

# ScanBox<sup>pro</sup>

Instructions for use  
Instruções de uso  
Petunjuk penggunaan

Phone support + Cheek retractor  
Suporte para smartphone + Afastador de bochechas  
Penyangga ponsel + Retraktor pipi

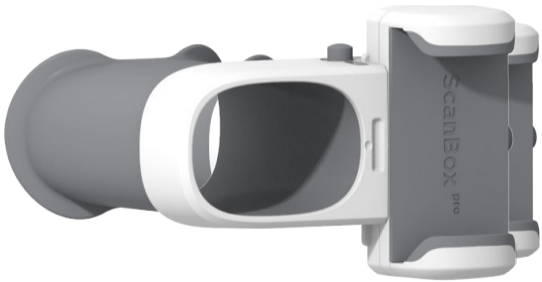
 **DentalMonitoring**

Rx Only

**REF** 1009-001

**REF** 1010-001

**REF** 1012-001



## TABLE OF CONTENTS / ÍNDICE / DAFTAR ISI

<b>I.</b>	<b>Glossary</b>	<b>4</b>
	<b>Glossário</b>	<b>4</b>
	<b>Glosarium</b>	<b>4</b>
<b>II.</b>	<b>Description</b>	<b>6</b>
	<b>Descrição</b>	<b>6</b>
	<b>Deskripsi</b>	<b>6</b>
<b>III.</b>	<b>Instructions for use</b>	<b>14</b>
	<b>Instruções de uso</b>	<b>22</b>
	<b>Petunjuk penggunaan</b>	<b>30</b>

## I. GLOSSARY / GLOSSÁRIO / GLOSARIUM



CE marking  
Marca CE  
Tanda CE

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Caution: Consult the instructions for use for important cautionary information

Atenção: consulte as instruções de uso para obter informações importantes sobre precauções

Perhatian: Baca petunjuk penggunaan untuk mendapatkan informasi peringatan penting

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Consult instructions for use  
Consulte as instruções de uso  
Baca petunjuk penggunaan



Batch number  
Número de lote  
Nomor batch

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Caution: Federal law restricts the sale of this device on medical prescription only

Atenção: a lei federal norte-americana restringe a venda deste dispositivo apenas sob prescrição médica

Perhatian: Hukum federal membatasi penjualan alat ini untuk pembelian dengan resep medis saja

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Manufacturer  
Fabricante  
Produsen



Non-sterile  
Não estéril  
Non-steril

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Keep away from sunlight  
Manter ao abrigo da luz solar  
Jauhkan dari sinar matahari

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**REF**

Catalogue number  
Número de catálogo  
Nomor katalog

---

**MD**

Medical device  
Dispositivo médico  
Alat kesehatan

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Keep dry  
Manter seco  
Jaga tetap kering

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**Qty**

Quantity  
Quantidade  
Jumlah

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**UDI**

Unique Device Identifier  
Identificador exclusivo do dispositivo  
Penanda Peralatan Unik

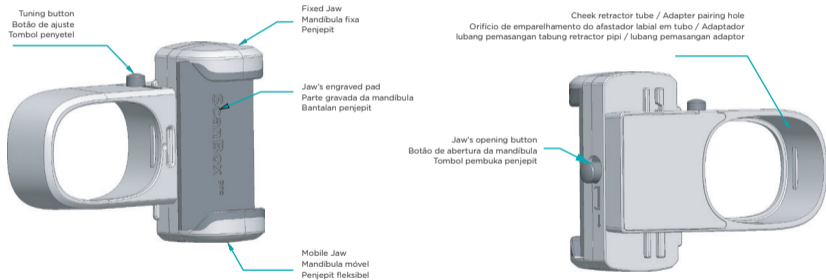
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**PAT**

Patent abbreviation  
Abreviatura de patente  
Singkatan paten

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## II. DESCRIPTION / DESCRIPTION / DESKRIPSI

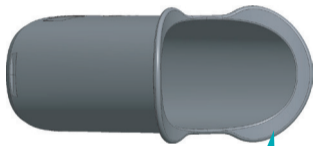




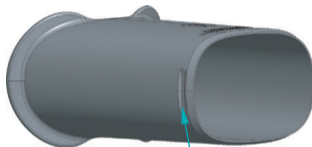
Cheek retractor tube pairing hole  
Orifício de emparelhamento do afastador labial em tubo  
Lubang pemasangan tabung retractor pipi



Clipping system  
Sistema de grampeamento  
System kliping



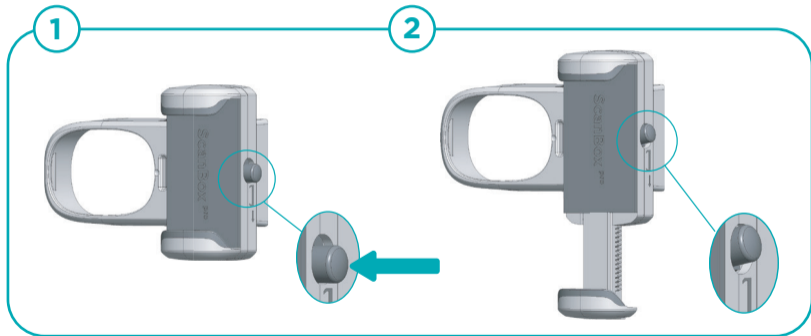
Tube collar  
Abraçadeira do afastador  
Kerah tabung

