis & Urticaria Pigmentosa
Melanocytic Nevus
Melanonychia
Melanosis
Melasma
Miliaria
Milk Spots (Milia)
Molluscum Contagiosum
Mongolian Spot
Morphea
Mucinosis

reference text and images.

Mucocele & Ranula
Mucous & Mixoid Cyst
Muehrcke Lines (Apparent Leukonychia Striata)
Mycetoma
Mycobacterial Marinum - Fish Tank Granuloma
Mycobacterium Ulcerans - Buruli Ulcer
Necrobiosis Lipoidica
Necrolytic Migratory Erythema
Necrosis
Neonatal-Infantile Acne
Netherton Syndrome - Ichthyosis
Neurofibromatosis
Neurotic Excoriation
Nevus Achromicus (Depigmentosus)
Nevus Anemicus
Nevus Comedonicus
Nevus of Ota or Ito
Ochronosis
Onychogryphosis
Onycholysis
Onychomycosis
Oral Candidiasis
Orf Virus - Ecthyma Contagiosum
Other Bacterial Diseases
Other Benign Moles
Other Conditions

Other Fibroma-Fibromatosis
Other Fungal Infections
Other Infestations
Other Vascular Problems
Other Viral Diseases
Otitis Externa
Pachyonychia Congenita
Panniculitis
Papular Mucinosis & Scleromyxedema
Papular Urticaria (Arthropod Bites & Stings)
Parapsoriasis
Paronychia
Pearl Penile Papules
Pellagra
Perforating Dermatoses
Periorificial Dermatitis
Photosensitivity & Photodermatitis
Piebaldism
Pilar Cyst
Pilomatricoma
Pitted Keratolysis (Superficial Bacterial Infection)
Pityriasis Alba
Pityriasis Amiantacea
Pityriasis Lichenoides
Pityriasis Rosea
Pityriasis Rubra Pilaris
Poikiloderma
Poisonous Plants - Rhus Dermatitis
Polymorphous Light Eruption
Pompholyx (Dyshidrosis)
Porokeratosis
Poroma
Porphyria & Pseudoporphyria
Porphyria Cutanea Tarda
Postinflammatory Hypopigmentation

Postinflammatory Hyperpigmentation
Pressure Ulcer/Injury
Progressive Macular Hypomelanosis
Prurigo Nodularis
Pruritic Urticarial Papules and Plaques of Pregnancy
Pruritic-Neurotic Diseases
Pseudofolliculitis Barbae (Razor Bumps)
Pseudoxanthoma Elasticum
Psoriasis
Psoriasis Arthritis
Pterygium
Purpura
Pustular Psoriasis
Pyoderma Faciale (Rosacea Fulminans)
Pyogenic Granuloma
Racquet Nail
Radiodermatitis - Radiation Burn
Raynaud Syndrome
Reactive Arthritis
Relapsing Polychondritis
Reticulate Pigment Disorders
Rhinophyma - Rosacea Swelling
Rosacea
Rubella (German Measles)
Sarcoidosis
Scabies
Scarlet Fever
Scarring Alopecia
Scars
Scurvy - Vitamin C Deficiency
Sebaceous Adenoma & Sebaceoma
Sebaceous Gland Hyperplasia
Sebaceous Nevus
Seborrheic Dermatitis
Seborrheic Keratosis

reference text and images.

Solar (Senile) Purpura
Solar Comedones - Favre Racouchot
Syndrome
Solar Elastosis
Solar Lentiginosities
Splinter Hemorrhage
Sporotrichosis (Rose Thorn Disease)
Stasis Dermatitis (Varicose Eczema)
Steatocystoma - Sebocystomatosis
Striae (Stretch Marks)
Subungual Exostosis
Subungual Hematoma
Subungual Hyperkeratosis
Sun Burn - Phototoxic Reaction
Sun Damage & Photoaging
Syphilis
Syringoma
Systemic Sclerosis
Telangiectasia
Temporal (Giant Cell) Arteritis
Terry's Nails
Tinea
Tinea Nigra
Tinea Versicolor
Trachonychia
Traction Alopecia
Transient Neonatal Pustulosis
Trichobacteriosis (Trichomycosis)

Trichoepithelioma
Trichotillomania
Trophic Ulcer (Mal Perforans)
Tuberculosis
Tuberous Sclerosis Complex
Tungiasis
Urticaria
Varicella Zoster Virus
Venous Lake
Venous Malformation (Cavernous
Hemangioma)
Venous Problems
Venous Ulcer
Viruses of Pox Family
Vitiligo
White Sponge Nevus
Wounds & Ulcers
Xanthelasma
Xanthogranuloma
Xanthoma
Xerosis - Asteatotic Eczema
Yaws
Yellow Nail Syndrome
Zinc Deficiency & Acrodermatitis

notes.

Please report any serious incident that has occurred in your use of the Belle 1K. Reports should be to BelleTorus Corporation at support@belle.ai and to the competent authority of the Member State in which the user and/or patient is established.

The software device in its current version is safe to use for 1 year from the date of release. This is the period during which the performance of the software, the support and maintenance commitments of the software device software are guaranteed.

THANK YOU.

Belle 1KTM