

URGENTE - Aviso de Segurança

Trilogy 100, Trilogy 200, Garbin, Garbin Plus, Trilogy O2, Trilogy 202, Trilogy EC
Versões do software lançadas desde 29 de janeiro de 2015: 13.2.04, 13.2.05, 14.0.00 e 14.1.01
Registro ANVISA 10216710280 e 10216710291

Prezado Cliente,

Os dispositivos Philips Respironics Trilogy, que operam com as versões do software citadas acima e com prescrições duplas habilitadas, podem estar suscetíveis a uma alteração acidental entre as prescrições ativas em resposta à interação específica do usuário. Isso pode ocorrer sem exigir do usuário a confirmação da alteração. Porém, os dispositivos continuam exibindo precisamente a prescrição ativa no canto superior esquerdo da tela. O dispositivo não se altera espontaneamente.

Se o usuário não perceber a alteração entre as prescrições, isso poderia representar um risco aos pacientes. Não houve relatos de dano ou ferimento associado a esse problema.

Os dispositivos afetados podem continuar sendo usados de acordo com este Aviso de Segurança.

Este Aviso de Segurança pretende informá-lo sobre:

- A descrição do problema e sob quais circunstâncias ele pode ocorrer
- As ações do cliente/usuário para evitar os riscos aos pacientes
- As ações da Philips Respironics para solucionar o problema

Este documento contém informações importantes para a segurança contínua e o uso apropriado do seu equipamento

Revise as informações a seguir com todos os membros de sua equipe que precisam ter conhecimento do conteúdo desta comunicação. É importante compreender as implicações desta comunicação.

Guarde uma cópia com as Instruções de Uso do equipamento.

Estamos notificando os clientes sobre esse problema por meio deste Aviso de Segurança e em breve forneceremos uma atualização do software para os dispositivos afetados. Você será notificado quando a atualização do software estiver disponível.

Caso tenha alguma dúvida ou necessite de mais informações, entre em contato com a nossa Central de Soluções no telefone 0800-701-7789. Atendimento de segunda a sexta das 07 as 19h.

Este aviso foi relatado às agências reguladoras apropriadas.

Agradecemos o seu apoio ao responder este Aviso de Segurança e nos desculpamos sinceramente por qualquer inconveniente que essa ação possa provocar.

Atenciosamente,

Alexandre Villar
PCMS – National Support Specialist
Philips HealthCare - Brasil



PRODUTOS AFETADOS	Os modelos afetados incluem as unidades Trilogy 100, Trilogy 200, Garbin, Garbin Plus, Trilogy O2, Trilogy EC e Trilogy 202 com as versões do software 13.2.04, 13.2.05, 14.0.00 ou 14.1.01. Essas versões foram colocadas em produção e liberadas para atualização em campo em 29 de janeiro de 2015.
DESCRIÇÃO DO PROBLEMA	<p>Os dispositivos Trilogy listados são compatíveis com as prescrições de terapia dupla, e duas prescrições podem ser programadas por um profissional de saúde específicas para as necessidades do paciente, conforme prescrito pelo médico. A Philips Respironics teve conhecimento de que os Ventiladores Trilogy com versões do software 13.2.04, 13.2.05, 14.0.00 ou 14.1.01 estão suscetíveis a uma alteração acidental entre as prescrições. Isso pode ocorrer sob um determinado conjunto de condições operacionais e após uma sequência específica de pressionamentos de teclas sem exigir que o usuário confirme a alteração.</p> <p>Os dispositivos continuam exibindo precisamente a prescrição ativa no canto superior esquerdo da tela. Visto que essa alteração da prescrição foi acidental e não foi exigida nenhuma confirmação, o usuário pode não ter percebido essa alteração.</p>
RISCO ENVOLVIDO	Na ocorrência desse problema, é possível que os pacientes recebam uma ventilação insuficiente para a sua sessão de terapia pretendida, o que pode prejudicá-los.
COMO IDENTIFICAR OS PRODUTOS AFETADOS	<p>De acordo com o Manual do Usuário do dispositivo, a versão do software pode ser obtida da seguinte maneira:</p> <ul style="list-style-type: none"> • Após pressionar o botão power [energia] para iniciar a terapia, a tela de Startup [Inicialização] é exibida momentaneamente, indicando o nome do dispositivo e a versão do software. • Na tela Main Menu [Menu Principal], navegue até a seção Information [Informações], pressione o botão direito, navegue até a versão do software do dispositivo.
AÇÃO A SER TOMADA PELO CLIENTE / USUÁRIO	<ol style="list-style-type: none"> 1. Preencha e devolva o Formulário de Resposta Comercial 2. Os dispositivos afetados podem continuar sendo usados de acordo com as Instruções de Uso do dispositivo e com este Aviso de Segurança. 3. Notifique os usuários com os dispositivos afetados sobre o seguinte: <ul style="list-style-type: none"> ○ Verifique a prescrição correta para a sua sessão de terapia, exibida no canto superior esquerdo da tela do Trilogy 4. De acordo com seus procedimentos operacionais e/ou cronograma de manutenção habituais, atualize o software do dispositivo assim que for disponibilizado.
AÇÕES PLANEJADAS PELA PHILIPS	Em breve liberaremos o software atualizado do dispositivo para evitar o problema descrito anteriormente. O software atualizado do dispositivo estará disponível em my.respironics.com . Você receberá outra carta informando a disponibilidade do software atualizado.
INFORMAÇÕES ADICIONAIS E SUPORTE	Caso tenha alguma dúvida ou necessite de mais informações em relação a esse comunicado, entre em contato com a nossa Central de Soluções no telefone 0800-701-7789. Atendimento de segunda a sexta das 07 às 19h.