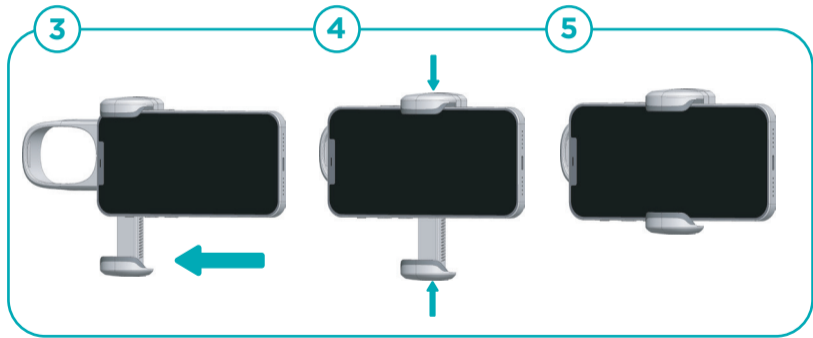


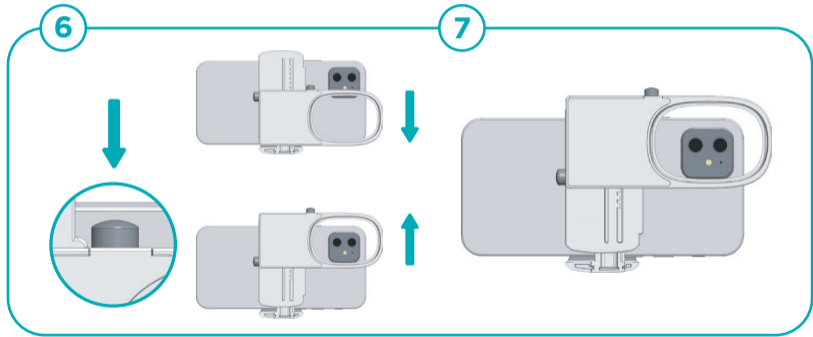
Clipping system  
Sistema de fixação  
Sistem kliping



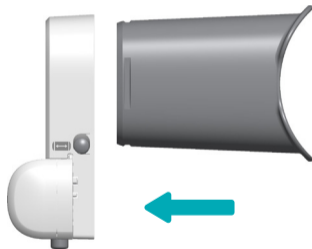
PHONE SUPPORT OPERATING PROCEDURE SCHEMATICS  
ESQUEMA DO PROCEDIMENTO DE OPERAÇÃO DO SUPORTE DE CELULAR  
SKEMA PROSEDUR PENGOPERASIAN PENYANGGA PONSEL



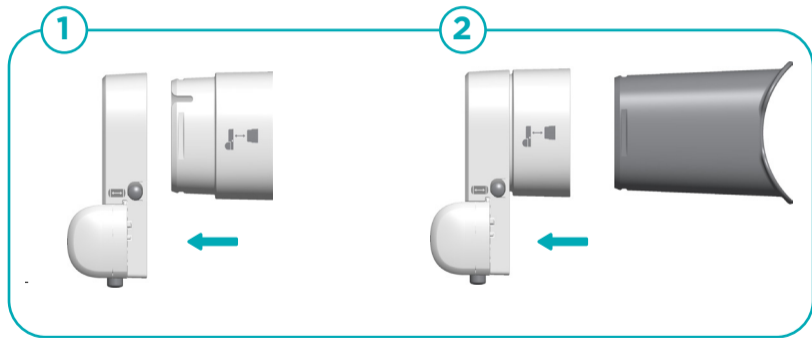




PHONE SUPPORT AND CHEEK RETRACTOR TUBE ASSEMBLY GUIDE  
GUIA DE MONTAGEM DO SUPORTE TELEFÔNICO E TUBO RETRATOR DE BOCHECHA  
PANDUAN PERAKITAN PENYANGGA TELEPON DAN TABUNG RETRAKTOR PIPi



PHONE SUPPORT, ADAPTER AND CHEEK RETRACTOR TUBE ASSEMBLY GUIDE, IF REQUESTED BY THE APPLICATION  
GUIA DE MONTAGEM DO SUPORTE TELEFÔNICO, ADAPTADOR E TUBO RETRATOR DE BOCHECHA, SE SOLICITADO PELO APLICATIVO  
PANDUAN PERAKITAN PENYANGGA TELEPON, ADAPTOR DAN TABUNG RETRAKTOR PIPI, JIKA DIMINTA OLEH APLIKASI



### III. INSTRUCTIONS FOR USE

#### PRESENTATION

**2 packs of ScanBox<sup>PRO</sup> are available:**

- **ScanBox<sup>PRO</sup> S-M pack** (REF 1009-001) containing one **Phone support** (REF 1005-001), one **Cheek Retractor Tube Size S** (REF 1006-001), one **Cheek Retractor Tube Size M** (REF 1007-001), one **Adapter** (REF 1013-001) and one mesh pouch.
- **ScanBox<sup>PRO</sup> M-L pack** (REF 1010-001, REF 1012-001) containing one **Phone support** (REF 1005-001), one **Cheek Retractor Tube Size M** (REF 1007-001), one **Cheek Retractor Tube Size L** (REF 1008-001), one **Adapter** (REF 1013-001) and one mesh pouch.

#### INTENDED PURPOSE

**ScanBox<sup>PRO</sup>** retracts the cheeks to allow a full view of a patient's mouth to take pictures of the intraoral cavity.

#### INDICATIONS

**ScanBox<sup>PRO</sup>** is intended to be used as part of a scanning procedure guided by softwares, developed, and marketed by DentalMonitoring, to monitor intraoral health and orthodontic treatments.

