



São Paulo, 22 de outubro de 2021

**NOTIFICAÇÃO IMPORTANTE  
AÇÃO DE CAMPO ITERO**

Prezado(a) doutor(a),

Estamos entrando em contato por você ser participante do programa de aluguel/ comodato/ demonstração do *scanner* iTero Element.

Este contato é para informar que a Align Technology realizará uma ação de campo para a remoção de um dispositivo de rastreamento (GPS) que foi instalado nos *scanners* iTero Element para controle de estoque e suprimento.

**Identificação do problema**

Quando os *scanners* iTero Element foram distribuídos no Brasil em 2020, como parte do programa de aluguel/comodato/demonstração, um dispositivo de rastreamento (GPS) foi adicionado à parte traseira do *scanner* para ajudar no gerenciamento do inventário e fornecimento das unidades. A Align Technology desde então descobriu que a adição desta unidade de rastreamento pode interferir na fonte de alimentação de energia, o que leva a falhas para ligar e desligar o *scanner* corretamente.

Embora não haja relatos de ferimentos ou de impacto clínico no paciente como resultado da inclusão deste componente, as inconveniências causadas a doutores e funcionários são inaceitáveis. Por isso, pedimos desculpas e faremos a correção. Assim, estamos contatando proativamente todos os consultórios que participam do programa para agendar a remoção do dispositivo de rastreamento (GPS).

Os produtos afetados estão listados abaixo:

Modelo do produto	Número de registro na ANVISA
iTero Element 2	80194750005
iTero Element 5D	80194750005

A lista de *scanners* afetados com números de série pode ser encontrada no final desta comunicação.



### **Possíveis riscos relacionados ao problema**

Nenhum ferimento ou lesão foi relatado por nenhum paciente ou qualquer doutor. Conforme relatado por alguns usuários, alguns sistemas iTero não puderam ser ligados ou foram desligados inesperadamente. Não há risco conhecido para pacientes ou usuários quando ocorre esse modo de falha, mas o impacto sobre a eficiência e as práticas no consultório é inaceitável.

### **Diretrizes e ações a serem tomadas**

**Não tente remover o dispositivo GPS por conta própria.** A equipe de Logística da Align entrará em contato diretamente com você para agendar um horário conveniente, a partir da confirmação de recebimento desta comunicação em um prazo de até 60 dias, para que um técnico da Evoy, fornecedor especializado contratado pela Align, vá ao seu consultório e remova o dispositivo. Estimamos que a remoção não deva levar mais do que 15 minutos. Se preferir ligar antes para agendar um horário para este serviço, entre em contato com a equipe de Customer Success pelo número 0800 8787 030.

Pedimos desculpas por qualquer inconveniente que isso tenha causado a você, ao seu consultório e aos seus pacientes. Permanecemos comprometidos em oferecer produtos da mais alta qualidade a você e aos seus pacientes.

Caso tenha alguma dúvida, entre em contato conosco diretamente em 0800 8787 030.

Obrigado,

DocuSigned by:  
  
EB94B3A39FED486...