Números de Série Afetados

TV110102040	TV114041029	TV110061013	TV112011102	TV11404162E
TV01508180C	TV114041032	TV110061014	TV112011103	TV114041631
TV01508180D	TV114041624	TV110061015	TV112011104	TV114041634
TV01508180E	TV114041628	TV110061016	TV112011105	TV114041635
TV01508180F	TV114041632	TV110061018	TV112011106	TV114041637
TV015081811	TV114041633	TV110061019	TV112011107	TV114041638
TV015081812	TV114041643	TV110061021	TV112011108	TV114041639
TV112012431	TV114041646	TV110061022	TV112011368	TV11404163B
TV112040505	TV114041655	TV110061023	TV112011369	TV11404163D
TV112040510	TV1141023B0	TV110061024	TV112011370	TV11404163F
TV112111332	TV1141023B9	TV110061025	TV112011371	TV114041640
TV112111334	TV11504216B	TV110061026	TV112011372	TV114041641
TV112111417	TV11504216C	TV110061027	TV112011373	TV114041645
TV113030107	TV11504216E	TV110061028	TV112011374	TV114041647
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TV113030123	TV11504217C	TV110061030	TV112011842	TV11404164C
TV113030614	TV11504217E	TV110061031	TV112011844	TV11404164D
TV114040753	TV115042180	TV110061032	TV112011845	TV11404164E
TV110121403	TV115042181	TV110061033	TV112011846	TV11404164F
TV111031739	TV115042208	TV110061034	TV112011849	TV114041650
TV111031757	TV11504220A	TV110061035	TV112011855	TV114041652
TV112011841	TV115042211	TV110061036	TV112011856	TV114041656
TV112040902	TV115042212	TV110061037	TV112011859	TV114041657
TV112041229	TV115042216	TV110061038	TV112011863	TV114041658
TV112041609	TV11504221B	TV110061039	TV112011865	TV114041659
TV112111409	TV115042222	TV110061040	TV112011866	TV11404165A
TV113030406	TV11504223B	TV110061041	TV112011867	TV11404165B
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TV113030419	TV115042250	TV110061043	TV112012420	TV11404165D
TV113030427	TV111031844	TV110061044	TV112012421	TV11404165E
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TV11404072F	TV112010952	TV110061046	TV112012424	TV114070289
TV11404076B	TV112010959	TV110061047	TV112012434	TV114070703
TV11404165F	TV112010961	TV110061048	TV112012436	TV114070704
TV110032354	TV112010968	TV110061049	TV112012437	TV114070705
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TV110111948	TV113080621	TV110061103	TV112021721	TV11407070F
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TV110121414	TV113080644	TV110061107	TV112021728	TV114070712
TV110121426	TV113091375	TV110061108	TV112021729	TV114070713
TV110121436	TV114040739	TV110061109	TV112021730	TV114070714
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TV112040926	TV114040761	TV110061112	TV112021732	TV114070717



TV112111228	TV114040763	TV110061113	TV112021734	TV114070718
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TV112111247	TV114040774	TV110061115	TV112021736	TV11407071B
TV112111257	TV11404081A	TV110061116	TV112021737	TV11407071C
TV112111411	TV11404081F	TV110061117	TV112021738	TV11407071E
TV113030433	TV114040826	TV110061118	TV112021739	TV11407071F
TV113102413	TV11404100E	TV110061119	TV112021740	TV114070720
TV113102415	TV114041024	TV110061120	TV112040905	TV114070721
TV115021270	TV114041028	TV110061121	TV112040908	TV114070722
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TV111031771	TV11404102B	TV110061123	TV112040917	TV114070724
TV111031822	TV11404102E	TV110061124	TV112040922	TV114070727
TV111031823	TV114041035	TV110061125	TV112040934	TV114070728
TV111031834	TV11404162C	TV110061126	TV112040939	TV114070729
TV111090802	TV114041636	TV110061127	TV112040940	TV11407072A
TV111090807	TV114041642	TV110061128	TV112041209	TV11407072F
TV111090815	TV114041654	TV110061129	TV112111262	TV114070730
TV111090828	TV113102405	TV110061130	TV113030412	TV114070731
TV111090834	TV11310241C	TV110061131	TV113030425	TV114070732
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TV112110956	TV111090921	TV110091709	TV113030101	TV115021243
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TV113030415	TV115042178	TV110091712	TV113030109	TV115021245
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TV114040746	TV115051283	TV110091721	TV113030129	TV115021252
TV11404075C	TV115051284	TV110091723	TV113030131	TV115021253
TV114040762	TV115051285	TV110091725	TV113030132	TV115021254
TV114040766	TV115051286	TV110091727	TV113030133	TV115021255
TV114040767	TV115051287	TV110091729	TV113030134	TV115021256
TV114040769	TV115051288	TV110091730	TV113030135	TV115021257
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TV114041622	TV11505128A	TV110091732	TV113030401	TV115021259
TV114041625	TV11505128B	TV110091733	TV113030403	TV11502125B
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TV114041630	TV11505128D	TV110091735	TV113030405	TV11502125D
TV11404163A	TV11505128E	TV110091737	TV113030407	TV11502125E



TV11404163E	TV11505128F	TV110101319	TV113030409	TV115021261
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TV114041649	TV115051291	TV110101322	TV113030411	TV115021264
TV113030104	TV115051292	TV110101323	TV113030416	TV115021268
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