#### TARGET GROUPS

- **Target population:** **ScanBox<sup>PRO</sup>** is indicated for patients over the age of 6.
- **Intended users:** **ScanBox<sup>PRO</sup>** is intended to be used by:
  - Healthcare professional in professional healthcare facilities, such as a dental practice.
  - Lay persons over the age of 6 in a non-healthcare environment, such as the patient's own home.

- **Type of use/reuse:** ScanBox<sup>pro</sup> is reusable and can be used:
  - Multiple times by a single patient

## CLINICAL BENEFITS

There is no direct clinical benefit for the use of ScanBox<sup>pro</sup>. ScanBox<sup>pro</sup> is intended to be used to ease the taking of scans that will be processed by DentalMonitoring softwares.

## CLINICAL PERFORMANCES

ScanBox<sup>pro</sup> has no clinical performances as it has no direct action and effect on the patient.

## TECHNICAL SPECIFICATIONS

ScanBox<sup>pro</sup> biocompatibility was assessed, and the product was demonstrated to be non-cytotoxic, non-sensitizing and non-irritating.

## SIDE EFFECTS

No known side effects.

## CONTRAINDICATIONS

ScanBox<sup>pro</sup> should not be used in the event of injured skin or injured mucous membrane.

ScanBox<sup>pro</sup> is not intended for surgical or post-surgery use, nor to take intra-oral pictures with products other than those marketed by DentalMonitoring.

## WARNINGS, PRECAUTIONS, NOTICES

### • Warnings

No known warnings.

### • Precautions

ScanBox<sup>pro</sup> is provided in a non-sterile form. Clean the ScanBox<sup>pro</sup> before and after each use. Please refer to the appropriate cleaning procedure to avoid any health issue requiring medical attention.

Do not clean with household cleaning products.

The **Phone support** and the **Adapter** are not sterilizable and do not submerge it in any liquid. Refer to the cleaning procedure to avoid any contamination.

The following population should be assisted by a third party in device use:

- children up to 12;
- visually impaired adults or children;
- hearing impaired adults or children;
- adults or children with any other condition that might prevent the patient from adequately operating the device.

For patients with deciduous teeth, the guardian's vigilance is required to ensure that deciduous teeth do not fall out when placing the **Cheek Retractor Tube**.

If your smartphone is not correctly held in position when the jaw of the **Phone support** is tightened, do not force, this could damage your smartphone or the device. If you haven't already done it, remove the protective cover from your phone and try again.

Do not use the **ScanBox<sup>pro</sup>** if it is broken.

Do not introduce the **Adapter** into the mouth.

#### • **Notices**

This is not a toy. Children should be supervised to ensure that they do not play with the device.

### **INSTRUCTIONS BEFORE USE**

Before use, you should wash your hands with soap and water or hydroalcoholic gel. You must also clean the **ScanBox<sup>pro</sup>** and your smartphone (following its manufacturer's recommendations) before each use.



Refer to the cleaning procedure for the appropriate steps to follow.

## PAIRING UP THE PHONE SUPPORT WITH YOUR PHONE

For the numbering below, please refer to the **Phone support** operating procedure schematics.

Launch the application you want to use on your phone before using the **ScanBox<sup>PRO</sup>**.

Hold the **Phone support** with the jaw's engraved pad facing you (1). Open the jaw by pressing the jaw's opening button (2). Place your phone against the fixed jaw and slide it horizontally to align the flash and lens with the tube pairing hole (3).

Clamp the jaw onto your phone by pressing firmly on the mobile jaw (4). Remove the protective cover of your phone if necessary.

Make sure that your phone is held firmly (5).

Move your phone vertically so that the flash and lens are in the tube pairing hole.

To do this, hold down the tuning button and move the jaw vertically (6).

Release the tuning button when you are finished (7).

## PAIRING UP THE PHONE SUPPORT WITH THE CHEEK RETRACTOR TUBE

When your phone is placed correctly, connect the **Cheek Retractor Tube** to the **Phone support** by inserting the end of the tube with the clipping system into the tube pairing hole on the device.

You will hear a "click" when the **Cheek Retractor Tube** is properly attached.

## PAIRING UP THE PHONE SUPPORT WITH THE ADAPTER AND THE CHEEK RETRACTOR TUBE - ONLY IF THE APPLICATION REQUEST YOU TO USE THE ADAPTER

The **Adapter** may be required depending on your phone model; the application automatically detects whether the **Adapter** is required and informs you accordingly.

When your phone is placed correctly, connect the **Adapter** to the **Phone support** by inserting the end of the **Adapter** with the clipping system into the tube pairing hole on the **Phone support** (1). You will hear a “click” when the **Adapter** is properly attached.

Then, connect the **Cheek Retractor Tube** to the **Adapter** by inserting the end of the tube with the clipping system into the **Adapter** pairing hole (2).

You will hear a “click” when the **Cheek Retractor Tube** is properly attached.

## INSERTING THE CHEEK RETRACTOR TUBE IN YOUR MOUTH

Appropriate sizing should be determined within a healthcare facility.

If not possible, first try to use the biggest size of **Cheek Retractor Tube** available. If you feel discomfort or pain, change for the smaller size.

Once the **ScanBox<sup>PRO</sup>** is assembled, hold the device without touching the collar that goes in the mouth with your hands. The screen of your phone needs to be facing out. First, insert one side of the tube collar into your mouth and then the other. Make sure that the collar is inserted correctly in your mouth: the tube must not escape from your mouth when moving it laterally.

Check if the tube is correctly applied: teeth and gums should be visible without experiencing pain or discomfort.

In the event of significant pain or discomfort, refer to your healthcare facility to check you have the appropriate tube size.