Ritesh Sharma

VP e Gerente Geral, Latam

Align Technology



**ITERO ELEMENT 2:** Lista de números de série afetados

BLX2018W45A400	BLX2020W36A366	BLX2020W40A088	BLX2020W44A205	BLX2020W50A066
BLX2018W46A005	BLX2020W37A169	BLX2020W40A109	BLX2020W44A208	BLX2020W50A074
BLX2019W05A030	BLX2020W37A175	BLX2020W40A112	BLX2020W44A209	BLX2020W50A091
BLX2019W05A074	BLX2020W37A194	BLX2020W40A116	BLX2020W44A212	BLX2020W50A098
BLX2019W30A187	BLX2020W37A276	BLX2020W40A117	BLX2020W44A213	BLX2020W50A101
BLX2019W37A285	BLX2020W37A340	BLX2020W42A013	BLX2020W44A219	BLX2020W50A107
BLX2019W37A295	BLX2020W37A397	BLX2020W42A015	BLX2020W44A222	BLX2020W50A108
BLX2019W37A347	BLX2020W38A002	BLX2020W42A022	BLX2020W44A283	BLX2020W50A110
BLX2019W42A327	BLX2020W38A017	BLX2020W42A055	BLX2020W44A350	BLX2020W50A113
BLX2019W48A094	BLX2020W38A040	BLX2020W42A079	BLX2020W44A357	BLX2020W50A115
BLX2019W48A164	BLX2020W38A055	BLX2020W42A080	BLX2020W44A362	BLX2020W50A118
BLX2019W48A231	BLX2020W38A073	BLX2020W42A082	BLX2020W44A363	BLX2020W50A120
BLX2019W49A203	BLX2020W38A087	BLX2020W42A084	BLX2020W44A369	BLX2020W50A135
BLX2019W50A001	BLX2020W38A089	BLX2020W42A085	BLX2020W44A375	BLX2020W50A138
BLX2019W50A009	BLX2020W38A097	BLX2020W42A088	BLX2020W44A379	BLX2020W50A139
BLX2019W50A043	BLX2020W38A163	BLX2020W42A096	BLX2020W44A390	BLX2020W50A141
BLX2019W50A190	BLX2020W38A164	BLX2020W42A103	BLX2020W44A393	BLX2020W50A142
BLX2019W50A215	BLX2020W38A180	BLX2020W42A104	BLX2020W44A394	BLX2020W50A143
BLX2019W50A383	BLX2020W38A188	BLX2020W42A107	BLX2020W44A409	BLX2020W50A144
BLX2019W50A384	BLX2020W38A193	BLX2020W42A108	BLX2020W44A410	BLX2020W50A149
BLX2019W52A441	BLX2020W38A196	BLX2020W42A110	BLX2020W44A427	BLX2020W50A183
BLX2020W02A294	BLX2020W38A198	BLX2020W42A111	BLX2020W49A066	BLX2020W50A234
BLX2020W05A111	BLX2020W38A211	BLX2020W43A403	BLX2020W49A067	BLX2020W50A235
BLX2020W06A242	BLX2020W38A215	BLX2020W43A404	BLX2020W49A069	BLX2020W50A236
BLX2020W10A028	BLX2020W38A234	BLX2020W43A409	BLX2020W49A087	BLX2020W50A237
BLX2020W10A030	BLX2020W39A113	BLX2020W43A471	BLX2020W49A100	BLX2020W50A242
BLX2020W10A069	BLX2020W39A127	BLX2020W43A488	BLX2020W50A002	BLX2020W50A247
BLX2020W10A092	BLX2020W39A134	BLX2020W43A489	BLX2020W50A005	BLX2020W50A248
BLX2020W10A094	BLX2020W39A139	BLX2020W43A490	BLX2020W50A011	BLX2020W50A251
BLX2020W10A097	BLX2020W39A153	BLX2020W43A578	BLX2020W50A012	BLX2020W50A253
BLX2020W10A107	BLX2020W39A159	BLX2020W44A149	BLX2020W50A015	BLX2020W50A258
BLX2020W10A276	BLX2020W40A002	BLX2020W44A162	BLX2020W50A016	BLX2020W50A261
BLX2020W12A069	BLX2020W40A006	BLX2020W44A163	BLX2020W50A023	BLX2020W50A271
BLX2020W12A466	BLX2020W40A013	BLX2020W44A164	BLX2020W50A032	BLX2020W50A274
BLX2020W12A496	BLX2020W40A024	BLX2020W44A181	BLX2020W50A053	BLX2020W50A283
BLX2020W13A080	BLX2020W40A026	BLX2020W44A183	BLX2020W50A054	BLX2020W50A350
BLX2020W36A253	BLX2020W40A031	BLX2020W44A184	BLX2020W50A057	BLX2020W50A353
BLX2020W36A281	BLX2020W40A032	BLX2020W44A193	BLX2020W50A061	BLX2020W50A360
BLX2020W36A295	BLX2020W40A073	BLX2020W44A203	BLX2020W50A064	



**ITERO ELEMENT 5D:** Lista de números de série afetados

BLX2019W38A280	BLX2020W46A156	BLX2020W46A116	BLX2021W02A291	BLX2020W47A365
BLX2019W47A576	BLX2020W46A129	BLX2020W46A122	BLX2020W46A463	BLX2020W47A366
BLX2020W42A612	BLX2020W46A130	BLX2020W46A125	BLX2020W46A529	BLX2019W38A280
BLX2020W43A383	BLX2020W42A603	BLX2020W46A098	BLX2020W47A036	BLX2020W47A405
BLX2020W43A319	BLX2020W42A634	BLX2020W02A337	BLX2020W46A459	BLX2020W47A290
BLX2020W43A377	BLX2020W46A133	BLX2020W43A037	BLX2020W46A497	BLX2020W47A287
BLX2019W52A381	BLX2020W43A332	BLX2020W39A077	BLX2020W47A258	BLX2020W47A396
BLX2020W43A283	BLX2020W43A337	BLX2020W46A383	BLX2020W47A076	BLX2020W47A313
BLX2020W43A340	BLX2020W43A343	BLX2020W46A330	BLX2020W47A278	BLX2020W47A309
BLX2020W43A342	BLX2020W43A360	BLX2020W46A386	BLX2020W47A096	BLX2020W47A335
BLX2020W43A285	BLX2020W43A355	BLX2020W46A324	BLX2020W47A042	BLX2020W11A181
BLX2020W43A269	BLX2020W43A331	BLX2020W46A370	BLX2020W47A129	BLX2020W11A191
BLX2020W43A276	BLX2020W43A356	BLX2020W46A475	BLX2020W47A087	BLX2020W14A254
BLX2020W43A311	BLX2020W43A324	BLX2020W46A392	BLX2020W47A127	BLX2020W10A058
BLX2020W43A322	BLX2020W46A440	BLX2020W47A320	BLX2020W47A050	BLX2020W14A224
BLX2020W46A086	BLX2020W43A328	BLX2020W47A360	BLX2020W47A053	BLX2020W14A066
BLX2020W43A268	BLX2020W46A079	BLX2020W47A402	BLX2020W47A049	BLX2020W11A156
BLX2020W42A565	BLX2020W46A075	BLX2020W46A403	BLX2020W47A105	BLX2020W14A229
BLX2020W42A461	BLX2020W46A081	BLX2020W46A358	BLX2020W47A101	BLX2020W12A401
BLX2020W42A411	BLX2020W46A101	BLX2020W43A345	BLX2020W47A196	BLX2019W47A583
BLX2020W42A575	BLX2020W46A077	BLX2020W46A376	BLX2020W47A032	BLX2020W12A286
BLX2020W42A580	BLX2020W46A127	BLX2020W46A519	BLX2020W47A083	BLX2020W12A581
BLX2020W42A620	BLX2020W46A076	BLX2020W46A377	BLX2020W47A151	BLX2020W12A198
BLX2020W46A154	BLX2020W46A071	BLX2020W46A110	BLX2020W47A043	BLX2019W47A723
BLX2020W46A150	BLX2020W46A123	BLX2020W46A107	BLX2020W47A098	BLX2020W39A051
BLX2020W46A155	BLX2020W46A074	BLX2020W46A067	BLX2020W47A099	BLX2020W39A061
BLX2020W46A152	BLX2020W46A124	BLX2020W47A216	BLX2020W47A329	BLX2020W46A157
BLX2020W46A151	BLX2020W46A117	BLX2020W46A428	BLX2020W47A300	
BLX2020W46A134	BLX2020W46A068	BLX2020W53A080	BLX2020W47A369	

**Certificado de Conclusão**

Identificação de envelope: 8A4918E31DA24CE99D99D6B83C905E33

Status: Concluído

Assunto: Carta ANVISA - Align Technology\_1021

Envelope fonte:

Documentar páginas: 4

Assinaturas: 1

Certificar páginas: 4

Rubrica: 0

Assinatura guiada: Ativado

Selo com Envelopeld (ID do envelope): Desativado

Fuso horário: (UTC-08:00) Hora do Pacífico (EUA e Canadá)

Remetente do envelope:

Natália Meraio

2820 Orchard Parkway

San Jose, CA 95134

nmeraio@aligntech.com

Endereço IP: 179.189.225.14

**Rastreamento de registros**

Status: Original

Portador: Natália Meraio

Local: DocuSign

22/10/2021 06:16:01

nmeraio@aligntech.com

**Eventos do signatário****Assinatura****Registro de hora e data**

Ritesh Sharma

rsharma@aligntech.com

VP and General Manager, LATAM Americas Sales

Align Technology, Inc.

Nível de segurança: E-mail, Autenticação da conta (Nenhuma)

DocuSigned by:



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Adoção de assinatura: Estilo pré-selecionado

Usando endereço IP: 179.189.225.14

Enviado: 22/10/2021 06:21:14

Visualizado: 25/10/2021 06:19:53

Assinado: 25/10/2021 06:19:57

**Termos de Assinatura e Registro Eletrônico:**

Aceito: 24/11/2020 12:35:20

ID: 145f2fab-cd5c-4b94-a845-d0744230b51a

**Eventos do signatário presencial****Assinatura****Registro de hora e data****Eventos de entrega do editor****Status****Registro de hora e data****Evento de entrega do agente****Status****Registro de hora e data****Eventos de entrega intermediários****Status****Registro de hora e data****Eventos de entrega certificados****Status****Registro de hora e data****Eventos de cópia****Status****Registro de hora e data****Eventos com testemunhas****Assinatura****Registro de hora e data****Eventos do tabelião****Assinatura****Registro de hora e data****Eventos de resumo do envelope****Status****Carimbo de data/hora**

Envelope enviado

Com hash/criptografado

22/10/2021 06:21:14

Entrega certificada

Segurança verificada

25/10/2021 06:19:53

Assinatura concluída

Segurança verificada

25/10/2021 06:19:57

Concluído

Segurança verificada

25/10/2021 06:19:57

**Eventos de pagamento****Status****Carimbo de data/hora****Termos de Assinatura e Registro Eletrônico**

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**Required hardware and software**

Operating Systems:	Windows2000 or WindowsXP
Browsers (for SENDERS):	Internet Explorer 6.0 or above
Browsers (for SIGNERS):	Internet Explorer 6.0, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	Allow per session cookies Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

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