## UNPAIRING THE PHONE SUPPORT AND THE CHEEK RETRACTOR TUBE

Remove the **Phone support**, by holding the **Cheek Retractor Tube** in place with your hand and pulling the device forward.

## INSTRUCTIONS FOR REUSABLE DEVICES

The following cleaning procedure must be followed:

- **Clean the smartphone camera lens**, if needed, following its manufacturer's recommendations.

- **Clean the Phone support:**

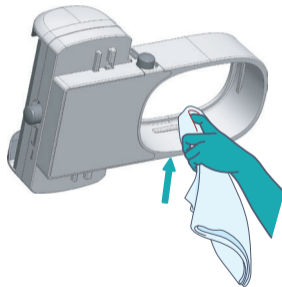
Before and after each use, clean the whole **Phone support** (see the picture below) by using a biocide wipe or a biocide spray paired with single-use paper towels

Let the **Phone support** air dry.

Then store in the provided mesh pouch.

The **Adapter** shall follow the same cleaning procedure as the phone support.

## CLEANING



- **Clean the Cheek Retractor Tube:**

Before and after each use, clean with soap, such as Sanex 0%, and cold water.

If necessary, gently brush the surface with a soft bristle brush and make sure it is completely clean.

Rinse with cold water.

Let the **Cheek Retractor Tube** air dry.

Then store it in the provided mesh pouch, in a dry and clean place, avoiding compression of the **Cheek Retractor Tube** with other objects.

### **INSTRUCTIONS FOR DAMAGED PACKAGING**

If the packaging is damaged or opened before use, return the pack to your healthcare facility.

### **INSTRUCTIONS FOR VERIFICATION**

The device must be properly assembled before use.

### **STORAGE**

The **ScanBox<sup>PRO</sup>** should be stored in the provided mesh pouch, away from solar radiation, compression and moisture.

Keep away from any heat source.

### **DISPOSAL**

Dispose of it in accordance with your local recycling regulations.

### **LIST OF REQUIRED NON-PROVIDED PRODUCTS**

DentalMonitoring (REF 2001-001), SmileMate (REF 2002-001)

## **WARRANTY**

One year from the date of original purchase.

## **TRAVEL**

In the event of travel, the devices should be kept in the provided mesh pouch.

Please make sure the devices are not too tightly packed to prevent any deformation or breakage during transport.

### III. INSTRUÇÕES DE USO

#### APRESENTAÇÃO

**Estão disponíveis 2 embalagens de ScanBox<sup>PRO</sup>:**

- Embalagem **ScanBox<sup>PRO</sup> S-M** (REF 1009-001) contendo um **Suporte de celular** (REF 1005-001), um **Afastador labial em tubo** tamanho S (REF 1006-001), um **Afastador labial em tubo** tamanho M (REF 1007-001), um **Adaptador** (REF 1013-001) e uma bolsa de malha;
- Embalagem **ScanBox<sup>PRO</sup> M-L** (REF. 1010-001, REF. 1012-001) contendo um **Suporte de celular** (REF 1005-001), um **Afastador labial em tubo** tamanho M (REF 1007-001), um **Afastador labial em tubo** tamanho L (REF 1008-001), um **Adaptador** (REF 1013-001) e uma bolsa de malha;

#### FINALIDADE PREVISTA

O **ScanBox<sup>PRO</sup>** tem como objetivo afastar os lábios para proporcionar uma visão completa da cavidade oral do paciente, facilitando a captura de fotografias intraorais.

#### INDICAÇÕES

O **ScanBox<sup>PRO</sup>** é projetado para ser utilizado como componente de um procedimento de digitalização controlado por software, desenvolvido e comercializado pela Dental Monitoring, com o propósito de monitorar a saúde intraoral e tratamentos ortodônticos.

#### GRUPOS-ALVO

- **População-alvo** O **ScanBox<sup>PRO</sup>** é indicado para pacientes com mais de 6 anos de idade.

- **Utilizadores previstos** O **ScanBox<sup>PRO</sup>** é projetado para ser utilizado por:
  - profissionais de saúde em clínicas e consultórios profissionais, como consultórios dentários;
  - leigos com mais de 6 anos de idade em ambientes não relacionados com cuidados de saúde, como a própria residência do paciente.
- **Tipo de utilização/reutilização** O **ScanBox<sup>PRO</sup>** é re-utilizável e pode ser usado:
  - múltiplas vezes por um só paciente.

## BENEFÍCIOS CLÍNICOS

Não existem benefícios clínicos diretos associados à utilização do **ScanBox<sup>PRO</sup>**. O propósito do **ScanBox<sup>PRO</sup>** é simplificar a captura de digitalizações que serão posteriormente processadas pelos softwares desenvolvidos pela Dental Monitoring.

## DESEMPENHOS CLÍNICOS

O **ScanBox<sup>PRO</sup>** não apresenta desempenhos clínicos uma vez que não tem qualquer ação ou efeito diretos no paciente.

## ESPECIFICAÇÕES TÉCNICAS

Foi avaliada a biocompatibilidade do **ScanBox<sup>PRO</sup>**, e ficou demonstrado que o produto não é citotóxico, não produz sensibilização nem irritação.

## EFEITOS SECUNDÁRIOS

Não se conhecem efeitos secundários.

## CONTRAINDICAÇÕES

O **ScanBox<sup>PRO</sup>** não deve ser utilizado caso existam ferimentos na epiderme ou nas membranas mucosas. O **ScanBox<sup>PRO</sup>** não é destinado a uso cirúrgico ou pós-cirúrgico, nem à captura de fotografias intraorais com produtos que não sejam os comercializados pela Dental Monitoring.

## ADVERTÊNCIAS, PRECAUÇÕES, AVISOS

### • Advertências

Não se conhecem quaisquer advertências.

### • Precauções

O **ScanBox<sup>PRO</sup>** apresenta-se em forma não estéril. Limpe o **ScanBox<sup>PRO</sup>** antes e depois de cada utilização. Consulte o procedimento de limpeza para evitar qualquer problema de limpeza que exija atenção médica.

Não limpe com produtos de limpeza doméstica.

O **suporte do celular** e o **Adaptador** não são esterilizáveis e não devem ser submersos em nenhum líquido. Consulte o procedimento de limpeza para evitar qualquer contaminação.

As seguintes pessoas devem ser auxiliadas por terceiros ao utilizar o dispositivo:

- crianças de até aos 12 anos de idade;
- adultos ou crianças com deficiência visual;
- adultos ou crianças com deficiência auditiva;

- adultos ou crianças com qualquer outro problema que possa impedir que o paciente utilize o dispositivo de forma adequada.

Para pacientes com dentes decíduos, é importante que um responsável pelo paciente supervisione o procedimento para garantir que os dentes decíduos não caiam ao utilizar o **Afastador labial em tubo**. Se o seu smartphone não estiver devidamente fixado quando a mandíbula do suporte do celular for apertada, evite exercer pressão para não causar danos ao smartphone ou ao dispositivo. Caso ainda não o tenha feito, retire a capa protetora do seu celular e tente novamente.

Não utilize o **ScanBox<sup>PRO</sup>** se estiver danificado.

Não introduza o **Adaptador** em sua boca.



- **Avisos**

Este dispositivo não é um brinquedo. É importante supervisionar crianças para garantir que não brinquem com o dispositivo.

## INSTRUÇÕES ANTES DE UTILIZAR

Antes de utilizar, lembre-se de lavar as mãos com água e sabão ou usar gel hidroalcoólico. Além disso, é necessário limpar tanto o **ScanBox<sup>PRO</sup>** quanto o seu smartphone (de acordo com as instruções do fabricante) antes de cada utilização. Consulte o procedimento de limpeza para seguir as etapas adequadas.

## EMPARELHAMENTO DO SUPORTE DE CELULAR COM O SEU SMARTPHONE

Em relação aos números seguintes, consulte o esquema do procedimento de operação do **Suporte de celular**.

Abra o aplicativo no seu celular antes de utilizar o **ScanBox<sup>PRO</sup>**.

Segure no suporte do celular com a face gravada da mandíbula voltada para si (1). Abra a mandíbula pressionando o botão de abertura da mandíbula (2). Coloque o seu celular contra a mandíbula fixa e faça-a deslizar horizontalmente para alinhar o flash e a lente da câmera com o orifício do tubo (3).

Fixe a mandíbula móvel ao celular pressionando firmemente (4). Retire a capa protetora do seu celular, se necessário.

Assegure-se de que o seu celular está firmemente fixo (5).

Desloque o seu celular verticalmente, de modo que o flash e a lente da câmera fiquem no orifício do tubo. Para tal, pressione continuamente o botão de ajuste e desloque a mandíbula verticalmente (6).

Liberte o botão de ajuste quando terminar (7).

## EMPARELHAMENTO DO SUPORTE DE CELULAR COM O AFASTADOR LABIAL EM TUBO

Quando o seu celular estiver corretamente posicionado, conecte o **Afastador labial em tubo** ao suporte do celular, inserindo a extremidade do tubo com o sistema de fixação no orifício do tubo existente no dispositivo. Você ouvirá um “clique” quando o **Afastador labial em tubo** estiver devidamente fixado.

## EMPARELHAR O SUPORTE CELULAR COM O ADAPTADOR E O AFASTADOR LABIAL EM TUBO - SOMENTE SE O APLICATIVO SOLICITAR O USO DO ADAPTADOR

O **Adaptador** pode ser necessário, dependendo do modelo do seu telefone; o aplicativo detecta automaticamente se o **Adaptador** é necessário e o informa adequadamente.

Quando o seu celular estiver corretamente posicionado, conecte o **Adaptador** ao suporte do celular, inserindo a extremidade do **Adaptador** com o sistema de fixação

no orifício do suporte do celular (1). Você ouvirá um “clique” quando o **Adaptador** estiver devidamente fixado.

Em seguida, conecte o **Afastador labial em tubo** ao **Adaptador**, inserindo a extremidade do tubo com o sistema de fixação no orifício do **Adaptador** (2). Você ouvirá um “clique” quando o **Afastador labial em tubo** estiver devidamente fixado.

## INTRODUÇÃO DO AFASTADOR LABIAL EM TUBO

O tamanho adequado do tubo deve ser determinado na clínica ou consultório.

Caso isso não seja possível, comece por utilizar o tamanho maior de **Afastador labial em tubo** que estiver disponível. Se sentir desconforto ou dor, mude para o tamanho menor.

Uma vez montado o **ScanBox<sup>pro</sup>**, segure o dispositivo sem tocar com as mãos na abraçadeira que entra na boca. A tela do seu celular deve ficar voltada para fora.

Primeiro, insira um lado da abraçadeira do afastador na boca e, em seguida, o outro. Assegure-se de que a abraçadeira é inserida corretamente na boca: o tubo não pode escapar da boca quando se deslocar lateralmente.

Verifique se o tubo está corretamente inserido: dentes e gengivas devem ser visíveis, sem dor ou desconforto. Caso sinta dor ou desconforto significativo, consulte a sua clínica ou consultório para verificar se tem o tamanho de tubo adequado.

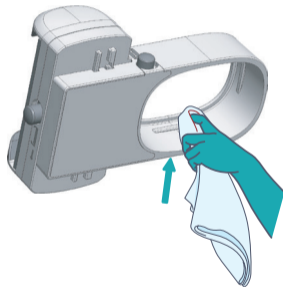
### DESEMPARELHAMENTO DO SUPORTE DE CELULAR DO AFASTADOR LABIAL EM TUBO

Retire o suporte do celular, imobilizando o **Afastador labial em tubo** com a mão e puxando o dispositivo para a frente.

### INSTRUÇÕES PARA DISPOSITIVOS REUTILIZÁVEIS

Deve ser seguido o seguinte procedimento de limpeza

## LIMPEZA



peza:

- Limpe a lente da câmara do smartphone, se necessário, seguindo as recomendações do fabricante.
- Antes e depois de cada utilização, limpe todo o suporte do telefone (ver imagem abaixo) usando um lenço biocida ou um spray biocida combinado com toalhas de papel descartáveis

Deixe o **Suporte de celular** secar ao ar livre.

Em seguida, guarde na nécessaire prevista (bolsa de malha).

O **Adaptador** deve seguir o mesmo procedimento de limpeza que o **Suporte celular**.

- Limpe o **Afastador labial em tubo**:

Antes e depois de cada utilização, limpe com sabão, e água fria.

Se necessário, escove suavemente a superfície com uma escova de cerdas macias e assegure-se de que está completamente limpo.

Enxague com água fria.

Deixe o **Afastador labial em tubo** secar ao ar livre.

Em seguida, guarde-o na nécessaire prevista (bolsa de malha), em local limpo e seco, evitando a compressão do **Afastador labial em tubo** contra as outras peças.

## INSTRUÇÕES PARA EMBALAGENS DANIFICADAS

Se a embalagem se apresentar danificada ou aberta antes da utilização, retorne a embalagem à sua clínica ou consultório.

## INSTRUÇÕES PARA VERIFICAÇÃO

O dispositivo deve ser devidamente montado antes da utilização.

## ARMAZENAMENTO

O **ScanBox<sup>pro</sup>** deve ser guardado na nécessaire fornecida (bolsa de malha), ao abrigo da luz solar direta, humidade e protegido contra compressão.

Mantenha afastado de qualquer fonte de calor.

## ELIMINAÇÃO

Elimine de acordo com a regulamentação local relativa a reciclagem.

## LISTA DE PRODUTOS NECESSÁRIOS NÃO INCLUÍDOS NA EMBALAGEM

Dental Monitoring (REF 2001-001), SmileMate (REF 2002-001)

## GARANTIA

Um ano a partir da data de compra original.

## VIAGENS

Em caso de viagem, os dispositivos devem ser mantidos na respetiva nécessaire fornecida (bolsa de malha). Assegure-se de que os dispositivos não são embalados em espaço insuficiente para evitar qualquer deformação ou quebra durante o transporte.

### III. PETUNJUK PENGGUNAAN

#### PENYEDIAAN

Terdapat dua paket **ScanBox<sup>PRO</sup>**:

- Paket **ScanBox<sup>PRO</sup>** S-M (REF 1009-001) berisi satu **Penyangga Telepon** (REF 1005-001), satu **Tabung Retraktor Pipi** Ukuran S (REF 1006-001), satu **Tabung Retraktor Pipi** Ukuran M (REF 1007-001), satu **Adaptor** (REF 1013-001) dan satu kantong .
- Paket **ScanBox<sup>PRO</sup>** M-L (REF 1010-001, REF 1012-001) berisi satu **Penyangga Telepon** (REF 1005-001), satu **Tabung Retraktor Pipi** Ukuran M (REF 1007-001), satu **Tabung Retraktor Pipi** Ukuran L (REF 1008-001 ), satu **Adaptor** (REF 1013-001) dan satu kantong .

#### TUJUAN PENGGUNAAN

**ScanBox<sup>PRO</sup>** berfungsi untuk menarik pipi dan memu-

ngkinkan pengamatan penuh ke dalam mulut pasien untuk mengambil gambar rongga intraoral.

#### INDIKASI

**ScanBox<sup>PRO</sup>** ditujukan untuk digunakan sebagai bagian dari prosedur pemindaian dengan panduan perangkat lunak yang dikembangkan dan dipasarkan oleh Dental Monitoring, untuk memantau kesehatan intraoral dan perawatan ortodontik.

#### KELOMPOK SASARAN

- **Populasi sasaran:** **ScanBox<sup>PRO</sup>** ditujukan untuk pasien berusia di atas 6 tahun.
- **Pengguna yang dituju:** **ScanBox<sup>PRO</sup>** ditujukan untuk digunakan oleh:
  - Tenaga kesehatan profesional di fasilitas kesehatan, seperti praktik dokter gigi.

- Orang awam berusia di atas 6 tahun di luar lingkungan kesehatan, seperti rumah pribadi pasien.

- **Jenis penggunaan/penggunaan ulang: ScanBox<sup>pro</sup>** dapat digunakan kembali dan dapat digunakan:
  - Beberapa kali pada satu pasien.

### MANFAAT KLINIS

Tidak ada manfaat klinis langsung dari penggunaan **ScanBox<sup>pro</sup>**. **ScanBox<sup>pro</sup>** ditujukan untuk memudahkan pemindaian gambar yang kemudian diproses oleh perangkat lunak Dental Monitoring.

### KINERJA KLINIS

**ScanBox<sup>pro</sup>** tidak memiliki kinerja klinis karena tidak memberikan tindakan dan efek langsung terhadap pasien.

### SPESIFIKASI TEKNIS

Biokompatibilitas **ScanBox<sup>pro</sup>** telah dinilai dan terbukti tidak bersifat sitotoksik, tidak menyebabkan sensitivitas, dan tidak menyebabkan iritasi.

### EFEK SAMPING

Tidak ada efek samping yang ditemukan.

### KONTRAINDIKASI

**ScanBox<sup>pro</sup>** tidak boleh digunakan jika terdapat luka pada kulit atau selaput lendir.

**ScanBox<sup>pro</sup>** tidak ditujukan untuk penggunaan dalam operasi atau pascaoperasi, atau untuk pengambilan gambar intraoral dengan produk selain yang dipasarkan Dental Monitoring.

## PERINGATAN, PENCEGAHAN, PERHATIAN

### • Peringatan

Tidak ada peringatan umum.

### • Pencegahan

**ScanBox<sup>pro</sup>** diberikan dalam keadaan tidak steril. Bersihkan **ScanBox<sup>pro</sup>** setiap sebelum dan sesudah penggunaan. Harap ikuti prosedur pembersihan yang sesuai untuk menghindari masalah kesehatan yang membutuhkan perawatan medis.

Jangan dibersihkan dengan produk pembersih rumah tangga.

**Penyangga Telepon** dan **Adaptor** tidak dapat disterilkan dan jangan direndam dalam cairan apa pun. Ikuti prosedur pembersihan untuk menghindari kontaminasi.

Penggunaan alat oleh pengguna berikut harus dibantu oleh pihak ketiga:

- anak di bawah 12 tahun;
- orang dewasa atau anak tunanetra;

- orang dewasa atau anak tunarungu;
- orang dewasa atau anak dengan kondisi lain yang mungkin menghambat pasien dalam mengoperasikan alat dengan benar.

Untuk pasien dengan gigi susu, diperlukan perhatian wali untuk memastikan bahwa gigi susu tidak tanggal saat **Silinder Retraktor Pipi** dipasang.

Jika ponsel Anda tidak terpasang dengan tepat saat penjepit **Penyangga ponsel** dikencangkan, jangan dipaksa karena dapat merusak ponsel atau alat. Lepaskan case pelindung ponsel Anda, jika belum, lalu coba lagi.

Jangan gunakan **ScanBox<sup>pro</sup>** jika rusak.

Jangan memasukkan **Adaptor** ke dalam mulut.

### • Perhatian

Alat ini bukan mainan. Anak-anak harus diawasi untuk memastikan mereka tidak bermain-main dengan alat.



## PETUNJUK SEBELUM PENGGUNAAN

Sebelum penggunaan, cuci tangan Anda dengan air dan sabun atau gel hidroalkohol. Anda juga harus membersihkan **ScanBox<sup>PRO</sup>** dan ponsel Anda (sesuai dengan rekomendasi produsen ponsel) sebelum digunakan.

Lihat prosedur pembersihan untuk mengetahui langkah-langkah yang tepat untuk diikuti.

## MENYAMBUNGAN PENYANGGA PONSEL DENGAN PONSEL ANDA

**Untuk penomoran di bawah, silakan lihat skema prosedur pengoperasian Penyangga ponsel.**

Buka aplikasi yang ingin Anda gunakan di ponsel Anda sebelum menggunakan **ScanBox<sup>PRO</sup>**.

Pegang **Penyangga ponsel** dengan bantalan penjepit menghadap Anda (1). Buka penjepit dengan menekan tombol pembuka penjepit (2). Tempatkan ponsel Anda pada penjepit, lalu geser secara hori-

zontal untuk menyejajarkan flash dan lensa dengan lubang pemasangan silinder (3).

Kencangkan penjepit ke ponsel Anda dengan menekannya secara kuat (4). Lepaskan case pelindung ponsel Anda jika perlu.

Pastikan ponsel Anda terpasang dengan kuat (5).

Geser ponsel Anda ke atas atau ke bawah sehingga flash dan lensa sejajar dengan lubang pemasangan silinder.

Caranya, tekan dan tahan tombol penyetel dan gerakkan penjepit secara vertikal (6).

Lepaskan tombol penyetel jika sudah selesai (7).

## MENYAMBUNGAN PENYANGGA PONSEL DENGAN SILINDER RETRAKTOR PIPIS

Jika ponsel Anda sudah terpasang dengan benar, sambungkan **Silinder Retraktor Pipis** ke **Penyangga ponsel** dengan memasukkan ujung silinder berpenjepit ke dalam lubang pemasangan silinder pada alat.

Anda akan mendengar bunyi “klik” saat **Silinder Retraktor Pipi** terpasang dengan benar.

### **MENYAMBUNGAN PENYANGGA TELEPON DENGAN ADAPTOR DAN TABUNG RETRAKTOR PIP, HANYA JIKA APLIKASI MEMINTA ANDA UNTUK MENGGUNAKAN ADAPTOR.**

**Adaptor** mungkin diperlukan tergantung pada model ponsel anda; aplikasi secara otomatis mendeteksi apakah **Adaptor** diperlukan dan memberi tahu anda sebagaimana mestinya.

Jika telepon Anda sudah terpasang dengan benar, sambungkan **Adaptor** ke **Penyangga Telepon** dengan memasukkan ujung **Adaptor** yang dilengkapi sistem klip ke dalam lubang pemasangan tabung pada **Penyangga Telepon** . Anda akan mendengar bunyi “klik” ketika **Adaptor** terpasang dengan benar (1).

Kemudian sambungkan **Tabung Retraktor Pipi** ke

**Adaptor** dengan cara memasukkan ujung tabung yang dilengkapi sistem klip ke dalam lubang pemasangan **Adaptor** (2).

Anda akan mendengar bunyi “klik” saat **Tabung Retraktor Pipi** terpasang dengan benar.

### **MEMASUKKAN SILINDER RETRAKTOR PIP KE DALAM MULUT ANDA**

**Pemilihan ukuran yang tepat harus dilakukan di fasilitas kesehatan.**

Jika tidak memungkinkan, coba dahulu ukuran **Silinder Retraktor Pipi** yang paling besar. Jika Anda merasa kurang nyaman atau sakit, ganti ke ukuran yang lebih kecil.

Setelah **ScanBox<sup>PRO</sup>** dipasang, pegang alat dengan tangan Anda tanpa menyentuh leher silinder yang masuk ke dalam mulut. Layar ponsel Anda harus menghadap ke luar.

Pertama, masukkan salah satu sisi leher silinder ke

dalam mulut Anda, lalu masukkan sisi yang lain. Pastikan leher silinder masuk dengan benar ke dalam mulut Anda: silinder tidak boleh lepas dari mulut saat Anda menggerakkannya ke samping.

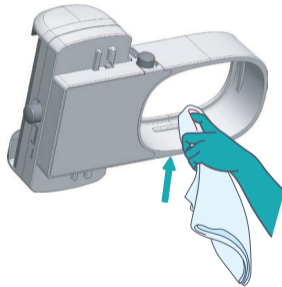
Periksa apakah silinder sudah terpasang dengan benar: gigi dan gusi harus terlihat tanpa terasa sakit atau tidak nyaman.

Jika mengalami rasa sakit atau tidak nyaman yang parah, kunjungi fasilitas kesehatan Anda untuk memastikan ukuran silinder sudah sesuai.

### MELEPAS PENYANGGA PONSEL DAN SILINDER RETRAKTOR PIPIS

Lepas **Penyangga ponsel**, dengan menahan **Silinder Retraktor Pipis** menggunakan tangan Anda dan menariknya ke depan.

## PEMBERSIHAN



## PETUNJUK UNTUK ALAT YANG DAPAT DIGUNAKAN KEMBALI

Prosedur pembersihan berikut harus diikuti:

- Bersihkan lensa kamera ponsel jika diperlukan, sesuai dengan rekomendasi produsen.
- Bersihkan Penyangga ponsel: Sebelum dan sesudah digunakan, bersihkan seluruh **penyangga ponsel** (lihat gambar di bawah) dengan menggunakan tisu biosida atau semprotan biosida yang dipadukan dengan tisu sekali pakai.

### Keringkan Penyangga ponsel.

Lalu simpan di kantong jaring yang disediakan.

**Adaptor** bisa mengikuti prosedur pembersihan yang sama seperti penyangga telepon

- Bersihkan **Silinder Retraktor Pipi**:

- Bersihkan dengan sabun, seperti Sanex 0%, dan air dingin sebelum dan sesudah digunakan.

Jika perlu, sikat permukaan secara lembut dengan sikat bulu halus dan pastikan permukaannya benar-benar bersih. Bilas dengan air dingin.

### Keringkan **Silinder Retraktor Pipi**.

Lalu simpan di kantong jaring yang disediakan, di tempat yang kering dan bersih. Jangan sampai **Silinder Retraktor Pipi** terimpit benda lain.

## PETUNJUK UNTUK KEMASAN RUSAK

Jika kemasan rusak atau terbuka sebelum digunakan, kembalikan ke fasilitas kesehatan Anda.

## PETUNJUK UNTUK VERIFIKASI

Alat harus dipasang dengan benar sebelum digunakan.

## **PENYIMPANAN**

**ScanBox<sup>PRO</sup>** harus disimpan di dalam kantong jaring yang disediakan, jauh dari paparan sinar matahari, tekanan, dan kelembapan.

Jauhkan dari sumber panas.

## **PEMBUANGAN**

Buang sesuai dengan peraturan daur ulang di wilayah Anda.

## **DAFTAR PRODUK YANG DIPERLUKAN TETAPI TIDAK DISERTAKAN**

Dental monitoring (REF 2001-001), SmileMate (REF 2002-001)

## **GARANSI**

Satu tahun dari tanggal pembelian asli.

## **PERJALANAN**

Saat dibawa dalam perjalanan, alat harus disimpan di kantong jaring yang disediakan.

Pastikan alat tidak dikemas terlalu rapat untuk mencegah deformasi atau kerusakan selama perjalanan.

## USER ASSISTANCE INFORMATION INFORMAÇÕES SOBRE ASSISTÊNCIA AO USUÁRIO

Please report any serious incident that occurred in relation to the device to **support@dental-monitoring.com** and to the local competent authority for medical devices.

To find your local user assistance phone number:  
**www.dental-monitoring.com**

Por favor, comunique qualquer incidente grave que ocorra com o dispositivo a **support@dental-monitoring.com** e às autoridades locais competentes para assuntos relacionados com dispositivos médicos.

Para localizar o número de telefone local dos serviços de assistência ao usuário: **www.dental-monitoring.com**

## INFORMASI BANTUAN PENGGUNA

Harap laporkan insiden serius yang terjadi sehubungan dengan alat ke **support@dental-monitoring.com** dan kepada otoritas setempat yang berwenang atas alat kesehatan.

Untuk menemukan nomor telepon bantuan pengguna di wilayah Anda: **www.dental-monitoring.com**

## DATE / DATE / TANGGAL

January / Janeiro de / Januari  
2024

### **Detentor da Notificação:**

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